# Gap analysis report

## Needs Assessment – Falsified Medical Products (NA-FAMED) of the MEDICRIME Convention

COUNCIL OF EUROPE
CONSEIL DE L'EUROPE

# Gap analysis report

## Needs Assessment – Falsified Medical Products (NA-FAMED) of the MEDICRIME Convention

MEDICRIME Secretariat
Directorate General I- Human Rights and Rule of Law

Council of Europe

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# ABBREVIATIONS

| | |
|---|---|
| AMG | Medicinal Product Act, 2005, as amended (Germany) |
| AMWHV | Medicines and Drug Manufacturing Ordinance (Germany) |
| CC | Criminal Code |
| CoE | Council of Europe |
| EU | European Union |
| GHL | General Health Law -Ley General de Salud (México) |
| IVDR | In Vitro Diagnostic Medical Device Regulation (2017/746) |
| LMPMD | Law on Medicinal Products and Medical Devices (North Macedonia) |
| MDR | European Union Medical Device Regulation (2017/745) |
| MPG | Law on Medical Devices (Germany) |
| MPDG | Medical Device Implementation Law (Germany) |
| NA-FAMED | Needs Assessment-Falsified Medical Products |
| OWiG | Law on Administrative Contraventions (Ordnungswidrigkeitengesetz) (Germany) |
| PC | Penal Code |
| StGB | Criminal Code (Austria and Germany) |

# EXECUTIVE SUMMARY

Launched by the Council of Europe (hereinafter, CoE), the multiregional project entitled "Needs Assessment - Falsified Medical Products" (NA-FAMED) is aimed at providing technical assistance and supporting CoE member States and other countries to fight against the falsification of medical products and other similar crimes. Against this background, a questionnaire to establish a baseline assessment on the state of readiness of CoE member States and other countries to fight against this growing crime was drafted and sent to 40 countries around the world. The summary report of the responses received to this questionnaire illustrates that some countries have already begun the implementation of national laws that facilitate a preparedness to sign and ratify the MEDICRIME Convention.As the countries reported on in this report have not yet signed or ratified the Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health (hereinafter, the "MEDICRIME Convention" or "the Convention"), with one exception1. This report is not a monitoring exercise. It provides support to those countries in indicating areas where correspondence may exist between national laws and the MEDICRIME Convention, or where further work may be needed to facilitate implementation on reaching ratification

The substantive Criminal Law provisions of the Convention (Articles 5-13) are underpinned by the Definitions (Article 4). Unless these definitions are adequately implemented into internal laws the substantive provisions will be deficient and thus weaken the application of the MEDICRIME Convention and the ability of the countries to combat counterfeiting of medical products and similar crimes involving threats to public health. If the base offences of the Convention (Articles 5-8) are deficient, the applicability of other provisions (Articles 9 -13) will not be possible.

It should be noted that the MEDICRIME Convention has been designed to comprehensively deal through the criminal law with crises that threaten public health, as the COVID-19 pandemic, that involve criminal acts, endanger the rights and welfare of victims, and challenge national and international cooperation to combat medical product counterfeiting, as defined in Articles 1 and 4.j.

The study outlines in IV. General Report the general horizontal issues that are reported in a number of countries in responses to the questionnaire. There follows the study recommendations and conclusions.

The individual country reports proceed in V. Country Reports through the format of the questionnaire in identifying areas where the CoE could provide support towards ratification and full implementation of the MEDICRIME Convention.

1. Guinea

# I. INTRODUCTION

## 1.1 Context

The CoE is conducting this Gap Analysis Survey to assess the level to which current domestic criminal and other legislation support the prohibition and enforcement against counterfeit2/falsified medical products as criminal offences for the purpose of protecting public health. This is the first part of a two-part survey. The focus of this first part is on the definitions and the substantive criminal law. It also begins to ascertain the extent of criminal actions related to medical product counterfeiting and similar crimes prosecuted by countries. In addition, the MEDICRIME Secretariat, as part of the NA-FAMED survey, is recording details of the different agencies/organisations in countries on the distribution of responsibilities for enforcing against the counterfeiting of medical products and similar crimes. Part 2 of the NA-FAMED survey will be circulated at a future date and will focus on the non-substantive criminal law aspects of the MEDICRIME Convention.

## 1.2 Objective

The purpose of the NA- FAMED survey is to identify for the CoE how best it can support its member States and other countries build a criminal law and supporting framework under the MEDICRIME Convention to combat counterfeit/falsified medical products[3] and similar crimes involving threats to public health. This is the criminal law approach, which aims at criminalising behaviour that balances and complements the public health approach to protect the medical product. The gap analysis aims to improve and strengthen legal, regulatory and policy frameworks in different countries. NA-FAMED will identify the main beneficiaries and the legal and procedural issues leading to criminalisation of the production and trade in falsified medical products.

## 1.3 Methodology

The NA-FAMED survey was distributed to one national consultant in the relevant national legislation for each of the 40 countries involved in the survey. These countries excluded, mostly, Parties to the MEDICRIME Convention that were previously surveyed in the General Overview Questionnaire[4] on the implementation of the MEDICRIME Convention in 2020. The national consultant was free to contact their national Ministries/ agencies that are normally involved in combating counterfeit/falsified medical products (Justice, Health, Police Service, Customs Service, health product regulatory authority, etc). This approach is to achieve an objective review of legislation in place in the selected countries in the survey in relation to the Criminal Law provisions that address the counterfeiting, as defined in the MEDICRIME Convention, of medical products. It also provides data on some case law in the selected countries in the survey. The data obtained from this survey enables an assessment to be made on the legislative needs by country in order to correspond with the provision of the MEDICRIME Convention should the country wish to ratify the Convention and complete implementation. Wherever a non-response was provided, it was taken that no relevant provision in the internal law could be found by the national consultant to correspond with the MEDICRIME Convention.

2. See definition of the term '*counterfeit*' in Article 4.j), MEDICRIME Convention
3. See definition of the term '*medical product*' in Article 4.a), MEDICRIME Convention
4. General Overview Questionnaire on the Implementation of the MEDICRIME Convention. Available at: https://rm.coe.int/t-medicrime-2020-cp-e-country-profile-questionnaire/1680a0ba04

It is noted that the countries included in the survey have not ratified the Convention and have no obligations at this stage to come into correspondence with it. The NA-FAMED report implies a prospective analysis related to the level of needs for implementation of certain provisions of the MEDICRIME Convention of countries included in the study in view of their potential accession to the Convention. This has been done to facilitate an early assessment of laws of those countries to enable them to achieve correspondence with the MEDICRIME Convention at an early stage. No obligation has been assumed up to now by those countries related to the MEDICRIME Convention, and consequently the present study must be considered in those prospective terms. The intention by the Council of Europe is to facilitate the identification of areas where the implementation of the MEDICRIME Convention would require legislative activity by the country.

The submissions by the national consultants were requested to be in either the English or French language, or both. Only one consolidated response to the Survey was submitted by each national consultant. The survey assessors, in drafting this report, were not in a position to translate and interpret appropriately from different languages other than from the English and French languages.

The NA-FAMED questionnaire was grouped under two main sections. The choice of these sections did not seek to prioritise the various provisions of the Convention: equal importance was attached to all rights and principles therein. This report was conducted based on the information provided by national consultants under the headings of: Preliminary (matters) and Substantive Criminal Law. The General Report on horizontal review, those issues looking in a horizontal way and not on a country-by-country way, comments only on the issues of greatest importance to the MEDICRIME Convention implementation. Many other issues are listed in the chapter "Country Reports – an assessment by the Report drafters on responses received from national consultants" and are reflected in the state of implementation chart of the MEDICRIME Convention.

National consultants were also requested to provide information on case law from their respective countries relevant to matters contained in the MEDICRIME Convention. This was requested under the heading of *Case-law (law enforcement or jurisprudential) analysis*.

As regards the CoE member States and the other countries considered in the NA-FAMED survey that have not signed or ratified the MEDICRIME Convention to date, this report seeks to assess existing legislation of those countries against the selected articles of the MEDICRIME Convention. This permits countries identify legislative gaps and consequential legislative needs that may assist them prepare to reach full ratification and subsequent implementation. It is meant to indicate, as at a minimum, what is absent and if included, would be sufficient in law in circumstances where the country sought to ratify the MEDICRIME Convention.

The reporting in this report is based on the following considerations:

- Where correspondence between internal laws and the specific article of the Convention is absent a comment in each article is made.
- Where there is a sufficiency of correspondence with the specific article in the MEDICRIME Convention, but different wording is used in internal laws, it is recommended, for the avoidance of any doubts on the intent of the Convention provision, and national language permitting and being respected, the language and wording of the Convention be adopted.
- Where the internal law provision is different, though sufficient in intent and content, this will be stated.
- Where the internal law provision is incomplete, further action will be needed and this will be stated.
- Where correspondence with the specific article of the Convention is found, no further action is recommended.

## 1.4 Countries participating

A total of 40 countries were circulated with the NA-FAMED survey from which 36 countries responded. One country withdrew and no response was received at the time of drafting of this report from the national consultant in relation to Israel, Luxembourg and the Netherlands. A total of 22 responses were received to the survey on case-law. The report was concluded based on the information received.

The participating CoE member States are the following: Andorra, Armenia, Austria, Azerbaijan, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, Georgia, Germany, Greece, Iceland, Ireland, Italy, Latvia, Lithuania, Montenegro, North Macedonia, Norway, Poland, Romania, Serbia, Slovak Republic, Slovenia, Sweden and United Kingdom.

The participating non-CoE member States are the following: Canada, Ecuador, Guinea, Japan, Mexico, Morocco, Tunisia and United States of America.

## 1.5 Limitations

This report is based on submissions made by national consultants on the relevant national laws. They do not necessarily reflect the respective national government's opinion. Web links are provided by the national consultant in support of the submissions made. These links may not be exhaustive and have not been independently verified. They are provided for information only in this report.

Laws contemplated by countries but not enacted at the time of drafting of this report are not taken into consideration, even where the national consultant included this information. The reason for this is that no assessment can be made on laws in draft form only. Laws enacted but not yet entered into force at the completion date of this report have been included only for information and not to assess correspondence with the MEDICRIME Convention.

### Medical Device Regulation 2017/745/EU (MDR)

The EU made new regulations in 2017 on medical devices, namely Regulation (EU) 2017/745 on medical devices (MDR) and Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR). The implementation date for Regulation 2017/745 is 26 May 2021. This Regulation provides a definition of a falsified medical device. EU member States are required to implement the regulation from that date and include any national enforcement measures. Where a member State of the EU has, prior to the drafting of this report, implemented legislative provisions necessary to give effect to certain provisions that correspond with the MEDICRIME Convention this has been taken into consideration in this report. It is recognised that from 26 May 2021 the remaining EU Member States included in this report will also have taken into account the effect of those regulations. Their correspondence with certain articles of the MEDICRIME Convention should then have altered. However, such EU member States may require that further actions still be needed to come into full correspondence with all articles of the MEDICRIME Convention, in particular any criminal law enforcement requirements.

# II. GENERAL REPORT

This horizontal study is intended to

- identify issues in common to the member States and other countries considered in this report, for noting where the implementation process may be facilitated and enhanced and
- to identify for the CoE how best it can support member States build a criminal law and supporting framework under the MEDICRIME Convention to combat counterfeit/falsified medical products and similar crimes involving threats to public health.

## 2.1. Applicable Law

It is noted that the internal laws that may be used in the countries in this report to address the falsification of medical products and similar crimes involving threats to public health are:

i. a mixture of the criminal and regulatory laws;
ii. in some countries, it is mainly the penal laws that are used to contain criminal law provisions on the falsification of medical products;
iii. in other countries it is mainly the regulatory law provision;
iv. in some, there is no applicable law.

In most countries, the two types of laws are not coordinated towards and not intended for the challenges now raised by the issues contemplated by the MEDICRIME Convention. These include the use of definitions where they may not be an applicable offence. Offences may not apply where there is no applicable base offence. This may arise, for example, in relation to aiding or abetting and attempt.

In no case could there be found a single law dealing with the counterfeiting of medical products and similar crimes involving threats to public health.

## 2.2. Issues Analysed

### General comment

The MEDICRIME Convention was drafted with the intent that it be a holistic instrument with an interlinking fabric of support between provisions. It has been observed that countries included in this report, in the absence of specific criminal laws relating to the counterfeiting of medical products and similar crimes involving threats to public health, may rely on disparate provisions in both regulatory and the general criminal laws which were intended for different purposes. This approach would make ratification of the Convention challenging. In most of the national laws of countries included in this study in relation to specific articles, it is noted that it is the regulatory provisions that exist and that in some cases, the breach of these provisions can have a sanction that is criminal in nature. This position tends to obscure that the regulatory provisions are intended to regulate the manufacture, supply and marketing of medical products with a view to providing safe, efficacious and quality medical products, and act as a preventive measure for potential breaches. Such laws, in most case, did not contemplate that they would be used in the manner of the criminal law to investigate and prosecute intentional

offending with the intention that there be a penal sanction, but this is generally the only avenue open in the absence of any, not alone specific criminal law provisions. Examples of this relate to such areas as are contemplated by the substantive articles of the Convention, in particular Article 5-9 and 11. This applies also to Article 10 and 12, MEDICRIME Convention which were not considered in the NA-FAMED study. Where there is a reliance on the criminal law, and not on regulatory laws, it is often on laws that are inappropriate or inapplicable. An example of this is a reliance on the Criminal Code and similar laws to provide for the offences of aiding and abetting and attempt. In some such cases the application of the Criminal Code may not apply outside the specified offences and sanctions provided for in the Code. These generally do not apply to medical products. It is recognised that in a limited number of cases that it is the Criminal Code that is used to address counterfeiting and other intentional offending relating to medicinal products and or medical devices. In most such cases, the provision is very general and requires more specificity to come into full correspondence with the MEDICRIME Convention.

It is important to emphasise at this point that according to Article 1 (Object and Scope) the MEDICRIME Convention is a criminal law instrument to prevent and combat threats to public health through the criminalisation of certain acts; protecting the rights of victims of the offences established under this Convention; and promoting national and international co-operation.

The NA-FAMED report limits its analysis to the sphere of definitions (Article 4, MEDICRIME Convention), to the offences established based on Articles 5 – 8, to the aiding and abetting and attempt (Article 9), to corporate liability (Article 11), and to the aggravating circumstances (Article 13). Due the methodological approach chosen in this report, other provisions have not been considered at this time. These include Article 10 (Jurisdiction), Article 12 (Sanctions and measures), and Article 14 (Previous convictions) as well as Investigation, prosecution and procedural law aspects implied by the MEDICRIME Convention (Chapter III), Co-operation of authorities an information exchange (Chapter IV), Measures for prevention (Chapter V), Measures for protection (Chapter VI) and International Cooperation (Chapter VII). As these latter mentioned provisions of the MEDICRIME Convention also imply important obligations for Parties, further analysis related to these topics will have to be developed in the future.

## Analysis of the different articles considered

### Article 4 – definitions

No country included in this report has national laws which include full implementation of all the definitions included in Article 4 of the MEDICRIME Convention. The importance of the implementation of such definitions must be highlighted as they are the basis for the correct application of the criminal offences established in Chapter II of the MEDICRIME Convention. Different terms with similar meanings to the terms in Article 4 have been observed. In order to ensure homogeneity, it is recommended that the terms used in Article 4 be used when drafting legislation towards ratification of the Convention.

### Articles 5 - 8

In most of the countries included in the report, the legislation is mostly regulatory or general and does not provide for offences in the criminal law that would correspond with the offences contemplated by Article 5–8, MEDICRIME Convention. In some countries, specific criminal law provisions are used. It is important to refer to the Explanatory Report to the Convention when it states, "in the case of an individual committing an offence established under Articles 5 and 6, Parties must provide for prison sentences that can give rise to extradition".

**Other Substantive Criminal Law Provisions:** Article 9 (aiding or abetting and attempt), Article 11 (Corporate liability) and Article 13 (aggravating circumstances) are directly connected with the way in which each country establishes the offences of Articles 5-8 MEDICRIME Convention. The implementation at the internal level of Articles 9-13 MEDICRIME Convention only achieves full significance based on an adequate criminalisation of Articles 5-8 MEDICRIME Convention by each country.

As the Convention ensures the harmonisation at the international level (at least for the countries that have signed and ratified the Convention) for these offences, the absence of such for a great number of countries results in a weak and uncoordinated response to the counterfeiting of medical products and similar crimes. This facilitates intentional offending, in particular, by organised criminal groups, and the consequential threat to public health. Countries need to think on the international cooperation level to address the threat at the local level.

The national consultants, in 22 countries, submitted examples of case law relating to prosecutions involving medical products (see Appendix 4). It was not intended that the submissions be analysed for correspondence to the MEDICRIME Convention as none of the countries, not having ratified the Convention, have obligations under it.

In relation to the MEDICRIME Convention, the following can be extrapolated from the submissions made.

The type of offending behaviours contemplated by the MEDICRIME Convention in Articles 5-8, 9 and 11, appear to have existed for many years in the past and will continue to do so and be prosecuted, utilising varying provision in the 22 countries included in the Case law review survey. There is no evidence, regionally or globally, to suggest that this type of offending behaviour relating to counterfeit (falsified) medical products and similar crimes involving threats to public health will not continue. It is, therefore, reasonable to assume that these 22 countries will continue to be confronted with such crimes. For the remainder of the 16 countries in the NA-FAMED report for whom no submissions were made on case law by the national consultants, it is reasonable to assume that they are in no different a position than the 22 countries just mentioned. The national consultants were not instructed on the number of prosecutions to report on. Of the 22 countries, some national consultants submitted a single example of a recent relevant prosecution, while in other countries cases going back many years were submitted.

Aggravating circumstances, as contemplated by Article 13 a-e, MEDICRIME Convention, appeared to have played a part in several the case law submissions made. It is unclear the extend of all such circumstances that played a part in the offending behaviours prosecuted, even where there was no law existed to provide for the aggravating circumstances to be considered by the Court in determining sanctions.

The reports on prosecution in the 22 countries appeared to have based these on the criminal law, administrative law and general (e.g., Trademark law). It cannot be reported that there was a consistent approach on which choice of law would be used when looking horizontally across countries. This suggests the absence of a harmonised approach across countries in prosecutable offences relating to counterfeit/falsified medical products and similar crimes.

It is unclear whether the offences involved in some prosecutions attracted a custodial sentence sufficient enough to enable extradition under the Convention, if any custodial sentence was possible. It is noted that Article 12 MEDICRIME Convention provides that for the offences contemplated by Articles 5 and 6, when committed by natural persons, penalties should involve the deprivation of liberty that may give rise to extradition.

The case law review reported by national consultants suggests that had the countries involved in the NA-FAMED survey ratified the MEDICRIME Convention, they would have had at their disposal a dedicated criminal law framework to address the offending behaviours in a consistent and harmonised manner for the purpose of comprehensively and effectively prosecuting counterfeiting (falsification) of medical products and similar crimes involving threats to public health.

This report, in the following section of the Country Report, assesses specific provisions of the country laws for correspondence with the relevant article of the Convention. While an overall assessment of correspondence with the Convention should be reflected by this approach, this has not always been possible due to the absence of a definition and or the base criminal law offence.

## 2.3. Conclusions

1. The responses to the questionnaire by national consultants having surveyed the national laws indicate that countries are attempting to address the counterfeiting of medical products and other similar crimes involving threats to public health through whatever existing laws are available notwithstanding that such laws were not sufficiently comprehensive or intended for this purpose.
2. The countries recognise the threat existing to public health from falsified medical products and similar crimes. They have, in many cases put in place laws that partially, though not wholly or comprehensively, support an early ratification and implementation of the MEDICRIME Convention.
3. The NA-FAMED survey report identifies for the CoE member States and other countries included in this survey, legal and procedural gaps that need to be closed for the criminalisation of the products and trade of falsified medical products.
4. The CoE can now establish how best it can support member States and other countries build a criminal law and supporting framework under the MEDICRIME Convention to combat counterfeit/falsified medical products and similar crimes involving threats to public health.

## 2.4. Recommendations

It is recommended that:

1. In the drafting of internal laws to prepare for ratification and implementation of the MEDICRIME Convention, a single holistic law encompassing all elements provided for in the Convention be enacted.
2. A hybrid approach to drafting the implementing law be used whereby the criminal law and the regulatory law reference points co-exist. This avoids a disjointed approach of trying to relate medical product technical details, such as definitions, to disconnected criminal law offences. It would facilitate simpler and friendlier use for investigation and prosecution of intentional offending and ensure better outcomes for protecting public health.
3. The general criminal law may adequately implement the corresponding provision in the Convention, for example in Articles 9 and 11, to the extent that the domestic law adequately implements the offences defined in the Convention. This is reliant on such offences being implemented in the internal law, then criminalisation of the commission of such offence arises automatically.
4. Isolated reliance on provisions in other laws should not be used as correspondence with specific articles in the Convention as this will defeat the intent and spirit of the Convention. It would weaken the impact on combating counterfeit medical products and other similar crimes involving threats to public health.

# III. COUNTRY REPORTS

The Country Report assessment is made for specific articles and not in a holistic way to provide a guide at this time on the possible extent of correspondence with those specific articles of the Convention by national legislation. The General Report, above, should be read regarding the full implementation of the MEDICRIME Convention.

## 3.1 Andorra

### Article 4 - Definitions

a. Article 4.a MEDICRIME Convention – Medical Product
No provision could be found in internal laws corresponding with Article 4.a, MEDICRIME Convention.
Further action is needed to fully correspond with Article 4.a, MEDICRIME Convention.

b. Article 4.b MEDICRIME Convention – Medicinal Product
No provision could be found in internal laws corresponding with Article 4.b, MEDICRIME Convention.
Further action is needed to fully correspond with Article 4.b, MEDICRIME Convention.

c. Article 4.c MEDICRIME Convention -Active substance
No provision could be found in internal laws corresponding with Article 4.c, MEDICRIME Convention.
Further action is needed to fully correspond with Article 4.c, MEDICRIME Convention.

d. Article 4.d MEDICRIME Convention – Excipient
No provision could be found in internal laws corresponding with Article 4d, MEDICRIME Convention.
Further action is needed to fully correspond with Article 4.d, MEDICRIME Convention.

e. Article 4.e MEDICRIME Convention – Medical Device
No provision could be found in internal laws corresponding with Article 4$^{e}$, MEDICRIME Convention.
Further action is needed to fully correspond with Article 4.e, MEDICRIME Convention.

f. Article 4.f MEDICRIME Convention – Accessory
No provision could be found in internal laws corresponding with Article 4f, MEDICRIME Convention.
Further action is needed to fully correspond with Article 4.f, MEDICRIME Convention.

g. Article 4.g MEDICRIME Convention – Parts and materials
No provision could be found in internal laws corresponding with Article 4.g, MEDICRIME Convention.
Further action is needed to fully correspond with Article 4.g, MEDICRIME Convention.

h. Article 4.h MEDICRIME Convention – Document
No provision could be found in internal laws corresponding with Article 4h, MEDICRIME Convention.
Further action is needed to fully correspond with Article 4.h, MEDICRIME Convention.

i. Article 4.i MEDICRIME Convention – Manufacturing
No provision could be found in internal laws corresponding with Article 4.i, MEDICRIME Convention.
Further action is needed to fully correspond with Article 4.i, MEDICRIME Convention.

j. Article 4.j MEDICRIME Convention – Counterfeit
No provision could be found in internal laws corresponding with Article 4.j, MEDICRIME Convention.
Further action is needed to fully correspond with Article 4.j, MEDICRIME Convention.

k. Article 4.k MEDICRIME Convention – Victim
No provision could be found in internal laws corresponding with Article 4.k, MEDICRIME Convention.
Further action is needed to fully correspond with Article 4.k, MEDICRIME Convention.

## CHAPTER II – SUBSTANTIVE CRIMINAL LAW

### Article 5 – Manufacturing of counterfeits

Article 276.1 and 2 Criminal Code (CC) of Andorra (LLei 9/2005, qualificada del Codi Penal). Pharmaceutical crimes, as regards medicinal products, provides for endangerment resulting from a failure to meet technical standards. This offence describes a substandard medicinal product which may not necessarily also be counterfeit. A counterfeit medicinal product may and usually be made substandard in its production and an offence under this provision may assist the prosecution. It will not, however substitute for an offence of the manufacture or adulteration of a counterfeit medical product. It does not correspond with Article 5, MEDICRIME Convention. No provisions in internal law, as regards active substances, excipients, medical devices, parts, material, and accessories, can be found corresponding with Article 5, MEDICRIME Convention.

Further action is needed to correspond with Article 5, MEDICRIME Convention.

### Article 6 – Supplying, offering to supply, and trafficking in counterfeits

Art. 276.3 CC describes partly the ingredients of a counterfeit medicinal product, as regards placing it on the market. This provision does not adequately encompass all the requirements of Article 6, MEDICRIME Convention and does not include active substances, excipients, medical devices, parts, material, and accessories.

Further action is required to fully correspond with Article 6, MEDICRIME Convention.

### Article 7 – Falsification of documents

Art. 435 CC corresponds with Article 7, MEDICRIME Convention.

### Article 8 – Similar crimes involving threats to public health

8.a.i: Article 276.1 and 2 CC partially correspond with Article 8.a.i, MEDICRIME Convention.

8.a.ii: No provision could be found in internal laws corresponding with Article 8.a.ii, MEDICRIME Convention.

8.b. No provision could be found in internal laws corresponding with Article 8.b, MEDICRIME Convention.

Further action is required to correspond fully with Article 8 MEDICRIME Convention.

### Article 9 – Aiding or abetting and attempt

9.1: Article 23 CC, as regards aiding and abetting, corresponds with Article 9.1, MEDICRIME Convention.

9.2: Article 276.6 CC, as regards attempt, corresponds with Article 9.1, MEDICRIME Convention.

### Article 11 – Corporate liability

11.1. a, b, c: No provision could be found in internal laws corresponding with Article 11.1, MEDICRIME Convention.

11.2: No provision could be found in internal laws corresponding with Article 11.1, MEDICRIME Convention.

11.3: According to Article 71, Criminal Code, and jurisprudence of Andorran courts the liability of a legal person may be civil or administrative.

11.4: Such liability shall be without prejudice to the criminal liability of the natural persons who have committed the offence according to Andorran Domestic Criminal Law and jurisprudence of Andorran courts. This corresponds with Article 11.4, MEDICRIME Convention.

Further action is needed to correspond with Article 11.1 and 11.2, MEDICRIME Convention.

### Article 13 – Aggravating circumstances

13.a: Article 276 in connection with art. 102 and 113 and following ones of the Criminal Code

13.b and c: Article 30.3 CC, as regards an abuse of trust but not specifying the circumstance of acting in the course of a professional duty or as a duty of a manufacturer or in trade, partially corresponds with Article 13.b and c, MEDICRIME Convention. Art. 276.5 Criminal Code is also applicable.

13.d: No provision could be found in internal laws corresponding with Article 13. d, MEDICRIME Convention.

13.e: Article 30.7 CC partially corresponds with Article 13.e, MEDICRIME Convention.

13.f: Article 30.7 CC corresponds with Article 13.f, MEDICRIME Convention.

Further action is needed to fully correspond with Article 13, MEDICRIME Convention.

## 3.2 Armenia

### Article 4 - Definitions

a. Article 4.a, MEDICRIME Convention – Medical Product
No provision in internal law, as regards the term 'medical product' could be found corresponding to Article 4.a, MEDICRIME Convention.
The term should be defined to correspond with Art 4.a, MEDICRIME Convention.

b. Article 4.b, MEDICRIME Convention – Medicinal Product
Article 3, Law on Medicines, as regards medicinal products, corresponds with Article 4.b, MEDICRIME Convention.
Article 3, p.1.11, Law on Medicines, as regards investigational medicinal products, corresponds with Article 4.b, MEDICRIME Convention.

c. Article 4.c, MEDICRIME Convention -Active substance
Article 3, p.1.8, Law on Medicines, defines the term 'substance' rather than active substance. This is similar to, but does not fully correspond with Article 4.c, MEDICRIME Convention.
Further action is needed to fully correspond with Article 4.c, MEDICRIME Convention.

d. Article 4.d, MEDICRIME Convention – Excipient
Law on Medicines, Art. 3, p.1.10, Law of Medicines, defines the term 'excipient' similar to the term 'substance' and does not fully correspond with Article 4.d, MEDICRIME Convention.
Further action is needed to fully correspond with Article 4.d, MEDICRIME Convention.

e. Article 4.e, MEDICRIME Convention – Medical Device
No provision in internal law, as regards the term 'medical device' could be found corresponding to Article 4.e, MEDICRIME Convention.
Action is needed to correspond with Article 4.e, MEDICRIME Convention.

f. Article 4.f, MEDICRIME Convention – Accessory
No provision in internal law, as regards the term 'accessory' could be found corresponding to Article 4.f, MEDICRIME Convention.
Action is needed to correspond with Article 4.f, MEDICRIME Convention.

g. Article 4.g, MEDICRIME Convention – Parts and materials
No provision in internal law, as regards the terms 'parts', and 'materials', could be found corresponding to Article 4.g, MEDICRIME Convention.
Action is needed to correspond with Article 4.g, MEDICRIME Convention.

h. Article 4.h, MEDICRIME Convention – Document
No provision in internal law, as regards the term 'document', could be found corresponding to Article 4.h, MEDICRIME Convention.
Action is needed to correspond with Article 4.h, MEDICRIME Convention.

i. Article 4.i, MEDICRIME Convention – Manufacturing
Article 3, p.1.18 Law on Medicines, as regards the term 'Manufacturing' only refers to the term 'Manufacture', which in turn, only refers to medicinal products. No provision in internal law, as regards active substances, excipients, medical devices, parts and materials, and accessories, could be found to correspond with Article 4.1, MEDICRIME Convention.
Further action is needed to correspond with Article 4.i, MEDICRIME Convention.

j. Article 4.j MEDICRIME Convention – Counterfeit
Article 3, p.1.15, Law on Medicines, as regards medicinal products, corresponds with Article 4.j, MEDICRIME Convention. There is no corresponding provision, as regards medical devices corresponding to Article 4.j, MEDICRIME Convention.
Further action is needed to fully correspond with Article 4.j, MEDICRIME Convention.

k. Article 4.k MEDICRIME Convention – Victim
Article 58, Code of Criminal Procedure, corresponds to Article 4.k, MEDICRIME Convention.

## CHAPTER II – SUBSTANTIVE CRIMINAL LAW

### Article 5 – Manufacturing of counterfeits

Article 280.2, Criminal Code provides a general law offence for the manufacture of a false drug. There is no similar provision as regards medical devices and accessories, parts or materials. There is insufficient correspondence with Article 5, MEDICRIME Convention.

Further action is needed to fully correspond with Article 5, MEDICRIME Convention.

### Article 6 – Supplying, offering to supply, and trafficking in counterfeits

Article. 280.2 Criminal Code provides a general criminal law offence for the supply of a false drug.

There is no similar provision as regards medical devices and accessories, parts, or materials. There is insufficient correspondence with Article 6, MEDICRIME Convention.

Further action is needed to fully correspond with Article 6, MEDICRIME Convention.

### Article 7 – Falsification of documents

Article 325, CC provides criminal liability for forgery of an official document, which could also be a document related to medical products. This provision is general criminal law. It corresponds with Article 7, MEDICRIME Convention.

### Article 8 – Similar crimes involving threats to public health

8.a.i: Article 280.2, paragraph 1, CC refers to a pharmaceutical practice without a licence, the breach of which is a criminal offence. However, it is unclear what the scope of the pharmaceutical practice means. A condition for this offence requires that this negligently causes damage to human health, which is not a condition in Article 8.a.1, MEDICRIME Convention.

8.a.ii: No provision in internal law corresponds with Article 8.aii, MEDICRIME Convention.

8.b: No provision in internal law corresponds with Article 8.b, MEDICRIME Convention.

Further action is needed to correspond with Article 8, MEDICRIME Convention.

### Article 9 – Aiding or abetting and attempt

9.1: Article 38, part. 1, CC; Article 39, part. 2, C; Article. 39, part 5, CC corresponds with Article 9.i, MEDICRIME Convention.

9.2: Article 33, parts 1and 2, CC criminalises the attempt of all criminal offences regulated in the CC. The penalties applicable to a completed criminal act shall also apply to attempt. The aider or abettor is punished in general as well and the penalties applicable to offenders of a criminal offence shall also apply to the aider or abettor and the helper. Article 33, CC corresponds with Article 9.2, MEDICRIME Convention.

### Article 11 – Corporate liability

No provision in internal law corresponds with Article 11, MEDICRIME Convention.

Action is needed to correspond with Article 11, MEDICRIME Convention.

### Article 13 – Aggravating circumstances

13.a: Articles 280 and Article 280.2 and 4, CC are constituent elements of the offence.

13.b: No provision in internal law corresponds with Article 13.b, MEDICRIME Convention.

13.c: No provision in internal law corresponds with Article 13.c, MEDICRIME Convention.

13.d: Article 63, paragraph 12, CC provides as aggravating circumstance the committal of crime in a way that is dangerous for society. This is considered to be too general to fully correspond with Article 13 d, MEDICRIME Convention.

13.e: Article 63 paragraph 3 CC corresponds with Article 13.e, MEDICRIME Convention.

13.f: Article 63 paragraph 1, CC corresponds with Article 13.e, MEDICRIME Convention.

Further action is needed to fully correspond with Article 13 MEDICRIME Convention.

## 3.3 Austria

### Article 4 - Definitions

a. Article 4.a MEDICRIME Convention – Medical Product
No provision in internal law, as regards the term 'medical product', corresponds with Article 4.a, MEDICRIME Convention.
Further action is needed to fully correspond with Article 4.a MEDICRIME Convention.

b. Article 4.b MEDICRIME Convention – Medicinal Product
§ 1 Abs.1 no. 1 and 2 Medicinal Product Act 2005 (AMG) and §2a Abs. 14 AMG, as regards investigational medicinal products correspond with Article 4.b MEDICRIME Convention. It is noted that the wording of § 1 Abs.1 no. 1 does not use the term 'presentation' but the term used in its place, 'intent', is interpreted in Austrian medicines jurisprudence as being the same as 'presentation.

c. Article 4.c MEDICRIME Convention – Active substance
§ 1 Abs. 4a AMG defines the term 'active ingredients' to correspond with Article 4.c MEDICRIME Convention. The term 'active ingredients' is separately defined in § 2 Abs. 24a Austrian Ordinance on Good Manufacturing Practices - AMBO 2009 and has the same meaning as in § 1 Abs. 4a AMG.

d. Article 4.d MEDICRIME Convention – Excipient
§ 1 Abs. 4b AMG defines the term 'excipient to correspond with Article 4.d MEDICRIME Convention.

e. Article 4.e MEDICRIME Convention – Medical Device
§ 1 Abs. 2 Medical Devices Act corresponds with Article 4.e MEDICRIME Convention.

f. Article 4.f MEDICRIME Convention – Accessory
§ 2 Abs. 2 Medical Device Act (MPG) corresponds to Article 4.f MEDICRIME Convention.

g. Article 4.g MEDICRIME Convention – Parts and materials
There is no legal definition of the term 'parts' and 'materials'.
Action is needed to correspond with Article 4.g MEDICRIME Convention.

h. Article 4.h MEDICRIME Convention – Document
There is no legal definition of the term 'document.
Action is needed to correspond with Article 4.h MEDICRIME Convention.

i. Article 4.i MEDICRIME Convention – Manufacturing
§ 2 Abs.10 AMG, as regards medicinal products and active substances, corresponds with Article 4.i MEDICRIME Convention. Excipients are not specifically defined and use the European Guidelines based on Article 47 of Directive 2001/83/EC.
§2 Abs.7 and 8 MPG, as regards medical devices and accessories, correspond with Article 4.i MEDICRIME, Convention.

j. Article 4.j MEDICRIME Convention – Counterfeit
§ 1 Abs. 25 and 26 AMG, implement Directive 2011/62/EU, amending Directive 2001/83, EC, as regards medicinal products and active substances, respectively, and correspond with Article 4.j MEDICRIME Convention. There is no definition of the term 'counterfeit' as regards medical devices.
Further action is needed to fully correspond with Article 4.j MEDICRIME Convention.

k. Article 4.k MEDICRIME Convention – Victim
§ 65. 1. C, Criminal Procedure Code 1975, is general law and is not specific to medical products. § 65. 1.C defines the term 'victim' as "any other person who has suffered damage as a result of a criminal act or who could otherwise have been impaired in their legally protected legal interests. This corresponds the intent of Article 4.k MEDICRIME Convention.

**CHAPTER II – SUBSTANTIVE CRIMINAL LAW**

### Article 5 – Manufacturing of counterfeits

§ 82b Abs. 1, AMG provides an offence corresponding to Article 5.1, MEDICRIME Convention as regards medicinal products, active substances, or excipients. Adulteration is considered to be encompassed in manufacturing of a counterfeit medicinal product and no separate offence exists. There is no offence as regards medical devices, accessories, parts, and materials.

Further action is needed to fully correspond with Article 5, MEDICRIME Convention.

### Article 6 – Supplying, offering to supply, and trafficking in counterfeits

§ 82b. 2 AMG corresponds with Article 6, MEDICRIME Convention, as regards medicinal products, active substances, and excipients. There is no offence as regards medical devices, accessories, parts, and materials.

Further action is needed to fully correspond with Article 6 MEDICRIME Convention.

### Article 7 – Falsification of documents

§ 82b Abs. 7 AMG corresponds with Article 7, MEDICRIME Convention. No provision in internal law can be found as regards the falsification of documents related to medical devices, parts, materials, and accessories.

Further action is needed to fully correspond with Article 7 MEDICRIME Convention.

### Article 8 – Similar crimes involving threats to public health

8.a.i: §§ 84 Abs. 1. No.s 5, 6, 7, 7a, 9, 17, and 25 AMG correspond with Article 8. a. (i), MEDICRIME Convention.

8.a.ii: §§111 Abs. 1 no.1 to 6 and 39 Medical Devices Act (MPG) correspond with Article

8.a (ii) MEDICRIME Convention.

8.b: §§ 108 and 146, Criminal Code (StGB) are general law provisions regarding deception and fraud and not specific to medical products. They adequately correspond with Article 8.b, MEDICRIME Convention.

### Article 9 – Aiding or abetting and attempt

§§ 12 and 15, StGB correspond with Article 9, MEDICRIME Convention.

### Article 11 – Corporate liability

11.1: Section 2.1, The Association Responsibility Act corresponds with Article 11.1, MEDICRIME Convention.

11.2: Sections 3.1 and 3.2, The Association Responsibility Act., corresponds with Article.

11.2, MEDICRIME Convention.

11.3: Domestic law, as regards criminal, administrative and civil liability, corresponds with Article 11.3, MEDICRIME Convention.

11.4: Section 3.4, The Association Responsibility Act corresponds with Art. 11.4, MEDICRIME Convention.

### Article 13 – Aggravating circumstances

13.a: § 82b Abs. 6 AMG provides for aggravating circumstances in relation to medicinal products where the conduct results in the death of a person or serious bodily injury (Section 84 (1) StGB) of a larger number of people. This, as regards medicinal products, corresponds with Article 13.a, MEDICRIME Convention.
There are no aggravating circumstances provided in the MPG for medical devices.
Further action is needed to correspond fully with Article 13.a, MEDICRIME Convention.

13.b: § 82b Abs. 3 and 5 AMG provides for aggravating circumstances for specified healthcare professionals - doctor, dentist, veterinarian, pharmacist, dentist, or midwife. This is a restricted list of professionals. Article 13.b, MEDICRIME Convention is not restricted to healthcare professionals.
There are no aggravating circumstances provided in the MPG for medical devices.
Further action is needed to correspond fully with Article 13.b, MEDICRIME Convention.

13.c: AMG and MPG do not provide for aggravating circumstances that correspond with Article 13.c, MEDICRIME Convention. § 32.(1), (2), and (3) StGB provide for sentencing guidance for the Criminal Law. These include the negative or indifferent attitude of the perpetrator to legally protected values and the level of premeditation. § 32. StGB encompasses, to an extent, the intent of Article 13, c, MEDICRIME Convention as regards medicinal products and medical devices.
Further action is required to fully correspond with Article 13.c, MEDICRIME Convention.

13.d: AMG and MPG do not provide for aggravating circumstances that correspond with Article 13.d, MEDICRIME Convention. § 32.(1), (2), and (3) StGB provide for sentencing guidance for the Criminal Law. These include the negative or indifferent attitude of the perpetrator to legally protected values and the level of premeditation. § 32. StGB encompasses, to an extent, the intent of Article 13, d, MEDICRIME Convention as regards medicinal products and medical devices.
Further action is required to fully correspond with Article 13.d, MEDICRIME Convention.

13.e: AMG and MPG do not provide for aggravating circumstances that correspond with Article 13.e, MEDICRIME Convention. § 278a, StGB provides for aggravating circumstances for involvement in organised crimes and this is not specifically focused on crimes that relate to medical products. However, the provision does not exclude conduct involving medical product related crime and it specifies circumstance that aims at the recurring and planned commission of serious criminal acts that threaten life and physical integrity, among others. This sufficiently encompasses the intent of Article 13, e, MEDICRIME Convention as regards medicinal products and medical devices.

13.f: AMG and MPG do not provide for aggravating circumstances that correspond with Article 13.f, MEDICRIME Convention. § 33 Abs. 1 No. 1 and 2 StGB corresponds with Article 13.f, MEDICRIME Convention.

## 3.4 Azerbaijan

### Article 4 - Definitions

a. Article 4.a MEDICRIME Convention – Medical Product
No provision in internal law could be found corresponding with Article 4.a, MEDICRIME Convention.
Action is necessary to correspond with Article 4.a, MEDICRIME Convention.

b. Article 4.b MEDICRIME Convention – Medicinal Product
Article 1.0.1, Law of the Republic of Azerbaijan on Medicinal products, as regards medicinal products, correspond substantially with Article 4.b, MEDICRIME Convention. There is no term found in the law of medicinal products defined relating to investigational medicinal products, but Article 6.5.4, in relation to authorisations exemptions, approximate to the term 'investigational medicinal products. Article 1.0.5 Law of the Azerbaijan Republic about veterinary Science, 2005, amended 2020, as regards veterinary medicines, substantially correspond with Article 4.b, MEDICRIME Convention.

c. Article 4.c MEDICRIME Convention -Active substance
Article 1.0.3, Law of the Republic of Azerbaijan on Medicinal products provides a definition of the term 'active substance', which is not as broad as, but partially corresponds with Article 4, MEDICRIME Convention. When combined with Article 1.0.2, which uses the term 'drugs' when used in the manufacture of medicinal products, both correspond substantially with Article 4.c, MEDICRIME Convention.

d. Article 4.d MEDICRIME Convention – Excipient
No provision in internal law can be found corresponding with Article 4.d, MEDICRIME Convention. The term 'excipient' is defined by the decision of the Collegium of the Ministry of Health, which is a normative-legal act according to the Constitution of the Republic of Azerbaijan (Article 148. I. 6).
Further action is needed to correspond fully with Article 4.d, MEDICRIME Convention.

e. Article 4.e MEDICRIME Convention – Medical Device
Article 1.0.1, Law of the Republic of Azerbaijan on Medicinal products, as regards medical devices, provides a definition of the term that is not as comprehensive as, but partially corresponds with Article 4.3, MEDICRIME Convention.
Further action is needed to fully correspond with Article 4.e, MEDICRIME Convention.

f. Article 4.f MEDICRIME Convention – Accessory
No provision in internal law can be found corresponding with Article 4.f, MEDICRIME Convention.
Action is needed to correspond with Article 4.f, MEDICRIME Convention.

g. Article 4.g MEDICRIME Convention – Parts and materials
No provision in internal law can be found corresponding with Article 4.g, MEDICRIME Convention.
Action is needed to correspond with Article 4.g, MEDICRIME Convention.

h. Article 4.h MEDICRIME Convention – Document
No provision in internal law can be found corresponding with Article 4.h, MEDICRIME Convention.
Action is required to correspond with Article 4.h, MEDICRIME Convention.

i. Article 4.i MEDICRIME Convention – Manufacturing
Articles 2.1 and 3.6, Law of the Republic of Azerbaijan on Medicinal products, describe the process of the manufacture of medicinal products, but does not cover the manufacture of active substances or excipients. It does not include the manufacture of medical devices, materials of such devices, including designing devices, the parts, or materials, or of bringing medical devices, the parts or materials to their final state, as well as accessories.
Further action is needed to fully correspond with Article 4.i, MEDICRIME Convention.

j. Article 4.j MEDICRIME Convention – Counterfeit
No provision in internal law can be found corresponding with Article 4.j, MEDICRIME Convention.
Action is needed to correspond with Article 4.j, MEDICRIME Convention.

k. Article 4.k MEDICRIME Convention – Victim
Article 87, Criminal Procedure Code substantially corresponds with Article 4.k, MEDICRIME Convention.

## CHAPTER II – SUBSTANTIVE CRIMINAL LAW

### Article 5 – Manufacturing of counterfeits

Article 68-4.1 Code of Administrative Offences, provides an offence for the production of Falsified Medications. It is unclear whether this provision includes medical devices as the term 'medication' rather than 'medicinal product' is used (see the inclusion of medical devices under the term 'medicinal product' in 4. b, above). This partially corresponds with Article 5, MEDICRIME Convention.

Further action is needed to fully correspond with Article 5 MEDICRIME Convention.

### Article 6 – Supplying, offering to supply, and trafficking in counterfeits

Article 68-4.1 Code of Administrative Offences provides an offence for the storage for sale, sale and importation of falsified medications. It is unclear whether this provision includes medical devices as the term 'medication' rather than 'medicinal product' is used (see the inclusion of medical devices under the term 'medicinal product' in 4. b, above). This partially corresponds with Article 6, MEDICRIME Convention.

Further action is needed to fully correspond with Article 6 MEDICRIME Convention.

### Article 7 – Falsification of documents

Article 313, Criminal Code, which provides for the preparation of false documents and the act of tampering with documents, corresponds with Article 7, MEDICRIME Convention.

### Article 8 – Similar crimes involving threats to public health

8.a.i: Article 200.1.1, Criminal Code, as regards unauthorised medicinal products Partially corresponds with Article 8, MEDICRIME Convention. Article 5.1.1, 5.1.2, and 5.1.1, Law of the Republic of Azerbaijan on Medicinal products, as regards manufacturing, wholesale, and retail sales, require State Authorisations. There are no offences for breaches of these requirements in this law. Article 68.4.1, Code of Administrative Offences, as regards the manufacture, storage for sale, retail sale and placing on the market of medications, provide for equivalent offences. This corresponds with Article 8.a.i, MEDICRIME Convention.

8.a.ii: It is unclear whether the provisions mentioned immediately above include medical devices as the term 'medication' rather than 'medicinal product' is used (see the inclusion of medical devices under the term 'medicinal product' in 4. b, above).

Further action is required to fully correspond with Article 8.a, MEDICRIME Convention.

8.b: No provision in internal law could be found corresponding to Article 8.b, MEDICRIME Convention.

Action is required to fully correspond with Article 8.b, MEDICRIME Convention.

### Article 9 – Aiding or abetting and attempt

9.1: Articles 31, 32, 33, Criminal Code, as regards aiding and abetting, correspond with Article 9.1, MEDICRIME Convention.

9.2: Article 29, Criminal Code, as regards attempt, corresponds with Article 9.2, MEDICRIME Convention.

### Article 11 – Corporate liability

11.1: Article 99-4, Criminal Code correspond to Article 11.1, MEDICRIME Convention.

11.2: Article 99-4.1, Criminal Code corresponds with Article 11.2, MEDICRIME Convention.

11.3: Article 18, Law of the Republic of Azerbaijan on Medicinal products corresponds with Article 11.3, MEDICRIME Convention.

11.4: Article 99-4.2; Article 99-4.3; and Article 99-4.4, Criminal Code corresponds with Article 11.4, MEDICRIME Convention.

### Article 13 – Aggravating circumstances

13.a: Article 200-1.4, Criminal Code, as regards the act involves the death of a person by negligence or other grave consequences, corresponds with Article 13.a, MEDICRIME Convention.

13.b: No provision in internal law could be found corresponding with Article 13.b, MEDICRIME Convention.

Action is needed to correspond with Article 13.b, MEDICRIME Convention.

13.c: No provision in internal law could be found corresponding with Article 13.c, MEDICRIME Convention.

Action is needed to correspond with Article 13.c, MEDICRIME Convention.

13.d: No provision in internal law could be found corresponding with Article 13.d, MEDICRIME Convention.

Action is needed to correspond with Article 13.d, MEDICRIME Convention.

13.e: Article 200-1.2.2 Criminal Code corresponds with Article 13.e, MEDCRIME Convention.

13.f: Article 200-1.2.1, Criminal Code corresponds with Article 13.f, MEDICRIME Convention.

## 3.5 Bulgaria

### Article 4 - Definitions

a. Article 4.a MEDICRIME Convention – Medical Product
No provision in internal law, as regards the term 'medical product', could be found corresponding with Article 4.a, MEDICRIME Convention. It is noted that there are separate definitions of medicinal product and medical device.
Further action is needed to fully correspond with Art 4.a MEDICRIME Convention.

b. Article 4.b MEDICRIME Convention – Medicinal Product
Article 3, 'Law on Medicinal Products in human medicine', as regards medicinal products for human use, and §1, pt. 9, Law on Veterinary Medicines corresponds, as regards medicinal products for veterinary use, corresponds to Article 4.b, MEDICRIME Convention.
No provision in internal law, as regards the term 'investigational medicinal products' could be found corresponding to Article 4.b MEDICRIME Convention.
Further action is needed to fully correspond with Art 4.b MEDICRIME Convention.

c. Article 4.c MEDICRIME Convention -Active substance
Pt. 1 of §1, 'Law on Medicinal Products in human medicine' corresponds with Article 4c, MEDICRIME Convention, except that it does not include medicinal products for veterinary use.
Action is needed to correspond with Art 4.c MEDICRIME Convention.

d. Article 4.d MEDICRIME Convention – Excipient

Pt. 46 of §1, 'Law on Medicinal Products in human medicine' refers to the term 'auxiliary substance' and corresponds with Article 4c, MEDICRIME Convention. The Law on Veterinary Medicines does not correspond with Article 4.d, MEDICRIME Convention.
Further action is needed to fully correspond with Article 4.d, MEDICRIME Convention.

e. Article 4.e MEDICRIME Convention – Medical Device
Pt. 29, §1, Law on Medical Devices, 2007 corresponds with Article 4[e], MEDICRIME Convention.

f. Article 4.f MEDICRIME Convention – Accessory
Pt. 29, §1, Law on Medical Devices, 2007, corresponds with Article 4[e], MEDICRIME Convention.

g. Article 4.g MEDICRIME Convention – Parts and materials
No provision in internal law, as regards the terms 'parts' and 'materials' could be found to correspond with Article 4.g, MEDICRIME Convention.

Action is needed to correspond with Art 4.g MEDICRIME Convention.

h. Article 4.h MEDICRIME Convention – Document
Article 93, pts 5 and 6 of the Criminal Code provide for the definitions of a document and a falsified document, respectively, in general. Pt. 5 of §1, Law on Medicinal Products in human medicine defines the term "valid documentation" as documentation in compliance with requirements of the law in regards of content and completeness. Pt 9 of §1, Law on Medical Devices uses the term "Identification data of the device" to describe documents. Apart from the provisions of the Criminal Code, the other definitions are insufficient on their own, but in combination with the Criminal Code they are sufficient to correspond with Article 4h MEDICRIME Convention. It is recommended that one definition be provided by law to encompass the intent of Article 4.h, MEDICRIME Convention.

i. Article 4.i MEDICRIME Convention – Manufacturing
Pt. 52 of §1. The Law of Medicinal Products in human medicine corresponds with Article 4.i MEDICRIME convention. §1, pt. 90, Law on Veterinary Medicines corresponds with Article 4.i, MEDICRIME Convention.
There is no definition in the Law of Medical Devices for the term 'manufacturing' as regards medical devices and accessories.
Further action is needed to fully correspond with Art 4.i MEDICRIME Convention.

j. Article 4.j MEDICRIME Convention – Counterfeit
Pt. 81a. § 1. The Law of Medicinal Products in human medicine defines the term 'falsified' and it corresponds with Article 4.j MEDICRIME Convention. There is no equivalent definition for medical devices or for medicinal products for veterinary use.
Further action is needed to fully correspond with Art 4.j MEDICRIME Convention.

k. Article 4.k MEDICRIME Convention – Victim
Article 74, Code of Criminal Procedure, 2006, defines the term 'victim' generally and with a scope that encompasses any victim of a property or non-property crime.
Further action is needed to fully correspond with Art 4.k MEDICRIME Convention.

## CHAPTER II – SUBSTANTIVE CRIMINAL LAW

### Article 5 – Manufacturing of counterfeits

Art. 284a of Law on Medicinal Products in human medicine creates an administrative violation for manufacturing, exporting, and importing of falsified medicinal products not requiring intentional conduct in relation to medicinal products for human use. Due to the absence of the requirement for intentional conduct, this does not correspond with Article 5.1. MEDICRIME Convention. There is no corresponding offence in relation to medicinal products for veterinary use or for medical devices, accessories, parts, and materials.

Clarification is required on the status of adulteration to ensure that it corresponds with Article 5.2 MEDICRIME Convention.

Art. 350a of Criminal Code provides a criminal offence for producing veterinary medical products that puts the life or health of another at risk. Notwithstanding that this provision may address aspects of the intent required, it does not correspond with Article 5, MEDICRIME Convention.

Action is needed to correspond with Art 5.1 MEDICRIME Convention.

### Article 6 – Supplying, offering to supply, and trafficking in counterfeits

Art. 284a of Law on Medicinal Products in human medicine provides as an administrative violation the exporting, importing, keeping in stock, trading, or rendering with falsified medicinal products. This administrative offence does not require intentional conduct in relation to medicinal products for human. Due to the absence of the requirement for intentional conduct, this does not correspond with Article 6.1 MEDICRIME Convention. There is no corresponding offence in relation to medicinal products for veterinary use or for medical devices, accessories, parts and materials. Art. 350a of Criminal Code provides a criminal offence for placing on the market veterinary medical products that puts the life or health of another at risk. Notwithstanding that this provision may address aspects of the intent required of the Convention, it does not correspond with Article 6, MEDICRIME Convention.

Action is needed to correspond with Art 6, MEDICRIME Convention.

### Article 7 – Falsification of documents

Articles 308 and 319, Criminal Code (CC) provide for criminal offences relating to documents generally and not specifically to medical products. The offences incorporate the spirit and intent of Article 7 MEDICRIME Convention.

Further action is needed to fully correspond with Article 7, MEDICRIME Convention.

### Article 8 – Similar crimes involving threats to public health

8.a.i. ii. Apart from the requirement for intentional conduct, as required by Article 8 MEDICRIME Convention, Article 281 of Law on Medicinal Products in human medicine and Article 119 of Law on Medical Devices provide for administrative offences for breaches relating to behaviours corresponding to the behaviours mentioned in Article 8 MEDICRIME Convention. No provision in internal law can be found in relation to medicinal products for veterinary use that corresponds with Articles 8.a. i.

Action is needed as regards the criminalisation of intentional behaviours and the inclusion of medicinal products for veterinary use to correspond with Article 8.a, MEDICRIME Convention.

8.b. There is no provision for criminalisation in relation to the commercial use of original documents outside their intended use within the legal medical product supply chain.

Action is needed to correspond with Art 8.b, MEDICRIME Convention.

### Article 9 – Aiding or abetting and attempt

Articles 20 and 21, CC correspond with Article 9.1 MEDICRIME Convention.

Articles 17 and 18, CC correspond with Article 9.2 MEDICRIME Convention.

### Article 11 – Corporate liability

Article 83a of the Administrative Violations and Punishments Law, 1969, as amended, is a general law provision that does not specifically address medical products. Apart from not having any provision for criminal law liability, Article 83a correspond with Article11.1. a, b and c, 11.2, 11.3. and 11.4 MEDICRIME Convention.

### Article 13 – Aggravating circumstances

Aggravating circumstances are not enumerated for in the substantive laws and there is no correspondence with Article 13 MEDICRIME Convention. Articles 54, § 2 and 56, CC provide that the Court in its punishment may consider such circumstances where they are not a substantive element of the crime.

Action is needed to correspond with Article 13, MEDICRIME Convention.

## 3. 6 Canada

### Article 4 - Definitions

a. Article 4.a MEDICRIME Convention – Medical Product
No provision in internal law, as regards the term 'medical product' could be found corresponding with Article 4.a, MEDICRIME Convention.
Action is needed to correspond with Article 4.a, MEDICRIME Convention.

b. Article 4.b MEDICRIME Convention – Medicinal Product
Article 2, Food and Drugs Act R.S.C., 1985, as regards the term 'medicinal product', provides a similar definition under the term 'drug'. This substantially corresponds with Article 4.b, MEDICRIME Convention.

c. Article 4.c MEDICRIME Convention -Active substance
C.01A.001 (1), Division 1A, Food and Drug Regulations, C.R.C., as regards the term 'active substance', is similar but not fully corresponding with Article 4.c, MEDICRIME Convention.
Further action is needed to fully correspond with Article 4.c, MEDICRIME Convention.

d. Article 4.d MEDICRIME Convention – Excipient
No provision in internal law, as regards the term 'excipient' could be found corresponding with Article 4.d, MEDICRIME Convention.
Further action is needed to fully correspond with Article 4.d, MEDICRIME Convention.

e. Article 4.e MEDICRIME Convention – Medical Device
Article 2, Food and Drugs Act R.S.C., 1985, as regards the term 'medical device", provides a similar definition under the term 'device'. This substantially corresponds with Article 4.e, MEDICRIME Convention.

f. Article 4.f MEDICRIME Convention – Accessory
No provision in internal law, as regards the term 'accessory', could be found corresponding with Article 4.f, MEDICRIME Convention.
Action is needed to correspond with Article 4.f, MEDICRIME Convention.

g. Article 4.g MEDICRIME Convention – Parts and materials
No provision in internal law, as regards the terms 'parts' and 'materials', could be found corresponding with Article 4.g, MEDICRIME Convention.
Action is needed to correspond with Article 4.g, MEDICRIME Convention.

h. Article 4.h MEDICRIME Convention – Document
No provision in internal law, as regards the term ''document', could be found corresponding with Article 4.h, MEDICRIME Convention.
Action is needed to correspond with Article 4.h, MEDICRIME Convention.

i. Article 4.i MEDICRIME Convention – Manufacturing
No provision in internal law, as regards the term 'manufacturing', could be found corresponding with Article 4.i, MEDICRIME Convention.
Action is needed to correspond with Article 4.i, MEDICRIME Convention.

j. Article 4.j MEDICRIME Convention – Counterfeit
Part 4.0, Policy on Counterfeit Health Products (POL-0048), as regards the term 'counterfeit', provides a definition of counterfeit health product that is similar in intent, but not in wording, and when taken together with the following explanations provided in Part 4.0, they approximate to the meaning in Article 4.j, MEDICRIME Convention. However, as a policy document that does not constitute part of the Food and Drugs Act or its associated regulations this does not apply as a definition intended in the manner used in Articles 5-8, 9 and 11, MEDICRIME Convention. There is no correspondence with Article 4.j, MEDICRIME Convention.
Action is needed to correspond with Article 4.j, MEDICRIME Convention.

k. Article 4.k MEDICRIME Convention – Victim
Article 2, Criminal Code, as regards the term 'victim', is similar in meaning and intent and corresponds with Article 4.k, MEDICRIME Convention.

## CHAPTER II – SUBSTANTIVE CRIMINAL LAW

### Article 5 – Manufacturing of counterfeits

No provision in internal law could be found corresponding with Article 5, MEDICRIME Convention.
Action is needed to correspond with Article 5, MEDICRIME Convention.

### Article 6 – Supplying, offering to supply, and trafficking in counterfeits

No provision in internal law could be found corresponding with Article 6, MEDICRIME Convention.
Action is needed to correspond with Article 6, MEDICRIME Convention.

### Article 7 – Falsification of documents

Article 366 (1) and (2), Criminal Code, correspond with Article 7, MEDICRIME Convention.

### Article 8 – Similar crimes involving threats to public health

No provision in internal law could be found corresponding with Article 8.a and b, MEDICRIME Convention.
Action is needed to correspond with Article 8, MEDICRIME Convention.

### Article 9 – Aiding or abetting and attempt

9.1: Article 21(1) and (2), Criminal Code, as regards aiding and abetting, corresponds with Article 9.1, MEDICRIME Convention.
9.2: Article 24(1), Criminal Code, as regards attempt, corresponds with Article 9.2, MEDICRIME Convention.

### Article 11 – Corporate liability

11.1.a, b, c: Article 22.2, Criminal Code corresponds with Article 11.1.a, b and c, MEDICRIME Convention.

11.2: Article 22.1, Criminal Code corresponds with Article 11.2, MEDICRIME Convention.

11.3: Criminal, civil, and administrative sanctions are applicable to legal persons and correspond with Article 11.3, MEDICRIME Convention.

11.4: Article 22.2, Criminal Code corresponds with Article 11.4, MEDICRIME Convention.

### Article 13 – Aggravating circumstances

13.a: Article 380.1(1) (c.1), Criminal Code, partially corresponds with Article 13.a, MEDICRIME Convention.

13.b-f: No provision in internal law, as regards aggravating circumstances, could be found to correspond with Article 13.b-f, MEDICRIME Convention.

Further action is required to correspond with Article 13, MEDICRIME Convention.

## 3.7 Cyprus

### Article 4 - Definitions

a. Article 4.a MEDICRIME Convention – Medical Product
No provision in internal law, as regards the term 'medical product', could be found corresponding with Article 4.a, MEDICRIME Convention. It is noted that there are separate definitions of medicinal product and medical device.
Further action is needed to fully correspond with Art 4.a MEDICRIME Convention.

b. Article 4.b MEDICRIME Convention – Medicinal Product
Article 2, The Medicinal Products for Human Use (Control of Quality, Supply and Prices) Law of 2001 to 2020 and Article 2, The Veterinary Medicinal Products (Control of Quality, Registration, Circulation, Manufacturing, Providing and Use) Law of 2006 to 2011, together correspond to Article 4.b, MEDICRIME Convention. No legal definition for the term 'investigational medicinal products' is provided.
Further action is needed to fully correspond with Art 4.b MEDICRIME Convention.

c. Article 4.c MEDICRIME Convention -Active substance
Article 2, The Medicinal Products for Human Use (Control of Quality, Supply and Prices) Law of 2001 to 2020 corresponds to Art 4.c MEDICRIME Convention. There is no legal definition of the term 'active substance" in relation to veterinary medicinal products.
Further action is needed to fully correspond with Art 4.c MEDICRIME Convention.

d. Article 4.d MEDICRIME Convention – Excipient
Article 2, The Medicinal Products for Human Use (Control of Quality, Supply and Prices) Law of 2001 to 2020 corresponds to Article 4.d. No definition for the term excipient for veterinary medicinal products is provided.
Further action is needed to fully correspond with Art 4.d, MEDICRIME Convention.

e. Article 4.e MEDICRIME Convention – Medical Device
Regulation 2, The Basic Requirements (Medical Devices) Regulations of 2003 as amended, corresponds with Article 4.e, MEDICRIME Convention.

f. Article 4.f MEDICRIME Convention - Accessory
Regulation 2, The Basic Requirements (Medical Devices) Regulations of 2003, as amended, corresponds with Article 4.f, MEDICRIME Convention.

g. Article 4.g MEDICRIME Convention – Parts and materials
No provision could be found in internal laws corresponding with Article 4.g, MEDICRIME Convention.
Further action is needed to fully correspond with Art 4.g, MEDICRIME Convention.

h. Article 4.h MEDICRIME Convention – Document
No provision could be found in internal laws corresponding with Article 4.h. MEDICRIME Convention.
Further action is needed to fully correspond with Art 4.h, MEDICRIME Convention.

i. Article 4.i MEDICRIME Convention – Manufacturing
No provision could be found in internal laws corresponding with Article 4.i, MEDICRIME Convention.
Further action is needed to fully correspond with Art 4.i, MEDICRIME Convention.

j. Article 4.j MEDICRIME Convention – Counterfeit
Article 2, The Medicinal Products for Human Use (Control of Quality, Supply and Prices) Law of 2001 to 2020 corresponds with Article 4.j as regards medicinal products for human use. The law does not cover medicinal products for veterinary use, medical devices, active substances, excipients, parts, materials, and accessories as well as documents.
Further action is needed to fully correspond with Art 4.j MEDICRIME Convention.

k. Article 4.k MEDICRIME Convention – Victim
No provision could be found in internal laws corresponding with Article 4.k, MEDICRIME Convention.
Further action is needed to fully correspond with Art 4.k, MEDICRIME Convention.

## CHAPTER II – SUBSTANTIVE CRIMINAL LAW

### Article 5 – Manufacturing of counterfeits

5.1: Article 99(1)(d), The Medicinal Products for Human Use (Control of Quality, Supply and Prices) Law of 2001 to 2020 creates an offence not requiring intentional conduct in relation to medicinal products for human use corresponding to Article 5.1. There is no corresponding offence in relation to medicinal products for veterinary use or for medical devices, accessories, parts, and materials.

Further action is needed to correspond with Art 5.1 MEDICRIME Convention.

5.2. Clarification is required on the status of adulteration to ensure that it corresponds with Article 5.2 MEDICRIME Convention.

### Article 6 – Supplying, offering to supply, and trafficking in counterfeits

6.1. Article 100, The Customs Code Law creates a criminal offence for the breach of any prohibited act in Customs Laws or other laws. Apart from the requirement for intentional conduct, as required by Article 6.1 MEDICRIME Convention Article 99(1)(d), The Medicinal Products for Human Use (Control of Quality, Supply and Prices) Law of 2001 to 2020 corresponds to Article 6 MEDICRIME Convention. There is no provision in relation to medicinal products for veterinary use and for medical devices.

Action is needed to correspond with Art 6.1 MEDICRIME Convention.

### Article 7 – Falsification of documents

No provision could be found in internal laws corresponding with Article 7, MEDICRIME Convention.

Action is needed to correspond with Art 7 MEDICRIME Convention.

### Article 8 – Similar crimes involving threats to public health

8.a.i: Apart from the requirement for intentional conduct, as required by Article 8 MEDICRIME Convention, the wording of Article 99(1)(a), (b) and (c), Medicinal Products for Human Use (Control of Quality, Supply and Prices) Law of 2001 to 2020 and Article 100(1)(a), (b) and (c), Veterinary Medicinal Products (Control of Quality, Registration, Circulation, Manufacturing, Providing and Use) Law of 2006 to 2011 correspond with Article 8 MEDICRIME Convention for authorisations, in so far as such an activity is not covered by Articles 5, 6 and 7, in relation to the manufacturing, the keeping in stock for supply, importing, exporting, supplying, offering to supply or placing on the market of medicinal products.

Further action is required as regards the criminalisation of intentional behaviours to correspond fully with Article 8.a.i, MEDICRIME Convention.

8.a.ii: Apart from the requirement for intentional conduct, as required by Article 8 MEDICRIME Convention, the wording of Article 52, The Basic Requirements for Specific Products Categories Law of 2002 to 2013 correspond to the requirement of Article 8 MEDICRIME Convention, in so far as such an activity is not covered by Articles 5, 6 and 7, in relation to not being in compliance with the conformity requirements as regards manufacturing, the keeping in stock for supply, importing, exporting, supplying, offering to supply or placing on the market of medical devices.

Further action is needed as regards the criminalisation of intentional behaviours in order to correspond fully with Article 8.a.ii, MEDICRIME Convention.

8.b: No provision could be found in internal laws corresponding with Article 8.b, MEDICRIME Convention.

Action is needed to correspond with Art 8.b, MEDICRIME Convention.

### Article 9 – Aiding or abetting and attempt

No provision could be found in internal laws corresponding with Article 9, MEDICRIME Convention. Action is needed to correspond with Art 9 MEDICRIME Convention.

### Article 11 – Corporate liability

11.1. a, b, and c, 11.2, 11.3, and 11.4: Article 100, Medicinal Products for Human Use (Control of Quality, Supply and Prices) Law of 2001 to 2020 and Article 101, The Veterinary Medicinal Products (Control of Quality, Registration, Circulation, Manufacturing, Providing and Use) Law of 2006 to 2011 correspond with the requirements of Article 11 MEDICRIME Convention. No provision could be found in internal laws in relation to Article 11 requirements as regards medical devices.

Further action is required to fully correspond with Art 11, MEDICRIME Convention.

### Article 13 – Aggravating circumstances

No provision could be found in internal laws corresponding with Article 13, MEDICRIME Convention. Action is needed to correspond with Art 13 MEDICRIME Convention.

## 3.8 Czech Republic

### Article 4 - Definitions

a. Article 4.a MEDICRIME Convention – Medical Product
Section 1, Medicines Act defines the term 'medical product' that includes medicinal products and medicinal substances. These relate only to human use and not veterinary use. There is no inclusion for medical devices in this definition.
Further action is needed to correspond with Art 4.a MEDICRIME Convention.

b. Article 4.b MEDICRIME Convention – Medicinal Product
Section 2, Medicines Act corresponds with Article 4.b MEDICRIME Convention. There is no specific definition for investigational medicinal products.
Further action is needed to fully correspond with Art 4.b MEDICRIME Convention.

c. Article 4.c MEDICRIME Convention -Active substance
Section 2, Medicines Act corresponds with Article 4.c MEDICRIME Convention.

d. Article 4.d MEDICRIME Convention – Excipient
Section 2, Medicines Act corresponds with Article 4.d MEDICRIME Convention.

e. Article 4.e MEDICRIME Convention – Medical Device
Section 2, Medical Device Act, 2004 corresponds with Article 4.e MEDICRIME Convention.

f. Article 4.f MEDICRIME Convention – Accessory
Section 3(5), Medical Device Act, 2004 corresponds with Article 4.f MEDICRIME Convention.

g. Article 4.g MEDICRIME Convention – Parts and materials
No provision could be found in internal laws corresponding with Article 4.g, MEDICRIME Convention.
Action is needed to correspond with Art 4.g, MEDICRIME Convention.

h. Article 4.h MEDICRIME Convention – Document
No provision could be found in internal laws corresponding with Article 4.h, MEDICRIME Convention.
Action is needed to correspond with Art 4.h, MEDICRIME Convention.

i. Article 4.i MEDICRIME Convention – Manufacturing
Section 5.c. of the Medical Devices Act, as regards medical devices, corresponds with Article 4.i MEDICRIME Convention. There is no correspondence as regards the manufacture of accessories. No provision could be found in internal laws, as regards the manufacture of medicinal products, corresponding with Article 4.i, MEDICRIME Convention.
Further action is needed to correspond with Art 4.i MEDICRIME Convention.

j. Article 4.j MEDICRIME Convention – Counterfeit
Section 5 (14), Medicines Act, as regards medical products for human use, corresponds to Article 4.j MEDICRIME Convention. There is no correspondence with Article 4.j as regards medical products for veterinary use and medical devices

k. Article 4.k MEDICRIME Convention – Victim
Section 2 (2-4), Act on Victims of Crime Act provides a general law definition. It does not include psychological injury.
Further action is needed to fully correspond with Art 4.k MEDICRIME Convention.

## CHAPTER II – SUBSTANTIVE CRIMINAL LAW

### Article 5 – Manufacturing of counterfeits

Section 146, Criminal Code (CC) is general criminal law creating an intentional offence of causing bodily harm. While this could be used in conjunction with an offence of the manufacture of a falsified medical product, there is no correspondence with Article 5 MEDICRIME Convention notwithstanding that there is a definition that there is a definition of a falsified medicinal product.

Action is needed to correspond with Art 5, MEDICRIME Convention.

### Article 6 – Supplying, offering to supply, and trafficking in counterfeits

Section 251 CC is general criminal law creating an intentional offence for 'Unauthorized Business Activities'. While this could be used in conjunction with an offence specified in Article 6 MEDICRIME Convention, there is no correspondence with Article 6 MEDICRIME Convention.

Action is needed to correspond with Art 6 MEDICRIME Convention.

### Article 7 – Falsification of documents

Section 348 CC is general criminal creating an intentional offence for forgery and alteration of 'Public Documents'. While this could substantially correspond with the requirements of Article 7 MEDICRIME Convention it appears restricted to 'public documents generally and may not capture all documents intended by Article 7.

Further action is needed to fully correspond with Art 7, MEDICRIME Convention.

### Article 8 – Similar crimes involving threats to public health

8.a.i. ii: Sections 103, 104, 105 and 108 of the Medicines Act requires authorisations Which create administrative offences for the non-compliance with authorisation requirements of medicinal products for human use. Medicinal Products for veterinary use also need to be considered.

Title XIV, Medical Device Act 2014, as regards medical devices, provides offences relating to the non-compliance and non-conformity requirements laid out in Title VI of the Act. These administrative offences do not require intentional behaviour and do not correspond with Article 8.a, MEDICRIME Convention.

Action is required to correspond with Art 8.a, MEDICRIME Convention.

8.b: No provision could be found in internal laws corresponding with Article 8.b, MEDICRIME Convention.

Action is needed to correspond with Art 8.b, MEDICRIME Convention.

### Article 9 – Aiding or abetting and attempt

Sections 21, 23 and 24 CC, as regards, attempts, accomplices, and participants, relate to intentional behaviours, respectively. As no intentional behaviours are provided for relating to Article 5-8, MEDICRIME Convention there is no correspondence with Article 9, MEDICRIME Convention.

Action is needed to correspond with Art 9, MEDICRIME Convention.

### Article 11 – Corporate liability

Sections 8 and 9, Act on Liability of Legal Entities 2012 contains the elements of corporate Liability provided for in Article 11.1, 11.2, and 11.4, MEDICRIME Convention. According to the Act on Liability of Legal Entities, the legal persons in the Czech Republic may be criminally liable for all the criminal offences specified in the MEDICRIME Convention.

### Article 13 – Aggravating circumstances

Section 42, Criminal Code provides for aggravating circumstances which may be supplemented by The Court according to the circumstance of the case. There is sufficient correspondence, though not direct, between Section 42 and Article 13. a-e, but not relating to Article 13. f MEDICRIME Convention.

## 3.9 Denmark

### Article 4 - Definitions

a. Article 4.a MEDICRIME Convention – Medical Product
No provision in internal law, as regards the term 'medical product', could be found corresponding with Article 4.a, MEDICRIME Convention. It is noted that there are separate definitions of medicinal product and medical device. Further action is needed to fully correspond with Article 4.a, MEDICRIME Convention.

b. Article 4.b MEDICRIME Convention – Medicinal Product
§ 2(1) Danish Medicines Act corresponds with Article 4.b, MEDICRIME Convention, except for investigational medicinal products which are not defined.
Further action is needed to fully correspond with Article 4.b, MEDICRIME Convention.

c. Article 4.c MEDICRIME Convention -Active substance
§ 2(3) The Medicines Act corresponds with Article 4.c, MEDICRIME Convention.

d. Article 4.d MEDICRIME Convention – Excipient
§ 2(4) The Medicines Act corresponds with Article 4.d, MEDICRIME Convention.

e. Article 4.e MEDICRIME Convention – Medical Device
§ 1(2)(1), Executive Order on Medical Devices 2008 corresponds with Article 4.e, MEDICRIME Convention.

f. Article 4.f MEDICRIME Convention – Accessory
§ 1(2)(2), Executive Order on Medical Devices 2008 corresponds with Article 4.f, MEDICRIME Convention.

g. Article 4.g MEDICRIME Convention – Parts and materials
No provision could be found in internal laws, as regards the terms 'parts' and 'materials', corresponding with Article 4.g, MEDICRIME Convention.
Action is needed to correspond with Article 4.g, MEDICRIME Convention.

h. Article 4.h MEDICRIME Convention – Document
§171, (2) and (3), the Criminal Code (CC) provides a legal definition for the term 'document'. This does not include the term 'tampering'.
Further action is needed to fully correspond with Article 4.h, MEDICRIME Convention.

i. Article 4.i MEDICRIME Convention – Manufacturing
§3 (6), 'Order on the manufacture and importation of medicinal products and intermediate products' , as regards medicinal products, and §3 (3), 'Order on the manufacture, importation, and distribution of active substances for the manufacture of medicinal products', as regards active substances, approximately corresponds with Article 4.i, MEDICRIME Convention.
There is no legal definition of the term 'manufacturing' as regards medical devices. §1 (6), Medical Device Order, 2006, defines the term 'manufacturer' and this, as regards medical devices, partly corresponds with Article 4.i, MEDICRIME Convention.
Further action is needed in order fully correspond with Article 4.i, MEDICRIME Convention.

j. Article 4.j MEDICRIME Convention – Counterfeit
No provision could be found in internal laws, as regards the term 'counterfeit', corresponding with Article 4.j, MEDICRIME Convention.
Action is needed to correspond with Article 4.j, MEDICRIME Convention.

k. Article 4.k MEDICRIME Convention – Victim
No provision could be found in internal laws, as regards the terms 'victim, corresponding with Article 4.k, MEDICRIME Convention.
Action is needed to correspond with Article 4.k, MEDICRIME Convention.

## CHAPTER II – SUBSTANTIVE CRIMINAL LAW

### Article 5 – Manufacturing of counterfeits

§ 38. a, Order of the Law on Medicinal Products, 2018, as regards medicinal products, but not active substances or excipients, corresponds with Article 5, MEDICRIME Convention.

No provision could be found in internal laws, as regards medical devices, accessories, parts and materials, corresponding with Article 5, MEDICRIME Convention.

Further action is needed to correspond with Article 5, MEDICRIME Convention.

### Article 6 – Supplying, offering to supply, and trafficking in counterfeits

§ 38. a, Order of the Law on Medicinal Products, 2018, as regards medicinal products, but not active substances or excipients, corresponds with Article 6, MEDICRIME Convention.

No provision could be found in internal laws, as regards medical devices, accessories, parts and materials, corresponding with Article 6, MEDICRIME Convention.

Further action is needed to fully correspond with Article 6, MEDICRIME Convention.

### Article 7 – Falsification of documents

§ 171 (1) CC 2005 is a general criminal law provision and is not specific to medical products. § 171 (1) CC does not include the act of 'tampering'. It otherwise corresponds with Article 7, MEDICRIME Convention.

Further action is needed to fully correspond with Article 7, MEDICRIME Convention.

### Article 8 – Similar crimes involving threats to public health

8.a.i: § 39, Order of the Law on Medicinal Products, 2018, as regards medicinal products but not active substances or excipients corresponds with Article 8.a. i, MEDICRIME Convention.

8.a.ii: § 4, (1), (2) and (3), § 21(1)(1), Medical Devices Order, 2008, as regards medical devices, but not accessories, parts, and materials, correspond with Article 8.a.ii, MEDICRIME Convention.

8.b: No provision could be found in internal laws corresponding with Article 8.b, MEDICRIME Convention.

Further action is needed to fully correspond with Article 8. a and b, MEDICRIME Convention.

### Article 9 – Aiding or abetting and attempt

§ 21 (1) and § 23 (1), CC correspond with Article 9.2 and 9.1, MEDICRIME Convention, respectively.

### Article 11 – Corporate liability

11.1. a, b, c: § 27. (1) CC is general in scope and only requires that the natural person at fault be one who is connected to the legal person, not that it requires the natural person be a person with the power of representation has authority to take decisions or be in control. Depending on the circumstances of the natural person at fault, § 27. (1), CC could correspond with Article 11.1.a, b, and c, MEDICRIME Convention. 11.2. § 27. (1) CC general in scope and only requires that the natural person at fault be one who is connected to the legal person, not that it requires the liability to arise where the lack of supervision or control of a natural person facilitated the commission of the offence. Depending on the circumstances of the natural person at fault, § 27. (1), CC could correspond to a limited extent with Article 11.2, MEDICRIME Convention.

11.3. There is administrative and civil liability and 26. (1) CC provides for criminal liability of the legal person and correspond with Article 11.3, MEDICRIME Convention.

11.4: there is correspondence with Article 11.4, MEDICRIME Convention.

### Article 13 – Aggravating circumstances

*§ 81. (1) and (8), Penal Code corresponds with Article 13. b, c and f, MEDICRIME Convention.*

*§ 80. (2) could be interpreted to correspond with Article 13.a, MEDICRIME Convention.*

Further action is needed to correspond with Article 13. d, and e, MEDICRIME Convention.

## 3.10 Ecuador

### Article 4 - Definitions

a. Article 4.a MEDICRIME Convention – Medical Product
No provision in internal law could be found to correspond with Article 4.a, MEDICRIME Convention. There are separate definitions of the terms' medicine' and 'medical device', both components of the term medical product. Action is needed to correspond with Article 4.a, MEDICRIME Convention.

b. Article 4.b MEDICRIME Convention – Medicinal Product
Article 259, Health Organic Law, as regards authorised medicinal products for human use only, substantially corresponds with Article 4.b, MEDICRIME Convention. There is no provision corresponding to Article 4.b as regards unauthorised medicinal products, or for investigational medicinal products.
Further action is needed to correspond with Art 4.b, MEDICRIME Convention.

c. Article 4.c MEDICRIME Convention - Active substance
Article 3. Health Regulations Bioequivalence in Medicine for Human Consumption corresponds substantially with Article 4.c, MEDICRIME Convention.

d. Article 4.d MEDICRIME Convention – Excipient
Article 2, Requirement for Industrial Registration of Drug Producers, and Article 52, Regulation for Obtaining Sanitary Registration of Biological Medicines, substantially correspond with Article 4.d, MEDICRIME Convention.

e. Article 4.e MEDICRIME Convention – Medical Device
The Health Organic Law, except for software designated by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, substantially corresponds with Article 4.e, MEDICRIME Convention.
Further action is needed to fully correspond with Art 4.e, MEDICRIME Convention.

f. Article 4.f MEDICRIME Convention – Accessory
Article 3, Health Regulations for the Control of Medical Devices, Human Use, correspond with Article 4.f, MEDICRIME Convention.

g. Article 4.g MEDICRIME Convention – Parts and materials
Article 3, Health Regulations for the Control of Medical Devices, Human Use, correspond with Article 4.g, MEDICRIME Convention.

h. Article 4.h MEDICRIME Convention – Document
No provision in internal law could be found to correspond with Article 4.h, MEDICRIME Convention.
Action is needed to correspond with Art 4.h, MEDICRIME Convention.

i. Article 4.i MEDICRIME Convention – Manufacturing
Article 3, Health Regulations for Obtaining the Health Registration, is similar in intent, but more general than Article 4.i, MEDICRIME Convention.
Further action is needed to fully correspond with Art 4.i, MEDICRIME Convention.

j. Article 4.j MEDICRIME Convention – Counterfeit
Article 3, Technical Health Standards for the Control of Products for Human Consumption Regulations, corresponds with Article 4.j, MEDICRIME Convention. Clarification is required on the application of this definition to medicinal products for veterinary use and medical devices, accessories, parts, and materials.
Further action is needed to fully correspond with Art 4.j, MEDICRIME Convention.

k. Article 4.k MEDICRIME Convention – Victim
Article 441 (1) and (2), Integral Criminal Organic Code, is general Criminal Law and is not specific to medical products. Other than including legal person as victims, it corresponds with Article 4.k, MEDICRIME Convention.

## CHAPTER II – SUBSTANTIVE CRIMINAL LAW

### Article 5 – Manufacturing of counterfeits

Article 217.1, Integral Criminal Organic Code, except for medicinal products for veterinary use, substantially corresponds with Article 5, MEDICRIME Convention.

Further action is needed to fully correspond with Art 5, MEDICRIME Convention.

### Article 6 – Supplying, offering to supply, and trafficking in counterfeits

Article 217.1, Integral Criminal Organic Code, except for medicinal products for veterinary use, substantially corresponds with Article 6, MEDICRIME Convention.

Further action is needed to fully correspond with Art 6, MEDICRIME Convention.

### Article 7 – Falsification of documents

Article 217.1, Integral Criminal Organic Code criminalises the person who possesses a counterfeit or adulterated container or packaging. This does not include the act of falsification, including other documents nor in relation to medicinal products for veterinary use. This is insufficient to correspond with Article 7, MEDICRIME Convention.

Further action is needed to fully correspond with Art 7, MEDICRIME Convention.

### Article 8 – Similar crimes involving threats to public health

8.a. i: Article 140, Health Organic Law, as regards medicinal products for human use only, prohibits the importation, marketing, and sale without registration. This does not criminalise this behaviour and appears to be an administrative prohibition only. This law does not provide for a similar prohibition for medicinal products for veterinary use.

8.a. ii: It is unclear whether there is a requirement for medical devices to be in compliance with conformity requirements to be placed on the market. Where such a requirement exists in regulatory laws, there is no criminalisation in law for a breach of such requirement.

8.b: No provision in internal law could be found to correspond with Article 8, b, MEDICRIME Convention.

Action is required to correspond with Art 8. a and b, MEDICRIME Convention.

### Article 9 – Aiding or abetting and attempt

Article 43 and 39, Integral Criminal Organic Code, as regards accomplices and attempts, respectively, correspond with Article 9, MEDICRIME Convention.

### Article 11 – Corporate liability

11.1. a, b, c: Article 49, Integral Criminal Organic Code, corresponds with Article 11.1, a, b, and c, MEDICRIME Convention.

11.2: Clarification is required on whether Article 49, Integral Criminal Organic Code, as regards the lack of supervision or control by the natural person, corresponds with Article 11.2, MEDICRIME Convention.

11.3: Article 564, Integral Criminal Organic Code, corresponds with Article 11.3, MEDICRIME Convention.

11.4. Article 49, Integral Criminal Organic Code, corresponds with Article 11.4, MEDICRIME Convention.

Further action is needed to fully correspond with Article 11.2, MEDICRIME Convention.

### Article 13 – Aggravating circumstances

13.a: Article 217.1, Integral Criminal Organic Code corresponds with Article 13.a, MEDICRIME Convention.

13.b: Article 217.1, Integral Criminal Organic Code corresponds with Article 13.b, MEDICRIME Convention.

13.c: There is no correspondence in internal law with Article 13. c, MEDICRIME Convention.

13.d: There is no correspondence in internal law with Article 13. d, MEDICRIME Convention.

13.e: There is no correspondence in internal law with Article 13. e, MEDICRIME Convention.

13. f: Article 57, Integral Criminal Organic Code corresponds with Article 13.f, MEDICRIME Convention.

Further action is needed to correspond with Article 13.c, d and e, MEDICRIME Convention.

## 3.11 Estonia

### Article 4 - Definitions

a. Article 4.a MEDICRIME Convention – Medical Product
No provision, as regards the term 'medical product', could be found in internal law corresponding with Article 4.a, MEDICRIME Convention. It is noted that there are separate definitions for the terms 'medicinal products' and 'medical device'.
Action is needed to correspond with Article 4. a, MEDICRIME Convention.

b. Article 4.b MEDICRIME Convention – Medicinal Product
§ 2 Medicinal Products Act 2004 (MPA), as amended, corresponds with Article 4.b, MEDICRIME Convention. § 2 MPA does not use the term 'presentation' within the meaning of 'medicinal product', but the sense is the same as in Article 4.b, MEDICRIME Convention. The term 'investigational medicinal products' is not defined in § 2 and is encompassed in the meaning of 'medicinal product'.

c. Article 4.c MEDICRIME Convention -Active substance
§ 5(1) MPA corresponds with Article 4.c, MEDICRIME Convention.

d. Article 4.d MEDICRIME Convention – Excipient
§ 5(3) MPA, while more general in wording, corresponds with Article 4.d, MEDICRIME Convention.

e. Article 4.e MEDICRIME Convention – Medical Device
§ 3(1) Medical Devices Act, 2004 (MDA), as amended, corresponds with Article 4.e, MEDICRIME Convention.

f. Article 4.f MEDICRIME Convention – Accessory
§ 4 MDA corresponds with Article 4.f, MEDICRIME Convention.

g. Article 4.g, MEDICRIME Convention – Parts and materials

No provision, as regards the terms 'parts', and 'materials", could be found in internal law corresponding with Article 4.g, MEDICRIME Convention.
Action is needed to correspond with Article 4.g, MEDICRIME Convention.

h. Article 4.h MEDICRIME Convention – Document
No provision, as regards the term 'document', could be found in internal law corresponding with Article 4.h, MEDICRIME Convention.
Action is needed to correspond with Article 4.h, MEDICRIME Convention.

i. Article 4.i MEDICRIME Convention – Manufacturing
§ 16. (2,) MPA, does not specifically provide this definition, but effectively does so in relation to the requirement for a Manufacturing Authorisation. This provision, in conjunction with § 16(7), and § 2(1) and 8(1) of the Rules for Manufacturing Medicinal Products 2014, correspond, as regards medicinal products, active substances and excipients with Article 4.1, MEDICRIME Convention.
No provision in the MDA can be found to specifically provide the definition as regards medical devices. § 15(1) MDA refers, as regards the liability of manufacturers, to some of the requirements of the term 'Manufacturing' in Article 4.i, MEDICRIME Convention.
No provision in the MDA can be found to specifically provide the definition of the term 'manufacturing', as regards the term 'accessories.
Action is needed to correspond with Article 4. i, MEDICRIME Convention.

j. Article 4.j MEDICRIME Convention – Counterfeit
§ 10.1 MPA, as regards medicinal products, corresponds with Article 4.j, MEDICRIME Convention. No provision in the MDA can be found to specifically provide the definition of the term 'counterfeit' (or 'falsified'). There is no correspondence with Article 4.j, MEDICRIME Convention. Further action is needed to fully correspond with Article 4.j, MEDICRIME Convention.

k. Article 4.k MEDICRIME Convention – Victim
§ 37(1) Code of Criminal Procedure does not correspond directly or sufficiently with Article 4.k, MEDICRIME Convention. § 37(1) requires that the illegal act be directed at the victim and this does not appear to encompass any indirect suffering by the victim and does not include resultant psychological effects on the victim. However, the status of victim is applied to a person who suffers due to the death of a person close to the victim and caused by the illegal act. This is general criminal law and may otherwise be applied to counterfeit medicinal products. As breaches of the MDA are misdemeanours, they do not attract the status of 'victim' within their scope.
Action is needed to correspond with Article 4.k, MEDICRIME Convention.

## CHAPTER II – SUBSTANTIVE CRIMINAL LAW

### Article 5 – Manufacturing of counterfeits

§ 104, MPA provides for the penalty for violation of the requirements for handling medicinal products. While §3. (1), MPA includes the act of manufacturing in the definition of the term 'handling' it is noted that §3 (3) confines the act of handling to public authorities, unless otherwise stated.

Public authorities, in this context, include governmental authorities, state agencies administered by Governmental authorities, and local authorities. § 104, MPA does not appear to extend beyond this.

Without further clarification, it is considered that § 104 MPA does not correspond with Article 5, MEDICRIME Convention.

### Article 5.1, MEDICRIME Convention.

MDA does not provide an offence for the manufacturing (or any term corresponding to manufacturing) of a counterfeit (falsified) medical device. MDA does not correspond with Article 5.1, MEDICRIME Convention.

**§ 194, Penal Code, 2001, as amended, criminalises the trafficking of medicinal products for the purpose of acts that include manufacturing. It is unclear whether § 194, Penal Code could correspond with Article 5.1, MEDICRIME Convention.**

Action is needed to correspond with Article 5, MEDICRIME Convention.

### Article 6 – Supplying, offering to supply, and trafficking in counterfeits.

§ 3 MPA, as regards medicinal products and active substance, and with the caveat regarding the scope of the MDA to public authorities (as referred to above in Article 5), may not enable §104 MPA to correspond with Article 6, MEDICRIME Convention.

MDA, as regards medical devices, does not provide an offence for the behaviours listed in Article 6.1, MEDICRIME Convention and does not correspond with Article 6.1, MEDICRIME Convention.

§ 194, Penal Code, 2001, as amended, criminalises the trafficking of medicinal products

for the purpose of acts that include behaviours covered by Article 6, MEDICRIME Convention. It is unclear whether § 194, Penal Code could correspond with Article .1, MEDICRIME Convention.

Action is needed to correspond with Article 6, MEDICRIME Convention.

### Article 7 – Falsification of documents

§§ 344, 345, and 346, Penal Code are general Criminal Law provisions and not specific to medical products. These provision concern counterfeit documents and damage to official documents and could potentially correspond with the intent of Article 7, MEDICRIME Convention.

Further action is needed to fully correspond with Article 7, MEDICRIME Convention.

### Article 8 – Similar crimes involving threats to public health.

8.a. i: §§ 104 and 106, MPA, as regards medicinal products, correspond with Article 8.a.i, MEDICRIME Convention.

8.a. ii: § 39 MDA, as regards medical devices and accessories, corresponds with Article 8.a.ii, MEDICRIME Convention.

8.b: There is no correspondence in law with Article 8.b, MEDICRIME Convention.

Action is needed to correspond with Article 8.b, MEDICRIME Convention.

### Article 9 – Aiding or abetting and attempt

9.1. § 22, Penal Code, as regards 'aiding and abetting, apart from consideration of the caveat contained in § 23, corresponds with Article 9.1, MEDICRIME Convention. § 23 Penal Code does not penalise aiding or abetting as regards misdemeanours. § 112 MPA permits extrajudicial proceedings in relation to § 104 and § 106 as misdemeanours only. § 104 and § 106 relate to the violation of requirements for handling of medicinal products and marketing authorisations, respectively. There is no provision in the MDA regarding violation of requirements for handling of medical devices and none for counterfeit medical devices, accessories, parts, and materials. There is no correspondence in internal law with Article 9.1, MEDICRIME Convention.

Further action is needed to fully correspond with Article 9.1, MEDICRIME Convention.

9.2: § 25 and § 25.1 Penal Code corresponds with Article 9.2, MEDICRIME Convention.

### Article 11 – Corporate liability

11.1. a, b, and c: § 14. (1), Penal Code, corresponds with Article 11.1, a, b, and c, MEDICRIME Convention.

11.2: § 13 Penal Code provides for liability for omissions where the legal person was required to act. When taken in conjunction with § 16(4) Penal Code, which provides for indirect intent where foreseeability of the consequences of a failure to act occurs, correspond with Article 13.2, MEDICRIME Convention.

11.3: § 14. Penal Code, as regards criminal liability, §§ 104 and 106 MPA and §39 MDA, with the exception of manufacturing, as regards administrative liability, and civil liability, together correspond with Article 11.3. MEDICRIME Convention.

Further action is needed to fully correspond with Article 11.3, MEDICRIME Convention.

11.4: § 14(2) Penal Code, as regards the liability of the legal person without prejudice to the criminal liability of the natural persons who committed the act, correspond with Article 11.4, MEDICRIME Convention.

### Article 13 – Aggravating circumstances

§ 58 Penal Code provides for aggravating circumstance. This does not correspond with Article 13, a -f, MEDICRIME Convention. The Courts may interpret the Penal Code to correspond with Article 13, MEDICRIME Convention. This potentially arises in § 58 (7), which provides an aggravating circumstance for the commission of the offence in a manner which is dangerous to the public such as to correspond with Article 13.a, MEDICRIME Convention, or §255 Penal Code, which provides for offences against Public Security as regards criminal organisations, to correspond with Article 13.e, MEDICRIME Convention.

Further action is needed to fully correspond with Article 13, MEDICRIME Convention.

## 3.12 Finland

### Article 4 – Definitions

a. Article 4.a MEDICRIME Convention – Medical Product
No provision could be found in internal laws corresponding with Article 4.a, MEDICRIME Convention. It is noted that there are separate definitions of the terms 'medicinal products' and 'medical devices'.
Further action is needed to fully correspond with Article 4.a, MEDICRIME Convention.

b. Article 4.b MEDICRIME Convention – Medicinal Product
Section 3, Medicines Act 1987, as amended, except of investigational medicinal products, corresponds with Article 4.b MEDICRIME Convention.
Further action is needed to fully correspond with Article 4.b, MEDICRIME Convention.

c. Article 4.c MEDICRIME Convention -Active substance
Section 5, Medicines Act 1987, as amended, corresponds with Article 4.c, MEDICRIME Convention.

d. Article 4.d MEDICRIME Convention – Excipient
Article 5. (c) Medicines Act 1987, as amended, corresponds with Article 4.d, MEDICRIME Convention.

e. Article 4.e MEDICRIME Convention – Medical Device
Section 1, Medical Device Act 2010, substantially corresponds with Article 4.e, MEDICRIME Convention.

f. Article 4.f MEDICRIME Convention – Accessory
Section 5. (6), Medical Devices Act 2010, corresponds with Article 4.f, MEDICRIME Convention.

g. Article 4.g MEDICRIME Convention – Parts and materials
No provision could be found in internal laws corresponding with Article 4.g, MEDICRIME Convention.
Further action is needed to fully correspond with Article 4.g, MEDICRIME Convention.

h. Article 4.h MEDICRIME Convention – Document
No provision could be found in internal laws corresponding with Article 4.h, MEDICRIME Convention.
Further action is needed to fully correspond with Article 4.h, MEDICRIME Convention.

i. Article 4.i MEDICRIME Convention – Manufacturing
No provision, as regards the manufacturing of medicinal products, medical devices or accessories, could be found in internal laws corresponding with Article 4.i, MEDICRIME Convention. Section 5. (13), Medical Device Act 2010, contains the definition of 'manufacturer' which specifies the different processes required for the definition of 'manufacturing' of medical devices and accessories.
Further action is needed to fully correspond with Article 4.i, MEDICRIME Convention.

j. Article 4.j MEDICRIME Convention – Counterfeit
Section 3.a, Medicines Act 1987, as amended, corresponds with Article 4.j, MEDICRIME Convention.

k. Article 4.k MEDICRIME Convention – Victim
No provision, as regards the term 'victim', could be found in internal laws corresponding with Article 4.k, MEDICRIME Convention.
Action is needed to fully correspond with Article 4.k, MEDICRIME Convention.

**CHAPTER II – SUBSTANTIVE CRIMINAL LAW**

### Article 5 – Manufacturing of counterfeits

No provision, as regards the manufacturing of counterfeits, could be found in internal laws corresponding with Article 5, MEDICRIME Convention.

Action is needed to correspond with Article 5, MEDICRIME Convention.

### Article 6 – Supplying, offering to supply, and trafficking in counterfeits

No provision, as regards the supplying, offering to supply, and trafficking in counterfeit medical products could be found in internal laws corresponding with Article 6, MEDICRIME Convention.

Action is needed to correspond with Article 6, MEDICRIME Convention.

### Article 7 – Falsification of documents

Section 1, Chapter 33, Criminal Code (CC) provides the offence of 'forgery'. This corresponds with Article 7, MEDICRIME Convention.

### Article 8 – Similar crimes involving threats to public health

8.a.ii: Sections 8, 17, 17.a, 19, 20. a, and 32, Medicines Act 1987, as amended, corresponds with Article 8.a.i, MEDICRIME Convention.

8.a.ii: Sections 6, 8, and 9, Medical Device Act, 2010, corresponds with Article 8.a.ii, MEDICRIME Convention.

8.b: There is no correspondence with Article 8.b, MEDICRIME Convention.

Further action is needed to fully correspond with Article 8.b, MEDICRIME Convention.

### Article 9 – Aiding or abetting and attempt

Section 6, Chapter 5, CC 1989, as amended, provides an offence for abetting and requires intentional conduct. As there is no provision for the criminalisation of offences in internal law corresponding to those contained in Articles 5-8, MEDICRIME Convention, there is no correspondence with Article 9, MEDICRIME Convention.

Action is needed to correspond with Article 9, MEDICRIME Convention.

### Article 11 – Corporate liability

Section 2, Chapter 9, CC 1989, as amended, which regulates the liability of legal persons in Finland, does not cover offences under the Medicines Act. There is no corresponds with Article 11, MEDICRIME Convention.

Action is needed to correspond with Article11, MEDICRIME Convention.

### Article 13 – Aggravating circumstances

Section 4, CC 1989, provides for the regulation of general principles (515/2003) by which sentence are determined in just proportion to the harmfulness and dangerousness of the offending, the motives for the acts and other culpability of the offender manifest in the offence. This potentially applies to Article 13. a-d, MEDICRIME Convention. Section 5, Chapter 6, CC 1989, as amended, correspond with Article 13. e and f, MEDICRIME Convention.

Further action is needed to fully correspond with Article 13, MEDICRIME Convention.

## 3.13 Germany

### Article 4 - Definitions

a. Article 4.a MEDICRIME Convention – Medical Product
No provision, as regards the term 'medical product', could be found in internal law corresponding with Article 4.a, MEDICRIME Convention. It is noted that the terms 'medicinal product' and 'medical device' are separately defined.
Action is needed to correspond with Article 4. a, MEDICRIME Convention.

b. Article 4.b MEDICRIME Convention – Medicinal Product
§ 2 para 1, Medicinal Product Act, 2005, as amended (AMG) does not use the term 'presentation' within the meaning of 'medicinal product', but the sense of the wording is considered by the AMG to be the same as that in Article 4.b, MEDICRIME Convention. The term 'investigational medicinal product' is not defined in the AMG and is considered to be encompassed in the meaning of 'medicinal product'. The AMG provides reference to 'investigational medicinal products' within its text. § 2 para 1 AMG is considered to correspond with Article 4.b, MEDICRIME Convention.
Further action is needed to fully correspond with Article 4.b, MEDICRIME Convention.

c. Article 4.c MEDICRIME Convention -Active substance
§ 4 para 19 AMG corresponds with Article 4.c, MEDICRIME Convention.

d. Article 4.d MEDICRIME Convention – Excipient
§ 2 para 2, Medicines and Drug Manufacturing Ordinance (AMWHV) corresponds with Article 4.d, MEDICRIME Convention.

e. Article 4.e MEDICRIME Convention – Medical Device
§ 3 Nr. 1, Law on Medical Devices (MPG) corresponds with Article 4.e, MEDICRIME Convention. It is noted that the Medical Device Implementation Law (MPDG) (implementing Regulation (EU) 2017/745) has been adopted in Germany in 2020 and due to be implemented from May 2021. § 3.1 corresponds with Article 4.e MEDICRIME Convention.

f. Article 4.f MEDICRIME Convention -Accessory
§ 3 Nr. 9 MPG corresponds with Article 4.f, MEDICRIME Convention. It is noted that the Medical Device Implementation Law (MPDG) (implementing Regulation (EU) 2017/745) has been adopted in Germany in 2020 and due to be implemented from May 2021. § 2 para 1 sentence 2MPDG corresponds with Article 4.f, MEDICRIME Convention.

g. Article 4.g MEDICRIME Convention – Parts and materials
No provision, as regards the terms 'parts', and 'materials", could be found in internal law corresponding with Article 4.g, MEDICRIME Convention. While § 13 para 2 MPDG refers to counterfeit parts and materials, it does not define either parts or materials.
Action is needed to correspond with Article 4.g, MEDICRIME Convention.

h. Article 4.h MEDICRIME Convention – Document
No provision, as regards the term 'document', could be found in internal law corresponding with Article 4.h, MEDICRIME Convention.
Action is needed to correspond with Article 4.h, MEDICRIME Convention.

i. Article 4.i MEDICRIME Convention – Manufacturing
§ 4 para. 14 AMG, as regards medicinal products, corresponds with Article 4.i, MEDICRIME Convention. § 20a AMG, as regards active substances, does not define the term 'manufacturing', but references its part relating to the manufacture of medicinal products. It is considered to correspond with Article 4.i, MEDICRIME Convention.
§ 3 Nr. 15 MPG and § 2 para 1 sentence 2 MPDG do not define the term 'manufacturing' as regards medical devices. Both laws define the term 'manufacturer' which encapsulates some of the components of the definition of the term 'manufacturing', but excluding parts and materials, and accessories.
Further action is needed to fully correspond with Article 4.i, MEDICRIME Convention as regards medical devices, parts and materials, and accessories.

j. Article 4.j MEDICRIME Convention – Counterfeit
§ 4 para. 40 AMG and § 4 para 41 AMG, as regards medicinal products and active substances, respectively correspond with Article 4.j, MEDICRIME Convention.
MPG does not contain a legal definition of the term 'counterfeit' (or falsified). § 2 para 1 sentence 2 MPDG corresponds with Article 4.j, MEDICRIME Convention.
Further action is needed to fully correspond with Article 4.j, MEDICRIME Convention.

k. Article 4.k MEDICRIME Convention – Victim
No provision, as regards the term 'victim, could be found in internal law corresponding with Article 4.k, MEDICRIME Convention.
Action is needed to correspond with Article 4.k MEDICRIME Convention.

## CHAPTER II – SUBSTANTIVE CRIMINAL LAW

### Article 5 – Manufacturing of counterfeits

§ 8 para 2 AMG, as regards medicinal products and active substances, corresponds with Article 5, MEDICRIME Convention. MPG, as regards medical devices, does not provide an intentional conduct offence corresponding with Article 5.1, MEDICRIME Convention. § 13 para 1 MPDG, as regards medical devices, parts, and material, but not accessories, correspond with Article 5.1, MEDICRIME Convention.

Further action is needed to correspond with Article 5, MEDICRIME Convention.

### Article 6 – Supplying, offering to supply, and trafficking in counterfeits

§ 8 para 2 AMG, as regards medicinal products and active ingredients, and except for import and export, correspond with Article. 6, MEDICRIME Convention. There is no offence in MPG that corresponds with Article 6, MEDICRIME Convention. While § 4 para 2 MPG prohibits the putting into circulation of medical devices, if they are provided with a misguiding identification, description, or presentation. It is unclear that this refers to counterfeit devices or to regulatory behaviours not intended to be associated with counterfeiting. § 13 para 1 MPDG corresponds with Article 6, MEDICRIME Convention.

Further action is needed to correspond fully with Article 6 MEDICRIME Convention.

### Article 7 – Falsification of documents

*§ 267 para 1 Criminal Code (*StGB), as interpreted from German jurisprudence, does not apply to the falsification of documentation envisaged by Article 7, MEDICRIME Convention.

Action is needed to correspond with Article 7 MEDICRIME Convention.

### Article 8 – Similar crimes involving threats to public health

8.a.i: § 13 (1), para 1 and 3, as regards manufacturing authorisations, § 52a (1), as regards wholesaling authorisations, and § 21 (1), as regards marketing authorisations, AMG, as regards medicinal products and active substances correspond with Article 8, a, i, MEDICRIME Convention.

8.a.ii: § 6 para 1 sentence 1 and 2, MPG corresponds with Article 8, a. ii, MEDICRIME Convention. §11, §12 and §13, MPDG, the penalties for contravention are provided by §92 and §93 MPDG, correspond with Article 8.a.ii, MEDICRIME Convention.

8.b: No provision could be found in internal law corresponding with Article 8.b, MEDICRIME Convention.
Action is needed to correspond with Article 8.b, MEDICRIME Convention.

### Article 9 – Aiding or abetting and attempt

9.1: § 26, and § 27, StGB, as regards abetting and aiding, respectively, correspond with Article 9.1, MEDICRIME Convention.

9.2: § 23 (1) StGB provides for the criminalisation of attempts for serious offences and only when expressly stated for less serious offences. No indication is provided in law as to the level of seriousness attaching to offences in Articles 5-8, MEDICRIME Convention. § 95 para 2 AMG provides for the criminalisation of attempts as regards medicinal products but does not include all the relevant offences in relation to Articles 5 - 8, MEDICRIME Convention. Relevant offences are contained in § 96 which does not contain any provision for the criminalisation of attempts. § 92 MPDG, as regards intentional offences mentioned in this section, correspond with Article 9.2 MEDICRIME Convention.

Further action is needed to fully correspond with Article 9.2 MEDICRIME Convention.

### Article 11 – Corporate liability

11.1: § 30 para 1, 2 and 3, Law on Administrative Contraventions (OWiG) corresponds with Article 11.1.a, b and c, MEDICRIME Convention.

11.2: No provision in OWiG could be found that correspond with Article 11.2, MEDICRIME Convention.

Action is needed to fully correspond with Article 11.2 MEDICRIME Convention.

11.3: § 30 OWiG provides for administrative liability. Liability may also be civil, but not criminal. This corresponds with Article 11.3, MEDICRIME Convention. It is noted that, while the wording of § 30 provides for the commission of a criminal offence or an administrative offence, the Constitutional jurisprudence has ruled out the application of criminal liability for legal persons.

11.4: No provision in OWiG could be found that corresponds with Article 11.4, MEDICRIME Convention. However, it is a basic principle of German criminal law that corporate liability will not exclude the criminal liability of any natural person.

### Article 13 – Aggravating circumstances

§ 46 para 1 and 2 StGB provides the general principles, with an indicative list of aggravating circumstances in paragraph 2 to support the decision on fixing a penalty by the Courts. This is general Criminal Law that does not specifically consider criminal offending as regards medical product and also does not exclude it.

13.a: § 95 para 3 AMG corresponds, as regards medicinal products and active substances, with Article 13.a, MEDICRIME Convention. There is no correspondence in the MPG with Article 13.a, MEDICRIME Convention. § 92 para 5 MPDG corresponds with Article 13.a, MEDICRIME Convention.

13.b: There is no correspondence, as regards AMG, MPG and MPDG, with Article 13. b, MEDICRIME Convention. It is noted that § 46 para 2, StGB contains a circumstance with regard to the degree of breach of the offender's duties, it is not considered to fully correspond with Article 13.b, MEDICRIME Convention.

13.c: There is no correspondence, as regards AMG, MPG and MPDG, with Article 13. c, MEDICRIME Convention. It is noted that § 46 para 2, StGB contains a circumstance with regard to the degree of breach of the offender's duties, it is not considered to fully correspond with Article 13.c, MEDICRIME Convention.

13.d: There is no correspondence, as regards AMG, MPG and MPDG, with Article 13. d, MEDICRIME Convention.

13.e: § 95 para (3).2, AMG, as regards medicinal products and active substances, corresponds with Article 13. e, MEDICRIME Convention. § 92 para 5 MPDG corresponds with Article 13. e, MEDICRIME Convention.

13.f: There is no correspondence, as regards AMG, MPG and MPDG, with Article 13. f, MEDICRIME Convention. It is noted that § 46 para 2, StGB contains a circumstance regarding the offender's prior history, it is not considered to fully correspond with Article 13.f, MEDICRIME Convention.

Further action is needed to fully correspond with Article 13. a, b, c, d and f, MEDICRIME Convention.

## 3.14 Georgia

### Article 4 - Definitions

a. Article 4.a MEDICRIME Convention – Medical Product
   No provision, as regards the term 'medical product', could be found in internal law corresponding with Article 4.a, MEDICRIME Convention.
   Action is needed to correspond with Article 4. a, MEDICRIME Convention.

b. Article 4.b MEDICRIME Convention – Medicinal Product
   Article 1. (13) Law of Georgia on Medicines and Pharmaceutical Activities, on the term 'Pharmaceuticals' as regards the term 'medicinal products', does not correspond with Article 4.b, MEDICRIME Convention. This is because the terms "medicinal product" and 'investigational medicinal products' are not defined. In addition, the term 'pharmaceuticals' in internal law is general and, unlike the provision of the Convention, does not include specific information as to the purpose and circumstances of their use.
   Action is needed to correspond with Article 4. b, MEDICRIME Convention.

c. Article 4.c MEDICRIME Convention -Active substance

Article. 1. (42), Law of Georgia on Medicines and Pharmaceutical Activities refers to the 'pharmaceuticals substance'. The term 'substance is general and refers to any substance used in the manufacture of a medicinal product, does not fully correspond with Article 4.c, MEDICRIME Convention.
Further action is needed to fully correspond with Article 4. c, MEDICRIME Convention.

d. Article 4.d MEDICRIME Convention – Excipient
No provision, as regards the term 'excipient', could be found in internal law corresponding with Article 4.d, MEDICRIME Convention.
Action is needed to correspond with Article 4. d, MEDICRIME Convention.

e. Article 4.e MEDICRIME Convention – Medical Device
Article 1. (12), Law of Georgia on Medicines and Pharmaceutical Activities uses the term 'medical goods' which is a general term encompassing products within the notion of medical devices, as contained in Article 4.e, MEDICRIME Convention. However, due to the generally of Article 1. (12) it does not sufficiently correspond with Article 4.e, MEDICRIME Convention.
Further action is needed to fully correspond with Article 4.e, MEDICRIME Convention.

f. Article 4.f MEDICRIME Convention – Accessory
No provision, as regards the term 'accessory', could be found in internal law corresponding with Article 4.f, MEDICRIME Convention.
Action is needed to correspond with Article 4. f, MEDICRIME Convention.

g. Article 4.g MEDICRIME Convention – Parts and materials
No provision, as regards the term 'parts' and 'materials', could be found in internal law corresponding with Article 4.e, MEDICRIME Convention.
Action is needed to correspond with Article 4.g, MEDICRIME Convention.

h. Article 4.h MEDICRIME Convention – Document
No provision, as regards the term 'document', could be found in internal law correspondence with Article 4.h, MEDICRIME Convention. Article 1. (4), 1. (7), 1. (51), and 1 (52), Law of Georgia on Medicines and Pharmaceutical Activities refers to various documents, but not all relevant documents that may be intended by Article 4.h, MEDICRIME Convention.
Action is needed to correspond with Article 4.h, MEDICRIME Convention.

i. Article 4.i MEDICRIME Convention – Manufacturing
Article1. (47), Law of Georgia on Medicines and Pharmaceutical Activities, as regards the Manufacturing of a pharmaceutical product, does not include the manufacturing of a medical device or accessory, or parts and materials. This general law provision does not adequately correspond with Article 4.i, MEDICRIME Convention.
Further action is needed to fully correspond with Article 4.i, MEDICRIME Convention.

j. Article 4.j MEDICRIME Convention – Counterfeit
Article 1. (33), Law of Georgia on Medicines and Pharmaceutical Activities, as regards counterfeit pharmaceutical products, is general in nature. It does not adequately correspond with Article 4.j, MEDICRIME Convention.
Action is needed to correspond with Article 4.j, MEDICRIME Convention.

k. Article 4.k MEDICRIME Convention – Victim
Article 3. (22), Criminal Procedure Code of Georgia, provides that a person is considered a victim if it is established that they have suffered a damage because of a crime (notwithstanding of what the crime was). While this is general in nature, it sufficiently corresponds with Article 4.k, MEDICRIME Convention.

## CHAPTER II – SUBSTANTIVE CRIMINAL LAW

### Article 5 – Manufacturing of counterfeits

Article 197, Criminal Code (CC) of Georgia provides for the general offence of falsification. The generality of this provision is such that it is considered not to sufficiently correspond with Article 5, MEDICRIME Convention.

Further action is needed to fully correspond with Article 5, MEDICRIME Convention.

### Article 6 – Supplying, offering to supply, and trafficking in counterfeits

Article 197, CC provides for the general offence of falsification. The generality of this provision is such that it does not specify the targeted offending as envisaged by the Convention, such as offering to supply, keeping in stock, importing, and exporting of counterfeit medical products. It does not sufficiently correspond with Article 5, MEDICRIME Convention.

Further action is needed to fully correspond with Article 6, MEDICRIME Convention.

### Article 7 – Falsification of documents

Article 362 CC provides for the general offence of making, purchase, storage for sale or use, sale or use of forged identity cards or other official documents. This provision is considered too general to sufficiently correspond with the intent of Article 7, MEDICRIME Convention.

Further action is needed to fully correspond with Article 7, MEDICRIME Convention.

### Article 8 – Similar crimes involving threats to public health

8.a.i, ii: Article 246 CC provides for a criminal offence for an Illegal medical or pharmaceutical practice that results in health damage. While this offence addresses the actual resulting impact of illegal medical and pharmaceutical products, it does not encompass the intent of Article 8.a, MEDICRIME Convention.

Action is needed to correspond with Article 8.a.i and ii, MEDICRIME Convention.

8.b: No provision could be found to correspond with Article 8.b, MEDCRIME Convention.

Action is needed to correspond with Article 8.b, MEDICRIME Convention.

### Article 9 – Aiding or abetting and attempt

9.1: Article 24 (1, 2, 3) and 25 (3) CC, as regards aiding and abetting, does not envisage the criminalising intended by and is does not sufficiently correspond with Article 9.1, MEDICRIME Convention.

9.2: Article 19 (1, 2) CC, as regards attempt, does not envisage the criminalising intended by and is does not sufficiently correspond with Article 9.2, MEDICRIME Convention.

Action is needed to correspond with Article 9.1 and 9.2, MEDICRIME Convention.

### Article 11 – Corporate liability

11.1. a, b, c: Article 107(2) and (3) CC provides for the criminal liability for legal entities only if the relevant article of the CC determines the liability of a legal entity. The application of these provisions only applies to the forging of documents, but not otherwise. There is insufficient correspondence with Article 11.1. a, b, and c, MEDICRIME Convention.

Further action is needed to fully correspond with Article 11.1. a, b, and c, MEDICRIME Convention.

11.2: Article 107(4) CC provides for the criminal liability for legal entities only if the relevant article of the CC determines the liability of a legal entity. The application of these provisions only applies to the forging of documents, but not otherwise. There is insufficient correspondence with Article 11.2, MEDICRIME Convention.

Further action is needed to fully correspond with Article 11.2, MEDICRIME Convention.

11.3: The general laws correspond with Article 11.3, MEDICRIME Convention.

11.4: The general laws correspond with Article 11.4, MEDICRIME Convention.

### Article 13 – Aggravating circumstances

Article 17, 197(3) and (4), and Article 246(2), CC are not completely in compliance with the corresponding provision of the MEDICRIME Convention, as it does not cover all aggravating circumstances envisaged by the Convention, which should entail a more severe liability for committing the crime under specific circumstances. In particular:

b) the offence was committed by persons abusing the confidence placed in them in their capacity as professionals.

c) the offence was committed by persons abusing the confidence placed in them as manufacturers as well as suppliers.

d) the offences of supplying and offering to supply were committed having resort to means of large-scale distribution, such as information systems, including the Internet.

e) the offence was committed in the framework of a criminal organization.

The circumstances outlined above are the aggravating circumstances for other crimes envisaged by the Criminal Code and not the ones that would be relevant for achieving the objective of the Convention.

## 3.15 Greece

### Article 4 - Definitions

a. Article 4.a MEDICRIME Convention – Medical Product
No provision, as regards the term 'medical product', could be found in internal law corresponding with Article 4.a, MEDICRIME Convention. It is noted that there are separate definitions for the terms 'medicinal products' and 'medical device'.
Action is needed to correspond with Article 4. a, MEDICRIME Convention.

b. Article 4.b MEDICRIME Convention – Medicinal Product
Ministerial Decision 32221/2013 - published in ΦΕΚ Β'/ 2485 / 3-10-2013, Article 2. 1, as regards medicinal products for human use, corresponds with Article 4.b, MEDICRIME Convention. No provision for a definition, as regards medicinal products for veterinary use or for investigational medicinal products, could found in internal law corresponding with Article 4.b, MEDICRIME Convention.
Further action is needed to correspond with Article 4.b, MEDICRIME Convention.

c. Article 4.c MEDICRIME Convention -Active substance
Ministerial Decision 32221/2013 - published in ΦΕΚ Β'/ 2485 / 3-10-2013, Article 2. 2, as regards the term 'active substance' corresponds with Article 4.c, MEDICRIME Convention.

d. Article 4.d MEDICRIME Convention – Excipient
Ministerial Decision 32221/2013 - published in ΦΕΚ Β'/ 2485 / 3-10-2013, Article 2.4, as regards the term 'excipient', substantially corresponds with Article 4.d, MEDICRIME Convention.

e. Article 4.e MEDICRIME Convention – Medical Device
Ministerial Decision 130648/2009 published in ΦΕΚ 2198/Β/2-10-2009), Article 2.1, as regards the term 'medical device', corresponds with Article 4.e, MEDICRIME Convention.

f. Article 4.f MEDICRIME Convention – Accessory
Ministerial Decision 130648/2009 published in ΦΕΚ 2198/Β/2-10-2009), Article 2.1, as regards the term 'accessory', corresponds with Article 4.f, MEDICRIME Convention.

g. Article 4.g MEDICRIME Convention – Parts and materials
No provision in internal law could be found to correspond with Article 4.g, MEDICRIME Convention.
Action is needed to correspond with Article 4.g, MEDICRIME Convention.

h. Article 4.h MEDICRIME Convention – Document
No provision in internal law could be found to correspond with Article 4.h, MEDICRIME Convention.
Action is needed to correspond with Article 4.h, MEDICRIME Convention.

i. Article 4.i MEDICRIME Convention – Manufacturing
No provision in internal law, as regards the term 'manufacturing' could be found corresponding to Article 4.i, MEDICRIME Convention. It is noted that the term 'manufacturer' in relation to medical devices can be found defined in Ministerial Decision 130648/2009 published in ΦΕΚ 2198/Β/2-10-2009), Article 2.1, and while this describes some of the functions intended by Article 4.1, MEDICRIME Convention, it does not correspond with it.

Action is needed to correspond with Article 4.i MEDICRIME Convention.

j. Article 4.j MEDICRIME Convention – Counterfeit
Ministerial Decision 32221/2013 - published in ΦΕΚ Β΄/ 2485 / 3-10-2013, Part 1, Article 36, as regards the term 'counterfeit', as regards medicinal products for human use, corresponds, with Article 4.j, MEDICRIME Convention. Law 721/1977 on the approval of the circulation and control of veterinary medicinal products partially corresponds with Article 4.j, MEDICRIME Convention. No provision in internal law, as regards medical devices, could be found corresponding with Article 4.j, MEDICRIME Convention.
Further action is needed to correspond with Article 4.j, MEDICRIME Convention.

k. Article 4.k MEDICRIME Convention – Victim
Article 55.i, Law 4478/2017, published in ΦΕΚ 91/Α/23-6-2017, as regards the term 'victim' is provided in relation to the implementation of the Council of Europe Convention on Laundering, Search, Seizure and Confiscation of the Proceeds from Crime and on the Financing of Terrorism (Warsaw Convention, CETS 198, 2005). It is unclear whether, in internal law, this provision is applicable outside of Law 4487/2017.
No specific provision in internal law can be found to correspond with Article 4.k, MEDICRIME Convention.
Action is needed to correspond with Article 4.k, MEDICRIME Convention.

## CHAPTER II – SUBSTANTIVE CRIMINAL LAW

### Article 5 – Manufacturing of counterfeits

5.1: Ministerial Decision 32221/2013, published in ΦΕΚ Β΄/ 2485 / 3-10-2013, Art. 175. 3, provides for administrative fines to produce counterfeit medicines. This does not correspond with Article 5.1, MEDICRIME Convention.

5.2: Article 19.9, Legislative Decree 96/1973 relates to pharmaceutical products that are adulterated, but not the act of adulterating the product. As this provision is related to the finding on inspection of adulterated pharmaceutical products and those not in compliance with approved composition, it is unclear whether the provision is intended as a licensing provision, an administrative law matter, or as a criminal offence.

Action is required to correspond with Article 5.1 and 5.2, MEDICRIME Convention.

### Article 6 – Supplying, offering to supply, and trafficking in counterfeits

Article 19, §9, Legislative Decree 96/1973, as regards pharmaceutical products, prohibits the distribution or holding such products with the intention of selling them. Ministerial Decision 32221/2013, published in ΦΕΚ Β΄/ 2485 / 3-10-2013, Art. 175. 3, provides for administrative fines to distribute, broker, import and export of counterfeit medicines.

Clarification is required on the status of this offence as regards the intentional conduct required by the MEDICRIME Convention.

No provision in internal law applicable to medical devices can be found to correspond with Article 6, MEDICRIME Convention.

Further action is needed to fully correspond with Article 6, MEDICRIME Convention.

### Article 7 – Falsification of documents

Article 216.1, Penal Code is a general criminal law offence that is not specific to the type of documents contemplated by Article 7, MEDICRIME Convention. It is sufficient to correspond with Article 7.

### Article 8 – Similar crimes involving threats to public health

8.a.i: Ministerial Decision 32221/2013, published in ΦΕΚ Β΄/ 2485 / 3-10-2013, Article 175.3, provides for administrative fines for non-compliances set out in the Ministerial Decision on the production, distribution, import and export active substances and excipients. No provision can be found in internal law, as regards medicinal products for human use or medicinal products for veterinary use, to correspond with Article 8.a.ii, MEDICRIME Convention.

8.a. ii: No provision in internal law, as regards medical devices, could be found corresponding with Article 8.a.ii, MEDICRIME Convention.

8.b: No provision in internal law, as regards medical devices, could be found corresponding with Article 8.b, MEDICRIME Convention.

### Article 9 – Aiding or abetting and attempt

Articles 45 and 46, Penal Code, as regards aiding and abetting, correspond with Article 9, MEDICRIME Convention.

### Article 11 – Corporate liability

No provision in internal law could be found corresponding with Article 11, MEDICRIME Convention. In Greece, the legal person acts only through their representatives and cannot be on their own be subject to the criminal law.

Action is needed to correspond with Article 11, MEDICRIME Convention.

### Article 13 – Aggravating circumstances

Law 5607/1932, and Article 19.9, Legislative Decree 97/1973, both regarding recidivist offending behaviours involving pharmaceutical offences but other medical products, may partially correspond with Article 13.f, MEDICRIME Convention.

Internal law does not correspond with article 13, MEDICRIME Convention.

Further action is needed to correspond with Article 13, MEDICRIME Convention.

## 3.16 Guinea

### Article 4 – Definitions

a. Article 4.a MEDICRIME Convention – Medical Product
Article 1.a, Loi L/2018/024/AN, 2018, on medicines, health products and the practice of the profession of pharmacy, provides for the meaning of the term "produit de santé" (health product) and it is insufficient to fully correspond with Article 4.a, MEDICRIME Convention.
Further action is needed to fully correspond with Article 4.a, MEDICRIME Convention.

b. Article 4.b MEDICRIME Convention – Medicinal Product
Article 1. b, Law L/2018/024/AN,2018, as regards the term 'medicinal product', but excluding investigational medical products, substantially corresponds with Article 4.b, MEDICRIME Convention.
Further action is needed to fully correspond with Article 4.b, MEDICRIME Convention.

c. Article 4.c MEDICRIME Convention -Active substance
Article 1. t, Law L/2018/024/AN 2018, as regards the term 'active substance', corresponds with Article 4.c MEDICRIME Convention.

d. Article 4.d MEDICRIME Convention – Excipient
Article 1.u, Law L/2018/024/AN 2018, as regards the term 'excipient' corresponds with Article 4.d, MEDICRIME Convention.

e. Article 4.e MEDICRIME Convention – Medical Device
Article 1. p, Law L/2018/024/AN 2018, as regards the term 'medical device', corresponds with Article 4.e MEDICRIME Convention.

f. Article 4.f MEDICRIME Convention – Accessory
Article 1. v, Law L/2018/024/AN 2018, as regards the term 'accessory', corresponds with Article 4.f MEDICRIME Convention.

g. Article 4.g MEDICRIME Convention – Parts and materials
Article 1. w, Law L/2018/024/AN 2018, as regards the terms 'parts' and 'materials', corresponds with Article 4.g MEDICRIME Convention.

h. Article 4.h MEDICRIME Convention – Document

Article 1. y, Law L/2018/024/AN 2018, as regards the term 'document', corresponds with 4.h MEDICRIME Convention.

i. Article 4.i MEDICRIME Convention – Manufacturing
Article 1. x, Law L/2018/024/AN 2018, as regards the term 'manufacturing,' corresponds with 4.i MEDICRIME Convention.

j. Article 4.j MEDICRIME Convention – Counterfeit
Article 35 Law L/2018/024/AN 2018, as regards the term 'counterfeit', corresponds with 4.j MEDICRIME Convention.

k. Article 4.k MEDICRIME Convention – Victim
No provision in internal law, as regards the term 'victim', corresponds with Article 4.k, MEDICRIME Convention.
Action is needed to correspond with Article 4.k, MEDICRIME Convention.

## CHAPTER II – SUBSTANTIVE CRIMINAL LAW

### Article 5 – Manufacturing of counterfeits

Article 35 in conjunction with Article 169, Law L/2018/024/AN 2018, and Article 880 Criminal Code (L/2016/59/AN), do not sufficiently correspond with Article 5, MEDICRIME Convention.

Further action is needed to fully correspond with Article 5 MEDICRIME Convention.

### Article 6 – Supplying, offering to supply, and trafficking in counterfeits

Article 170 Law L/2018/024/AN 2018, and Article 880 Criminal Code do not sufficiently correspond with Article 6, MEDICRIME Convention.

Further action is needed to fully correspond with Article 6 MEDICRIME Convention.

### Article 7 – Falsification of documents

Art. 585 Criminal Code corresponds with Article 7 MEDICRIME Convention.

### Article 8 – Similar crimes involving threats to public health

8.a.i. ii: Article 177, Law L/2018/024/AN 2018, in conjunction with Article 75 and following ones, do not sufficiently correspond with Article 8.a.i and ii, MEDICRIME Convention.

Further action is needed to fully correspond with Article 8.a. MEDICRIME Convention.

8.b: No provision in internal law can be found to correspond with Article 8.b, MEDICRIME Convention.

Further action is needed to correspond fully with Article 8.a and b, MEDICRIME Convention.

### Article 9 – Aiding or abetting and attempt

9.1: Article 173, Law L/2018/024/AN 2018, and Articles 19 and 20, Criminal Code, correspond with Article 9.1 MEDICRIME Convention.

9.2: Article 172, Law L/2018/024/AN 2018, and Article 18 Criminal Code, correspond with Article 9.2 MEDICRIME Convention (see also art. 18 Criminal Code).

### Article 11 – Corporate liability

11.1. a, b, c: Article 16, Criminal Code corresponds with Article 11.1. a, b, c, MEDICRIME Convention

11.2: No provision in internal law could be found to correspond with Article 11.2, MEDICRIME Convention.

Action is needed to correspond with Article 11.2, MEDICRIME Convention.

11.3: Article 16, Criminal Code corresponds with Article 11.3, MEDICRIME Convention.

11.4: Article 16, Criminal Code corresponds with article 11.4, MEDICRIME Convention.

### Article 13 – Aggravating circumstances

13.e: Article 161, Criminal Code, corresponds with Article 13.e, MEDICRIME Convention.

13.f: Article 99, Criminal Code, corresponds with Article 13.f, MEDICRIME Convention.

No provision in internal law could be found corresponding with Articles 13, a, b, c and d MEDICRIME Convention.

Further action is needed to correspond with Articles 13, a, b, c and d MEDICRIME Convention.

## 3.17 Iceland

### Article 4 - Definitions

a Article 4.a MEDICRIME Convention – Medical Product
No provision, as regards the term 'medical product', could be found in internal law corresponding with Article 4.a, MEDICRIME Convention. It is noted that the terms 'medicinal product' and 'medical device' are separately defined.
Action is needed to correspond with Article 4.a MEDICRIME Convention.

b. Article 4.b MEDICRIME Convention – Medicinal Product
Article 3(3), Medicinal Products Act, 2020, corresponds with Article 4.b, MEDICRIME Convention. The term 'investigational medicinal products' is not defined and is considered to be encompassed in the meaning of 'medicinal product'.

c. Article 4.c MEDICRIME Convention -Active substance
Article 3(22) Medicinal Products Act, 2020, corresponds with Article 4.c, MEDICRIME Convention.

d. Article 4.d MEDICRIME Convention – Excipient
Article 3(5), Medicinal Products Act, 2020, corresponds with Article 4.d, MEDICRIME Convention.

e. Article 4.e MEDICRIME Convention – Medical Device
Article 3(1), Act on Medical Devices, 2001, as amended, corresponds with Article 4.e, MEDICRIME Convention.

f. Article 4.f MEDICRIME Convention – Accessory
Article 2(2), Regulation on Medical Devices, 2010, corresponds with Article 4.f, MEDICRIME Convention.

g. Article 4.g MEDICRIME Convention – Parts and materials
No provision, as regards the terms 'parts' 'materials", could be found in internal law corresponding with Article 4.g, MEDICRIME Convention.
Action is needed to correspond with Article 4.g MEDICRIME Convention.

h. Article 4.h MEDICRIME Convention – Document
No provision, as regards the term 'document', could be found in internal law corresponding with Article 4.h, MEDICRIME Convention.
Action is needed to correspond with Article 4.h MEDICRIME Convention.

i. Article 4.i MEDICRIME Convention – Manufacturing
Article 3(2), Medicinal Products Act, 2020, as regards medicinal products, but not active substances and excipients, corresponds with Article 4.i, MEDICRIME Convention.
There is no legal definition of the term 'manufacturing' as regards medical devices. The term 'manufacturer' is defined in §3.2, Act on Medical Devices Act, 2001, and this incorporates, as regards medical devices, part of the definition in Article 4.i, MEDICRIME Convention.
Further action is needed to fully correspond with Article 4.i, MEDICRIME Convention.

j. Article 4.j MEDICRIME Convention – Counterfeit
Article 3. (3), Medicinal Products Act, 2020, corresponds with Article 4, j, MEDICRIME Convention.

k. Article 4.k MEDICRIME Convention – Victim
No provision, as regards the term 'victim', could be found in internal law corresponding with Article 4.k, MEDICRIME Convention.
Action is needed to correspond with Article 4.k MEDICRIME Convention.

## CHAPTER II – SUBSTANTIVE CRIMINAL LAW

### Article 5 – Manufacturing of counterfeits

No provision could be found in internal law that corresponds with Article 5, MEDICRIME Convention.

Action is needed to correspond with Article 5 MEDICRIME Convention.

### Article 6 – Supplying, offering to supply, and trafficking in counterfeits

No provision could be found in internal law that corresponds with Article 6, MEDICRIME Convention. It is noted that Article 173, Criminal Code (CC) 1940, as amended, penalises anyone who offers for sale or involved in the distribution of medicinal products knowing that those products do not possess the required properties and that their use could endanger human life and health. While this provision could potentially address some of the behaviours intended by Article 6, MEDICRIME Convention, it does not address, either directly or indirectly all of them.

Further action is needed to fully correspond with Article 6 MEDICRIME Convention.

### Article 7 – Falsification of documents

Articles 155-159, Criminal Code, 1940, as amended, correspond with Article 7, MEDICRIME Convention.

### Article 8 – Similar crimes involving threats to public health

8.a.i: Article 100. a, d, e, g, and Article 103. c, h and f, Medicinal Products Act, correspond with Article 8.a.i, MEDICRIME Convention.

8.a.ii: The Act on Medical Devices does not correspond with Article 8, a, ii, MEDICRIME Convention.

8.b: Section 157, CC, 1940, as amended, prohibits the use of a document for a different purpose than intended. This is a general criminal law provision which does not specifically focus on documentation intended for medical purposes but does not exclude its applicability. Section 157 corresponds with Article 8. MEDICRIME Convention. No provision in the Medicinal Product Act or the Act on Medical Devices can be found corresponding with Article 8.b, MEDICRIME Convention.

Action is needed to fully correspond with Article 8, a. ii, and 8.b, MEDICRIME Convention.

### Article 9 – Aiding or abetting and attempt

Article, 104, Medicinal Product Act, as regards attempts and acting as an accessory, corresponds with Article 9.1 and 9.2, MEDICRIME Convention. Articles 20 and 22, CC, 1940, as amended, as regards attempts and aiding and abetting, respectively, correspond with Article 9, MEDICRIME Convention.

### Article 11 – Corporate liability

11.1. a, b, c: Articles 19.c, CC, as amended, while not being specific on the conditions in 11.1, a, b, and c, corresponds with Article 11.1, MEDICRIME Convention.

11.2: Article 19, CC corresponds with Article 11.2, MEDICRIME Convention.

11.3: Article 92 and 93, Medicinal Products Act, as regards administrative and civil liability, respectively, and Article 19. d, CC, as regards criminal liability, correspond with Article 11.3, MEDICRIME Convention.

11.4: Article 103, Medicinal Products Act, as regards medicinal products, and Article 19. c, and d, correspond with Article 11.4, MEDICRIME Convention.

### Article 13 – Aggravating circumstances

13. a-d: No provision in the Criminal Code, the Medicinal Products Act and the Act on Medical Devices could be found to correspond with Article 13, a, b, c, and d, MEDICRIME Convention.

13.e: Article 175.a, CC corresponds with Article 13.e, MEDICRIME Convention.

13.f: Article 71, CC corresponds with Article 13.f, MEDICRIME Convention.

Further action is needed to fully correspond with Article 13 a – d, MEDICRIME Convention.

## 3.18 Ireland

### Article 4 - Definitions

a. Article 4.a MEDICRIME Convention – Medical Product
No provision, as regards the term 'medical product' could be found in internal law corresponding to Article 4.a, MEDICRIME Convention. It is noted that there are separate definitions of the terms 'medicinal product' and 'medical device'.
Action is needed to correspond with Article 4.a MEDICRIME Convention.

b. Article 4.b MEDICRIME Convention – Medicinal Product
Section 1(1) of the Irish Medicines Board Act 1995, as amended by section 10(c) of the Irish Medicines Board (Miscellaneous Provisions) Act 2006 refers to Directive 2001/83/EU, as amended, on the definition of medicinal products, and Article 3 of the Medicinal Products (Control of Manufacture) Regulations 2007, together and separately correspond with Article 4.b, MEDICRIME Convention.

c. Article 4.c MEDICRIME Convention -Active substance
Article 3 (1) of the Medicinal Products (Control of Manufacture) Regulations 2007 (S.I. 539 of 2007) corresponds with Article 4.c, MEDICRIME Convention.

d. Article 4.d MEDICRIME Convention – Excipient
Medicinal Products (Control of Manufacture) Regulations, 2007, S.I. 539 of 2007 corresponds with Article 4.d, MEDICRIME Convention.

e. Article 4.e MEDICRIME Convention – Medical Device
Section 1(1) of the Irish Medicines Board Act 1995, as amended by section 10(c) of the Irish Medicines Board (Miscellaneous Provisions) Act 2006 refers to the EU Directives on the definition of medical devices - Directive 2007/47/EU (amending directive 93/42/EU regarding medical devices). The definition has been implemented in Irish legislation in Regulation 5 (ii), European Communities (Medical Devices) (Amendment) Regulations 2009 (S.I. No. 110/2009) and corresponds with Article 4.e, MEDICRIME Convention.
Article 4.f MEDICRIME Convention – Accessory

f. European Communities (Medical Devices) Regulations, 1994 (S.I. No. 252/1994) corresponds with Article 4.f, MEDICRIME Convention.

g. Article 4.g MEDICRIME Convention – Parts and materials
No provision, as regards the terms 'parts' and 'materials' could be found in internal law corresponding to Article 4.a, MEDICRIME Convention.
Further action is needed to correspond with Article 4.g, MEDICRIME Convention.

h. Article 4. MEDICRIME Convention – Document
Sections 2 and 24, Criminal Justice (Theft and Fraud Offences) Act 2001, and Section 32A, Irish Medicines Board Acts 1995 and 2006, both correspond with Article 4.h, MEDICRIME Convention.

i. Article 4.i MEDICRIME Convention – Manufacturing
Regulation 3, Medicinal Products (Control of Manufacture) Regulations 2007 (S.I. 539 of 2009), as regards medicinal products for human use, Section 1, Animal Remedies Act 1993, as regards medicinal products for veterinary use, and Regulation 2, European Communities (Medical Devices) Regulations, 1994 (S.I. No. 252/1994), as regards medical devices, but not accessories, correspond with Article 4.i, MEDICRIME Convention.
Further action is needed to fully correspond with Article 4.i, MEDICRIME Convention.

j. Article 4.j MEDICRIME Convention – Counterfeit

Regulation 3, Medicinal Products (Control of Manufacture) Regulations, 2007, as amended by Medicinal Products (Control of Manufacture) (Amendment) Regulations 2013 (S.I. 163 of 2013), excluding medical devices, corresponds with Article 4.j, MEDICRIME Convention.
Further action is needed to fully correspond with Article 4.j, MEDICRIME Convention.

k. Article 4.k MEDICRIME Convention – Victim
Section 2. (1), Criminal Justice (Victims of Crime) Act 2017 corresponds with Article 4.k, MEDICRIME Convention.

## CHAPTER II – SUBSTANTIVE CRIMINAL LAW

### Article 5 – Manufacturing of counterfeits

Regulation 14B. (1) and 14.C, Medicinal Products (Control of Manufacture) Regulations, 2007, (S.I. 539 of 2007), as amended by Medicinal Products Control of Manufacture) (Amendment) Regulations 2013 (S.I. 163 of 3013), as regards medicinal products and active substances, respectively, correspond with Article 5, MEDICRIME Convention. There is no existing provision in law for falsified/counterfeit medical devices, accessories, and parts and material. A new law, yet to be enacted, is scheduled for implementation from May 2021 to include the falsification of medical devices, accessories and parts and materials.

Further action is needed to fully correspond with Article 5, MEDICRIME Convention.

### Article 6 – Supplying, offering to supply, and trafficking in counterfeits.

Regulation 14.B. Medicinal Products (Control of Wholesale Distribution) Regulations, 2007 (S.I. 538 of 2007), as amended by Regulation 6, Medicinal Products (Control of Wholesale Distribution) (Amendment) Regulations 2013 (S.I.164 of 2013), as regards medicinal products, corresponds with Article 6, MEDICRIME Convention. There is no existing provision in law for falsified/counterfeit medical devices, accessories, and parts and material. A new law, yet to be enacted, is scheduled for implementation from May 2021 to include the falsification of medical devices, accessories and parts and materials.

Further action is needed to fully correspond with Article 6, MEDICRIME Convention.

### Article 7 – Falsification of documents

Articles 25, 26, 27, 28, 29 and 30, Criminal Justice (Theft and Fraud Offences) Act 2001 correspond with Article 7, MEDICRIME Convention.

### Article 8 – Similar crimes involving threats to public health

8.a.i. ii, iii: Regulation 4, Medicinal Products (Control of Manufacture) Regulations, 2007 (S.I. 539 of 2007), Regulation 5, Medicinal Products (Control of Wholesale Distribution) Regulations 2007 (S.I. 538 of 2007), Regulation 6, Medicinal Products (Control of Placing on the Market) Regulations 2007 (S.I. 540 of 2007), as regards medicinal products for human use, European Communities (Animal Remedies) (No. 2) Regulations 2007 ( S.I. No. 786/2007), as regards medicinal products for veterinary use, and European Communities (Medical Devices) Regulations, 1994 (S.I. No. 252/1994), as regards medical devices, corresponds with Article 8.a.i, and ii, MEDICRIME Convention.

8.b: No provision in internal law can be found corresponding to Article 8.b.

Further action is needed to correspond with Article 8.b, MEDICRIME Convention.

### Article 9 – Aiding or abetting and attempt.

9.1: Section 22 of the Petty Sessions Ireland Act 1851 and Section 7 of the Criminal Law Act 1997, as regards aiding and abetting, corresponds with Article 9.1, MEDICRIME Convention.

9.2: Save where provided by a particular statute, any attempt to commit an indictable (serious) offence is capable of being prosecuted as being contrary to the Irish common law and corresponds with Article 9.2, MEDICRIME Convention.

### Article 11 – Corporate liability

Section 33, Irish Medicines Board Acts 1995 and 2006, correspond with Articles 11.1, 11.2, 11.3 and 11.4 MEDICRIME Conventions.

### Article 13 – Aggravating circumstances

Aggravating and mitigating factors are not part of the substantive criminal law and remain within judicial discretion which is guided by sentencing rules, principles and policies that must be applied.

Action is needed to correspond with Article 13, MEDICRIME Convention.

## 3.19 Italy

### Article 4 - Definitions

a. Article 4.a MEDICRIME Convention – Medical Product
No provision, as regards the term 'medical product' could be found in internal law corresponding to Article 4.a, MEDICRIME Convention. It is noted that there are separate definitions of the terms 'medicinal product' and 'medical device'.
Action is needed to correspond with Article 4.a, MEDICRIME Convention.

b. Article 4.b MEDICRIME Convention – Medicinal Product
Article 1.1.a, Legislative Decree No. 219 of 24 April 2006 on the implementation of Directive 2001/83/EC (Medicine Code), as regards medicinal products for human use, corresponds with Article 4.b, MEDICRIME Convention.

c. Article 4.c MEDICRIME Convention -Active substance
Article 1. 1. b-bis), Legislative Decree 219/2006, and Article 1. x) Legislative Decree 193/2006 correspond with Article 4.c, MEDICRIME Convention.

d. Article 4.d MEDICRIME Convention - Excipient
Article 1.1.b, b-ter) Legislative Decree 219/2006 substantially corresponds with Article 4.d, MEDICRIME Convention.

e. Article 4.e MEDICRIME Convention – Medical Device
Article 1. 2. a), Legislative Decree 1997 corresponds with Article 4.e, MEDICRIME Convention. This provision will be repealed by Regulation 2017/745/EU with effect from 26 May 2021 when the new definition of medical device will be implemented.

f. Article 4.f MEDICRIME Convention – Accessory
Article 1. 2. b), Legislative Decree 1997, corresponds with Article 4.f, MEDICRIME Convention. This provision will be repealed by Regulation 2017/745/EU with effect from 26 May 2021 when the new definition of medical device will be implemented.

g. Article 4.g MEDICRIME Convention – Parts and materials
The terms "parts" and "materials" as defined by the internal legislation correspond substantially to the definition established in the MEDICRIME Convention.

h. Article 4.h MEDICRIME Convention – Document
The term "document" as defined by the internal legislation corresponds substantially to the definition established in the MEDICRIME Convention.

i. Article 4.i MEDICRIME Convention – Manufacturing
The term "manufacturing" as defined by the internal legislation corresponds substantially to the definition established in the MEDICRIME Convention.

j. Article 4.j MEDICRIME Convention – Counterfeit
Article 1.1.nn-bis), Legislative Decree 1997
The term "counterfeit" as defined by the internal legislation corresponds substantially to the definition established in the MEDICRIME Convention.

k. Article 4.k MEDICRIME Convention – Victim
The term "victim" as defined by the internal legislation corresponds substantially to the definition established in the MEDICRIME Convention.

## CHAPTER II – SUBSTANTIVE CRIMINAL LAW

### Article 5 – Manufacturing of counterfeits

Article 441 Penal Code provides for the offence of adulteration and counterfeiting of products that are detrimental to public health. While not specified, this encompasses these acts in relation to medical products. An offence under this provision includes the required element of proving the detrimental effect on public health and falsification. Article 147,7-bis, Legislative Decree 219/2006 punishes the manufacturing of a falsified medicine. This offence does not require an element of endangerment, suffice that it is intentionally falsified. Article 5, MEDICRIME Convention requires that the act of manufacturing a falsified medical product constitutes the offence. While endangerment is not a required element of the offence, Article 13.a provides an aggravating circumstance for such.

While Article 441 Penal Code could be useful in prosecuting the counterfeiting of medical products, it cannot be used where endangerment cannot be proven. The Legislative Decree relates to medicinal products and not medical devices.

Further action is required to fully correspond with Article 5, MEDICRIME Convention.

### Article 6 – Supplying, offering to supply, and trafficking in counterfeits

Article 442, Penal Code provides for, in relation to adulterated and counterfeited products, the keeping for trade, places on the market for supply, or distributes. This offence requires the elements of endangerment of public health and falsification of the product, which is not specific to medical products. Article 147, 7-bis, Legislative Decree 219/2006 provides for the offence of distributing, importing, exporting, brokering, trading and selling by distance sales to the public, of falsified medicinal products. There is no similar provision in relation to medical devices. The element of endangerment to public health is not required in this offence.

Article 6, MEDICRIME Convention requires, in relation to a falsified medical product, a range of acts which Article 147,7-bis to constitutes the offence. While endangerment is not a required element of the offence, Article 13.a provides an aggravating circumstance for such.

While Article 442 Penal Code could be useful in prosecuting the counterfeiting of medical products, it cannot be used where endangerment cannot be proven. The Legislative Decree relates to medicinal products and not medical devices.

Further action is needed to fully correspond with Article 6, MEDICRIME Convention.

### Article 7 – Falsification of documents

No provision in internal law corresponds with Article 7, MEDICRIME Convention.
Action is needed to correspond with Article 7, MEDICRIME Convention.

### Article 8 – Similar crimes involving threats to public health

8.a.i: Articles 147 and 148 Legislative Decree 219/2006, as regards medicinal products for human use, and Art. 108 Legislative Decree nº 193/2006, as regards medicinal products for animal use, correspond with Article 8.a.i, MEDICRIME Convention.

8.a.ii: Articles 4 and 5, Legislative Decree, 46/1997, as regards medical devices, correspond with Article 8.a.ii, MEDICRIME Convention.

8.b: No provision in internal law can be found to correspond with Article 8.b, MEDICRIME Convention.

Action is needed to correspond with Article 8.b, MEDICRIME Convention.

### Article 9 – Aiding or abetting and attempt

9.1: Article 110, Penal Code, as regards aiding and abetting, corresponds with Article 9.1 MEDICRIME Convention.

9.2: Article 56, Penal Code, as regards attempt, corresponds with Article 9 MEDICRIME Convention.

For the offences referred to in Articles 440 and 442 the configurability of the attempt is controversial, having committed a crime of danger, and therefore there would be an excessive anticipation of the threshold of punishment.

### Article 11 – Corporate liability

11.1. a, b, c: Legislative Decree No 231/2001, as general corporate liability offences, corresponds with Article 11, a, b and c, MEDICRIME Convention. These offences are not specific to those contained in the MEDICRIME Convention established measures to ensure that legal persons can be held liable for certain crimes, when they are committed to their advantage by any natural person, acting individually or as a part of an organ of the legal person, who has a leading position within it based on: (a) representation of the legal entity; (b) the authority to take decisions on behalf of the legal entity; (c) the authority to exercise control within the legal entity. The outline of the procedure provided for in the MEDICRIME Convention is that governed by Legislative Decree 231/2001; however, currently, the conduct contained in the Convention is not provided for by general law. New provisions should therefore be introduced when the MEDICRIME Convention is ratified, providing for the criminal and/or administrative liability of legal persons, including for offences of infringement of medicinal products introduced by the Convention.

11.2: Article 5 paragraph.1 b) and article 7 Legislative Decree 231/2001 corresponds with Article 11.2, MEDICRIME Convention

11.3: Subject to the legal principles of the domestic criminal code and of the Legislative decree 231/01, the liability of a legal person may be civil or administrative and correspond with Article 11.3, MEDICRIME Convention.

11.4. Article 40, Penal Code corresponds with Article 11.4, MEDICRIME Convention.

### Article 13 – Aggravating circumstances

13.a: No provision in internal law could be found to correspond with Article 13.a, MEDICRIME Convention.

13.b: Article 61.11), Penal Code corresponds with Article 13.b, MEDICRIME Convention.

13.c: Article 61. 11), Penal Code corresponds with article 13.c, MEDICRIME Convention.

13.d: Article 112-quarter, 1 and 2, Legislative Decree 219/2006 provide for an offence encompassing elements of supplying having resort to means of remote sales of medicinal products, the penalty for which is prescribed by Article 112-ter Legislative decree 219/2006. Notwithstanding that this could be used in prosecution relating to this type of offence, it does not include all medical products. No aggravating circumstances could be found in internal law corresponding to Article 13.d, MEDICRIME Convention.

13.e: Article 416, Penal Code refers to criminal associations but not fully corresponds to Article 13.e, MEDICRIME Convention

13.f: Article 99, Penal Code corresponds with Article 13.f, MEDICRIME Convention.

Further action is needed to correspond with Article 13.a and f, MEDICRIME Convention.

## 3.20 Japan

### Article 4 - Definitions

a. Article 4.a MEDICRIME Convention – Medical Product
   The Law for Ensuring Quality, Efficacy, and Safety of Drugs and Medical Devices (commonly-called the Pharmaceutical and Medical Device Act) (SQESPM) does not correspond with Article 4.a, MEDICRIME Convention.
   Action is needed for the internal law to fully correspond with Article 4.a, MEDICRIME Convention.

b. Article 4.b MEDICRIME Convention – Medicinal Product
   Article 2(2), SQESPM, corresponds partially with Article 4.b, MEDICRIME Convention, except for the presentation criterion at Article 4.b.i, and as regards investigational medicinal products at Article 4.b.iii, MEDICRIME Convention.
   Further action is needed to correspond with Article 4.b, MEDICRIME Convention.

c. Article 4.c MEDICRIME Convention -Active substance
Article 3.1. (2) and (3), SQESPM, partially corresponds with the intent of Article 4.c, MEDICRIME Convention and is not separately or individually defined.
Further action is needed to correspond with Article 4.c, MEDICRIME Convention.

d. Article 4.d MEDICRIME Convention – Excipient
No provision in internal law could be found to correspond with Article 4.d, MEDICRIME Convention.
Action is needed to correspond with Article 4.d, MEDICRIME Convention.

e. Article 4.e MEDICRIME Convention – Medical Device
Article 2. (4), SQESPM is similar in intent, though not in word, and corresponds with Article 4.e, MEDICRIME Convention.

f. Article 4.f MEDICRIME Convention – Accessory
No provision in internal law could be found to correspond with Article 4.f, MEDICRIME Convention.
Action is needed to correspond with Article 4.f, MEDICRIME Convention.

g. Article 4.g MEDICRIME Convention – Parts and materials
No provision in internal law could be found to correspond with Article 4.g, MEDICRIME Convention.
Action is needed to correspond with Article 4.g, MEDICRIME Convention.

h. Article 4.h MEDICRIME Convention – Document
Articles 50, 51, and 52 SQESPM specify information on labelling requirements. However, this is insufficient and does not correspond with the intent or wording in Article 4.h, MEDICRIME Convention.
Action is needed to correspond with Article 4.h, MEDICRIME Convention.

i. Article 4.i MEDICRIME Convention – Manufacturing
No provision in internal law could be found to correspond with Article 4.i, MEDICRIME Convention.
Action is needed to correspond with Article 4.i, MEDICRIME Convention.

j. Article 4.j MEDICRIME Convention – Counterfeit
No provision in internal law could be found to correspond with Article 4.j, MEDICRIME Convention.
Action is needed to correspond with Article 4.j, MEDICRIME Convention.

k. Article 4.k MEDICRIME Convention – Victim
Article 2 (1) and (2), Basic Act on Crime Victims 2004, is a general law provision and not specific to medical products. It sufficiently corresponds with Article 4.k, MEDICRIME Convention.

## CHAPTER II – SUBSTANTIVE CRIMINAL LAW

### Article 5 – Manufacturing of counterfeits

Articles 55(2) and 64, SQESPM, except for active substances, excipients, accessories, parts and materials, correspond with Article 5, MEDICRIME Convention. It is noted that adulteration is considered as part of the manufacturing process.

Further action is needed to fully correspond with Article ,5 MEDICRIME Convention.

### Article 6 – Supplying, offering to supply, and trafficking in counterfeits

Articles 55(2) and 64, SQESPM, except for the acts of offering and export, and all activities in relation to active substances, excipients, accessories, parts, and materials, correspond with Article 6, MEDICRIME Convention.

Further action is needed to fully correspond with Article 6, MEDICRIME Convention.

### Article 7 – Falsification of documents

Article 159, Penal Code 1907, is a general Criminal Law provision and not specific to medical products. This corresponds with the intent of Article 7, MEDICRIME Convention.

### Article 8 – Similar crimes involving threats to public health

8.a.i. ii: Article 12(1), 13(1) and 14(1) SQESPM, as regards pharmaceutical medicinal products, and Articles 23-2 (1), 23-2(1), 23-2-3 (1), 23-2-4(1), and 23-2-5 (1) SQESPM, as regards medical devices, for which the penalties are prescribed by Articles 84 and 86 SQESPM, correspond with Article 8.a.i and ii, MEDICRIME Convention**.**

8.b: No provision in internal law could be found to correspond with Article 8.b, MEDICRIME Convention**.**

Action is needed to correspond with Article 8.b, MEDICRIME Convention.

### Article 9 – Aiding or abetting and attempt.

9.1: Articles 61 and 62 Penal Code corresponds with Article 9.1, MEDICRIME Convention.

9.2: Article 44, Penal Code, criminalises attempt, but limited to when punishable in a prohibition, and which includes fraudulent acts where a person obtains, or causes another to obtain an illegal profit by the means described. This may also include computer crimes.

The provisions of the Penal Code, the Customs Code 1954, Act on Punishment of Organized Crimes and Control of Proceeds of Crimes 1999, and SQESPM, individually and in combination, are insufficient to fully correspond with Article 9.2, MEDICRIME Convention.

Further action is needed to fully correspond with Article 9.2, MEDICRIME Convention.

### Article 11 – Corporate liability

11.1. a, b, c: Articles 75 and 90, SQESPM, correspond with Article 11.1, a, b, and c, MEDICRIME Convention.

11.2: Article 715 (1) and (2), Civil Code, as regards the lack of supervision or control by The natural person referred to in 11.1, has made possible the commission of an offence established under and corresponds with Article 11.2, MEDICRIME Convention.

11.3: Article 90, SQESPM, and Article 715, Civil Code, as regards criminal and Administrative liability, correspond with Article 11.3, MEDICRIME Convention.

11.4: Article 90, SQESPM, corresponds with Article 11.4, MEDICRIME Convention.

### Article 13 – Aggravating circumstances

13.a: Articles 204, 205, 209, and 210, Penal Code, in combination, is sufficient to correspond with the intent of Article 13.a, MEDICRIME Convention.

13.b: Laws relating to healthcare practitioners provide for aggravating factors in relation to professional sanctions where they have committed a crime or wrongful act related to pharmaceutical affairs or medicine. These potentially may also relate to criminal acts as described under the MEDICRIME Convention. No other professionals are included in aggravating circumstance. Neither SQESPM nor the Penal Code have any provisions that fall within Article 13.b, MEDICRIME Convention. There is insufficient correspondence with Article 13b, MEDICRIME Convention.

Further action is needed to fully correspond with Article 13.b, MEDICRIME Convention.

13.c: Article 75. (1) SQESPM provides for the rescinding of authorisations where there have been abuses of authorisations, including by manufacturers and suppliers. This does not include the offences relating to counterfeiting of medical products and is insufficient to correspond with Article 13.c, MEDICRIME Convention.

Further action is needed to fully correspond with Article 13.a, MEDICRIME Convention.

13.d: While Article 6, Act on Regulation of Transmission of Specified Electronic Mail, prohibits sending advertisement by email where the sender's details are falsified, this potentially could be used in prosecutions regarding offences in Articles 5, 6, 7 and 8 MEDICRIME Convention, However, this provision, while it could support a prosecution of offences contemplated by the Convention, is not intended for such offences, but for the regulation of advertisements by email. It is not an aggravating circumstance intended by Article 13, d, MEDICRIME Convention.

Articles 12 and 15, Act on Specified Commercial Transactions, 1976, could potentially be used in prosecutions in relation to medical products involved in offending described in Article 5, 6, 7 and 8, MEDICRIME Convention. However, they are more correctly intended To regulate commercial activity, not as aggravating circumstances intended by Article 13.d, MEDICRIME Convention.

Further action is needed to fully correspond with Article 13.d, MEDICRIME Convention.

13.e: The SQESPM, Penal Code or the Act on Punishment of Organized Crimes and Control of Proceeds of Crime, as regards aggravating circumstances where the offence was committed in the framework of a criminal organisation, in so far as they do not already form part of the constituent elements of the offence, do not correspond with Article 13.e, MEDICRIME Convention.

Further action is required to fully correspond with Article 13e, MEDICRIME Convention.

13.f: Articles 57 and 59, Penal Code correspond with Article 13.f, MEDICRIME Convention.

## 3.21 Latvia

### Article 4 - Definitions

a. Article 4.a MEDICRIME Convention – Medical Product
No provision, as regards the term 'medical product', could be found in internal law which corresponds with Article 4.a, MEDICRIME Convention. It is noted that there are separate definitions of the terms 'medicinal product' and 'medical device'.
Action is needed to correspond with Article 4.a, MEDICRIME Convention.

b. Article 4.b MEDICRIME Convention – Medicinal Product
Section 1.17, Pharmaceutical Law, except for investigational medicinal products, corresponds with Article 4. b, MEDICRIME Convention.
Further action is required to fully correspond with Article 4.b, MEDICRIME Convention.

c. Article 4.c MEDICRIME Convention -Active substance
Section 1.16, Pharmaceutical Law, corresponds with Article 4.c, MEDICRIME Convention.

d. Article 4.d MEDICRIME Convention – Excipient
Section $12^2$ Pharmaceutical Law, substantially corresponds with Article 4.d, MEDCIRIME Convention.

e. Article 4.e MEDICRIME Convention – Medical Device
Article 21, Medical Treatment Law, substantially corresponds with Article 2.e, MEDICRIME Convention.
Further action is needed to fully align with Article 4.e, MEDICRIME Convention.

f. Article 4.f MEDICRIME Convention – Accessory
Paragraph 2.13, Procedures for registration, conformity assessment, distribution, operation, and technical supervision of medical devices, (Regulation 689), corresponds with Article 4.f, Medical Devices

g. Article 4.g MEDICRIME Convention – Parts and materials
No provision in internal law, as regards the terms 'parts' and 'materials', could be found which corresponds with Article 4.g, MEDICRIME Convention.
Action is required to correspond with Article 4.g, MEDICRIME Convention.

h. Article 4.h MEDICRIME Convention – Document
No provision in internal law, as regards the terms 'documents', could be found which corresponds with Article 4.h, MEDICRIME Convention.
Action is required to correspond with Article 4.h, MEDICRIME Convention.

i. Article 4.i MEDICRIME Convention – Manufacturing
Section 1.21, Pharmaceutical Law, as regards the manufacturing of medicinal products, mentions some of the activities in the manufacturing process, and does not sufficiently correspond with Article 4.i, MEDICRIME Convention. Paragraph 34, Procedures for registration, conformity assessment, distribution, operation, and technical supervision of medical devices, (Regulation 689), as regards the manufacturing of medical devices, does not adequately correspond with Article 4.i, MEDICRIME Convention.
Further action is needed to fully correspond with Article 4.i, MEDICRIME Convention.

j. Article 4.j MEDICRIME Convention – Counterfeit
Section 1. $16^1$ Pharmaceutical Law, as regards medicinal products, except for medical devices, corresponds with Article 4.j, MEDICRIME Convention.
Further action is needed to fully correspond, as regards medical devices, with Article 4. J, MEDICRIME Convention.

k. Article 4.k MEDICRIME Convention – Victim
No offence in internal law, as regards the term 'victim' can be found which corresponds with Article 4.k, MEDICRIME Convention. While the definition of the term 'victim' can be found in Section 43, Law on Administrative Liability, this is not a definition applicable in the criminal law.
Action is needed to correspond with Article 4.k, MEDICRIME Convention.

## CHAPTER II – SUBSTANTIVE CRIMINAL LAW

### Article 5 – Manufacturing of counterfeits

No provision in internal law, as regards the intentional manufacturing of a counterfeit medical products, active substances, excipients, parts, materials, and accessories, can be found which corresponds with Article 5, MEDICRIME Convention. Section 92 and 97(2), Pharmaceutical Law provides for fines in cases of the manufacturing or preparation of falsified medical products and active substance for human use and veterinary use, Respectively. Paragraph 68.10, Procedures for the Licensing of Pharmaceutical Activity (Regulation 800 of 2011), provides for the revocation of licences from manufacturers, and importers of falsified medicinal products for human and veterinary use, falsified investigational medicinal products and falsified active substances. None of these administrative provisions correspond with Article 5 MEDICRIME Convention.

Action is required to fully correspond with Article 5, MEDICRIME Convention.

### Article 6 – Supplying, offering to supply, and trafficking in counterfeits

No provision in internal law, as regards the intentional supplying or the offering to supply, including brokering, the trafficking, including keeping in stock, importing, and exporting of a counterfeit medical products, active substances, excipients, parts, materials, and accessories, can be found which correspond with Article 6, MEDICRIME Convention. Section 91, Pharmaceutical Law provides for fines in cases of the import, export, or distribution of falsified medical products and active substance for human use and Section 97(1), Pharmaceutical Law, in cases of the distribution of medicinal products for veterinary use, and falsified active substances. Paragraph 68.10, Procedures for the Licensing of Pharmaceutical Activity (Regulation 800 of 2011), provides for the revocation of licences from distributors and importers of falsified medicinal products for human and veterinary use, falsified investigational medicinal products and falsified active substances. None of these administrative provisions correspond with Article 6 MEDICRIME Convention.

Action is required to correspond with Article 6, MEDICRIME Convention.

### Article 7 – Falsification of documents

No provision in internal law can be found which corresponds with Article 7, MEDICRIME Convention. It is noted that Section 190, The Criminal Law, provides the intentional offence, relating to smuggling, for the use of false documents and it is qualified by the requirement to be committed on a significant scale. This does not correspond with the intent of Article 7, MEDICRIME Convention.

Action is required to correspond with Article 7, MEDICRIME Convention.

### Article 8 – Similar crimes involving threats to public health

8.a.i. ii: No provision in internal law can be found which corresponds with Article 8.a.i and ii, MEDICRIME Convention.

8.b: No provision in internal law can be found which corresponds with Article 8.b, MEDICRIME Convention.

Action is required to correspond with Article 8.a and b, MEDICRIME Convention.

### Article 9 – Aiding or abetting and attempt

No provision in internal law can be found which corresponds with Article 9, MEDICRIME Convention. It is noted that as no intentional offence, as contemplated by Article 5-8, MEDICRIME Convention, exist in internal law, there can be no applicable offence corresponding with Article 9, MEDICRIME Convention.

Action is required to correspond with Article 9.1 and 9.2, MEDICRIME Convention.

### Article 11 – Corporate liability

11.1 – 11.4: No provision in internal law can be found which corresponds with Article 11.1– 11.4, MEDICRIME Convention. It is noted that no intentional offence, as contemplated by Article 5-8, MEDICRIME Convention, exist in internal law, there can be no applicable offence corresponding with Article 11, MEDICRIME Convention.

Action is required to correspond with Article 11, MEDICRIME Convention.

### Article 13 – Aggravating circumstances

No provision in internal law can be found which corresponds with Article 13, MEDICRIME Convention.

Action is required to correspond with Article 13, MEDICRIME Convention.

## 3.22 Lithuania

### Article 4 - Definitions

a. Article 4.a MEDICRIME Convention – Medical Product
No provision, as regards the term 'medical product', could be found in internal law corresponding to Article 4.a, MEDICRIME Convention. It is noted that there are separate definitions of the terms 'medicinal product' and 'medical device'.
Action is needed to correspond with Article 4.a, MEDICRIME Convention.

b. Article 4.b MEDICRIME Convention – Medicinal Product
Article 2. 47, 2. 50 and 2. 79, the Law on Pharmacy of the Republic of Lithuania corresponds with Article 4.b, MEDICRIME Convention.

c. Article 4.c MEDICRIME Convention -Active substance
Article 2. 72.1, Law on Pharmacy of the Republic of Lithuania corresponds with Article 4.c, MEDICRIME Convention.

d. Article 4.d MEDICRIME Convention – Excipient
Article 3. 30.2, Law on Pharmacy of the Republic of Lithuania, while broadly formulated, substantially corresponds with Article 4.d, MEDICRIME Convention.

e. Article 4.e MEDICRIME Convention – Medical Device
Article 2.7, Law on the Health System of the Republic of Lithuania corresponds with Article 4.e, MEDICRIME Convention.

f. Article 4.f MEDICRIME Convention – Accessory
Regulation 7.5, Technical Regulation on the Safety of Medical Devices, 2009, corresponds with Article 4.f, MEDICRIME Convention.

g. Article 4.g MEDICRIME Convention – Parts and materials
No provision, as regards the terms 'parts' and 'materials", could be found in internal law corresponding to Article 4.g, MEDICRIME Convention.
Action is needed to correspond with Article 4.g, MEDICRIME Convention.

h. Article 4.h MEDICRIME Convention – Document
No provision, as regards the term 'document", could be found in internal law corresponding to Article 4.h, MEDICRIME Convention.
Action is needed to correspond with Article 4.h, MEDICRIME Convention.

i. Article 4.i MEDICRIME Convention – Manufacturing
Article 2. 48 and 2.55, Law on Pharmacy of the Republic of Lithuania, as regards medicinal products, define 'Manufacturing of an investigational medicinal product' and 'Manufacture of a medicinal product', respectively. These definitions, together or separately, do not adequately correspond with Article 4.i, MEDICRIME Convention. No provision, as regards the term 'manufacturing' of active substances and excipients can be found in internal law corresponding with Article 4.i, MEDICRIME Convention. Regulation 2.8, Law on the Health System of the Republic of Lithuania, as regards medical devices, defines the term 'Manufacturer' and includes in this many of the elements contained in the term 'Manufacturing', but do not sufficiently

correspond with Article 4.i, MEDICRIME Convention. No provision, as regards the term 'manufacturing' of accessories can be found in internal law corresponding with Article 4.i, MEDICRIME Convention.
Action is needed to fully correspond with Article 4.i, MEDICRIME Convention.

j. Article 4.j MEDICRIME Convention – Counterfeit
Article 2.8.1, Law on Pharmacy of the Republic of Lithuania, corresponds with Article 4.j, MEDICRIME Convention.

k. Article 4.k MEDICRIME Convention – Victim
No provision, as regards the term 'victim", could be found in internal law corresponding to Article 4.h, MEDICRIME Convention.
Action is required to correspond with Article 4.k, MEDICRIME Convention.

## CHAPTER II – SUBSTANTIVE CRIMINAL LAW

### Article 5 – Manufacturing of counterfeits

Article 275, Criminal Code (CC) provides an offence for endangerment arising from unauthorised manufacture of medicines and medicinal substances. While this may support a prosecution in relation to activities contemplated by Article 5, MEDICRIME Convention, the CC provision is insufficient to correspond with the Convention. No provision in internal law can be found regarding the intentional manufacturing of a counterfeit active substances, excipient, medical device, parts, materials, and accessories.

Action is needed to correspond with Article 5 MEDICRIME Convention.

It should be also noted that the legal liability concerning the mere fact of manufacturing the falsified medicinal products etc. is foreseen in the Code of the Administrative Offences. Article 63 of this Code foresees the administrative liability for manufacturing the falsified medicinal products, import from the third countries, export, wholesale distribution, sale and brokering of falsified medicinal products.

The provisions mentioned above refer to medicines or medicinal substances but not to medical devices and other elements.

### Article 6 – Supplying, offering to supply, and trafficking in counterfeits

No provision in internal law could be found to correspond with Article 6, MEDICRIME Convention. It is noted that while Article 2.8.1, Law on Pharmacy of the Republic of Lithuania provide a definition for counterfeit medicinal product (see Art 4.j above), no provision for offence in internal law could be found to be associated with this.

Article 44.7, Code of Administrative Offences provides penalties in relation to the import and export from and to third countries, wholesale distribution, brokering, retail sales and remote selling of a falsified medicinal preparation. This provision also includes aggravating circumstances in relation to these activities. Clarification is required on whether Article 44.7 is intended as the offence to be associated with Article 2.8.1, above, or merely as penalties.

Further action is needed to fully correspond with Article 6 MEDICRIME Convention.

### Article 7 – Falsification of documents

Article 300.1 CC foresees criminal liability for any type of falsification of a document, regardless of the sphere (medical, legal, economic etc.) to which it is related. Article 300.1 CC corresponds with Article 7, MEDICRIME Convention.

### Article 8 – Similar crimes involving threats to public health

8.a.i, ii: Article 202 CC provides offences for dealing in economic, commercial, financial, and professional activities without authorisation and is not specific to products intended by the MEDICRIME Convention. This provision could be used in the prosecution of offences contemplated by Article 8.a.i and ii, MEDICRIME Convention. Article 275 CC is specific to unauthorised pharmaceutical products and is more general than what is contemplated by Article 8.a.i. This provision does not apply to medical devices. No provision in internal law can be found to correspond with Article 8.a.ii, MEDICRIME Convention. It is noted that Article 199 concerning the smuggling and deception of Customs, respectively, may also support Article 8.a requirements.

8.b: No provision in internal law can be found to correspond with Article 8.b, MEDICRIME Convention.

Further action is required to fully correspond with Article 8 MEDICRIME Convention.

### Article 9 – Aiding or abetting and attempt

9.1: Article 24 CC, as regards aiding and abetting, correspond with Article 9.1, MEDICRIME Convention.

9.2: Article 22 CC, as regards attempt, corresponds with Article 9.2, MEDICRIME Convention.

### Article 11 – Corporate liability

11.1: Article 20.2 CC corresponds with Article 11.1 MEDICRIME Convention.

11.2: Article 20.2 and 20.3 CC correspond with Article 11.2, MEDICRIME Convention.

11.3: General provisions of the Criminal Code, the Civil Code of the Republic of Lithuania and the Law on Pharmacy of the Republic of Lithuania show that depending on the certain action or omission in the field the liability of a legal person may be criminal, civil or administrative. This corresponds with Article 11.3, MEDICRIME Convention.

11.4: Article 20.5 CC corresponds with Article 11.4, MEDICRIME Convention.

### Article 13 – Aggravating circumstances

13.a and e: Article 60, Criminal Code corresponds with Article 13, MEDICRIME Convention.

Article 60, Criminal Code does not directly include (or include partially) the following aggravating circumstances foreseen in Article 13 of the MEDICRIME Convention:

13.b: the offence was committed by persons abusing the confidence placed in them in their capacity as professionals.

13.c: the offence was committed by persons abusing the confidence placed in them as manufacturers as well as suppliers.

13.d: the offences of supplying and offering to supply were committed having resort to means of large-scale distribution, such as information systems, including the Internet.

It should also be noted that sometimes some aggravating circumstances mentioned in the MEDICRIME Convention according to the national legislation could constitute a separate offence.

Further action is needed to fully correspond with Article 13. b, c, and d, MEDICRIME Convention.

## 3.23 Mexico

### Article 4 - Definitions

a. Article 4.a MEDICRIME Convention – Medical Product
No provision in internal law could be found to correspond with Article 4.a, MEDICRIME Convention.
Further action is needed to fully correspond with Art 4.a MEDICRIME Convention.

b. Article 4.b MEDICRIME Convention – Medicinal Product
Article 221-I and II, General Health Law -Ley General de Salud (GHL) is broader, but
substantially corresponds with Article 4.b, MEDICRIME Convention, with the exception that it does not include investigational medicinal products.
Further action is needed to correspond with Article 4.b, MEDICRIME Convention .

c. Article 4.c MEDICRIME Convention -Active substance
Article 221-III GHL as regards the term 'active substance', uses the term 'raw material' which has the same intent, but more restrictive in meaning and does not sufficiently correspond with Article 4.c, MEDICRIME Convention**.**
Further action is required to fully correspond with Article 4.c, MEDICRIME Convention.

d. Article 4.d MEDICRIME Convention – Excipient
Article 221-IV GHL, as regards the term 'excipient', uses the term ''additive' which has the same intent and sufficiently correspond with Article 4.d, MEDICRIME Convention 4.d, MEDICRIME Convention.
Further action is needed to fully correspond with Article 4.d, MEDICRIME Convention.

e. Article 4.e MEDICRIME Convention – Medical Device

Article 262 GHL, as regards the term 'medical device', uses not one but several terms to describe what the Convention understands to be covered under the term 'medical device'. The terms used are 1) medical equipment; 2) prostheses, orthotics, and functional aids; 3) diagnostic agents; 4) dental use inputs; 5) surgical and healing materials; and 6) hygienic products. Their intended use is included in each case. While this is not the same as a definition in the Convention, the intent and content are similar and with some modification would sufficiently correspond with Article 4.e, MEDICRIME Convention.
Further action is needed to correspond fully with Article 4e, MEDICRIME Convention.

f. Article 4.f MEDICRIME Convention – Accessory
Article 262-I GHL uses the term 'accessory' as part of what is included in the term 'medical equipment' and does not have any definition of what it is intended to mean and does not correspond with Article 4.f, MEDICRIME Convention.
Further action is required to correspond with Article 4.f, MEDICRIME Convention.

g. Article 4.g MEDICRIME Convention – Parts and materials
GHL contains numerous references to the word 'material' and does not use it in the manner intended in and not in correspondence with Article 4.g, MEDICRIME Convention.
Action is needed to correspond with Article 4.g. MEDICRIME Convention.

h. Article 4.h MEDICRIME Convention – Document
Article 221 –V GHL, as regards medicines, the term 'materials' to mean inputs for the packaging and packaging of the medicinal products. This does not encompass the meaning intended by and does not correspond with Article 4.h, MEDICRIME Convention.
Further action is needed to correspond fully with Article 4h, MEDICRIME Convention.

i. Article 4.i MEDICRIME Convention – Manufacturing
No provision in internal law could be found to correspond with Article 4i, MEDICRIME Convention. It is noted that Article 197, while not being a definition of the term 'manufacturing' includes many of its intended components regarding generally all processes intended by GHL.
Action is needed to correspond with Article 4.i, MEDICRIME Convention.

j. Article 4.j MEDICRIME Convention – Counterfeit
Articles 208 and 208 Bis GHL establishes a concept of falsification of a medicinal product in a more limited manner than established by and does not correspond with Article 4.j, MEDICRIME Convention.
Action is needed to correspond with Article 4.j, MEDICRIME Convention.

k. Article 4.k MEDICRIME Convention – Victim
No provision in internal law could be found to correspond with Article 4.k, MEDICRIME Convention.
Action is needed to correspond with Article 4.k, MEDICRIME Convention.

## CHAPTER II – SUBSTANTIVE CRIMINAL LAW

### Article 5 – Manufacturing of counterfeits

Article 464 Ter- I and -II, GHL, as regards medicinal products, active substances, and excipients, corresponds with Article 5.1 and 5.2, MEDICRIME Convention. No provision in internal law could be found to correspond with Article 5, MEDICRIME Convention, as regards medical devices, medical equipment, prostheses, orthotics and functional aids, diagnostic agents, dental use inputs, surgical and healing materials, and hygienic products in general.

Further action is needed for the internal law to fully correspond with Article 5, MEDICRIME Convention.

### Article 6 – Supplying, offering to supply, and trafficking in counterfeits

Article 464 Ter-III, GHL, as regards medicinal products, active substances, and excipients, partially corresponds with Article 6, MEDICRIME Convention. It is noted that the activity of brokering is not specifically included in this provision but may be considered to be part of the activity of trading. This requires to be clarified for full correspondence with Article 6, MEDICRIME Convention. No provision in internal law could be found to correspond with Article 6, MEDICRIME Convention, as regards medical devices, medical equipment, prostheses, orthotics and functional aids, diagnostic agents, dental use inputs, surgical and healing materials, and hygienic products in general.

Further action is needed for the internal law to fully correspond with Article 6, MEDICRIME Convention.

### Article 7 – Falsification of documents

No provision in internal law could be found to correspond with Article 7, MEDICRIME Convention.

Action is needed for the internal law to correspond with Article 7, MEDICRIME Convention.

### Article 8 – Similar crimes involving threats to public health

8.a.i: Article 464 Ter – I, GHL, as regards medicinal products, corresponds to a limited extent with Article 8.a.i, MEDICRIME Convention. No provision in internal law, as regards the import and export of medicinal products, could be found corresponding with Article 8.a.i, MEDICRIME Convention.

Further action is needed for the internal law to fully correspond with Article 8.a.i, MEDICRIME Convention.

8.a. ii: No provision in internal law, as regards medical device, could be found to correspond with Article 8.a. ii, MEDICRIME Convention.

Further action is needed for the internal law to fully correspond with Article 8.a.ii, MEDICRIME Convention.

8.b: No provision in internal law could be found to correspond with Article 8.b, MEDICRIME Convention.

Action is needed for the internal law to fully correspond with Article 8.b, MEDICRIME Convention.

### Article 9 – Aiding or abetting and attempt

9.1: Article 13-VI, Federal Criminal Code (FCC), describes a perpetrator or participant in any type of offence to the person who helps or assists another in the commission of a crime. This is a general criminal law provision and applies equally to offences in the GHL. While the terms 'aiding' and 'abetting' are not used, the provision of Article 13-VI are sufficient to correspond with Article 9.1, MEDICRIME Convention.

9.2: Article 12, FCC, as regards attempt, is a general criminal law provision that equally applies to offences in the GHL and corresponds with Article 9.2, MEDICRIME Convention.

### Article 11 – Corporate liability

11.1. a, b, c: No provision in internal law could be found that regulate the corporate liability in criminal proceedings in the case of offences established in MEDICRIME Convention, despite Article 11 Bis FCC which determines the criminal liability of a legal person. That occurs because the crimes established in Article 464 Ter of the GHL are not included in the list of offences indicated in Article 11 Bis, FCC that could enable a criminal prosecution of crimes committed by corporations. There is no correspondence with Article 11.a, b, c, MEDICRIME Convention.

11.2: No provision in internal law could be found to correspond with Article 11.2, MEDICRIME Convention.

11.3: Article 416, GHL provide for Administrative penalties. This corresponds with Article 11.3, MEDICRIME Convention. It is noted that there is no specific provision in internal law that regulates the corporate liability of the offences established in MEDICRIME Convention in a particular form.

11.4: No provision in internal law could be found to correspond with Article 8.b, MEDICRIME Convention.

Further action is needed for the internal law to fully correspond with Article 11.1, 11.2 and 11.4, MEDICRIME Convention.

### Article 13 – Aggravating circumstances

No provision in internal law could be found to correspond with Article 13, MEDICRIME Convention.

Further action is needed for the internal law to fully correspond with Article 13, MEDICRIME Convention.

## 3.24 Montenegro

### Article 4 - Definitions

a. Article 4.a MEDICRIME Convention – Medical Product

No provision could be found in internal laws corresponding with Article 4.a, MEDICRIME Convention.
Further action is needed to fully correspond with Article 4.a, MEDICRIME Convention.

b. Article 4.b MEDICRIME Convention – Medicinal Product
Articles 28 and 6 para 1 item 38 Law on Medicinal Products (Official Gazette of Montenegro No. 80/2020) correspond with Article 4.b, MEDICRIME Convention.

c. Article 4.c MEDICRIME Convention -Active substance
Law on Medicinal Products corresponds with Article 4.c, MEDICRIME Convention.

d. Article 4.d MEDICRIME Convention – Excipient
Law on Medicinal Products defines the term excipient in a way which is not fully corresponding with Article 4.d, MEDICRIME Convention.
Further action is needed to fully correspond with Article 4.d, MEDICRIME Convention.

e. Article 4.e MEDICRIME Convention – Medical Device
Law on Medical Devices (Official Gazette of Montenegro No.24/2019) corresponds with Article 4.e, MEDICRIME Convention.

f. Article 4.f MEDICRIME Convention – Accessory
Law on Medical Devices corresponds with Article 4.f, MEDICRIME Convention.

g. Article 4.g MEDICRIME Convention – Parts and materials
Article 9 para 1 item 69 Law on Medical Devices defines the concept of spare part of a medical device. This definition does not correspond with Article 4.g, MEDICRIME Convention.
Further action is needed to fully correspond with Article 4.g, MEDICRIME Convention.

h. Article 4.h MEDICRIME Convention – Document
Article 142 (29) Criminal Code of Montenegro covers the wide range of modalities of document including that which corresponds with Article 4.h, MEDICRIME Convention.

i. Article 4.i MEDICRIME Convention – Manufacturing
Law on Medical Devices refers to the manufacturing of a medical device in a manner that does not fully corresponds to Article 4.i, MEDICRIME Convention. No direct reference to the manufacturing of medicinal products is included in the internal legislation except for the mention that manufacture of medicinal products in Montenegro can only be performed by legal persons that have manufacturing authorization in accordance with the Law. There is no correspondence with Article 4.i, MEDICRIME Convention.
Action is needed to correspond with Article 4.i, MEDICRIME Convention.

j. Article 4.j MEDICRIME Convention – Counterfeit
Law on Medicinal Products (Official Gazette of Montenegro No. 80/2020) and Law on Medical Devices, together corresponds with Article 4.j, MEDICRIME Convention.

k. Article 4.k MEDICRIME Convention – Victim
Article 142 (11), Criminal Code of Montenegro defines the term victim in a manner that does not correspond with Article 4.k, MEDICRIME Convention.
Further action is needed to fully correspond with Article 4.k, MEDICRIME Convention.

## CHAPTER II – SUBSTANTIVE CRIMINAL LAW

### Article 5 – Manufacturing of counterfeits

Criminal Code of Montenegro does not correspond directly with Article 5 MEDICRIME Convention as it does not prescribe the manufacturing of counterfeited medical products as criminal offence. Article 3, Law on Medicinal Products corresponds with Article 5 MEDICRIME Convention as it prohibits the manufacture of falsified medicinal products. No intentional offence could be found, as regards for the intentional manufacture of falsified active substances, medical devices, excipients, accessories, parts, and materials, corresponding with Article 5, MEDICRIME Convention.

Further action is needed to fully correspond with Article 5, MEDICRIME Convention.

### Article 6 – Supplying, offering to supply, and trafficking in counterfeits

Article 284 of Criminal Code of Montenegro (Unlawful Trade) does not completely implement the corresponding provision of the MEDICRIME Convention, but it prescribes an offence in the case of an unauthorized sale, purchase or exchange of goods or objects whose trade is prohibited or restricted. This offence is general in nature and

very wide. Whether the movement of any goods is restricted or prohibited depends on the relevant regulations. Article 3, Law on Medicinal Products and Article 7, Law of Medical Devices prohibit trade of falsified medicinal product and falsified medicinal devices. No offence could be found, as regards falsified active substances, medical devices, excipients, accessories, parts, and materials, which corresponds with Article 6, MEDICRIME Convention.

Further action is needed to fully correspond with Article 6, MEDICRIME Convention.

### Article 7 – Falsification of documents

Articles 412-415, Criminal Code of Montenegro corresponds with the intent of Article 7, MEDICRIME Convention.

### Article 8 – Similar crimes involving threats to public health

8.a.i: Article 3, Law on Medicinal Products corresponds with Article 8.a.i, MEDICRIME Convention.

8.a.ii: Article 3, Law on Medicinal Products corresponds, with Article 8.a.i, MEDICRIME Convention.

8.b: No offence could be found which corresponds with Article 8.b, MEDICRIME Convention.

Further action is needed to fully correspond with Article 8, MEDICRIME Convention.

### Article 9 – Aiding or abetting and attempt

Arts. 24 (Instigation), 25 (Aiding), 26, 27 and 20 (Attempt), Criminal Code corresponds with the intent of Article 9 MEDICRIME Convention, but are inapplicable as regards Articles 5, 6 and 8, MEDICRIME Convention as these offences are not established as criminal offences under the Criminal Code of Montenegro. There is, therefore, no correspondence with Article 9, MEDICRIME Convention.

Action is needed to correspond with Article 9, MEDICRIME Convention.

### Article 11 – Corporate liability

11.1 and 11.2: Articles 4 and 5, Law on Criminal Liability of Legal entities (Published in the "Official Gazette of the Republic of Montenegro", Nos. 2/2007, 13/2007, 30/12 and 39/16) corresponds with 11 para 1 and 2 MEDICRIME Convention, but are inapplicable as regards Articles 5, 6 and 8, MEDICRIME Convention as these offences are not established as criminal offences under the Criminal Code of Montenegro. There is, therefore, no correspondence with Article 11.1 and 11.2, MEDICRIME Convention.

11.3: As Article 5,6, and 8, MEDICRIME Convention are not established as criminal offences under the Criminal Code of Montenegro, criminal liability of legal entities is not established related to those offences.

11.4: Article 6, Law on Criminal Liability of Legal Entities (Limits of liability of legal entity for criminal offences) prescribes that under the established legal conditions the legal entity shall be held liable for a criminal offence even if the responsible person who committed such criminal offence has not been convicted of such criminal offence. Furthermore, liability of a legal entity shall not exclude criminal liability of a responsible person for the criminal offence committed. Nevertheless, as Articles 5, 6 and 8 are not established as criminal offences under the Criminal Code of Montenegro, criminal liability of legal entities is not established related to those offences.

Further action is needed to correspond with Article 11, MEDICRIME Convention.

### Article 13 – Aggravating circumstances

13.a: The Criminal Code provides aggravating circumstances under the heading of Serious Offences against Human Health which means that if a criminal offence under Articles 287, 290, 291, 293, 296, 297 and 299 result in a serious body injury or severe damage to health of a person or grave damage to health of a person, or death of a person, the perpetrator shall be punished with a more severe prison sentence. Nevertheless, as Articles 5, 6 and 8, MEDICRIME Convention are not established as criminal offences under the Criminal Code of Montenegro, there is no correspondence with Article 13.a, MEDICRIME Convention.

13.b: No provision could be found in internal law corresponding with Article 13.b, MEDICRIME Convention.

13.c: No provision could be found in internal law corresponding with Article 13.c, MEDICRIME Convention.

13.d: No provision could be found in internal law corresponding with Article 13.d, MEDICRIME Convention.

13.e: Article 401.a, Criminal Code of Montenegro prescribes as a criminal offence the creation of a criminal organization. Nevertheless, as Articles 5, 6 and 8, MEDICRIME Convention are not established as criminal offences under the Criminal Code of Montenegro, there is no correspondence with Article 13.e, MEDICRIME Convention.

13.f: Article 43 and 44, Criminal Code of Montenegro provides for aggravating circumstances for recidivism and multiple recidivism, respectively. Nevertheless, as Article 5, 6 and 8, MEDICRIME Convention are not established as criminal offences under the Criminal Code of Montenegro, there is no correspondence with Article 13.f, MEDICRIME Convention.

Action is needed to correspond with Article 13.a-f, MEDICRIME Convention.

## 3.25 Morocco

### Article 4 - Definitions

a. Article 4.a MEDICRIME Convention – Medical Product
No provision in internal law could be found to correspond with Article 4.a, MEDICRIME Convention. There are separate definitions of the terms' medicine' and 'medical device', both components of the term medical product.
Action is needed to correspond with Article 4.a, MEDICRIME Convention.

b. Article 4.b MEDICRIME Convention – Medicinal Product
Article 1, Law nº 17-04, Medicines and Pharmaceutical Code, as regards the term 'medicinal product', does not include investigational medicinal products and otherwise corresponds with Article 4.b, MEDICRIME Convention.

c. Article 4.c MEDICRIME Convention - Active substance
Article 3, Law nº 17-04, as regards the term 'active substance' partially corresponds with the intent of Article 4.c, MEDICRIME Convention.
Further action is needed to fully correspond with Article 4.c, MEDICRIME Convention.

d. Article 4.d MEDICRIME Convention – Excipient
Article 1. 7, DECREE 2-14-841 of August 5, 2015 related to the marketing authorization of drugs for human use, as regards the term 'excipient', substantially corresponds with the intent of Article 4.d, MEDICRIME Convention relating to medicinal products for human use only. It does not include excipients intended for use in medicinal products for veterinary use.
Further action is needed to fully correspond with Article 4.d, MEDICRIME Convention.

e. Article 4.e MEDICRIME Convention – Medical Device
Article 1 and 3, Law No. 84-12 on medical devices, as regards the term 'medical device' substantially corresponds with Article 4.e, MEDICRIME Convention.
Further action is needed to fully correspond with Article 4.e, MEDICRIME Convention.

f. Article 4.f MEDICRIME Convention – Accessory
Article 1.3), Law No. 84-12 on medical devices, as regards the term 'accessory', corresponds with Article 4.f, MEDICRIME Convention.

g. Article 4.g MEDICRIME Convention – Parts and materials
No provision in internal law could be found to correspond with Article 4.g, MEDICRIME Convention.
Action is needed to correspond with Article 4.f, MEDICRIME Convention.

h. Article 4.h MEDICRIME Convention – Document
No provision in internal law could be found to correspond with Article 4.h, MEDICRIME Convention.
Action is needed to correspond with Article 4.h, MEDICRIME Convention.

i. Article 4.i MEDICRIME Convention – Manufacturing
Article 18, Law nº 17-04, on Medicines and Pharmaceutical Code, as regards medicinal products, and Article 1.7), Law No. 84-12 on medical devices, individually and together partially correspond with Article 4.i, MEDICRIME Convention. No provision in internal law could be found, as regards the manufacturing of accessories, corresponding to Article 4.i, MEDICRIME Convention.
Further action is needed to fully correspond with Article 4.i, MEDICRIME Convention.

j. Article 4.j MEDICRIME Convention – Counterfeit
No provision in internal law could be found to correspond with Article 4.j, MEDICRIME Convention. It is noted that Article 4, Law No. 13-83 is a general criminal law offence on the enforcement against fraud and

applies generally, to all goods, but not specifically, to medical products. Article 4 encompasses, generally, some of the components of the requirements of Article 4.j, MEDICRIME Convention.
For the avoidance of doubt on the interpretation of this section being applicable to the MEDICRIME Convention, a separate provision is needed to fully correspond with Article 4.j, MEDICRIME Convention.
Action is needed to correspond with Article 4.j, MEDICRIME Convention.

k. Article 4.k MEDICRIME Convention – Victim
Article 7, Criminal Procedure Act (Law No. 22-01), as regards the term 'victim', partially corresponds with Article 4.k, MEDICRIME Convention. It is noted that the provision does not include psychological effects.
Further action is needed to fully correspond with Article 4.k, MEDICRIME Convention.

## CHAPTER II – SUBSTANTIVE CRIMINAL LAW

### Article 5 – Manufacturing of counterfeits

Article 5. (1), Law No. 13-83 on the enforcement against fraud involving goods in general, specifies an offence that includes the falsification of medicinal products. As there is no definition of the term 'falsification' or 'counterfeit' in accordance with Article 4.j, MEDICRIME Convention, it is unclear on the extent to which Article 5 (1), Law No. 13-83 corresponds with article 5, MEDICRIME Convention.

Further action is needed to fully correspond with Article 5, MEDICRIME Convention.

### Article 6 – Supplying, offering to supply, and trafficking in counterfeits

No provision in internal law could be found to correspond with Article 6, MEDICRIME Convention.

Action is needed to correspond with Article 6, MEDICRIME Convention.

### Article 7 – Falsification of documents

No provision in internal law could be found to correspond with Article 7, MEDICRIME Convention.

Action is needed to correspond with Article 7, MEDICRIME Convention.

### Article 8 – Similar crimes involving threats to public health

8.a. i: Articles 150-156, Medicines and Pharmaceutical Code, Law 17-04, provide offences relating to the marketing of medicinal products that relates specifically to their risk. As these medicinal products may or may not have marketing authorisations, it is unclear whether they may correspond with Article 8.a.i, MEDICRIME Convention. As the law provides for offences for non-compliance with good manufacturing practice, it does not clarify whether this relates to substandard practices of intentional offences or whether it includes the failure to hold a manufacturer's authorisation where one is required. Clarification is required in the internal law to fully correspond with Article 8,a.i, MEDICRIME Convention.

8.a. ii: No provision in internal law could be found to correspond with Article 8.a.ii, MEDICRIME Convention.

8.b: No provision in internal law could be found to correspond with Article 8.b, MEDICRIME Convention.

Action is needed to correspond with Article 8.a and b, MEDICRIME Convention.

### Article 9 – Aiding or abetting and attempt

9.1: The combination of Articles 129 and 130 of the Criminal Code allows the following conclusions to be drawn: the existence of complicity requires the meeting of three elements: legal, material, and moral; The act of complicity is punishable only insofar as the main act itself falls within the scope of criminal law; The modalities of material expression of forms of complicity enacted by article 129 of the Criminal Code. are to be interpreted restrictively. Thus, only the modalities provided for in this article can serve as a basis to prosecution. Apart from these forms, there is no act of complicity.

9.2: Article 114, Criminal Code indicates the two conditions of the punishable attempt: a positive condition and a negative condition (absence of voluntary withdrawal). It should be noted that the penal legislator required the existence of a special provision to punish attempted crime. (Articles. 114, 115, 116 and 117, Criminal Code).

Further action is needed to fully correspond with Article 9, MEDICRIME Convention.

### Article 11 – Corporate liability

No provision in internal law could be found to correspond with Article 11, MEDICRIME Convention.

Action is needed to correspond with Article 11, MEDICRIME Convention

### Article 13 – Aggravating circumstances

No provision in internal law, as regards aggravating circumstances, could be found to correspond with Article 13 a-e, MEDICRIME Convention.

Articles 154, Criminal Code, as regards recidivism, corresponds with Article 13.f, MEDICRIME Convention.

Further action is needed to correspond with Article 13.a-e, MEDICRIME Convention.

## 3.26 North Macedonia

### Article 4 - Definitions

a. Article 4.a MEDICRIME Convention – Medical Product
No provision in internal law, as regards the term 'medical product', could be found corresponding with Article 4.a, MEDICRIME Convention. It is noted that there are separate definitions of medicinal product and medical device.
Further action is needed to fully correspond with Art 4.a MEDICRIME Convention.

b. Article 4.b MEDICRIME Convention – Medicinal Product
The Macedonian definition of medicinal product does not cover the veterinary use (only the human one is mentioned, and the veterinary issues are subject to another law)) and the point iii. of the respective Convention provision (an investigational medicinal product) is also not part of the Macedonian definition (LMPMD, art. 2, para 1). Therefore, the general law does not fully implement the MEDICRIME Convention in respect of article 4.b.
Article 2.1, Law on Medicinal Products and Medical Devices (LMPMD), as regards medicinal products for human, correspond to Article 4.b, MEDICRIME Convention. This provision, as regards medicinal products for veterinary use, and as regards investigational medicinal products, does not correspond with Article 4.b, MEDICRIME Convention.
Further action is needed to correspond with Article 4.b, MEDICRIME Convention.

c. Article 4.c MEDICRIME Convention -Active substance
Article 2.3, LMPMD partially corresponds but requires considerable amendment in order to fully correspond with Article 4.c, MEDICRIME Convention.
Further action is required to correspond with Article 4.c, MEDICRIME Convention.

d. Article 4.d MEDICRIME Convention – Excipient
Article 2, 4, LMPMD defines the term 'excipient' such that it does not require it to be essential for the integrity of the finished product and does not fully correspond with Article 4.d, MEDICRIME Convention.
Further action is needed to fully correspond with Article 4.d, MEDICRIME Convention.

e. Article 4.e MEDICRIME Convention – Medical Device
Article 2.49, LMPMD substantially corresponds with Article 4.e, MEDICRIME Convention.

f. Article 4.f MEDICRIME Convention - Accessory
No provision in internal law, as regards the term 'accessory", could be found. The wording of Article 2.49.1, LMPMD, as regards medical devices, includes the use of materials intended by their manufacturers to be used together with a medical device to enable its use. This could be interpreted to correspond, though not fully, with the intent of the term 'accessory', rather than the term 'material' in this context. The use of Article 2.49.1 wording becomes problematic as the intent of the law could relate to either the term 'accessory' or the terms 'parts' and 'materials', or all these terms, or even none of them.
Further action is needed to fully correspond with Article 4.f, MEDICRIME Convention.

g. Article 4.g MEDICRIME Convention – Parts and materials

No provision in internal law, as regards the terms 'parts', and 'materials', could be found. The Wording of Article 2.49.1, LMPMD, as regards medical devices, includes the use of materials intended by their manufacturers to be used together with a medical device to enable its use. This corresponds, though not fully, with the intent of the terms 'parts' and 'materials. The use of Article 2.49.1 wording becomes problematic as the intent of the law could relate to either the term 'accessory' or the terms 'parts' and 'materials', or all these terms, or even none of them.
Further action is needed to fully correspond with Article 4.g, MEDICRIME Convention.

h. Article 4.h MEDICRIME Convention – Document
No provision in internal law, as regards the term 'document', could be found corresponding with Article 4.h, MEDICRIME Convention. Article 2, LMPMD lists several documents, but is insufficient to correspond with Article 4.h. MEDICRIME Convention.
Action is needed to correspond with Article 4.h, MEDICRIME Convention.

i. Article 4.i MEDICRIME Convention – Manufacturing
No provision in internal law, as regards the term 'manufacturing', could be found corresponding with Article 4.h, MEDICRIME Convention.
Action is needed to correspond with Article 4.i, MEDICRIME Convention.

j. Article 4.j MEDICRIME Convention – Counterfeit
No provision in internal law, as regards the term 'counterfeit', could be found corresponding with Article 4.h, MEDICRIME Convention.
Action is needed to correspond with Article 4.j, MEDICRIME Convention.

k. Article 4.k MEDICRIME Convention – Victim
Article 122.22, North Macedonian Criminal Code (MCC) is the general criminal law and is not specific to medical product related crimes. It corresponds with the intent of Article 4.k, MEDICRIME Convention.

## CHAPTER II – SUBSTANTIVE CRIMINAL LAW

### Article 5 – Manufacturing of counterfeits

5.1. Art. 212 MCC criminalises the production of medicines or other treatments that are harmful to health. While counterfeit medical products create a risk of harm, the provision does not correspond with Article 5, MEDICRIME Convention.

Action is required to correspond with Article 5, MEDICRIME Convention.

### Article 6 – Supplying, offering to supply, and trafficking in counterfeits

Art. 212 MCC criminalises the trade in medicines or other treatments that are harmful to health. While counterfeit medical products create a risk of harm, the provision does not correspond with Article 6, MEDICRIME Convention.

Action is required to correspond with Article 5, MEDICRIME Convention.

### Article 7 – Falsification of documents

Article 361, 378 and 379 MCC, as regards the making of a false document or tampering with a document, correspond with Article 7, MEDICRIME Convention.

### Article 8 – Similar crimes involving threats to public health

Art. 212 MCC criminalises generally the production and trade in medicines or other treatments that are harmful to health. This does not sufficiently correspond with Article 8a.i and ii, MEDICRIME Convention. Article 212 does not criminalise intentional actions intended by Article 8.a regarding medicinal products and medical devices that require authorisation and compliance with conformity requirements where such requirements exist, and not already covered by Article 5, 6 and 7.

Further action is required to fully correspond with the intent of Article 8.a and b, MEDICRIME Convention.

### Article 9 – Aiding or abetting and attempt

9.1: Articles 23 and 24 MCC, as regards abetting and aiding, respectively, correspond with Article 9.1 MEDICRIME Convention.

9.2: Article 19 MCC, as regards crimes that are punishable by a maxim of at least five years, correspond with Article 9.2, MEDICRIME Convention. In all the other crimes the attempts are punishable only if it is specifically stipulated in a separate provision.

Further action is needed to fully correspond with Article 9.2, MEDICRIME Convention.

### Article 11 – Corporate liability

11.1**:** Article 28-a (1), MCC, as regards the legal person attracting liability when based on a power of representation of the legal person does not correspond fully with Article 11.1.a, MEDICRIME Convention as Article 28-a (2) restricts the liability in such cases to where there is a significant property benefit acquired or significant damaged has been caused to another.

Further action is required to correspond fully with Article 11, a, MEDICRIME Convention.

Article 28-a (1), as regards the legal person attracting liability when based on the authority to take decisions on behalf of and to exercise control within the legal person, corresponds with Article 11, b and c, MEDICRIME Convention.

11.2: Article 28-a (1), MCC, as regards the lack of supervision or control has made possible the commission of an offence, does not fully correspond with Article 11.2, MEDICRIME Convention as Article 28-a (2) restricts the liability in such cases to where there is a significant property benefit acquired or significant damaged has been caused to another.

Further action is required to fully correspond with Article 11.2 MEDICRIME Convention.

11.3: The criminal liability of the legal persons as well as the civil and administrative liability are stipulated in several laws that are part of the primary legislation.

11.4: Article 28-b (1) and (2) MCC corresponds with Article 11.4, MEDICRIME Convention.

### Article 13 – Aggravating circumstances

Article 39 MCC, apart from 39(4), is general in application and requires the Court to consider aggravating and alleviating circumstances. This does not correspond fully with Article 13, a, b, c, d and e, MEDICRIME Convention.

Article 39 (4) MCC, as regards recidivism, corresponds with Article 13.f, MEDICRIME Convention.

Further action is needed to fully correspond with Article 13, MEDICRIME Convention.

## 3.27 Norway

### Article 4 - Definitions

a. Article 4.a MEDICRIME Convention – Medical Product
No provision in internal law, as regards the term 'medical product', could be found corresponding with Article 4.a, MEDICRIME Convention. It is noted that there are separate definitions for the terms 'medicinal product' and 'medical device'.
Further action is needed to fully correspond with Art 4.a MEDICRIME Convention.

b. Article 4.b MEDICRIME Convention – Medicinal Product
*§ 1* Legemiddelloven 1992 (The Medicines Act) , as amended, and § 1.3, Regulations on Medicinal Products, 2009, as amended, correspond with Article 4.b, MEDICRIME Convention.

c. Article 4.c MEDICRIME Convention -Active substance
§ 1.2. (b), Regulations on the Manufacture and Import of Medicines, 2004, as amended, corresponds with Article 4.c, MEDICRIME Convention.

d. Article 4.d MEDICRIME Convention – Excipient

§ 1.2. (c), Regulations on the Manufacture and Import of Medicines, 2004, as amended, corresponds with Article 4.d, MEDICRIME Convention.

e. Article 4.e MEDICRIME Convention – Medical Device
§ 3, Medical Equipment Act, 2005, as amended, corresponds with Article 4.e, MEDICRIME Convention.

f. Article 4.f MEDICRIME Convention – Accessory
§ 3, Medical Equipment Act, 2005, as amended, includes the term 'accessory' in the definition of the term 'medical device' and does not separately define the term 'accessory'. § 1.5, Regulations on Medical Equipment, 2005, as amended, corresponds with Article 4.f, MEDICRIME Convention.

g. Article 4.g MEDICRIME Convention – Parts and materials
§ 3, Medical Equipment Act, 2005, as amended, includes the term 'material' in the definition of the term 'medical equipment' (medical device), but does not separately define the term 'material' or the term 'parts'. § 3, Medical Equipment Act, 2005 does not correspond with Article 4.g, MEDICRIME Convention.
Action is needed to correspond with Art 4.g, MEDICRIME Convention.

h. Article 4.h MEDICRIME Convention – Document
Section 361, Penal Code, 2005, as amended, provides a 'meaning' of the term 'document' A 'document' in this chapter means an information carrier relating to a legal matter of which is suitable as evidence for a legal matter'. This corresponds generally with the intent of Article 4.h, MEDICRIME Convention. §§ 2.17 and 18, Regulations on the Manufacture and Import of Medicines, while not a definition, incorporates what is intended in documentation as regards medicinal products being manufactured and imported.
Further action is needed to fully correspond with Art 4.h, MEDICRIME Convention.

i. Article 4.i MEDICRIME Convention – Manufacturing
§ 1.2. (f), Regulations on the Manufacture and Import of Medicines refers to the definition of the term 'manufacture' which encompasses the intent, though not the identical definition of Article 4.i, MEDICRIME Convention. § 1.5. (f), Regulations on Medical Equipment refers to the definition of the term 'manufacturer' which encompasses some, but not all aspects of the definition of 'manufacturing in Article 4.i, MEDICRIME Convention.
Further action, as regards medical products, is needed to fully correspond with Art 4.i, MEDICRIME Convention.

j. Article 4.j MEDICRIME Convention – Counterfeit
§ 1.2 (f), Regulations on the Manufacture and Import of Medicines, as regards medicinal products, active substances and excipients in manufacturing and importation, corresponds with the Article 4.j, MEDICRIME Convention. The definition of counterfeit is not found in other medical product legislation.
Further needed is required to fully correspond with Art 4.j, MEDICRIME Convention.

k. Article 4.k MEDICRIME Convention – Victim
No provision in internal law could be found to correspond with Article 4.k, MEDICRIME Convention.
Action is needed to correspond with Art 4.k, MEDICRIME Convention.

## CHAPTER II – SUBSTANTIVE CRIMINAL LAW

### Article 5 – Manufacturing of counterfeits

No provision in internal law could be found corresponding with Article 5, MEDICRIME Convention.

Action is required to correspond with Article 5, MEDICRIME Convention.

### Article 6 – Supplying, offering to supply, and trafficking in counterfeits

No provision in internal law could be found corresponding with Article 6, MEDICRIME Convention.

Action is required to correspond with Article 6, MEDICRIME Convention.

### Article 7 – Falsification of documents

Section 361, Penal Code, while not being specific to documents related to medical products, corresponds with the intent of Article 7, MEDICRIME Convention.

### Article 8 – Similar crimes involving threats to public health

8.a.i: § 31. Act on Medicines, as regards medicinal products, active substances, and excipients, corresponds with the intent of Article 8.a.i, MEDICRIME Convention.

8.a.ii: § 13. Medical Equipment Act, as regards medical devices, accessories, parts and materials, corresponds with Article 8.a.ii, MEDICRIME Convention.

8.b: No provision in internal law could be found corresponding with Article 8.b, MEDICRIME Convention.

Action is required to correspond with Article 8.b, MEDICRIME Convention.

### Article 9 – Aiding or abetting and attempt

9.1: Section 15, Penal Code, as regards aiding and abetting, criminalises any person who contributes to the violation of a law. While the terms 'aiding' and 'abetting' are not used, the section is sufficient to correspond with the intent of Article 9.1, MEDICRIME Convention.

9.2: Section 16, Penal Code, as regards attempts, corresponds with Article 9.2, MEDICRIME Convention.

### Article 11 – Corporate liability

11.1. a, b, c: Section 27, Penal Code is general in wording and application. It includes the circumstances of a violation by a person, without specifying their level of power of representation, authority to take decisions or ability to control, who has acted on behalf of an enterprise. This broadly corresponds with Article 11.1, MEDICRIME Convention.

11.2: Section 28, (c), Penal Code, corresponds with Article 11.2, MEDICRIME Convention.

11.3: Sections 29 and 30, Penal Code, and as regards medicinal products, active substances and excipients, § 5.12; Regulations on Medicinal Products, as regards the revocation of marketing authorisations: § 2.7, Regulations on the Manufacture and Import of Medicines; § 2.b, Regulations on Wholesale Business with Medicines, and§ 32, Act on Medicines, all combine to provide for criminal, civil, and administrative liability for legal persons. As regards Medical Devices, accessories, and parts and material, no corresponding provisions could be found to correspond with Article 11.3, MEDICRIME Convention.

11.4: Section 27, Penal Code corresponds with Article 11.4, MEDICRIME Convention.

Further action is required to fully correspond with Article 11.1 and 11.3, MEDICRIME Convention.

### Article 13 – Aggravating circumstances

13.a: Section 77. b, Penal Code corresponds with Article 13.a, MEDICRIME Convention.

13.b, c: Section 77. j, Penal Code corresponds with Article 13.b and c, MEDICRIME Convention.

13.d: No provision in internal law could be found corresponding with Article 13.d, MEDICRIME Convention.

13.e: Section 77. e, Penal Code corresponds with Article 13.e, MEDICRIME Convention.

13.f: Section 77. k, Penal Code corresponds with Article 13.f, MEDICRIME Convention.

Action is required to correspond with Article 13.d, MEDICRIME Convention.

## 3.28 Poland

### Article 4 - Definitions

a. Article 4.a MEDICRIME Convention – Medical Product
No provision in internal law, as regards the term 'medical products', can be found to correspond with Article 4.a, MEDICRIME Convention. It is noted that there are separate definitions of the terms 'medicinal products' and 'medical devices'.
Further action is needed to fully correspond with Article 4.a, MEDICRIME Convention.

b. Article 4.b MEDICRIME Convention – Medicinal Product.
Article 2. 32), Pharmaceutical Law, provides the definitions as regards the term 'medicinal product' but excluding 'investigational medicinal products'. Investigational medicinal products are separately defined in Article 2.2c, Pharmaceutical Law. Together, they correspond with Article 4.b, MEDICRIME Convention. Further action is needed to fully correspond with Article 4.b, MEDICRIME Convention.

c. Article 4.c MEDICRIME Convention -Active substance
Article 2.38c), Pharmaceutical Law, as regards the term 'active substance', is more expansive and corresponds with Article 4.c, MEDICRIME Convention.

d. Article 4.d MEDICRIME Convention – Excipient
Article 2.38d), Pharmaceutical Law, as regards the term 'excipient', substantially corresponds with Article 4.d, MEDICRIME Convention.
Further action is needed to fully correspond with Article 4.d, MEDICRIME Convention.

e. Article 4.e MEDICRIME Convention – Medical Device
Article 3, Act on Medical Devices, as regards the term 'medical device', corresponds with Article 4.e, MEDICRIME Convention.

f. Article 4.f MEDICRIME Convention – Accessory
Article 2.33), Pharmaceutical Law, as regards the term 'accessory', corresponds with Article 4.f, MEDICRIME Convention.

g. Article 4.g MEDICRIME Convention – Parts and materials
No provision in internal law, as regards the terms 'parts' and 'materials', can be found to correspond with Article 4.g, MEDICRIME Convention.
Further action is needed to fully correspond with Article 4.g, MEDICRIME Convention.

h. Article 4.h MEDICRIME Convention – Document
Article 14, Penal Code, as regards the term 'document', is general Criminal law and is not specific to the subject matter contained in the MEDICRIME Convention. It is broad in its interpretation and partially corresponds with the intent of Article 4.h, MEDICRIME Convention.
Further action is needed to fully correspond with Article 4.h, MEDICRIME Convention.

i. Article 4.i MEDICRIME Convention – Manufacturing
Article 2.42), Pharmaceutical Law, as regards the term 'manufacturing', provides the definition under the term 'manufacture of medical products. While it is broader in its definition and does not include excipients, it substantially corresponds with Article 4.i, MEDICRIME Convention. No provision in internal law, as regards the manufacturing of medical devices, accessories and parts and materials, could be found corresponding with Article 4.i, MEDICRIME Convention.
Further action is needed to fully correspond with Article 4.i, MEDICRIME Convention.

j. Article 4.j MEDICRIME Convention – Counterfeit
Article 2.38a), Pharmaceutical Law, as regards the term 'counterfeit' as it refers to medicinal products and active substances only, corresponds with Article 4.j, MEDICRIME Convention. No provision in internal law, as regards excipients, medical devices, accessories, parts and materials could be found to correspond with Article 4.j, MEDICRIME Convention.
Further action is needed to fully correspond with Article 4.j, MEDICRIME Convention.

k. Article 4.k MEDICRIME Convention – Victim
No provision in internal law, as regards the term 'victim', could be found to correspond with Article 4.k, MEDICRIME Convention.
Action is needed to correspond with Article 4.k, MEDICRIME Convention.

## CHAPTER II – SUBSTANTIVE CRIMINAL LAW

### Article 5 – Manufacturing of counterfeits

Article 124b, Pharmaceutical Law, as regards medicinal products and active substances only, corresponds with Article 5, MEDICRIME Convention. No provision in internal law, as regards excipients, medical devices, accessories, parts and materials could be found to correspond with Article 5, MEDICRIME Convention.

Further action is needed to fully correspond with Article 5, MEDICRIME Convention.

### Article 6 – Supplying, offering to supply, and trafficking in counterfeits

Article 124b, Pharmaceutical Law, provides the offence of intentionally supply a falsified medicinal product or active substance. While all the activities included in Article 6.1, MEDICRIME Convention are not contained in Article 124b, Polish criminal law doctrine interprets its provision such that it would correspond, as regards medicinal products and active substances only, with Article 6.1, MEDICRIME Convention. No provision in the internal law, as regards excipients, medical devices, accessories, parts, and materials could be found to correspond with Article 6, MEDICRIME Convention.

Further action is needed to fully correspond with Article 6, MEDICRIME Convention.

### Article 7 – Falsification of documents

Article 270, Penal Code corresponds with Article 7, MEDICRIME Convention.

### Article 8 – Similar crimes involving threats to public health

8.a.i: Articles124, 124.a, 125, 125.a, and 127.a, Pharmaceutical Law, together, as regards medicinal products for human and veterinary use, correspond with Article 8.a.i MEDICRIME Convention.

8.a.ii: Articles 93, 94, 95 and 96, Pharmaceutical Law, together, as regards medical devices, correspond with Article 8.a.ii, MEDICRIME Convention.

8.b: No provision in internal law, as regards the commercial use of original documents outside their intended use within the legal medical product supply chain, can be found to correspond with Article 8.b, MEDICRIME Convention.

Action is needed to correspond with Article 8. b, MEDICRIME Convention.

### Article 9 – Aiding or abetting and attempt

9.1: Article 19.3, Penal Code, as regards aiding and abetting, corresponds with Article 9.1 MEDICRIME Convention.

9.2: Article 13, Penal Code, as regards attempt, corresponds with Article 9.2, MEDICRIME Convention.

### Article 11 – Corporate liability

11.1. a, b, c: Article 16, Liability of Collective Subjects for Acts Prohibited under Punishment Act, corresponds with Article 11.1, a, b and c, MEDICRIME Convention.

11.2: Article 16, Liability of Collective Subjects for Acts Prohibited under Punishment Act, corresponds with Article 11.2, MEDICRIME Convention.

11.3: Criminal, administrative, and civil liability of the legal person is applicable and corresponds with Article 11.3, MEDICRIME Convention.

11.4: Article 6, Liability of Collective Subjects for Acts Prohibited under Punishment Act, corresponds with Article 11.4, MEDICRIME Convention.

### Article 13 – Aggravating circumstances

13.a: No provision in internal law could be found corresponding with Article 13.a, MEDICRIME Convention.

13.b and c: Article 53.2, Penal Code provides the general approach towards both aggravating and mitigating circumstances and includes a consideration of "…the type and degree of transgression against obligations imposed on the perpetrator…". While this potentially could partially include the abuse of confidence placed in the capacity of professionals or manufacturers as well as suppliers, this does not directly or adequately correspond with Article 13.b and c, MEDICRIME Convention.

13.d: Article 53.2, Penal Code provides the general approach towards both aggravating and mitigating circumstances. This does not directly or adequately correspond with Article 13.b and c, MEDICRIME Convention.

13.e: Article 258, Penal Code corresponds with Article 13.e, MEDICRIME Convention.

13.f: Article 64, Penal Code, provides for recidivism as an aggravating circumstance. This corresponds with Article 13, f, MEDICRIME Convention.

Further action is needed to fully correspond with Article 13.a, b, c, and d, MEDICRIME Convention.

## 3.29 Romania

### Article 4 - Definitions

a. Article 4.a MEDICRIME Convention – Medical Product
No provision in internal law could be found corresponding to Article 4. a, MEDICRIME Convention. It is noted that separate definitions exist for the terms 'medicinal product' and 'medical device'.
Further action is required to fully correspond with Article 4.a, MEDICRIME Convention.

b. Article 4.b MEDICRIME Convention – Medicinal Product
Article 699, item 1, Law no. 95/2006 on the healthcare does not correspond with Article 4.b, MEDICRIME Convention. Article 699, item 1, Law no. 95/2006 on the healthcare reform addresses only the medicinal products for human use and it does not include references to investigational medicinal products or to medicinal products for veterinary use.
Further action is needed to correspond with Article 4.b, MEDICRIME Convention.

c. Article 4.c MEDICRIME Convention - Active substance
Article 699, item 3 of Law no. 95/2006 on the healthcare reform may be construed as corresponding with Article 4.c, MEDICRIME Convention.

d. Article 4.d MEDICRIME Convention – Excipient
Article 699, item 4 of Law no. 95/2006 on the healthcare reform, does not completely correspond with article 4.d, MEDICRIME Convention.
Further action is required to correspond with Article 4.d, MEDICRIME Convention.

e. Article 4.e MEDICRIME Convention – Medical Device
Article 2, para. 1, items 1 and 3 of Government Decision no. 54/2009 regarding the requirements for placing medical devices on the market and Article 2, items 1 and 2 of Government Decision no. 798/2003 on establishing the conditions for the placing on the market and use of medical devices for in vitro diagnosis. These provisions, together and separately, correspond with Article 4.e, MEDICRIME Convention.

f. Article 4.f MEDICRIME Convention – Accessory
Article 2 para. 1 item 2 of Government Decision no. 54/2009 regarding the requirement for placing medical devices on the market, and Article 2, item 3, Government Decision no.798/2003 on establishing the conditions for the placing on the market and use of medical devices for in vitro diagnosis. These provisions, together and separately, correspond with Article 4.f, MEDICRIME Convention.

g. Article 4.g MEDICRIME Convention – Parts and materials
No provision in internal law could be found to correspond with Article 4.g, MEDICRIME Convention.

h. Article 4.h MEDICRIME Convention – Document
No provision in internal law could be found to correspond with Article 4.h, MEDICRIME Convention.
Action is needed to correspond with Article 4.h, MEDICRIME Convention.

i. Article 4.i MEDICRIME Convention – Manufacturing
No provision in internal law could be found to correspond with Article 4.i, MEDICRIME Convention. It is noted that the term 'manufacturer' is provided by Article 699 item 41 of Law no. 95/2006 on the healthcare reform as regards medicinal products for human use, by Article 2 paragraph 1 item 14 of Government Decision no. 54/2009 regarding the requirements for placing medical devices on the market as regards medical devices, and Article 2 items 6 of Government Decision no. 798/2003 on establishing the conditions for the placing on the market and use of medical devices for in vitro diagnosis, as regards medical devices for in-vitro diagnostics. These provisions do not sufficiently correspond with Article 4.i, MEDICRIME Convention.
Further action is needed to correspond with Article 4.i, MEDICRIME Convention.

j. Article 4.j MEDICRIME Convention – Counterfeit
Article 699, item 40 of Law no. 95/2006, corresponds with Article 4.j, MEDICRIME Convention.
Article 4.k MEDICRIME Convention – Victim

Article 79, Criminal Code (CC) refers to the term 'injured person'. While the term 'victim' is not specifically defined, Article 79 CC sufficiently corresponds with Article 4.k, MEDICRIME Convention.

## CHAPTER II – SUBSTANTIVE CRIMINAL LAW

### Article 5 – Manufacturing of counterfeits

Article 357. 2, Criminal Code (CC) provides for an offence for the preparation of a counterfeit or substituted medicine. This provision is limited to circumstances where the medicinal product is harmful to health. Article 357.2 does not contain provisions as regards active substances, excipients, medical devices, parts, materials, or accessories. This does not sufficiently correspond with Article 5, MEDICRIME Convention.

Further action is needed to fully correspond with Article 5, MEDICRIME Convention.

### Article 6 – Supplying, offering to supply, and trafficking in counterfeits

Article 357. 2, CC, provides for an offence for the offering or display for sale of counterfeit or substituted medicines that are harmful to health. Article 358.3, CC, provides for an offence for the sale of medicines knowing that they are counterfeit, altered or with their validity period expired if they are harmful to health. Article 358.3, CC, is limited to circumstances where the medicinal product is harmful to health. Neither Article 357.2 nor Article 358.3, CC, contain provisions as regards active substances, excipients, medical devices, parts, materials, or accessories.

This does not sufficiently correspond with Article 6, MEDICRIME Convention.

Further action is needed to fully correspond with Article 6, MEDICRIME Convention.

### Article 7 – Falsification of documents

The internal criminal law does not correspond directly with Article 7.1, MEDICRIME Convention as it does not provide a specific offence of the falsification of documents Related to medicinal products, active substances, excipients, parts, materials, or accessories. It is noted that Article 320, CC, as regards the making of a false official document and the adulteration of an official document, and Article 323, CC, as regards the use of an official document, are criminalised. These provisions may be sufficient to partially correspond with Article 7, MEDICRIME Convention.

Further action is necessary to fully correspond with Article 7, MEDICRIME Convention.

### Article 8 – Similar crimes involving threats to public health

8.a: No provision in internal law could be found to correspond with Article 8.a, i, or ii, MEDICRIME Convention. It is noted that the non-compliance with authorisations and compliance with the conformity requirements, as mentioned in Article 8.a, are considered as misdemeanours in the administrative law and are not criminalised. This does not correspond with Article 8.a, MEDICRIME Convention.

8.b: No offence in internal law could be found to correspond with Article 8.b, MEDICRIME Convention.

Action is required to correspond with Article 8.a and 8.b, MEDICRIME Convention.

### Article 9 – Aiding or abetting and attempt

9.1: Article 49, CC, as regards aiding and abetting, corresponds with Article 9.1 MEDICRIME Convention.

9.2: Article 32.1, CC, provides that attempt to commit an offence is criminalised. However, it is limited in the CC to provisions specifically permitting sanctioning for attempts. Neither article 357.2 and 358.3 are specifically provided for sanctions as regards attempt. This does not correspond with Article 9.2, MEDICRIME Convention.

Action is needed to correspond with Article 9.2, MEDICRIME Convention.

### Article 11 – Corporate liability

11.1. a, b, c: Article 135. 1, CC, creates legal criminal liability of legal persons where acts are committed by them and in their interest. This is the general criminal law and is it does address the requirements that legal personal can be held liable specifically for the offences contemplated in the Convention and does not correspond with Article 11.1, MEDICRIME Convention**.**

11.2: No provision in internal law can be found to correspond with Article 11.2, MEDICRIME Convention.

11.3: liability of legal persons can be civil or administrative, depending on the nature of the provision that stipulates the sanction imposed to the legal person.

11.4: The general law does not correspond with Article 11.4, MEDICRIME Convention as it does not provide a specific distinction in respect of the liability of legal or natural persons in relation to offences of counterfeiting of medical products.

Action is needed to correspond with Article 11, MEDICRIME Convention.

### Article 13 – Aggravating circumstances

13.a: The domestic law does not correspond directly with Article 13.a, of the MEDICRIME Convention as it does not provide a specific aggravating circumstance in determining the sanctions in relation to the offences established in accordance with this Convention. In Romania, if an offence caused the death of, or damage to the physical or mental health of the victim, the person found guilty may also be prosecuted and convicted for the offence of manslaughter (Article 192, CC) or any other offence against life or physical integrity stipulated in the CC.

13.b: No provision in internal law could be found to correspond with Article 13.b, MEDICRIME Convention.

13.c: No provision in internal law could be found to correspond with Article 13.c, MEDICRIME Convention.

13.d: No provision in internal law could be found to correspond with Article 13.d, MEDICRIME Convention.

13.e: The domestic criminal law does not correspond directly with Article 13.e, MEDICRIME Convention as it does not provide a specific aggravating circumstance if the offences established in accordance with this Convention are committed in the framework of a criminal organisation. The general law is used here to address the corresponding article of the Convention because it creates a general (ordinary) offence for an intentional act similar to the article of the convention and attracts a criminal conviction (article 367 CC).

13.f: The domestic criminal law does not correspond directly with Article 13.f, MEDICRIME Convention as it does not provide a specific aggravating circumstance if the perpetrator has previously been convicted of offences of the same nature as the offences established in accordance with this Convention. The general criminal provisions in Romania stipulate an additional sanction for the person who commits a repeated offence. These provisions regarding the punishment regime for repeated offences apply to any other offence provided by the Romanian criminal laws (Article 41, CC).

Further action is needed to fully correspond with Article 13, MEDICRIME Convention.

## 3.30 Serbia

### Article 4 - Definitions

a. Article 4.a MEDICRIME Convention – Medical Product
   No provision in internal law could be found to correspond with Article 4.a, MEDICRIME Convention. It is noted that there are separate definitions for the terms 'medicinal product' and 'medical device'.
   Further action is needed to fully correspond with Art 4.a MEDICRIME Convention.

b. Article 4.b, MEDICRIME Convention – Medicinal Product
   Article 14, Law on Medicinal Products and Medical Devices, as regards the term 'medicinal products', substantially corresponds with Article 4.b, MEDICRIME Convention with the exception that it does not include the term 'investigational medicinal products'.
   Further action is needed to correspond with Article 4.b, MEDICRIME Convention.

c. Article 4.c MEDICRIME Convention -Active substance

Article 2. Paragraph 1 Point 27), Law on Medicinal Products and Medical Devices, as regards the term 'active substance', corresponds with Article 4.c, MEDICRIME Convention.

d. Article 4.d MEDICRIME Convention – Excipient
Article 2. Paragraph 1 Point 28) Law on Medicinal Products and Medical Devices, as regards the term 'excipient', corresponds with Article 4.d, MEDICRIME Convention.

e. Article 4.e MEDICRIME Convention – Medical Device
Art. 2 Para 1 Law on Medical Devices, as regards the term 'medical device', corresponds with Article 4.e, MEDICRIME Convention.

f. Article 4.f MEDICRIME Convention – Accessory
Art. 2. Paragraph 1 Point 2) Law on Medicinal Products and Medical Devices, as regards the term 'accessory', corresponds with Article 4.f, MEDICRIME Convention.
The definition of the term "accessory" corresponds to that set out in Article 4 (f).

g. Article 4.g MEDICRIME Convention – Parts and materials
No provision in internal law could be found to correspond with Article 4.g, MEDICRIME Convention.
Further action is needed to fully correspond with Art 4.g, MEDICRIME Convention.

h. Article 4.h MEDICRIME Convention – Document
No provision in internal law could be found to correspond with Article 4.h, MEDICRIME Convention. While Article 2. Paragraph 1 Points 27), 34), 35), 36), 39), 56), 93) and Art. 93 Para 4 Law on Medical Devices describes different documents, this does not correspond with Article 4.h.
Further action is needed to fully correspond with Art 4.h, MEDICRIME Convention.

i. Article 4.i MEDICRIME Convention – Manufacturing
Article 95, Law on Medicinal Products and Medical Devices, as regards the manufacturing of medicinal products, substantially corresponds with Article 4.i, MEDICRIME Convention, except that it does not specifically include excipients. Article 2. Paragraph 1 Point 79 Law on Medical Devices, as regards the manufacturing of medical devices, substantially corresponds with Article 4.i, MEDICRIME Convention, except that it does not specifically include parts and materials and the designing of the device.
Further action is needed regarding both the manufacturing of medicinal products and medical devices definitions to fully correspond with Article 4.h, MEDICRIME Convention.

j. Article 4.j MEDICRIME Convention – Counterfeit
Article 2. Paragraph 1 Point 94) Law on Medical Devices, and Article. 2. Paragraph 1 Point 36) Law on Medicinal Products
and Medical Devices, individually and in combination substantially correspond with
Article 4.j, MEDICRIME Convention.
Further action is needed to fully correspond with Article 4.j, MEDICRIME Convention.

k. Article 4.k MEDICRIME Convention – Victim
Article 2. Paragraph 1 Point 11), Criminal Code uses the term 'injured party' as regards injury to personal or property rights. This corresponds with the intent of but not as specific as Article 4.k, MEDICRIME Convention.
Further action is needed to fully correspond with Article 4.k, MEDICRIME Convention.

## CHAPTER II – SUBSTANTIVE CRIMINAL LAW

### Article 5 – Manufacturing of counterfeits

Article 109. 5), Law on Medicinal Products and Medical Devices, as regards medicinal products, corresponds with Article 5, MEDICRIME Convention Article 67.5), Law on Medical Devices and Article 188.5) individually and together, as regards falsified medical devices, corresponds with Article 5, MEDICRIME Convention.

Art. 256.1 Criminal Code prohibits the production of harmful products. While this may support prosecutions for the manufacturing of a counterfeit medicinal product or a harmful medical device, it does not correspond with Article 5, MEDICRIME Convention.

### Article 6 – Supplying, offering to supply, and trafficking in counterfeits

Article 134. Paragraph 1 Points 5), 6), 7) and Paragraph 2 Law on Medicinal Products and Medical Devices as regards the sale of falsified medicinal products, partially corresponds with Article 6, MEDICRIME Convention. Article

82.9), Law on Medical Devices, as regards the placing on the market of a falsified medical devices, corresponds partially, with Article 6, MEDICRIME Convention.

Art. 256.1 Criminal Code prohibits the production and putting into circulation of harmful products. While this may support prosecutions for the manufacturing of a counterfeit medicinal product or a harmful medical device, it does not correspond with Article 6, MEDICRIME Convention.

Further action is required to correspond fully with Article 6, MEDICRIME Convention.

### Article 7 – Falsification of documents

The Articles 355 and 356 Criminal Code, correspond with Article 7.1, MEDICRIME Convention.

### Article 8 – Similar crimes involving threats to public health

8. a. i: Articles 109, 119, 134, and 217, Law on Medicinal Products and Medical Devices, as regards medicinal products, correspond with Article 8.a.i, MEDICRIME Convention.

8.a.ii: Article 126, Law on Medical Devices, and Article 188 and 217, Law on Medicinal Products and Medical Devices, prohibit the manufacture of a medical device that is not in conformance with its essential requirements, and the unauthorised manufacture of a medical device, respectively, correspond with Article 8.a.ii, MEDICRIME Convention. Art. 256.1 Criminal Code prohibits the production of harmful products. While this may support prosecutions for the manufacturing and marketing of a harmful medicinal product or a harmful medical device, it does not correspond with Article 8. a, MEDICRIME Convention.

8.b: No provision in internal law could be found to correspond with article 8.b, MEDICRIME Convention.

Further action is required to correspond fully with Article 8.a.ii, and 8.b, MEDICRIME Convention.

### Article 9 – Aiding or abetting and attempt

9.1: Article 34 and 35 Criminal Code, as regards aiding and abetting, correspond with Article 9.1, MEDICRIME Convention.

9.2: Article 30 and 355, Criminal Code, as regards attempt, corresponds with Article 9.2, MEDICRIME Convention.

### Article 11 – Corporate liability

11.1: Article 6, Law on The Liability of Legal Entities for Criminal Offences, generally correspond with Article 11.1, MEDICRIME Convention.

11.2: Article 6, Law on The Liability of Legal Entities for Criminal Offences, corresponds with Article 11.2, MEDICRIME Convention.

11.3: Legal entities are subject to Criminal Law, Administrative Law and Civil Law Requirements and correspond with Article 11.3, MEDICRIME Convention.

11.4: Article 7, Law on The Liability of Legal Entities for Criminal Offences, corresponds with Article 11.4, MEDICRIME Convention.

### Article 13 – Aggravating circumstances

Article 54, Criminal Code, provides for aggravating circumstances to be taken into consideration in the determining of sentence.

13.a: Article 259, Criminal Code, as regards death, grievous bodily harm, or serious health impairment, qualifies the correspondence with Article 13.a, MEDICRIME Convention.

13.b-e: No specific provision in internal law could be found to correspond with Article 13, b-e, MEDICRIME Convention.

13. f: Article 55, Criminal Code, as regards recidivism, corresponds with Article 13.f, MEDICRIME Convention.

Further action is needed to fully correspond with Article 13. b-e, MEDICRIME Convention.

## 3.31 Slovak Republic

### Article 4 - Definitions

a. Article 4.a MEDICRIME Convention – Medical Product
No provision in internal laws could be found corresponding with Article 4.a, MEDICRIME Convention.
Action is needed to correspond with Article 4.a, MEDICRIME Convention.

b. Article 4.b MEDICRIME Convention – Medicinal Product
The definition of a "medicinal product" in the Act No. 362/2011 Coll. of Laws is not identical with Article 4.b, MEDICRIME Convention and diverts from the definition in the Directive 2001/83/EC of the European Parliament and the Council. On the other hand, Section 2, paragraph 7 read in conjunction with Section 2, paragraph 5, and other related provisions cover most elements contained in Article 4(b) of the MEDICRIME Convention. The lack of explicit definition of the Investigational Medical Product makes it difficult to determine whether the definition of the medicinal product under Section 2, paragraph 7 also includes investigational medicinal product within the meaning of Article 4(b)(iii), MEDICRIME Convention.
Further action is needed to fully correspond with Article 4.b, MEDICRIME Convention.

c. Article 4.c MEDICRIME Convention -Active substance
The term "effectives substance" in Section 2, paragraph 33 of the Act No. 362/2011 Coll. of Laws does not fully correspond with the term "active substance" under Article 4(c), MEDICRIME Convention.
Further action is needed to fully correspond with Article 4.c, MEDICRIME Convention.

d. Article 4.d MEDICRIME Convention – Excipient
Section 2, paragraph 6 of the Act No. 362/2011 Coll. of Laws, as regards the term "excipient", under does not fully correspond with Article 4(d) of the MEDICRIME Convention.
Further action is needed to fully correspond with Article 4.d, MEDICRIME Convention.

e. Article 4.e MEDICRIME Convention – Medical Device
A new Section 143k, paragraph 1, Law on Medicinal Products and Medical Devices
(Act No. 362/2011 Coll. of Laws) corresponds with Article 4(e) of the MEDICRIME Convention.

f. Article 4.f MEDICRIME Convention – Accessory
Section 2. (19(d), Law on Medicinal Products and Medical Devices, includes the concept of accessories in the context of in vitro diagnostic medical devices and corresponds, to this limited extent with Article 4.f, MEDICRIME Convention. It is noted that Section 143k includes the basic concept of medical devices applying by 25 May 2021. This does not provide that accessories are considered as part of the medical device and does not provide a separate term of 'accessory. This does not fully correspond with Article 4.f, MEDICRIME Convention.
Further action is needed to fully correspond with Article 4.f, MEDICRIME Convention.

g. Article 4.g MEDICRIME Convention – Parts and materials
No provision in internal laws could be found corresponding with Article 4(g), MEDICRIME Convention.
Action is needed to correspond with Article 4.g, MEDICRIME Convention.

h. Article 4.h MEDICRIME Convention – Document
No provision in internal laws, as regards the term 'document', could be found corresponding with Article 4(h), MEDICRIME Convention.
Action is needed to correspond with Article 4.h, MEDICRIME Convention.

i. Article 4.i MEDICRIME Convention – Manufacturing
No provision in internal laws, as regards the term 'manufacturing', could be found corresponding with Article 4(i), MEDICRIME Convention.
Further action is needed to fully correspond with Article 4.i, MEDICRIME Convention.

j. Article 4.j MEDICRIME Convention – Counterfeit
The phrase "counterfeit medicinal product for human use" is defined in positive terms (what is a counterfeit medicinal product) in Section 2, paragraph 35 as well as in negative way (what is not a counterfeit medicinal product) in Section 2, paragraph 36 of the Act No. 362/2011 Coll. of Laws.
Further action is needed to fully correspond with Article 4.j, MEDICRIME Convention.

k. Article 4.k MEDICRIME Convention – Victim
No provision in internal laws, as regards the term 'victim', could be found corresponding with Article 4(k), MEDICRIME Convention. The definition of a "victim" under the Act No. 274/2017 Coll. of Laws is to be used

solely in the context of the application of the said Act. The Act No. 301/2005 Coll. of Laws operates with the term "injured party" whose definition to some extent overlaps with the above definition of a "victim." Action is needed to correspond with Article 4.k, MEDICRIME Convention.

## CHAPTER II – SUBSTANTIVE CRIMINAL LAW

### Article 5 – Manufacturing of counterfeits

Section 170b, Criminal Code, as regards medicinal products and medical devices, but not active substances, excipients, part, materials, and accessories, partially corresponds with Article 5, MEDICRIME Convention. It is noted that the extend of the falsification of manufacturing appears not to include the actual manufacturing of a falsified medicinal product and medical device. The provision includes activities of falsification of the identity and source of the medicinal product, and the identity, source, conformity assessment and conformity mark of the medical device.

Further action is needed to fully correspond with Article 5, MEDICRIME Convention.

### Article 6 – Supplying, offering to supply, and trafficking in counterfeits

Section 170b, Criminal Code, as regards medicinal products and medical devices, but not active substances, excipients, part, materials, and accessories, corresponds with Article 6, MEDICRIME Convention.

### Article 7 – Falsification of documents

Section 170b. (2), Criminal Code, criminalises the falsification of certain documentation related to the finished medicinal product and medical device. This is a specific provision for the mentioned documentation and not documents in general as contemplated by Article 7, MEDICRIME Convention. Section 170b (2) partially corresponds with Article 7, MEDICRIME Convention.

Further action is needed to fully correspond with Article 7, MEDICRIME Convention.

### Article 8 – Similar crimes involving threats to public health

8.a.i, ii: Section 170a (1), Criminal Code, corresponds with Article 8.a.i and ii, MEDICRIME Convention.

8.b: No provision in internal laws could be found corresponding with Article 8.b MEDICRIME Convention.

Action is needed to correspond with Article 8.b, MEDICRIME Convention.

### Article 9 – Aiding or abetting and attempt

9.1: Sections 13, 20 and 21, Criminal Code, together correspond with Article 9.1, MEDICRIME Convention.

9.2: Article 14, Criminal Code, corresponds with Article 9.2, MEDICRIME Convention.

### Article 11 – Corporate liability

11.1. a, b, c: Law on the Criminal Liability of legal persons (The Act No. 91/2016 Coll. of Laws) established criminal liability of legal/juridical persons, types of sanctions and the specifics of the Criminal proceedings against juridical persons. However, this Act only applies to specific categories of criminal offences as enumerated in Section 3. The Act does not apply to criminal offences under Sections 170, 170a, or 170b of the Criminal Code which provides for the criminalisation relating to medical products.

Further action is needed to fully correspond with Article 11.1, MEDICRIME Convention.

11.2: Section 4, Law on the Criminal Liability of legal persons (Act No. 91/2016 Coll. Of Laws) sets basic principles for establishing criminal liability of legal persons and is consistent with the requirements of Article 11. 2, MEDICRIME Convention. However, the

Act does not apply to criminal offences under Sections 170, 170a, or 170b of the Criminal Code which provides for the criminalisation relating to medical products.

Further action is needed to fully correspond with Article 11.2, MEDICRIME Convention.

11.3: The Criminal Code and the medicinal products and medical devices, create criminal and administrative liability. However, the Act does not apply to criminal offences under Sections 170, 170a, or 170b of the Criminal Code which provides for the criminalisation relating to medical products. Civil and administrative liability attaches to legal person and this corresponds with Article 11.3, MEDICRIME Convention.

11.4 No criminal liability for legal persons is established under the internal legislation in connection with the offences established in arts. 5-8 MEDICRIME Convention. There is no correspondence with Article 11.4, MEDICRIME Convention.

Further action is needed to fully correspond with Article 11.1, 11.2 and 11.4, MEDICRIME Convention.

### Article 13 – Aggravating circumstances

13.a: Sections 170a(3) and 170b(4(a)) and (5)(a), Criminal Code, as regards the causing of bodily harm or death, corresponds with Article 13 MEDICRIME Convention. However, these are qualified to the extent of the offending.

13.b: Section 170, (2) (a), Criminal Code, is limited to anyone in the provision of healthcare and while this could include professionals, it does not sufficiently correspond with Article 13.b, MEDICRIME Convention.

13.c: No provision in internal law, apart from Section 170 (2)(a), could be found to correspond with Article 13.c, MEDICRIME Convention.

13.d: Section 170a, (2) (d) and Section 170, b (3) (d) in connection with Section 122. (2), Criminal Code, as regards the commission of the offence publicly where it involves printed matter or the dissemination on radio, television or use of a computer network, could be interpreted as sufficiently corresponding with Article 13.d, MEDICRIME Convention.

13.e: Section 170.a and 170.b, Criminal Code, refer to the concept of 'dangerous grouping' and which is separate in the 'criminal group'. The term 'dangerous grouping' could be interpreted to correspond with the intent of Article 13.e, MEDICRIME Convention.

13.f: Section 170a, (2)(a) and Section 170b, (3) (a), Criminal Code correspond with Article 13.f, MEDICRIME Convention.

## 3.32 Slovenia

### Article 4 - Definitions

a. Article 4.a MEDICRIME Convention – Medical Product
No provision in internal law could be found to correspond with Article 4.a, MEDICRIME Convention. It is noted that there are separate definitions for the terms 'medicinal product' and 'medical device'.
Further action is needed to fully correspond with Art 4.a MEDICRIME Convention.

b. Article 4.b MEDICRIME Convention – Medicinal Product
Article 5, Medicinal Products Act 2014, as amended (MPA), apart from the term 'investigational medicinal product', corresponds with Article 4.b, MEDICRIME Convention. Clarification is required on whether the term 'investigational medicinal products' is considered as part of the term as part of the definition 'medicinal product'.
Action is needed to fully correspond with Article 4.b, MEDICRIME Convention.

c. Article 4.c MEDICRIME Convention -Active substance
Article 6.96, MPA corresponds with Article 4.c, MEDICRIME Convention.

d. Article 4.d MEDICRIME Convention – Excipient
Article 6.63, MPA corresponds with Article 4.d, MEDICRIME Convention.

e. Article 4.e MEDICRIME Convention – Medical Device
Article 3. (1), Medical Device Act 2009 (MDA), corresponds with Article 4.e, MEDICRIME Convention.

f. Article 4.f MEDICRIME Convention – Accessory
Article 3. (2), MDA, corresponds with Article 4.f, MEDICRIME Convention.

g. Article 4.g MEDICRIME Convention – Parts and materials

No provision in internal law, as regards the terms 'parts' and 'materials' could be found to correspond with Article 4.g, MEDICRIME Convention.
Action is needed to correspond with Art 4.g, MEDICRIME Convention.

h. Article 4.h MEDICRIME Convention – Document
No provision in internal law, as regards the term 'document' could be found to correspond with Article 4.h, MEDICRIME Convention
Action is needed to correspond with Art 4.h, MEDICRIME Convention.

i. Article 4.i MEDICRIME Convention – Manufacturing
No provision in internal law, as regards the term 'manufacturing' could be found to correspond with Article 4.i, MEDICRIME Convention.
Action is needed to correspond with Art 4.i, MEDICRIME Convention.

j. Article 4.j MEDICRIME Convention – Counterfeit
Article 6.62, as regards medicinal products, active substances, and excipients, corresponds with Article 4.j, MEDICRIME Convention. There is no legal definition of the term 'counterfeit' as regards medical devices, accessories and parts and materials.
Further action is needed to fully correspond with Art 4.i, MEDICRIME Convention.

k. Article 4.k MEDICRIME Convention – Victim
Article 144, Criminal Procedures Act, 1994, as amended (CPC), refers to 'injured party' when describing victims and includes one whom any of his personal or property rights have been violated or endangered by a criminal offense. Article 144 CPC, in a broad manner, corresponds with Article 4.k, MEDICRIME Convention.
Further action is needed to fully correspond with Art 4.k, MEDICRIME Convention.

## CHAPTER II – SUBSTANTIVE CRIMINAL LAW

### Article 5 – Manufacturing of counterfeits

No provision in internal law, as regards the counterfeiting (or falsification) of medical products, could be found to correspond with Article 5, MEDICRIME Convention. Article 183.(1), Criminal Code criminalises the manufacture of medicines or other medical remedies dangerous to health but does specifically not criminalises acts corresponding to Article 5, MEDICRIME Convention.

Action is needed to correspond with Art 5, MEDICRIME Convention.

### Article 6 – Supplying, offering to supply, and trafficking in counterfeits

No provision in internal law could be found to correspond with Article 6, MEDICRIME Convention Article 183. (1), Criminal Code criminalises the sale or otherwise supply of medicines or other medical remedies dangerous to health, but does not specifically criminalise acts corresponding to Article 6, MEDICRIME Convention.

Action is needed to correspond with Art 6, MEDICRIME Convention.

### Article 7 – Falsification of documents

Article 251. (1) and (3), Criminal Code, as regards the falsification of documents, corresponds with Article 7, MEDICRIME Convention.

### Article 8 – Similar crimes involving threats to public health

8.a.i: Article 20, as regards marketing authorisations, Article 90. (1), as regards manufacturing authorisations, and Article 97, as regards wholesaling authorisations of medicinal products, create mandatory provision in the MPA. The breach of such provisions results in offending conduct that is not punishable in the Criminal Law but is by administrative sanctions. Articles 20, 90. (1), and 97 MPA do not correspond with Article 8.a.i, MEDICRIME Convention.

Action is needed to correspond with Art 8.a.i, MEDICRIME Convention.

8.a. ii: Article 67. (1), as regards the compliance of requirements of the MDA, Article 67. (5) and (6), as regards the placing of the CE mark on medical devices, criminalises the acts of the legal person which are misdemeanours punishable by fines. This does not include all the requirements of Article 8.a.ii, MEDICRIME Convention.

Action is needed to correspond with Art 8.a.ii, MEDICRIME Convention.

8.b: No provision in internal law could be found to correspond with Article 8.b, MEDICRIME Convention Action is needed to correspond with Art 8.b, MEDICRIME Convention.

### Article 9 – Aiding or abetting and attempt

9.1: Article 20. (2), and Article 38, Criminal Code, as regards accomplices, aiding and abetting, corresponds with Article 9.1, MEDICRIME Convention.

9.2: Article 34, Criminal Code, as regards attempts, corresponds with Article 9.2, MEDICRIME Convention.

### Article 11 – Corporate liability

11.1. a, b, c: Article 4 and 5, Law on Liability of Legal Entities for Criminal Offenses 1999, as amended, corresponds with Article 11.1.a, b, and c, MEDICRIME Convention.

11.2: Article 4.4, and 5.3, Law on Liability of Legal Entities for Criminal Offenses corresponds with Article 11.2, MEDICRIME Convention.

11.3: Law on Liability of Legal Entities for Criminal Offenses and the MPA provide for Criminal Civil and Administrative liability for legal persons. This corresponds with Article 11.3, MEDICRIME Convention.

11.4: Article 5.4, Law on Liability of Legal Entities for Criminal Offenses, and Article 42,

Criminal Code corresponds with Article 11.4, MEDICRIME Convention.

### Article 13 – Aggravating circumstances

Article 49, Criminal Code provides the general rules for sentencing and correspond in some respects with Article 13, MEDICRIME Convention.

13.a: Article 183 (4) and (5), Criminal Code, which refer to the 'Production and marketing of harmful treatment agents' and their consequence in serious bodily injury or results in the death, respectively, correspond to Article 13.a, MEDICRIME Convention.

13.b: There is no correspondence with Article 13.b, MEDICRIME Convention.

13.c: There is no correspondence with Article 13.c, MEDICRIME Convention.

13.d: There is no correspondence with Article 13.d, MEDICRIME Convention.

13.e: Article 42, Criminal Code, as regards offending in the framework of a criminal organisation, corresponds with Article 13.e, MEDICRIME Convention.

13.f: Article 49. (3), Criminal Code, as regards previous history of the same type, corresponds with Article 13.f, MEDICRIME Convention.

Further action is needed to fully correspond with Article 13.b, c and d, MEDICRIME Convention.

## 3.33 Sweden

### Article 4 – Definitions

a. Article 4.a MEDICRIME Convention – Medical Product
   No provision in internal law could be found to correspond with Article 4.a, MEDICRIME Convention. It is noted that there are separate definitions for the terms 'medicinal product' and 'medical device'.
   Further action is needed to fully correspond with Art 4.a MEDICRIME Convention.

b. Article 4.b MEDICRIME Convention – Medicinal Product

Chapter 2, Section 1, Medicinal Products Act, as regards the term 'medicinal product', corresponds with Article 4.b, MEDICRIME Convention. No provision in internal law, as regards the term investigational product, other than a reference to Regulation (EU) No 536/2014 (human clinical trials), could be found to correspond with Article 4.b, MEDICRIME Convention.
Further action is needed to fully correspond with Article 4.b, MEDICRIME Convention.

c. Article 4.c MEDICRIME Convention -Active substance
Chapter 2, Section 1, Medicinal Products Act, as regards active substances, corresponds with Article 4.c, MEDICRIME Convention.

d. Article 4.d MEDICRIME Convention – Excipient
Chapter 2, Section 1, Medicinal Products Act, as regards the term 'excipient' substantially corresponds with Article 4.d, MEDICRIME Convention.
Further action is needed to fully correspond with Article 4.d, MEDICRIME Convention.

e. Article 4.e MEDICRIME Convention – Medical Device
Section 2, Medical Devices Act, as regards the term 'medical device' corresponds with Article 4.e, MEDICRIME Convention.

f. Article 4.f MEDICRIME Convention – Accessory
No provision in internal law, as regards the term 'accessory', could be found to correspond with Article 4.f, MEDICRIME Convention.

g. Article 4.g MEDICRIME Convention – Parts and materials
No provision in internal law, as regards the term 'accessory' could be found to correspond with Article 4.g, MEDICRIME Convention.
Action is needed to correspond with Article 4.g, MEDICRIME Convention.

h. Article 4.h MEDICRIME Convention – Document
Chapter 14, Section 1, Swedish Criminal Code uses the term 'instrument'. It is generally described and does not fully correspond with Article 4.h, MEDICRIME Convention.
Further action is needed to fully correspond with Article 4.h, MEDICRIME Convention.

i. Article 4.i MEDICRIME Convention – Manufacturing
Chapter 2, Section 1, Medicinal Products Act, as regards the term 'manufacturing' is inadequately described and does not correspond sufficiently with Article 4.i, MEDICRIME Convention.
Action is needed to correspond with Article 4.i, MEDICRIME Convention.

j. Article 4.j MEDICRIME Convention – Counterfeit
Chapter 2, § 1, Medicinal Products Act, as regards medicinal products, corresponds with Article 4.j, MEDICRIME Convention. No provision in internal law, as regards medical devices, could be found to correspond with Article 4.j, MEDICRIME Convention.
Further action, as regards medical devices, is needed to correspond with Article 4.j, MEDICRIME Convention.

k Article 4.k MEDICRIME Convention – Victim
No provision in internal law, as regards the term 'victim' could be found to correspond with Article 4.k, MEDICRIME Convention.
Action is required to correspond with Article 4.k, MEDICRIME Convention.

## CHAPTER II – SUBSTANTIVE CRIMINAL LAW

### Article 5 – Manufacturing of counterfeits

No provision in internal law could be found to correspond with Article 5, MEDICRIME Convention.

Action is needed to correspond with Article 5, MEDICRIME Convention.

### Article 6 – Supplying, offering to supply, and trafficking in counterfeits

No provision in internal law could be found to correspond with Article 6, MEDICRIME Convention.

Action is needed to correspond with Article 6, MEDICRIME Convention.

### Article 7 – Falsification of documents

Chapter 14, Sections 1 and 2; Swedish Criminal Code correspond with Article 7, MEDICRIME Convention.

### Article 8 – Similar crimes involving threats to public health

8.a. i: Chapter 16, Section 1.4, Medicinal Product Act, on criminalisation, as regards prohibition on manufacturing and importation without authorisation, Article 14.1, as regards prohibition on marketing without authorisation, and Chapter 9, Section 1, Medicinal Products Trading Act, as regards the wholesaling of medicinal products without authorisation, correspond with Article 8.a.i, MEDICRIME Convention.

8.a. ii: Article 17, Medical Device Act, as regards the intentional or negligent placing a medical device on the market without conforming to the essential requirements, corresponds to Article 8.a.ii, MEDICRIME Convention. However,

8.b): No provision in internal law could be found corresponding to Article 8.b, MEDICRIME Convention.

Further action is needed to correspond with article 8.b, MEDICRIME Convention.

### Article 9 – Aiding or abetting and attempt

9.1: Chapter 23, Section 4, Swedish Criminal Code, as regards aiding and abetting, provides that the provision applies in respect of any statute where offences arise. As the Medicinal Product Act, Medicinal Products Trading Act, and the Medical Device Act do not provide for the criminalisation of offences referred to in Article 5 and 6 MEDICRIME Convention, the provision in the Criminal code, as regards aiding and abetting, does not correspond with Article 9.1, MEDICRIME Convention.

9.2: Chapter 23, Section 1, Swedish Criminal Code, as regards attempt, provides that the provision applies in respect of any statute where offences arise. As the Medicinal Product Act, Medicinal Products Trading Act, and the Medical Device Act do not provide for the criminalisation of offences referred to in Article 5 and 6 MEDICRIME Convention, the provision in the Criminal code, as regards attempt, does not correspond with Article 9.2, MEDICRIME Convention.

Action is required to correspond with Article 9, MEDICRIME Convention.

### Article 11 – Corporate liability

11.1 and 11.2: Chapter 36, Section 7, Criminal Code, corresponds with Article 11.1 and 11.2 MEDICRIME Convention.

11.3: Swedish law provides for Criminal Law, Civil Law and Administrative liability corresponding to Article 11.3, MEDICRIME Convention.

11.4: It is unclear whether the Criminal Code corresponds with Article 11.4, MEDICRIME Convention.

It is noted that as Medicinal Product Act, Medicinal Products Trading Act, and the Medical Device Act do not provide for the criminalisation of offences referred to in Article 5 and 6 MEDICRIME Convention, the provision in the Criminal code, as regards corporate liability, may not correspond with Article 11.1, 11.2 and 11.4, MEDICRIME Convention.

The concept of corporate liability is recognised in several international legal agreements. It has previously been established that the provisions of a corporate fine as provided by Chapter 36, Section 7, Criminal Code meet the requirements of corporate liability. Based on these considerations, the provisions of Article 11 in the Convention are adequately implemented by Swedish legislation.

### Article 13 – Aggravating circumstances

Aggravating circumstances may be taken in consideration by the Courts in determining the sentence.

13.a: Chapter 29, Section 1, Criminal Code includes consideration on whether the act involved a serious attack on someone's life or health or personal security. This is more restrictive than the Convention as it introduces the gravity to seriousness. It substantially corresponds with Article 13.a, MEDICRIME Convention.

Further action is needed to fully correspond with Article 13.a, MEDICRIME Convention.

13.b and c: Chapter 29, Section 2, point 4, Criminal Code provides for the abuse of trust as an aggravating circumstance without specifying a profession or trade. This substantially corresponds with Article 13, b and c.

Further action is needed to correspond fully with Article 13.b and c, MEDICRIME Convention.

13.d: No provision in internal law could be found to correspond with Article 13.d, MEDICRIME Convention.

13.e: Chapter 29, Section 2, point 6, as regards commission in the framework of a criminal organisation, corresponds with Article 13.d, MEDICRIME Convention

13.f: Chapter 29, Section 4, Criminal Code as regards recidivism, corresponds with Article 13.f, MEDICRIME Convention.

Further action is needed to correspond with Article 13.d, MEDICRIME Convention.

## 3.34 Tunisia

### Article 4 - Definitions

a. Article 4.a MEDICRIME Convention – Medical Product
No provision in internal law, as regards the term 'medical product', could be found to correspond with Article 4.a, MEDICRIME Convention.
Action is needed to correspond with Article 4.a, MEDICRIME Convention.

b. Article 4.b MEDICRIME Convention – Medicinal Product
Article 21, Law nº 73-55, 1973, as regards the term medicinal product, substantially, but not fully, corresponds with Article 4.b, MEDICRIME Convention. No provision in Article 21 includes investigational medicinal products.
Action is needed to fully correspond with Article 4.b, MEDICRIME Convention.

c. Article 4.c MEDICRIME Convention - Active substance
No provision in internal law, as regards the term 'active substance', could be found to correspond with Article 4.c, MEDICRIME Convention.
Action is needed to correspond with Article 4.c, MEDICRIME Convention.

d. Article 4.d MEDICRIME Convention – Excipient
No provision in internal law, as regards the term 'excipient', could be found to correspond with Article 4.d, MEDICRIME Convention.
Action is needed to correspond with Article 4.d, MEDICRIME Convention.

e. Article 4.e MEDICRIME Convention – Medical Device
No provision in internal law, as regards the term 'medical device', could be found to correspond with Article 4.e, MEDICRIME Convention.
Action is needed to correspond with Article 4.e, MEDICRIME Convention.

f. Article 4.f MEDICRIME Convention – Accessory
No provision in internal law, as regards the term 'accessory', could be found to correspond with Article 4.f, MEDICRIME Convention.
Action is needed to correspond with Article 4.f, MEDICRIME Convention.

g. Article 4.g MEDICRIME Convention – Parts and materials
No provision in internal law, as regards the terms 'parts' and 'materials', could be found to correspond with Article 4.g, MEDICRIME Convention.
Action is needed to correspond with Article 4.g, MEDICRIME Convention.

h. Article 4.h MEDICRIME Convention – Document
Article 1, Annex to the Decree nº90-1400, 1990, contains reference to specific documents and does not define the term 'document'. No provision in internal law, as regards the term 'document', could be found to correspond with Article 4.h, MEDICRIME Convention.
Action is needed to correspond with Article 4.h, MEDICRIME Convention.

i. Article 4.i MEDICRIME Convention – Manufacturing
Article 1, Annex to the Decree nº90-1400, 1990, as regards the term 'manufacturing' of medicinal products, partially, but not fully, corresponds with Article 4.i, MEDICRIME Convention. No provision in internal law,

as regards the term 'manufacturing' of medical devices, could be found to correspond with Article 4.i, MEDICRIME Convention.

Action is needed to correspond with Article 4.i, MEDICRIME Convention.

j. Article 4.j MEDICRIME Convention – Counterfeit
No provision in internal law, as regards the term 'counterfeit', could be found to correspond with Article 4.j, MEDICRIME Convention.
Action is needed to correspond with Article 4.j, MEDICRIME Convention.

k. Article 4.k MEDICRIME Convention – Victim
No provision in internal law, as regards the term 'victim', could be found to correspond with Article 4.k, MEDICRIME Convention.
Action is needed to correspond with Article 4.k, MEDICRIME Convention.

## CHAPTER II – SUBSTANTIVE CRIMINAL LAW

### Article 5 – Manufacturing of counterfeits

No provision in internal law, as regards the offence of the intentional manufacturing of a counterfeit medical product, active substances, excipients, parts, materials, and accessories, could be found to correspond with Article 5, MEDICRIME Convention.

Action is needed to correspond with Article 5, MEDICRIME Convention.

### Article 6 – Supplying, offering to supply, and trafficking in counterfeits

No provision in internal law, as regards the offence of the intentional supply, or the offering to supply, including brokering, the trafficking, including keeping in stock, importing, and exporting of counterfeit medical product, active substances, excipients, parts, materials, and accessories, could be found to correspond with Article 6, MEDICRIME Convention.

Action is needed to correspond with Article 6, MEDICRIME Convention.

### Article 7 – Falsification of documents

Article 172, Criminal Code corresponds with Article 7, MEDICRIME Convention.

### Article 8 – Similar crimes involving threats to public health

8.a.i and ii: Law 85-91, 1985, as amended, requires authorisation for the manufacture and registration of medicines for human use, but it is unclear whether there is a criminal offence established for their intentional breach. No provision in internal law, as regards the intentional breach of authorisations relating to the keeping in stock for supply, importing, exporting, supplying, offering to supply or other requirements for authorisation, could be found to correspond with Article 8. a. i, and ii, MEDICRIME Convention.

8.b: No provision in internal law could be found to correspond with Article 8.b, MEDICRIME Convention.

Action is needed to correspond with Article 8. a and b, MEDICRIME Convention.

### Article 9 – Aiding or abetting and attempt

9.1: Article 32 Criminal Code, as regards 'aiding' or 'abetting', is a general criminal law offence that corresponds with the intent of Article 9.1, MEDICRIME Convention.

9.2: Article 59 Criminal Code, provides that 'attempt' is only punishable where the penalty is associated with a criminal offence with a minimum penalty of 5 years of imprisonment. This does not sufficiently correspond with Article 9.2 MEDICRIME Convention.

Further action is needed to correspond with Article 9.2 MEDICRIME Convention.

### Article 11 – Corporate liability

No provision in internal law could be found to correspond with Article 11, MEDICRIME Convention.

Action is needed to correspond with Article 11, MEDICRIME Convention.

### Article 13 – Aggravating circumstances

The Criminal Code provides as offences all the circumstances in Article 13. a -c and e and do not require them as aggravating circumstances.

13.a: Article 225, Criminal Code.

13.b: Article 297, Criminal Code.

13.c: Article 298, Criminal Code

13.d: Act on the competition and Prices.

13.e: Articles131 and 132, Criminal Code

13.f: Article 47, Criminal Code

## 3.35 United Kingdom

### Article 4 - Definitions

a. Article 4.a MEDICRIME Convention – Medical Product
No provision in internal law could be found to correspond with Article 4.a, MEDICRIME Convention. It is noted that there are separate definitions for the terms 'medicinal product' and 'medical device'.
Further action is needed to fully correspond with Art 4.a MEDICRIME Convention.

b. Article 4.b MEDICRIME Convention – Medicinal Product
Regulation 2(1), The Human Medicine Regulations 2012, as regards medicinal products, 2(1), The Medicines for Human Use (Clinical Trials) Regulations 2004, as regards investigational medicinal products, and Regulation 2(1), The Veterinary Medicine Regulations 2013, as regards medicinal products for veterinary use, correspond with Article 4.b, MEDICRIME Convention.

c. Article 4.c MEDICRIME Convention - Active substance
Regulation 8(1), Human Medicines Regulations 2012, as regards active substances for medicinal products for human use, corresponds with Article 4.c, MEDICRIME Convention. Part 3, Chapter 1, Section 14(1), Medicines and Medical Device Act 2021, as regards active substances for medicinal products for veterinary use, corresponds with Article 4.c, MEDICRIME Convention.

d. Article 4.d MEDICRIME Convention – Excipient
Regulation 8(1), Human Medicines Regulations 2012, as regards medicinal products for human use, broadly corresponds with Article 4.d, MEDICRIME Convention. While the Veterinary Medicines Regulations 2013 makes numerous references to excipients in its text it does not define the term.
Further action is needed to correspond fully with Article 4.d, MEDICRIME Convention.

e. Article 4.e MEDICRIME Convention – Medical Device
Regulation 2(1), Medical Devices Regulations 2002, corresponds with Article 4.e, MEDICRIME Convention.

f. Article 4.f MEDICRIME Convention – Accessory
Regulation 5(1), Medical Devices Regulations 2002, corresponds with Article 4.f, MEDICRIME Convention.

g. Article 4.g MEDICRIME Convention – Parts and materials
No provision in internal law could be found to correspond with Article 4.g, MEDICRIME Convention.
Further action is needed to fully correspond with Art 4.g, MEDICRIME Convention.

h. Article 4.h MEDICRIME Convention – Document
No provision in internal law could be found to correspond with Article 4.h, MEDICRIME Convention.
Further action is needed to fully correspond with Art 4.h, MEDICRIME Convention.

i. Article 4.i MEDICRIME Convention – Manufacturing
Regulation 8(1), Human Medicines Regulations 2012, as regards medicinal products for human use includes the term 'manufacture' which encompasses much of what is included in the term 'manufacturing' but does not define the term 'manufacturing. Regulation A17, Human Medicines Regulations 2012, as regards active substances; Regulation 5(3), Veterinary Medicines Regulations 2013, as regards medicinal products for veterinary use; and Regulation 2, Medical Devices Regulations 2002, as regards medical devices and accessories, correspond with Article 4.i, MEDICRIME Convention.
Further action is needed to fully correspond with article 4.i MEDICRIME Convention.

j. Article 4.j MEDICRIME Convention – Counterfeit
Regulation 8(1), Human Medicines Regulations 2012, as regards medicinal products for human use, corresponds with Article 4.j, MEDICRIME Convention. No provision in internal law, as regards medicinal products for veterinary use or for medical devices, could be found to correspond with Article 4.j, MEDICRIME Convention.
Further action is needed to correspond fully with Article 4.j, MEDICRIME Convention.

k. Article 4.k MEDICRIME Convention – Victim
No provision in internal law could be found to correspond with Article 4.k, MEDICRIME Convention.
Action is needed to correspond fully with Article 4.k, MEDICRIME Convention.

## CHAPTER II – SUBSTANTIVE CRIMINAL LAW

### Article 5 – Manufacturing of counterfeits

5.1: Section 2, Fraud Act 2006, as regards the jurisdictions of England, Wales, and Northern Ireland, and Section 49, Criminal Justice and Licensing (Scotland) Act 2010 are general Criminal Law fraud offences. This involves the dishonestly making of representation. While this may support a prosecution in relation to counterfeit medical products, it does not correspond with Article 5, MEDICRIME Convention.

Action is needed to correspond with Article 5, MEDICRIME Convention.

### Article 6 – Supplying, offering to supply, and trafficking in counterfeits

Section 2, Fraud Act 2006, as regards the jurisdictions of England, Wales, and Northern Ireland and Section 49, Criminal Justice and Licensing (Scotland) Act 2010 are general Criminal Law fraud offences. This involves the dishonestly making of representation. While this may support a prosecution in relation to counterfeit medical products, it does not correspond with Article 6, MEDICRIME Convention.

Action is needed to correspond with Article 6, MEDICRIME Convention.

### Article 7 – Falsification of documents

There is no correspondence with Article 7, MEDICRIME Convention.

Action is needed to correspond fully with Article 7, MEDICRIME Convention.

### Article 8 – Similar crimes involving threats to public health

8.a.i: Regulation 34(1), Human Medicines Regulations 2012, as regards manufacturing licences, Regulation 18(1), as regards wholesale dealing licences, and Regulation 47(1), as regards marketing authorisations, correspond with Article 8.a.ii, MEDICRIME Convention. Regulation 43(q), (r), (s), and 47(1) Veterinary Medicines Regulations 2013, as regards supply, correspond with Article 8.a.i, MEDICRIME Convention.

8.a.ii: Regulation 8, Medical Devices Regulations 2002, as regards placing on the market or putting into service in compliance with the essential requirements, corresponds with Article 8.a.i, MEDICRIME Convention. It is noted that Regulation 60A (1), Medicines and Medical Devices Act 2021, as regards supply and placing on the market, substantially corresponds with Article 8.a.(ii), MEDICRIME Convention.

8.b: No provision could be found in internal law to correspond with Article 8.b, MEDICRIME Convention.

Further action is needed to fully correspond with Article 8.b, MEDICRIME Convention.

### Article 9 – Aiding or abetting and attempt

9.1. Ss. 44, 45, 46, Serious Crime Act 2007, as regards England, Wales, and Northern Ireland, and Section 293. (2), Criminal Procedures (Scotland) Act, 1995, as regards Scotland, correspond with Article 9.1: MEDICRIME Convention. However, in the absence of an offence under Articles 5 and 6, MEDICRIME Convention, the internal laws have no effect in this regard.

9.2: Section. 1, Criminal Attempts Act 1981, as regards England and Wales, Section 294, Criminal Procedure (Scotland) Act 1995, as regards Scotland, and Section 3, The Criminal Attempts and Conspiracy (Northern Ireland) Order 1983, individually and together correspond with Article 9.2 MEDICRIME Convention. However, in the absence of an offence under Articles 5 and 6, MEDICRIME Convention, the internal laws have no effect in this regard.

Action is needed to correspond with Article 9, MEDICRIME Convention.

### Article 11 – Corporate liability

11.1: Section12, Fraud Act 2006, as regards England, Wales, and Northern Ireland, and Common Law (Purcell Meats (Scotland) Ltd. v. McLeod 1986 SCCR 672) as regards Scotland, and as regards medical product regulations for the UK, Regulation 338, Human Medicines Regulations 2012, Regulation 44(2), Veterinary Medicines Regulations 2013, and the provision of Regulation 60C, Medical Devices Regulations 2002 (inserted by Schedule 3, Medicines and Medical Device Act 2021), correspond with Article 11.1, MEDICRIME Convention.

11.2: Regulation 338, Human Medicines Regulations 2012, Regulation 44(2), Veterinary Medicines Regulations 2013, (and the provisions of Regulation 60C Medical Devices Regulations 2021correspond with Article 11.2, MEDICRIME Convention.

11.3: The liability can be criminal or civil.

11.4: S.12(2), Fraud Act 2006, as regards England, Wales and Northern Ireland, the Common Law, as regards Scotland, and as regards the U.K., S993, Companies Act 2006, and Regulation 338, Human Medicines Regulations 2012, Regulation 44(2), Veterinary Medicines Regulations 2013, correspond with Article 11.4, MEDICRIME Convention.

### Article 13 – Aggravating circumstances

Aggravating circumstances for the UK arise from a hybrid of statue, sentencing guidelines issued by a Sentencing Council established by statute, by court specific guidelines and sentencing guidelines made by superior courts. It is a matter for the courts to consider the guidelines in determining sentences.

Some of the specific guidance for aggravating circumstances provided by statute arise, such as in relation to Art. 13.e MEDICRIME Convention, for offences committed in the framework of a criminal organisation - S. 29 of the Criminal Justice and Licensing (Scotland) Act 2010, and in relation to Article 13.f, MEDICRIME Convention, for offences of the same nature previously committed – S. 65, Sentencing Act 2020, as regards England and Wales.

Further Action is required to correspond fully with Article 13, MEDICRIME Convention.

## 3.36 United States of America

### Article 4 - Definitions

a. Article 4.a MEDICRIME Convention – Medical Product
No provision in internal law, as regards the term 'medical product' could be found corresponding with Article 4.a, MEDICRIME Convention. It is noted that there are separate definitions of the terms 'medicinal product' and 'medical device'.
Action is needed to fully correspond with Article 4.a, MEDICRIME Convention.

b. Article 4.b MEDICRIME Convention – Medicinal Product
21 U.S.C. §321 (g)(1), corresponds with the meaning of Article 4.b, MEDICRIME Convention.

c. Article 4.c MEDICRIME Convention - Active substance
21 CFR 310.3 (g), and 21CFR §314.3 correspond to Article 4.c, MEDICRIME Convention.

d. Article 4.d MEDICRIME Convention – Excipient

21 CFR §201.117 includes a description of excipients under the heading of 'inactive ingredients' and does not separately define it. The term 'inactive ingredients' corresponds with Article 4.d, MEDICRIME Convention.

e. Article 4.e MEDICRIME Convention – Medical Device
21 U.S.C. §321 (h), as regards medical devices and which includes accessories, components, and material, approximates to the meaning of Article 4.e, MEDICRIME Convention. 21 U.S.C. 360 j(o) excludes software intended to be used in conjunction with the device.
Further action is needed to fully correspond with Article 4.e, MEDICRIME Convention.

f. Article 4.f MEDICRIME Convention – Accessory
The term 'accessory' is not defined. It is defined in a guidance document by the U.S. Food and Drug Administration (US FDA), and it corresponds with Article 4.f, MEDICRIME Convention.
Further action needed to fully correspond with Article 4.f, MEDICRIME Convention.

g. Article 4.g MEDICRIME Convention – Parts and materials
The term 'materials' is used throughout 21 U.S.C, Chapter 9, but is not defined, nor is the term 'parts'.
Action is needed to correspond with Article 4.g, MEDICRIME Convention.

h. Article 4.h MEDICRIME Convention – Document
18 U.S.C. § 2318, (b)(5), concerning the trafficking in counterfeit labels, illicit labels, or counterfeit documentation or packaging, corresponds with Article 4.h, MEDICRIME Convention.

i. Article 4.i MEDICRIME Convention – Manufacturing
The term 'manufacturing' is defined in a limited manner in some State laws, and in relation to blood products for human use, but not by federal law or in all States in relation to medical products. There is no correspondence with Article 4.i, MEDICRIME Convention.
Action is needed to fully correspond with Article 4.i, MEDICRIME Convention.

j. Article 4.j MEDICRIME Convention – Counterfeit
21 U.S. Code § 321(g)(1) defines the term 'counterfeit' in a manner that includes aspects of misrepresentation of identity of the medical product, but is insufficient to capture misrepresentation of source, including the history of the product. It is noted that U.S. Congressional reports include submissions that mention the term 'falsified' as regards medical products and define it in a manner consistent with Article 4.j, MEDICRIME Convention. However, the legal definition remains as that in 21 U.S. Code § 321(g)(1). This does not correspond with Article 4.j, MEDICRIME Convention.
Further action is needed to correspond with Article 4.j, MEDICRIME Convention.

k. Article 4.k MEDICRIME Convention – Victim
18 U.S.C. § 3771, (e), (2), (A) and (B), is a broad general criminal law definition that encompasses broadly the intent of Article 4.k, MEDICRIME Convention.

## CHAPTER II – SUBSTANTIVE CRIMINAL LAW

### Article 5 – Manufacturing of counterfeits

5.1: 21 U.S.C. § 331, (g), as regards medical products, and 21 U.S.C. § 331 (i), (3), as Regards causing any medical product to be counterfeit medicinal product, correspond with Article 5.1, MEDICRIME Convention.

5.2: 21 U.S.C. § 331 (2), as regards adulteration of medicinal products in interstate trade, corresponds with Article 5.,2, MEDICRIME Convention. However, this may not apply outside interstate trade.

Further action is needed to fully correspond with Article 5.2, MEDICRIME Convention.

### Article 6 – Supplying, offering to supply, and trafficking in counterfeits

18 U.S.C. § 2320 (a), (1), (2), and (4), as regards the trafficking in counterfeit goods or services, corresponds with Article 6, MEDICRIME Convention. 21 U.S.C. § 331, (a), and (c).

### Article 7 – Falsification of documents

21 U.S.C. § 331, as regards regulatory law, and 18 U.S.C. §495, as regards general forgery offences, respectively, sufficiently correspond with Article 7, MEDICRIME Convention.

### Article 8 – Similar crimes involving threats to public health

8.a.i., ii: 21 U.S.C. § 355 and §360 correspond with Article 8.a. i and ii, MEDICRIME Convention.

8.b: There is no correspondence, as regards the commercial use of original documents outside their intended use within the legal medical product supply chain, with Article 8.b, MEDICRIME Convention.

Action is needed to correspond with Article 8.b, MEDICRIME Convention.

### Article 9 – Aiding or abetting and attempt

9.1: 18 U.S.C. §2, as regards aiding and abetting, corresponds with Article 9.1.MEDICRIME Convention.

9.2: 18 U.S.C. § 371 is a general conspiracy criminal law provision that does not directly address attempt. 18 U.S.C. § 2320 includes attempts in the trafficking in counterfeit goods or services and Partially corresponds with Article 9.2, MEDICRIME Convention.

Further action is needed to correspond fully with Article 9.2, MEDICRIME Convention.

### Article 11 – Corporate liability

11.1. a, b, c: Case law precedent in the Common Law Legal System has ensured that corporate liability arises through the acts of its agents (New York Central & Hudson River Railroad Co. v. United States, 212 U.S. 481, 494-95 (1909)). This is not specified in statutory law and does not completely correspond with Article 11.1, MEDICRIME Convention.

11.2: U.S. case law has developed the doctrine of "responsible corporate official" which provides for corporate liability where offending results from a failure to supervise (United States v. Park, 421 U.S. 658 (1975)). This corresponds with the intent of Article 11.2, MEDICRIME Convention.

11.3: Criminal, civil, and administrative sanctions are applicable to legal persons and Correspond with Article 11.3, MEDICRIME Convention.

11.4: U.S. case law precedent has ensured that legal entities are held liable for the acts of and distinct from that of their servants and agents (New York Central & Hudson River Railroad Co. v. United States, 212 U.S. 481, 494-95 (1909)). This corresponds with Article 11.4, MEDICRIME Convention.

Further action is needed to correspond with Article 11.1, MEDICRIME Convention.

### Article 13 – Aggravating circumstances

13.a: 18 U.S.C. § 3571, USSG § 2N2.1, as regards the creation of a substantial risk of bodily injury or death, or bodily injury, death, or extreme psychological injury, corresponds to Article 13.a MEDICRIME Convention.

13.b, c, d, e, and f: There is no direct correspondence with Article 13. b – f. MEDICRIME Convention. Circumstance already forming part of the constituent elements of the offence obviate the requirement for aggravating circumstances in some instances. Sentencing guidelines are used to guide the Courts on aggravating circumstances and by 18 U.S. Code § 3553 - Imposition of a sentence.

Further action is needed to correspond with Article 13. b – f, MEDICRIME Convention.

# IV. APPENDICES

## Appendix 1- NA-FAMED -0- Gap Analysis Survey

**Gap Analysis Survey**

**Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health**

**(The MEDICRIME Convention)**

Moscow, 28.X.2011

| | |
|---|---|
| **NAME OF COUNTRY** | |
| **Name of person** | |
| **Position** | |
| **e-mail** | |
| **Telephone** | |
| **Twitter account** | |
| **LinkedIn account** | |

### I. Introduction

In the framework of the Project entitled "Needs Assessment - Falsified Medical Products" (NA-FAMED), the Council of Europe is conducting this **Gap Analysis Survey** to assess the level to which current domestic criminal and other laws support the prohibition and enforcement against counterfeit/falsified medical products as criminal offences for the purpose of protecting public health.

This is the first part of a two-part survey. The focus of this first part is on the definitions and the substantive criminal law. Part 2 may be circulated at a future date and will focus on the non-substantive criminal law aspects of the MEDICRIME.

Please note the object and purpose of the MEDICRIME Convention, as provided by its Article 1.1, while completing the Gap Analysis Survey

*Article 1 – Object and purpose*

*1 The purpose of this Convention is to prevent and combat threats to public health by:*

*a. providing for the criminalisation of certain acts;*

*b. protecting the rights of victims of the offences established under this Convention;*

*c. promoting national and international co-operation*

## II. Purpose of the Gap Analysis Survey

The purpose of this Gap Analysis Survey is to identify for the Council of Europe how best it can support its Member States and other countries build a criminal law and supporting framework under the MEDICRIME Convention to combat counterfeit/falsified medical products and similar crimes involving threats to public health. This is the criminal law approach, which aims at criminalising behaviour that balances and complements the public health approach, which aims at protecting the medical product.

Items that you will need to provide

| | |
|---|---|
| **Document A: Legislative Gap Analysis**<br>1. | Table to fill-in |
| **Appendix to Document A** | Explanation to be provided |
| **Document B: Case-law analysis**<br>2. Data collection of relevant cases on the falsification of medical products or similar crimes. Clear description and conclusion of it (is there a judgement?) | |
| **Document C: Overview document**<br>3. | Table to fill-in |

## III. Methodology

Only one consolidated response to the Survey should be submitted by each consultant/assessor. This submission should be in the English and/or French language as the Gap Analysis Survey assessors will not be in a position to properly translate and interpret from a different language. The consultant/assessor is free to contact his/her national Ministries/agencies that are normally involved in combating counterfeit/falsified medical products (Justice, Health, Police service, Customs, Health Product Regulatory Agency, etc).

## IV. Instructions to complete the Legislative Gap Analysis

The Legislative Gap Analysis requires responses to be provided in the Column 2 and in Column 3. In your responses in Columns 2 and 3, please **state only the reference to the domestic law provision** with a web link/hyper link to your laws if possible.

*(e.g., Col 3: Regulation 14 B (1), Medicinal Products (Control of Manufacture) Regulations 2013. (http://www.irishstatutebook.ie/eli/2013/si/163/made/en/print ). Add the reference to Appendix (No.), page 1(No.) for specifics on this provision).*

1. **Column 1:** provides a quote of the MEDICRIME Convention provision
2. **Column 2:** Place your responses for your country's **domestic Criminal Laws** that specifically corresponds to the MEDICRIME Convention (i.e. only responses that specifically implement the Criminal Law of the Convention are placed here)
3. **Column 3:** Place your response here for your **general domestic Laws** (including Criminal Laws/Regulatory Laws/Administrative Laws enacted or put in place for different objectives to the MEDICRIME Convention and which will attain an objective corresponding to the provision of the MEDICRIME Convention)

   *(e.g., for EU Member States, the transposition of Directive 2011/62/EU – Falsified Medicines Directive that has the object of protecting public health through protecting the medicinal product)*

4. Please provide in **narrative form** in an **Appendix**, in English and/or French languages

   a. **The text of the legislative provision that you refer to** in Columns 2 and/or 3
   *(e.g. "14B.(1) A person shall not manufacture, import or export a medicinal product if he or she knows, or there are sufficient grounds to suspect, that it is a falsified medicinal product").*

   b. state clearly **why the general laws (Column 3) adequately implement the corresponding provision** of the MEDICRIME Convention (Column 1).
   (*e.g. This provision is secondary law* and *was implemented to transpose the Directive 2011/62/EU (falsified medicines directive), the penalties for which, on summary conviction, are a fine not exceeding €4,000 or a term of imprisonment not exceeding 1 year, or both; on conviction on indictment, for a first offence to a fine not exceeding €120,000 or imprisonment for a term not exceeding 10 years or both; on conviction on indictment, for a second or subsequent offence, to a fine not exceeding €300,000 or imprisonment for a term not exceeding 10 years or both. It is secondary legislation providing an offence requiring the intentional conduct and attracts a criminal conviction). (http://www.irishstatutebook.ie/eli/2006/act/3/section/16/enacted/en/html#sec16 )*

   c. state clearly **if the general laws (Column 3) do not adequately or at all** implement **the corresponding provision** in the MEDICRIME Convention (Column 1).
   *(e.g. The general law does not completely/ adequately (exclude as applicable) implement the corresponding provision of the MEDICRIME Convention as it does not include medical devices. The purpose of the general law provision is to protect the public health by protecting the medicinal product whereas the purpose of the MEDICRIME Convention in this respect is to protect the public by criminalising the offending behaviours).*

   (*e.g. The domestic law does not correspond directly to Article (No.) of the MEDICRIME Convention as it does not provide a specific offence relating to medical products. The general law is used to address the corresponding article of the Convention because it creates a general offence for an intentional act similar to Article (No.) of the convention and attracts a criminal conviction…*

## V. Additional documents

This exercise will be completed with additional responses to be provided to additional documents, in particular a *case-law information document* and an *overview document*.

- The **case-law analysis** refers to any concrete case occurred in your country on the topic of falsified medical products and similar crimes. Only **relevant** cases are required. The reason is to find out whether there have been (or not) in your country any case or operations implemented by law-enforcement authorities that have tackled this topic. The idea is not to provide us with plenty of cases, just with those relevant.
- **Overview document**: some additional information from your country about this topic is always welcome.

The fulfilment of these both documents is self-explanatory.

## VI. Contact

In case of doubt or question, please do not hesitate to contact the MEDICRIME Secretariat at: **medicrime@coe.int**

## Appendix 2 - NA-FAMED - A1 -Document A

**LEGISLATIVE GAP ANALYSIS: please specify your country**

| MEDICRIME Convention provision | Domestic Criminal Law enacted specifically to implement the MEDICRIME Convention | General domestic laws (Criminal or Regulatory – specify which in each case) that correspond to the provision in Column 1 |
|---|---|---|
| **Column 1** | **Column 2** | **Column 3** |
| **Article 4 – Definitions** | | |
| 4.a. The term "medical product" shall mean medicinal products and medical devices | | |
| 4.b. The term "medicinal product" shall mean medicines for human and veterinary use, which may be:<br>i. any substance or combination of substances presented as having properties for treating or preventing disease in humans or animals.<br>ii any substance or combination of substances which may be used in or administered to human beings or animals either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis;<br>iii. an investigational medicinal product | | |
| 4.c. the term "active substance" shall mean any substance or mixture of substances that is designated to be used in the manufacture of a medicinal product, and that, when used in the production of a medicinal product, becomes an active ingredient of the medicinal product | | |

| | | |
|---|---|---|
| 4.d. the term "excipient" shall mean any substance that is not an active substance or a finished medicinal product, but is part of the composition of a medicinal product for human or veterinary use and essential for the integrity of the finished product | | |
| 4.e. the term "medical device" shall mean any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software, designated by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, designated by the manufacturer to be used for human beings for the purpose of:<br>i. diagnosis, prevention, monitoring, treatment, or alleviation of disease;<br>ii. diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap;<br>iii. investigation, replacement, or modification of the anatomy or of a physiological process;<br>iv. control of conception.<br>and which does not achieve its principal intended action in or on the human body by pharmacological, immunological, or metabolic means, but which may be assisted in its function by such means; | | |
| 4.f. the term "accessory" shall mean an article which whilst not being a medical device is designated specifically by its manufacturer to be used together with a medical device to enable it to be used in accordance with the use of the medical device intended by the manufacturer of the medical device | | |

| | | |
|---|---|---|
| 4.g. the terms "parts" and "materials" shall mean all parts and materials constructed and designated to be used for medical devices and that are essential for the integrity thereof | | |
| 4.h. the term "document" shall mean any document related to a medical product, an active substance, an excipient, a part, a material or an accessory, including the packaging, labeling, instructions for use, certificate of origin or any other certificate accompanying it, or otherwise directly associated with the manufacturing and/or distribution thereof | | |
| 4.i the term "manufacturing" shall mean:<br>i. as regards a medicinal product, any part of the process of producing the medicinal product, or an active substance or an excipient of such a product, or of bringing the medicinal product, active substance, or excipient to its final state;<br>ii as regards a medical device, any part of the process of producing the medical device, as well as parts or materials of such a device, including designing the device, the parts or materials, or of bringing the medical device, the parts or materials to their final state;<br>iii as regards an accessory, any part of the process of producing the accessory, including designing the accessory, or of bringing the accessory to its final state | | |
| 4.j. the term "counterfeit" shall mean a false representation as regards identity and/or source | | |

| | | |
|---|---|---|
| 4.k. the term "victim" shall mean any natural person suffering adverse physical or psychological effects as a result of having used a counterfeit medical product or a medical product manufactured, supplied or placed on the market without authorisation or without being in compliance with the conformity requirements as described in Article 8 | | |

| CHAPTER II – SUBSTANTIVE CRIMINAL LAW | | |
|---|---|---|
| **Article 5 – Manufacturing of counterfeits** | | |
| 5.1. Each Party shall take the necessary legislative and other measures to establish as offences under its domestic law, the intentional manufacturing of counterfeit medical products, active substances, excipients, parts, materials and accessories | | |
| 5.2. As regards medicinal products and, as appropriate, medical devices, active substances and excipients, paragraph 1 shall also apply to any adulteration thereof | | |

| **Article 6 – Supplying, offering to supply, and trafficking in counterfeits** | | |
|---|---|---|
| 6.1. Each Party shall take the necessary legislative and other measures to establish as offences under its domestic law, when committed intentionally, the supplying or the offering to supply, including brokering, the trafficking, including keeping in stock, importing and exporting of counterfeit medical products, active substances, excipients, parts, materials and accessories | | |

| Article 7 – Falsification of documents | | |
|---|---|---|
| 7.1. Each Party shall take the necessary legislative and other measures to establish as offences under its domestic law the making of false documents or the act of tampering with documents, when committed intentionally | | |

| Article 8 – Similar crimes involving threats to public health | | |
|---|---|---|
| Each Party shall take the necessary legislative and other measures to establish as offences under its domestic law, when committed intentionally, in so far as such an activity is not covered by Articles 5, 6 and 7:<br>a the manufacturing, the keeping in stock for supply, importing, exporting, supplying, offering to supply or placing on the market of:<br>i medicinal products without authorisation where such authorisation is required under the domestic law of the Party; or<br>ii medical devices without being in compliance with the conformity requirements, where such conformity is required under the domestic law of the Party;<br>b the commercial use of original documents outside their intended use within the legal medical product supply chain, as specified by the domestic law of the Party | | |

| Article 9 – Aiding or abetting and attempt | | |
|---|---|---|
| Each Party shall take the necessary legislative and other measures to establish as offences when committed intentionally, aiding or abetting the commission of any of the offences established in accordance with this Convention. | | |
| Each Party shall take the necessary legislative and other measures to establish as an offence the intentional attempt to commit any of the offences established in accordance with this Convention. | | |

| Article 11 – Corporate liability | | |
|---|---|---|
| Each Party shall take the necessary legislative and other measures to ensure that legal persons can be held liable for offences established in accordance with this Convention, when committed for their benefit by any natural person, acting either individually or as part of an organ of the legal person, who has a leading position within it based on:<br>a a power of representation of the legal person;<br>b an authority to take decisions on behalf of the legal person;<br>c an authority to exercise control within the legal person. | | |
| Apart from the cases provided for in paragraph 1, each Party shall take the necessary legislative and other measures to ensure that a legal person can be held liable where the lack of supervision or control by a natural person referred to in paragraph 1 has made possible the commission of an offence established in accordance with this Convention for the benefit of that legal person by a natural person acting under its authority. | | |

| | | |
|---|---|---|
| Subject to the legal principles of the Party, the liability of a legal person may be criminal, civil or administrative | | |
| Such liability shall be without prejudice to the criminal liability of the natural persons who have committed the offence | | |

| Article 13 – Aggravating circumstances | | |
|---|---|---|
| Each Party shall take the necessary legislative and other measures to ensure that the following circumstances, in so far as they do not already form part of the constituent elements of the offence, may, in conformity with the relevant provisions of domestic law, be taken into consideration as aggravating circumstances in determining the sanctions in relation to the offences established in accordance with this Convention:<br>a the offence caused the death of, or damage to the physical or mental health of, the victim;<br>b the offence was committed by persons abusing the confidence placed in them in their capacity as professionals;<br>c the offence was committed by persons abusing the confidence placed in them as manufacturers as well as suppliers;<br>d the offences of supplying and offering to supply were committed having resort to means of large scale distribution, such as information systems, including the Internet;<br>e the offence was committed in the framework of a criminal organisation;<br>f the perpetrator has previously been convicted of offences of the same nature | | |

## APPENDIX 1 - DESCRIPTION OF LAWS BY THE EXPERT

| MEDICRIME Provision | The text of the national legislative provision (column 2 and/or 3) | Why the general laws (column 2) adequately implements the corresponding provision | Does the general law (Column 3) adequately or at all implements the corresponding provision |
|---|---|---|---|
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## Appendix 4 - NA-FAMED Document B - Case Law (Law-enforcement or jurisprudential) analysis

**ANDORRA** No submission has been received on case law from the national consultant

**ARMENIA** (prepared by the national consultant Ms Alvina GYULUMYAN)

| PLEASE COLLECT ONLY RELEVANT CASES ON THE FALSIFICATION OF MEDICAL PRODUCTS OR SIMILAR CRIMES | | |
|---|---|---|
| **DATE AND CASE** | **DESCRIPTION** | **RESULT** |
| 30 November, 2016<br>Case՝՝՝ /0125/01/16 | Citizen of Armenia M.A. B. in the fall of 2015, without having a special pharmaceutical license, had prepared and sold 6 vials of eye drops and 3 vials of ear drops non-sterile counterfeit drugs that were not registered in the RA and didn't not meet the standard requirements as well as adopted qualitative and quantitative characteristics.<br>Assessing the nature of the crime committed by the defendant M.A. B., the degree of danger to society, as well as the specific actions he committed, the degree of implementation of the criminal intent and the damage caused as a result, as well as the social significance of the violated public relations, the direction of the state's criminal policy in this area, the behaviour of the defendant after committing the crime, as well as combining them with circumstances mitigating the responsibility and punishment of the defendant, with a positive characteristic of his personality and the absence of aggravating circumstances, the court ruled that M.A.B. should be convicted in accordance with part 2 of Article 280 of the RA Criminal Code, namely, the punishment of imprisonment for up to 1 (one) year. | The court decided to apply the sentence of 1 (one) year of imprisonment conditionally, to set a probation period of 1 (one) year, placing control over defendant's behaviour on the relevant territorial subdivision of the State Probation Service of the Ministry of Justice. |

**AUSTRIA** No submission has been received on case law from the national consultant

**AZERBAIJAN** (prepared by the national consultant Ms Ruhiyya ISAYEVA)

| PLEASE COLLECT ONLY RELEVANT CASES ON THE FALSIFICATION OF MEDICAL PRODUCTS OR SIMILAR CRIMES | | |
|---|---|---|
| **DATE AND CASE** | **DESCRIPTION** | **RESULT** |
| **1st case**<br>№ 1(101)-XXX/2021<br>Decision of the Baku Court on Grave Crimes of 05 February 2021 | A physical person is charged with Articles 200-1.2.2, 206.3.2 and 240.3.2 of the Criminal Code of the Republic of Azerbaijan for illegal acquisition, intentional storing, transportation and smuggling for the purpose of greed and sale in large amount[5] strong substances not related to narcotic drugs or psychotropic substances (i.e. smuggling across the customs border of the Azerbaijan Republic), as well as with storing in large amount unregistered[6] and non-transferable medicinal products. | Mr.X is found guilty of committing a criminal offence provided for in Articles 200-1.2.2, 206.3.2 and 240.3.2 of the Criminal Code of the Republic of Azerbaijan being sentenced under Article 200-1.2.2 to imprisonment for a term of 2 (two) years with deprivation for 2 (two) years of the right to hold managerial and financially responsible positions in state and local self-government bodies, as well as the right to engage in non-state (private) medical activities, under Article 206.3.2 to imprisonment for a term of 6 (six) years, and under Article 240.3.2 to imprisonment for a term of 5 (five) years.<br>Pursuant to Articles 66.3 and 66.4 of the Criminal Code of the Republic of Azerbaijan, the main and additional punishments are partially collected and Mr.X is sentenced to imprisonment for a term of 7 (seven) years with deprivation for 2 (two) years of the right to hold managerial and financially responsible positions in state and local self-government bodies, as well as the right to engage in non-state (private) medical activities. |

5. Under Article 200-1 of the Criminal Code of the Republic of Azerbaijan the «significant amount» mentioned in Article 200-1.1 means the amount from 1 000 (one thousand) to 2 000 (two thousand) manats (i.e. AZN), and «large amount» mentioned in Article 200-1.2.3 means the amount exceeding 2 000 (two thousand) AZN.
6. Here "unregistered" means without authorisation where such authorisation is required under the legislation of the Republic of Azerbaijan.

| PLEASE COLLECT ONLY RELEVANT CASES ON THE FALSIFICATION OF MEDICAL PRODUCTS OR SIMILAR CRIMES | | |
|---|---|---|
| **DATE AND CASE** | **DESCRIPTION** | **RESULT** |
| **2nd case**<br>№ 1(101)-XXX/2020<br>Decision of the Baku Court on Grave Crimes of 01 December 2020 | Three physical persons are charged with Articles 200-1.2.2, 200-1.2.3 and 206.3.2 of the Criminal Code of the Republic of Azerbaijan for intentional importing and storing, for the purpose of greed and sale, unregistered (i.e. without authorisation where such authorisation is required under the domestic law) medicinal products in large amount7, as well as for smuggling medicinal products in significant amount (i.e. import of which is not allowed to the Republic of Azerbaijan in accordance with the Law of the Republic of Azerbaijan "On Medicinal Products" (№208-IIIQ, dated 22 December 2006).<br>Total amount: 149 894.90 AZN (approx. 73 040 Euro) | Mr.X1, Mr.X2 and Mr X3 are found guilty of committing a criminal offence provided for in Articles 200-1.2.2, 200-1.2.3 and 206.3.2 of the Criminal Code of the Republic of Azerbaijan being sentenced under Articles 200-1.2.2 and 200-1.2.3 to imprisonment for a term of 2 (two) years with deprivation for 1 (one) year of the right to hold managerial and financially responsible positions in state and local self-government bodies for 1 (one) year, and under Article 206.3.2 to imprisonment for a term of 5 (five) years.<br>Pursuant to Article 66.3 of the Criminal Code of the Republic of Azerbaijan, the main punishments are partially collected and Mr.X1, Mr.X2 and Mr.X3 are sentenced to imprisonment for a term of 5 (five) years and 6 (six) months with deprivation of the right to hold managerial and materially responsible positions in state and local self-government bodies for 1 (one) year.<br>With regard to the application of Article 70 of the Criminal Code of the Republic of Azerbaijan to Mr.X1, Mr.X2 and Mr.X3, the sentence of imprisonment imposed on them is considered conditional with a probation period of 1 (one) year.<br>Mr.X1, Mr.X2 and Mr.X3 are obliged not to change their permanent place of residence without informing the bodies supervising their behaviour. |

7. Under Article 200-1 of the Criminal Code of the Republic of Azerbaijan the «significant amount» mentioned in the Article 200-1.1 means the amount from 1 000 (one thousand) to 2 000 (two thousand) manats (i.e. AZN), and «large amount» mentioned in the Article 200-1.2.3 means the amount exceeding 2 000 (two thousand) AZN.

| PLEASE COLLECT ONLY RELEVANT CASES ON THE FALSIFICATION OF MEDICAL PRODUCTS OR SIMILAR CRIMES | | |
|---|---|---|
| **DATE AND CASE** | **DESCRIPTION** | **RESULT** |
| **3rd case**<br>№ 1(101)-XXX/2020<br>Decision of the Baku Court on Grave Crimes of 21 September 2020 | A physical person is charged with Articles 200–1.2.2, 200–1.2.3 and 206.3.2 of the Criminal Code of the Republic of Azerbaijan for intentional importing and storing, for the purpose of greed and sale, unregistered medicinal products in large amount, as well as for smuggling medicinal products in significant amount.<br>Total amount: 87630,6 AZN (approx. 42 700 Euro) | Mr.X is found guilty of committing a criminal offence provided for in Articles 200–1.2.2, 200–1.2.3 and 206.3.2 of the Criminal Code of the Republic of Azerbaijan being sentenced under Article 206.3.2 to imprisonment for a term of 5 (five) years and 6 (six) months and under Articles 200-1.2.2 and 200-1.2.3 to imprisonment for a term of 3 (three) years.<br>Pursuant to Article 66.3 of the Criminal Code of the Republic of Azerbaijan, the punishments are partially collected and Mr.X1 is sentenced to imprisonment for a term of 6 (six) years.<br>Mr.X will pass his sentence in a general regime penitentiary institution. |
| **4th case**<br>№ 1(101)-XXX/2019<br>Decision of the Baku Court on Grave Crimes of 29 May 2019 | Nine physical persons are charged with Articles 200–1.2.1, 200-1.2.2, 200–1.2.3, 206.3.1, 206.3.2, 206.3.3 and 308.2 of the Criminal Code of the Republic of Azerbaijan for intentional misuse of their official powers in order to gain an illegal advantage for themselves and third parties in connection with the performance of their official duties as an official, causing significant damage to the legally protected interests of society and the state; for intentional importing and storing in a large amount the unregistered medicinal products for the purpose of sale, and for ensuring their sale; for engaging in illicit trafficking in medicinal products, repeatedly, being a group of persons who have previously conspired and using their official position to move secretly and outside the customs border of the Azerbaijan Republic, using fraudulently documents and means of customs identification, not declaring and misrepresenting large amounts of smuggled unregistered medicinal products of low-quality, not meeting the requirements of normative-technical documents. | Mr.X1, Mr.X2, Mr X3, Mr.X4, Mr.X5, Mr.X6, Mr.X7, Mr.X8 and Mr.X9 are found guilty of committing a criminal offence provided for in Articles 200–1.2.1, 200-1.2.2, 200–1.2.3, 206.3.1, 206.3.2, 206.3.3 and 308.2 of the Criminal Code of the Republic of Azerbaijan being sentenced under Articles 200-1.2.1, 200-1.2.2 and 200-1.2.3 to imprisonment for a term of 2 (two) years with deprivation for 1 (one) year of the right to hold managerial and financially responsible positions in state and local self-government bodies, under Articles 206.3.2 and 206.3.3 to imprisonment for a term of 5 (five) years and under Article 308.2 to imprisonment for a term of 3 (three) years with deprivation for 1 (one) year of the right to hold managerial and financially responsible positions in state and local self-government bodies.<br>Pursuant to Article 66.3 and 66.4 of the Criminal Code of the Republic of Azerbaijan, the punishments are partially collected and Mr.X1, Mr.X2, Mr X3, Mr.X4, Mr.X5, Mr.X6, Mr.X7, Mr.X8 and Mr.X9 are sentenced to imprisonment for a term of 6 (six) years with deprivation for 1 (one) year of the right to hold managerial and financially responsible positions in state and local self-government bodies.<br>In accordance with Article 70 of the Criminal Code of the Republic of Azerbaijan the sentence on imprisonment shall be conditionally applied with a probationary period of 2 (two) years. |

**BULGARIA** (prepared by the national consultant Ms Momiana GENEVA)

| PLEASE COLLECT ONLY RELEVANT CASES ON THE FALSIFICATION OF MEDICAL PRODUCTS OR SIMILAR CRIMES | | |
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| **DATE AND CASE** | **DESCRIPTION** | **RESULT** |
| | As concerns human medicine, the Criminal Code of Bulgaria (https://www.lex.bg/bg/laws/ldoc/1589654529) provides no responsibility for conduct identical or similar to that described in MEDICRIME. On that reason, there are not relevant cases. An investigation for relevant cases, where the producing, trading with, exporting and importing of counterfeit medical products was punished as fraud or unintentional causing of death or injury in mayor courts and attorney offices in Bulgaria, showed that there are no such cases – neither archived, nor even pending.<br><br>The Criminal Code of Bulgaria provides responsibility for producing or putting on the market of foodstuffs, animal feed, or veterinary medical products, or drinks (Art. 350a). The provision is in force since 2004. The detailed enquiry of jurisprudence shows that there are no such cases – neither archived, nor pending. | |

**CANADA** (prepared by the national consultant Mr David LIPKUS)

| PLEASE COLLECT ONLY RELEVANT CASES ON THE FALSIFICATION OF MEDICAL PRODUCTS OR SIMILAR CRIMES | | |
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| **DATE AND CASE** | **DESCRIPTION** | **RESULT** |
| November 5, 2020: Project Purify (Law Enforcement: Royal Canadian Mounted Police) | Project Purify is a multi-departmental partnership between the CBSA, Health Canada and the RCMP, which was established to enhance the identification, interception and tracking of unauthorized or counterfeit COVID-19 health-related products in British Columbia between March 20th and June 30th, 2020. | During this period, over 380 shipments of unauthorized content or counterfeit COVID-19- related goods were detained at the border, including: **48,000 COVID-19 test kits; 4.5 million units of personal protective equipment; 33,000 prescription tablets and pills; and over 1,500 other intercepts of fraudulent and potentially dangerous products** |

| PLEASE COLLECT ONLY RELEVANT CASES ON THE FALSIFICATION OF MEDICAL PRODUCTS OR SIMILAR CRIMES | | |
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| **DATE AND CASE** | **DESCRIPTION** | **RESULT** |
| R v Forrester, 2016 ONSC 8209 (September 29, 2016) R. v. Forrester, 2019 ONCA 255 (April 3, 2019) | North Bay Police Services obtained search warrants for individuals in North Bay. Those individuals (operators of this scheme were named to be Raymond Godreau and Grenville Sinclair and Julie Baks) were found to have in their possession prescriptions for Fentanyl, issued by Dr. Alan Sacksen in Barrie. The matter was referred to Barrie Police Services, who conducted their own investigation. They attended at the doctor's office and the doctor's own audit of his records indicated that approximately 19 false prescriptions were issued from his office. None of those individuals to whom prescriptions were issued were actual patients of Dr. Sacksen. One of the Individuals issued a prescription to "Sean Forrester" and gave it to Mr. Sinclair. Sean Forrester was never a patient of Dr. Sacksen. Ms. Saks had never met Sean Forrester, but simply acted on the information provided to her by Mr. Sinclair.<br><br>Mr. Sinclair and Ms. Baks were involved in a relationship at the time of the scheme. Mr. Sinclair's role was to obtain health card and other pertinent personal information from his associate, Mr. Godreau. Generally, Mr. Godreau would obtain health card numbers, dates of birth, addresses, postal codes and phone numbers from associates or acquaintances, and provide this information on a piece of paper to Mr. Sinclair.<br><br>On August 30th, 2013, she issued a prescription to one "Sean Forrester" and gave it to Mr. Sinclair. Sean Forrester was never a patient of Dr. Sacksen. Ms. Baks had never met Sean Forrester, but simply acted on the information provided to her by Mr. Sinclair.<br><br>The focus at Mr. Forrester's trial was whether or not Mr. Forrester attended at Shopper's Drug Mart on Young Street in Barrie on the dates in question to fill these prescriptions. Mr. Forrester denied his involvement.<br><br>*R v Forrester, 2016 ONSC 8209*<br><br>Mr. Forrester was charged as it related to the possession of a substance for the purpose of trafficking, contrary to section 5(2) of the Controlled Drug and Substances Act, S.C. 1996, c.19 [CDSA] and three counts related to possessing a forged document, in this case, a medical prescription, contrary to section 368(1)(d) of the Criminal Code, R.S.C., 1985, c. C-46 [Criminal Code]. | In 2016, Sean Forrester was found guilty on all six counts before the court. The Court concluded that the Crown proved beyond a reasonable doubt that Mr. Forrester was in possession of the medical prescription. It was given to him by Mr. Sinclair on August 30th, 2013. It was given to Mr. Sinclair by Ms. Baks, using a fake patient profile created when she was working at Dr. Sacksen's office. The medical prescription was forged. Mr. Forrester was not a legitimate patient of Dr. Sacksen. The forgery by Ms. Baks had been admitted and she has been found guilty with respect to this forgery. Further, Mr. Forrester knew he was not a patient of Dr. Sacksen, yet he took the prescription into Shopper's for filling knowing that the prescription was forged.<br><br>The Court was satisfied that Mr. Forrester knowingly used this forged document contrary toSection 368(1)(a) of the Criminal Code which provides that: "Everyone commits an offence who knowingly or believing that a document is forged...uses, deals with or acts on it as if it were genuine."<br><br>On Appeal (2019) the Court accepted the submission that there was no evidence to support the appellant's conviction for trafficking on October 30, 2013 given Mr. Sinclair's evidence that he could not recall having received the third batch of fentanyl patches from the appellant. The appeal with respect to the conviction on that count only was quashed and an acquittal was entered. The appeal was dismissed on the other counts. The outcome of this appeal did not alter the appellant's sentence - three years' incarceration, concurrent on all counts. |

| PLEASE COLLECT ONLY RELEVANT CASES ON THE FALSIFICATION OF MEDICAL PRODUCTS OR SIMILAR CRIMES | | |
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| **DATE AND CASE** | **DESCRIPTION** | **RESULT** |
| *R. v. Baks*, 2015 ONCA 560 July 28, 2015<br>*Amended - R. v. Baks*, 20155ONCA 615<br>September 16, 2015 | Based on the same facts and scheme as cited above (*R. v. Forrester);*<br>Ms. Baks participated in a fentanyl trafficking operation, along with a Mr. Godreau and a Mr. Sinclair. The operation involved the traffickingof 990 fentanyl patches of the highest potency of 100 micrograms.<br>Ms. Baks was employed in a physician's office. She created false patient profiles which she inputted into her employer's computer system without the physician's knowledge. She then created false fentanyl prescriptions for the fictitious patients. She gave the prescriptions to Mr. Sinclair. They were passed on by Mr. Sinclair, or more often by Mr. Godreau, to the fake patients, who had the prescriptions filled. The fentanyl patches were given to Mr. Sinclair or Mr. Godreau, who then trafficked them for profit. [Cited in *R. v. Imerovik*, 2019 ONSC 1969]<br>Baks appealed the convictions entered and sentence imposed by theOntario Court of Justice May 16, 2014:<br>**Conviction Appeal**:<br>Acquitted on 2 trafficking counts and two forgery counts were stayed.<br>**Sentence Appeal**:<br>The 9 year sentence was based on a joint submission. The court notes on appeal that this was a serious offence involving a large amount of avery dangerous drug. The appellant played a key role in the somewhatsophisticated scheme that led to the acquisition of the drugs. In doingso, she betrayed the trust of her employer, a doctor in whose name the fraudulent prescriptions were written. The court noted the following mitigating factors that were considered in allowing the appeal and varying the sentence to six years:<br>(1) The appellant is a young person who has no prior criminal recordand no history of criminal involvement; (2) The appellant's rehabilitative prospects are, by any measure, excellent; (3) She actedat the instigation and under some pressure from one of the "higher ups" in the scheme with whom she had a romantic relationship; and (4) The appellant provided early and full cooperation to the police. She gave a statement and testified against the two "higher ups". Oneof those two has since pled guilty. The timely and valuable assistanceprovided by the appellant had to be given significant weight on sentence.<br>The court also references R. v. Sinclair and notes that the co-accused (Sinclair) occupied a higher rung in the criminal enterprise than did the appellant. He recruited her and enlisted her involvement. It was reasonable for the court to lower this sentence than that imposed on the co-accused.<br>It is important to note that the court also references the limited case law available in respect of this drug and the circumstances present in this matter. | The court allocated the total sentence of **6 years**<br>among the various convictions:<br>On the **one count of trafficking in Oxycodone**: **3years;**<br>On the **twenty counts of trafficking in Fentanyl:5 years** concurrent to each other and to the sentence on count 1;<br>On the remaining **forgery charges**, **1 year on eachcount concurrent to each other, but consecutive to the sentences imposed on trafficking charges with 4 ½ months' credit for presentence custody, leaving a net sentence of 7 ½ months on the forgery charges**. |

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| **DATE AND CASE** | **DESCRIPTION** | **RESULT** |
| *R. v. Sinclair*, 2016 ONCA 683September 13, 2016 | *Based on the facts/scheme cited above (R. v. Forrester; R. v. Baks), Mr. Sinclair appealed his sentence of nine years based on the court's decision in R.v. Baks, 2015 ONCA 560, which reduced the sentence of the appellant's co-accused from nine to six years. The court agreed with the core of the appellant's submission. "The parity between Ms. Baks and the appellant (Sinclair) was at the heart of the appellant's nine-year sentence based on a joint submission." This court reduced Ms. Baks' sentence by three years because of a constellation of four "powerful mitigating factors". The court viewed that two of those factors applied to the appellant. The court notes that although the appellant did not co-operate with the authorities as early as Ms. Baks, his co-operation, notably by testifying against the kingpin of the criminal enterprise, was ultimately full and important.* | 9 Year Sentence reduced to **8 years** |
| *R. v. Godreau,* 2016 ONSC6318<br>October 12, 2016 | Based on the facts/scheme cited above (*R. v. Forrester; R. v. Baks; R. v.Sinclair)*, Mr. Godreau was sentenced after a trial to 10 years in federalpenitentiary. The trial judge relied on the sentences arrived at by the Court of Appeal for Ms. Baks and Mr. Sinclair. He noted the absence of mitigating factors and the fact that Mr. Godreau had a prior criminalrecord for drug trafficking. The court also noted that the evidence at trial established that the Defendant Godreau, if not the kingpin of the scheme, was every bit an equal participant in every aspect of the scheme: the fraudulent securing and conveying of health card information, the distribution of false prescriptions and the trafficking in Fentanyl for profit. | Sentenced to **10 years**<br>Convicted on all 15 counts on the indictment before the court:<br>▶ five counts of trafficking in the controlledsubstance Fentanyl;<br>▶ five counts of knowingly making a falsedocument; and<br>▶ five counts of knowingly using or utteringa forged document. |

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| **DATE AND CASE** | **DESCRIPTION** | **RESULT** |
| May 2005<br>King West Pharmacy, AbadirNasr<br>Hamilton, Ontario | According to the RCMP, for the first time in Canada, a pharmacist wascharged with dispensing counterfeit medical drugs to patients. Pfizer contacted the RCMP about this matter in May 2005.<br>Hamilton, Ontario, pharmacist Abadir Nasr, 28, was accused of dispensing fake Norvasc -- a medication used to treat high blood pressure and angina – following a complaint by a Victim who discovered her medication did not look right. Pfizer confirmed one ofthe pills sent to them was counterfeit and another was meant for distribution in Turkey. This prompted an investigation by the regionalcoroner of the deaths of individuals who filled prescriptions for Norvasc at this pharmacy. Nasr was charged with possession of property obtained by crime and fraud under $5,000. He was also charged with passing off with respect to the supply of Unapproved Norvasc and Counterfeit Norvasc.<br>Abadir Nasr initially stated that he bought the pills from an "unknown source, unknown friend" as testified by the Former Owner of the pharmacy who asked Nasr about the medication. Nasr submitted a sworn statement to which he stated that he never knowingly sold medication that is not licensed for sale in Canada and/or that was Counterfeit. He further submitted that he bought ten bottles from a Mr. Ali Hussein who identified himself as a wholesaler from Vancouver. Hussein advised Nasr he was from Pfizer and he noticed round pills in the first batch that he purchased, however when he called Pfizer (as a patient) he did not get a call back and dispensed the round pills. Nasr stated that when he noticed the pills in May were a "little darker" he had a feeling something was wrong and threw the pills out in a dumpster (to which non-legitimate Norvasc was found). Several witnesses (patients and partners of patients) testified to the numerous instances of discussion with Nasr regarding the differences in the colour and shape of the Norvasc dispensed. The Court noted the "significant" gap in the regulatory provisions concerning the sale and purchase of pharmaceuticals in its decision. The court also considered the credible evidence that pharmaceutical companies occasionally change the shape and/or colour of their pills – the court could not reasonably conclude that the changes in shape and colour demanded further inquiry by Nasr. The court concluded that there as at least a reasonable doubt that Nasr's actions / reactions were a product of negligence and/or lack of competence and was found not guilty on all counts.<br>**Additional Drug/Patient Details upon further Investigation**:<br>Approximately 44 patients had counterfeit Norvasc on hand. The drugscontained **talc** and no active medicinal ingredients.<br>Another 15 patients were given Norvasc manufactured by Pfizer, butspecifically for Egyptian and Mexican markets and not authorized forsale in Canada. 2 patients had Norvasc intended for the Turkish market. | *In the criminal case, Abadir Nasr was found not guilty of selling counterfeit Norvasc. The judge ruled that although the drug was counterfeit and contained no medicinal ingredients the Crown failed to prove that the accused knowingly sold counterfeit drugs.*<br>*On September 6, 2007, the Ontario College of Pharmacists found Mr. Nasr guilty of professional misconduct in his capacity as a dispensing pharmacist and as the owner and designated manager of the pharmacy. They ruled that Nasr could get his licence back after a one-year suspension as long as he underwent a public reprimand, paid $12,500 in costs to the college and took remedial training. His duties were restricted for an additional five years, including that he does not own a pharmacy and not be responsible for the acquisition of drugs at a pharmacy or work in a drugstore owned by a family member.* |

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| **DATE AND CASE** | **DESCRIPTION** | **RESULT** |
| September 2005<br>Richmond Hill Pharmacist, Ontario, AndrewSommerhalder | The RCMP executed search warrants on two pharmacies (one online) after a 6-month investigation stemming from a discovery by the Canada Border Services Agency (Customs) of two shipments of counterfeit Viagra tablets. The tablets contained significantly less of the drug's active ingredient, which Pfizer confirmed through testing. | Andrew Sommerhalder was charged with 11 offences under the Criminal Code, the Food and Drugs Act, and the Customs Act. for allegedly selling and distributing counterfeit Viagra at his two pharmacies (also distributed through the internet).<br>The Ontario College of Pharmacists shut down Direct Compounding, the online pharmacy which sold drugs over the Internet, and ordered Mr.<br>Sommerhalder to step down as manager of Optimum Compounding, the storefront outlet. |

**CYPRUS** No submission has been received on case law from the national consultant

**CZECH REPUBLIC** No submission has been received on case law from the national consultant

**ECUADOR** (prepared by the national consultant Ms María Fernanda ROMÁN FERRAND)

| PLEASE COLLECT ONLY RELEVANT CASES ON THE FALSIFICATION OF MEDICAL PRODUCTS OR SIMILAR CRIMES | | |
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| **DATE AND CASE** | **DESCRIPTION** | **RESULT** |
| Date: 02/12/2015,<br>Case: "OPERATIVO FARMACO I",<br>Country: Ecuador<br>Place: Cities Quito, Guayaquil and Santo Domingo de los Tshachilas | By means of an investigation carried out by the Judicial Police (UDAT), in response to an anonymous complaint, for more than 3 months, Operation "Farmaco I" was carried out in three cities in Ecuador: Quito, Santo Domingo de los Tsachilas and Guayaquil, in the City of Quito, a rudimentary labotarium is raided where a great amount of falsified medicines is found, and machinery for its elaboration, in this place two people are detained, In the city of Santo Domingo de los Tsachilas, there is a building where a large number of counterfeit tablets were dried to the environment with the name of Lipitor de Pfyzer and Arcoxia of Merck Sharp and Dome and in the city of Guayaquil, a building with a number of expired medicines.<br>    <br>In the following days, an inter-institutional meeting was convened, in which the Ministry of Public Health, the Public Prosecutor's Office, the Judicial Police, the Criminal Investigation Department, the Health Regulation Agency, Maria Fernanda Roman as an expert and representatives of the affected pharmaceutical companies participated, where the steps to be taken were decided: request of original products to the companies Pfyzer and Merck Sharp and Dome, requests of expert reports of recognition of place and documentary to criminalistics, chemical analysis of the tablet to the laboratory of the Central University of Ecuador and an analysis of the machinery found to an expert of the Judiciary Council, which marks the beginning of a criminal trial for falsification of medicines with the article 217 in force at that time. | Successfully, the dismantling of a gang dedicated to the production and marketing of counterfeit medicines in the city of Quito, where about 3 million doses were seized, among them, ARCOXIA, LIPITOR and G00, in a clandestine laboratory in the city of Quito, 3 people were arrested and the Fiscal Instruction was initiated, in which the following advice was given to the Prosecutor during the months of the instruction: Articulation with authorities from the Ministry of Health, ARCSA, National Police, Ministry of the Interior, Judicial Police (UDAT), Criminalistics; definition of experts and surveyors, identification of laboratories and study techniques for testing, among others.<br>With the support of institutions such as Criminalistics, Judicial Police (UDAT), and the Universidad Central del Ecuador, they allowed the first sentence in Ecuador to be issued in May 2016 for counterfeit medicines to one of the detainees, who is now under the so-called abbreviated procedure of the Integral Criminal Organic Code, granting him a 12-month sentence.<br>In November 2016, during the trial stage, the second detainee was sentenced to 6 years and 8 months.<br>**Results:**<br>3 detainees<br>7 break-ins<br>1 seized vehicle<br>3 million counterfeit medicines seized<br>2 sentenced |

| PLEASE COLLECT ONLY RELEVANT CASES ON THE FALSIFICATION OF MEDICAL PRODUCTS OR SIMILAR CRIMES | | |
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| **DATE AND CASE** | **DESCRIPTION** | **RESULT** |
| Date: 05/04/2016<br>Case: "OPERATIVO FARMACO II",<br>Country: Ecuador<br>Place: Cuenca City | The Judicial Police (UDAT), Unit of tax and customs crimes of the Judicial Police, through an investigation of more than 6 months, which begins with the report of the agency of regulation and Sanitary Control that lasts approximately 6 months. The UDAT achieves successfully, the dismantling of a gang dedicated to the production and commercialization of counterfeit medicines in the city of Cuenca, where medicines like MABTHERA and AVASTIN of ROCHE and MERONEM of ASTRAZENECA, among others, inside a laboratory and in a distributor in the city of Cuenca, 5 people were detained and the Fiscal Instruction is initiated, samples of the medicines seized in the chain of custody are sent to the city of Quito, to make the documental analysis in Criminalistic, who present a report where it is confirmed that the containers, labels and packages, are falsified.<br><br>Despite this, a report of the chemical analysis of the substance is requested, sending the sample to the headquarters of the ROCHE Pharmaceutical Laboratory, who confirm the presence of the active ingredient, which makes it difficult to process the case.<br><br>  <br><br>According to the investigations, the drug was diluted to obtain more product, that is to say from an original bottle, they made 3 counterfeit products. | **The case is closed and there is no sentence for those involved**, it should be noted that in this case there was no participation of the pharmaceutical companies concerned. |

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| **DATE AND CASE** | **DESCRIPTION** | **RESULT** |
| Date: 25/06/2017<br><br>Case: «OPERATIVO FARMACO IV - FORTALEZA 23»,<br><br>Country: Ecuador<br><br>Place: Cities Cuenca, Loja, Machala | As a result of a complaint by the Health Regulation and Control Agency, which indicates that in subsequent controls carried out in pharmacies in the provinces of Azuay, Loja, El Oro, Morona Santiago and Cañar, medicines of dubious origin were found, which did not comply with the characteristics of a duly registered medicine, which causes the control agency to take a long time, and an investigation lasting approximately 4 months is initiated. On July 25, 2017, in the operation "Drug IV", in which the Intervention and Rescue Group (GIR) of the National Police, the Judicial Police, the Prosecutor's Office and the Customs and Tax Crimes Unit participated, nearly 18 tons of allegedly counterfeit medicines were seized, which were distributed and sold through pharmacies and other points of sale in the provinces of the Ecuadorian south territory (Azuay, El Oro, Morona Santiago, Loja and Cañar).<br><br>The Mediveza case is the most important case in Ecuador's history related to alleged counterfeit medicines and one of the most relevant in Latin America. The accusation is based on Article 217 of the Criminal Code in force at the time, which criminalizes for the first time the counterfeiting of medicines in Ecuadorian territory. The judges of the Court of Criminal Guarantees of Cuenca will issue a sentence on Tuesday, January 8, 2019, starting at 4:00 p.m.<br><br>The Ministry of Public Health and the Agency for Regulation, Control and Sanitary - ARCSA, continue to be vigilant in the processes of importing, manufacturing, storing and commercializing products for human use and consumption. In this way, we guarantee access to safe medicines for the entire population.<br><br>According to the Prosecutor's Office, this is the largest case of counterfeit medicines in South America.<br><br>    | The Court of Penal Guarantees of Cuenca dictates in first instance five years of prison against Andrés V., manager of the company, for an alleged case of falsification and commercialization of medicines without sanitary registration for human use and consumption.<br><br>In the first instance, the Court of Criminal Guarantees of Azuay only found Marcelo V. guilty and acquitted María T., considering that she was not aware of the activities, a decision that was appealed by the Public Prosecutor's Office and the lawyers of the Ministry of Public Health (MSP) who acted as private prosecutors.<br><br>Those involved in the largest case of counterfeiting and distribution of medicines in the history of Ecuador were found guilty in the second instance.<br><br>Marcelo V. and Maria T., manager and president of MEDIVESA, were ratified with a five-year prison sentence for being the alleged perpetrators of this crime.<br><br>The reinstatement of the appeal hearing took place in the Court of Justice of Azuay and was conducted by the court composed of judges Julio Inga (speaker), Narcisa Ramos and Jenny Ochoa. Before giving their verdict, the judges presented their considerations to determine that the materiality of the crime and the participation of the defendants did exist.<br><br>After an analysis, the judges unanimously considered that Marcelo V. and María T. did indeed comply with the verbs included in crime inside the Article 217 of the Integral Criminal Organic Code , which condemns anyone who "imports, produces, manufactures, markets, distributes, or expands counterfeit medicines or medical devices.<br><br>The judges also determined that the drugs must be destroyed.<br><br>**Results:**<br>9 detainees<br>17 break-ins<br>6 vehicles seized<br>18 tons of seized illegal medicines<br><br>2 sentenced with the maximum penalty |

**ESTONIA** (prepared by the national consultant Dr Kärt PORMEISTER)

| PLEASE COLLECT ONLY RELEVANT CASES ON THE FALSIFICATION OF MEDICAL PRODUCTS OR SIMILAR CRIMES | | |
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| **DATE AND CASE** | **DESCRIPTION** | **RESULT** |
| 09.09.2011 Harju County Court case nr 1-11-9523 | E.N. was accused of ordering medicinal products from Taiwan and India that infringed upon IP rights of Pfizer inc, and by doing so E.N. was accused of importing and distributing counterfeit medicinal products without proper documentation (or by using counterfeit documentation). | E.N. was sentenced to 3 years of imprisonment with a probationary period of 3 years so in case there was no violation of the probation, E.N. would not have to serve any prison time. |
| 05.09.2013 Pärnu County Court case nr 1-13-6140 | R.V. was accused of illegally producing counterfeit medicinal products and selling them.<br>J.K. was accused of buying and brokering these counterfeit medicinal products | Both R.V. and J.K. were sentenced to 1 year of imprisonment.<br>R.V. was given a probationary period of 3 years so in case there was no violation of the probation, R.V. would not have to serve any prison time.<br>For J.K., the prison sentence was substituted with 730 hours of community service. |
| 05.01.2015 Pärnu County Court case nr 1-14-10149 | E.L. was accused of illegally obtaining from an unidentified person at least 162,1 grams of herbal crumbles that contained synthetic cannabinoids. E.L. mixed this with peppermint tea at home and packaged it for purposes of selling it. E.L. was accused of illegally manufacturing, distributing and possession with intent to distribute counterfeit medicinal products. | E.L. entered a plea deal and was sentenced with a fine of 800 euros. |
| 22.04.2015 Harju County Court case nr 1-15-2475 | R.D. was accused of ordering from residents of Hungary (but also from unidentified individuals elsewhere) counterfeit potency drugs (illegally manufactured), which he imported to Estonia without authorisation. | R.D. was sentenced with a fine of 6277,85 euros, but with a probationary period of 2 years 6 months so that in case there would be no violation during the probation period, R.D. would not have to pay this fine. |
| 08.09.2015 Tartu County Court case nr 1-15-1856 | P.N. was accused of importing counterfeit medicinal products which he had ordered via mail from Hongkong. | P.N. was sentenced to 1 year of imprisonment with a probationary period of 1 year 6 months so that in case of no violations of the probation P.N. would not have to serve this sentence.<br>P.N. was also ordered to pay 15,000 euros to the government on account of earnings made via the crime committed. |

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| 06.07.2016 Harju County Court case nr 1-16-5543 | Amongst other offenses, Y.S. was accused of obtaining and possession with the intent to distribute of counterfeit medicinal products (Cialis, Viagra, Zenegra, Kamagra, Kamagra Oral Jelly). | Y.S. entered a plea deal for a 2-year sentence, with a probationary period of 3 years so in case of no violation, Y.S. would not have to serve any time. |
| 22.01.2014 Tartu County Court case nr 3-12-975 | This case concerned a dispute over Dolo-Angin tablets and the decision of the State Agency of Medicines to classify them as a medicinal product. The product had been registered in Estonia as a medical device and had undergone conformity assessment in Luxembourg and had received a CE mark. Regardless of this, the State Agency of Medicines decided to classify the product as a medicinal product (which triggered various obligations, limitations and requirements that apply to medicinal products, but not medical devices). The European Court of Justice found in case C-109/12 that in order to classify as a medicinal product in accordance with Directive 2001/83 a product already classified in another Member State as a medical device bearing a CE marking in accordance with Directive 93/42, the competent authorities of a Member State must, before applying the classification procedure under Directive 2001/83, apply the procedure under Article 18 of Directive 93/42 and, where appropriate, the procedure under Article 8 of Directive 93/42. | The Tartu County Court repealed the decision of the State Agency of Medicines regarding the classification of the product as a medicinal product.<br>Although this case does not concern counterfeit medical products *per se*, marketing a medicinal product as a medical device might be deemed to fall under the definition of counterfeit medical products within the meaning of the Medicrime convention (false representation as regards identity). |

**FINLAND** (prepared by the national consultant Ms Anna-Riikka RUUTH)

| PLEASE COLLECT ONLY RELEVANT CASES ON THE FALSIFICATION OF MEDICAL PRODUCTS OR SIMILAR CRIMES | | |
|---|---|---|
| **DATE AND CASE** | **DESCRIPTION** | **RESULT** |
| YEAR 2019, "CASE HERTTA" | Year 2019 the Narcotics Unit of the Police Department of Helsinki investigated an aggravated narcotics offence. A group of Romanians imported several times Rivotril-tablets to Finland and distributed them in Helsinki area. Rivotril-tablets contained clonatzepam which is classified as narcotics in Finland. In medical use the common and similar tablet in Finland is Rivatril 2 mg.<br><br>After the last import in May 2019 the police seized 307.600 Rivotril-tablets. A large number of tablets were sold in street markets in Helsinki after the previous imports. The accused had started their journey from Romania, and driven to Budapest, Hungary to get the tablets. The import took place in Tornio, Finland where the accused had crossed the boarder of Sweden and Finland. The accused had two cars, one in Finnish license plates and another in Romanian plates. The tablets were hidden in the car with Finnish license plates because most likely the car with Romanian license plates would catch the attention of the boarder guards.<br><br>These tablets have not been legally manufactured by a legal pharmaceutical enterprise but the content is equal to the real clonatzepam tablets.<br><br>Smuggling of Rivotril-tablets to Finland is ongoing international organized crime that is derived from Romania. Smuggling of these tablets is a very good business because the smugglers pay 3-4 euros per 100 tablets and the price for 100 tablets in Finland is 70-100 euros. | Four people were convicted for four aggravated narcotics offense for imprisonment, three of them for six years six months and one for five years.<br><br>The police have also found out where the illegal manufacturer of the tablets is in Hungary. |
| YEAR 2018-2020 "OP HUNAJA" (ongoing investigation) | Finnish Customs is investigating a case where large amounts of falsified potency tablets were imported from third country to European Union although according to the documents, they should have been goods in transit on their way to Federation of Russia. In all the individual cases the transit is suspected of being used in criminal activities aiming to get the tablets out of customs control and placing them on the illegal market in Central Europe. The tablets were shipped to Finland from a third country, placed to a warehouse in Finland for indefinite period of time, then possibly transferred to another EU country and then back to Finland before they were shipped to some Central European country. Using several warehouses and sending the goods between the EU countries the suspects were trying to fade the origin of the tablets (third country) and to make it look like the tablets were originally from an EU country. At the end no tablets have been declared in Russia and the tablets have ended to other European Union countries or seized in Finland.<br><br>Customs has several suspects in Finland and the Finnish authorities have cooperated with other EU countries in this matter. The amount of illegal potency tablets is hundreds of kilos / hundreds of thousands of tablets. | The investigation is still ongoing. Finnish Customs has seized two batches of tablets and the Belgium Customs one based on information exchange and one for their own observation. |

**GERMANY** (prepared by the national consultant Mr Alexander ROTH)

| PLEASE COLLECT ONLY RELEVANT CASES ON THE FALSIFICATION OF MEDICAL PRODUCTS OR SIMILAR CRIMES | | |
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| **DATE AND CASE** | **DESCRIPTION** | **RESULT** |
| "Pillendienst Case" (a.k.a "Männerapotheke" or "Potsdam Case"), 2011 | Investigation and prosecution against a large-scale network of an international criminal organisation that distributed counterfeit Viagra and other lifestyle medicines, mainly in Germany and Austria. The activity of the organisation was 2008 to 2011, when it was smashed by a law enforcement operation in several countries. Leading law enforcement agencies was the Potsdam Prosecutor's Office and Zollfahndungsamt Berlin-Brandenburg (regional unit of ZKA, i.e. the German Custom's Police). No JIT, but international judicial and police cooperation with around 20 other countries. | Around 12 suspects arrested. Around 2 million euro confiscated. Around 100 members of the criminal organisation (including all major members) prosecuted, trialled and sentenced; primarily for commercial-style and organized trade in counterfeit medicines. Of the 4 leaders of the criminal organisation, 1 was sentenced to 6 years and 3 months and another one to 5 years and 4 months imprisonment. The third one was sentenced similarly in Austria. The fourth one committed suicide in prison before being brought to trial, after trying to escape from Romania to Moldova and being arrested by Romanian police and transferred to Germany on the basis of an EAW. Most other members were sentenced to prison terms on probation and/or a fine and/or confiscation of goods. The members with a minor significance within the criminal organistion usually paid (instead of being formally sentenced) an amount of money in favour of the state and/or non-profit organisations, and in return the criminal proceedings were discontinued. Last trials and convictions were as late as 2016/2017. |
| Lunapharm Case, 2017/2018 | Investigation and prosecution against, basically, a German company distributing a high-price medicine against cancer. There was evidence for manipulating the legal supply chain; probably the medicine was stolen in Greece and later re-introduced into the legal supply chain in Germany. Possibly, the medicine lost its effects due to an interruption of the cold chain. The huge affair caused major media interest and political scandal, since it could not be excluded (but also not proved) that a large number of cancer patients was treated in Germany with an ineffective (spoiled) medicine. | Around 1 million euro criminal profits freezed, 3 main supects brought to trial in 2019 for "organized and commercial-style trade in counterfeit medicines". The trial has not yet started due to capacity overload of the competent court. |
| Landgericht (Regional Court) Essen, verdict of 6th July 2018 (cited in the Law journal: "NJW", 2020, page 3123) | A pharmacist was producing medicines against cancer on an individual basis. In around 15.000 cases, he used either no active component, or a too small dose of the active component (in order to make more profit) | 12 years imprisonment (for fraud and breach of the AMG) and 17 million euro confiscation.<br>Note: it is not mentioned in the journal for which exact crime the pharmacist was convicted, but I guess for "commercial-style trade with counterfeit medicines" (and fraud) |

| PLEASE COLLECT ONLY RELEVANT CASES ON THE FALSIFICATION OF MEDICAL PRODUCTS OR SIMILAR CRIMES | | |
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| **DATE AND CASE** | **DESCRIPTION** | **RESULT** |
| Landgericht (Regional Court) Krefeld, verdict of 27th October 2017 (cited in the Law Journal PharmR 2019, p. 654) | A man was selling, via the internet, disinfectants (containing/producing hydrochloric acid) as "Medicine" (for oral application). | Three years and two months imprisonment for "negligent trade in questionable medicines" and tax evasion and other crimes.<br><br>The prosecutor's office filed an appeal to the Federal Court of Justice because the defendant was not convicted for intentional trade in questionable medicines. The appeal was rejected, because according to the Federal Court, the regional court believed rightly that the defendant was convinced (wrongly, but he was convinced) that, even if the use of a disinfectant as a medicine is against all standards of medicine "the positive effects outweighed the negative effects".<br><br>Note 1: The decision of the Federal Court of Justice is obviously wrong and was criticized.<br><br>Note 2: Commercializing "questionable" medicines (and medical devices) is another crime (besides counterfeit-related crimes) in AMG and MPG. Questionable means that the negative side effects outweigh the positive effects of the medicine/device. |

## Document B Appendix

**Germany – Case Law – Medical Devices**

### I. Introduction

From my own professional practice, I know that in quite some cases, investigations are conducted in Germany for offences under the Medicinal Products Act (AMG). There are also not many, but a few prominent cases in which offences under the Medicinal Products Act become known either through the general media or through the specialised legal press or verdict databases.

In contrast, I was not aware of a single investigation in the area of offences under the Medical Devices Act (MPG). I was also unable to find a judgement in this area via the specialised press and the relevant databases.

I therefore asked all German General public prosecutors' offices how many and which preliminary proceedings for offences under the MPG were pending there in the years 2016 to 2020 and what the outcome of these proceedings was.

The following preliminary remarks are necessary:

The MPG (still valid until May 2021) does not include the criminal offence of manufacturing or trafficking in counterfeit medical devices. However, it does contain other offences relating to medical devices in § 40, § 41 e.g. placing objectively dangerous medical devices on the market or distributing medical devices without CE marking. It was therefore to be expected that at least some proceedings for offences under § 40 or § 41 MPG would be found.

The German public prosecutors' offices or General public prosecutors' offices work with two different software systems for case management, which are also used for statistical data. Both software programmes have in common that each investigation case is recorded, usually, with only one "leading" offence. For example, if a seller sells a counterfeit medical device as genuine, fraud may possibly have been committed by the same act, but also an offence under trademark law (infringement of intellectual property) and an offence under the MPG (placing dangerous medical devices on the market). However, only one offence is entered into the case management programme. This is usually the offence with the highest penalty. Since the penalties under the MPG are rather low (this will change with the future MPDG), it is possible that these investigative procedures "disappear" in the statistics.

I therefore also asked the Prosecutors General, if possible, to ask the prosecutors in their district whether they individually remembered certain investigation proceedings in this area. If this was the case, these cases also will figure under II.

## II. Results of the Survey

The survey had the following result (sorted by federal state):

1. Baden-Württemberg

In Baden-Württemberg, a total of 44 preliminary proceedings were pending from 2016 to 2020.

In 8 of these 44 cases, charges were brought and the accused were sentenced to fines. Seven of these 8 cases concerned the incorrect disinfection of equipment by doctors or dentists. In some cases the sentences have already become final, in others the defendants have appealed.

In the eighth case, a very high fine was imposed (the exact amount was not reported) because the defendant, as the owner of a company, distributed products for performing colonic irrigation that were not CE-certified. The sentence is not final because the accused has appealed.

In the other cases, the proceedings are open (investigations are ongoing) or the proceedings have been discontinued for various reasons (e.g. no sufficient suspicion or insignificance).

2 Bavaria

Only 13 cases are reported from Bavaria between 2016 and 2020.

In this context, the Munich Public Prosecutor's Office mentions a very interesting case that is being conducted at the Traunstein Public Prosecutor's Office. Here, the two accused are accused of having sold test strips for testing blood sugar as "original goods" to German pharmacies, although these test strips were repackaged, re-imported and no longer fresh. A correct measurement result was no longer guaranteed. Unfortunately, the Munich General Prosecutor's Office has not indicated whether the proceedings have already been concluded, whether charges have been brought and what the verdict is.

Most of the other proceedings have been discontinued for various reasons or are still open.

3 Berlin

The Berlin Public Prosecutor's Office reports 22 preliminary proceedings. However, charges were brought and a verdict reached in only 2 cases (in both cases fines). Details have not been reported.

4 Brandenburg

In Brandenburg, three preliminary proceedings were pending. No charges were brought in any of these three cases.

5 Bremen

No cases are reported.

6 Hamburg

One case is reported for the period 2016 to 2020. The owner of a company sold medical devices without valid CE marking in 26 cases in 2018. Charges have been brought to court, but no verdict is yet available.

7. Hesse

In Hesse, a total of 24 investigations or criminal charges under the MPG were pending from 2016 to 2020. 6 proceedings are still open. The other proceedings were handed over to other public prosecutors' offices, or discontinued for various reasons. No charges have been brought so far.

8 Mecklenburg-Western Pomerania

Two investigations are reported from Mecklenburg-Western Pomerania, but no charges were brought and no convictions were handed down in any of the cases.

9. Lower Saxony

From Lower Saxony, data were only reported by individual public prosecutor's offices. As a rule, there were no proceedings at these public prosecutor's offices, but in any case no convictions.

10 North Rhine-Westphalia

North Rhine-Westphalia did not respond.

11. Rhineland-Palatinate

In Rhineland-Palatinate, three preliminary investigations were pending in 2016 to 2020. Two were discontinued due to insignificance. In the third case, the act was not classified as a criminal offence but as an administrative offence (and the case was therefore handed over to the administrative authority).

12 Saarland

No proceedings were pending during this period.

13 Saxony

Saxony did not reply.

14 Saxony-Anhalt

There were three proceedings, one of which was transferred to another Land. Two are still pending.

15 Schleswig-Holstein

Although Schleswig-Holstein is a rather small Land, it had the highest number of proceedings in the given period, namely 70. As can be seen from the answer of the Attorney General's Office of Schleswig-Holstein, the reason for this seems to be that the competent administrative authorities of Schleswig-Holstein carry out an above-average number of inspections, e.g. at hospitals, doctors and dentists, where they check the medical devices very closely. If the devices do not have proper CE marking, are not hygienically cleaned, etc., charges are filed with the public prosecutor's office for criminal offences under the MPG. Such precise controls are apparently not common in other federal states.

Seven cases have been dropped due to insignificance.

Eight cases have been dropped without formal charges against payment of a sum of money to the public purse or to a charitable institution or against the performance of hours of work.

In two cases, charges have been brought before the court. During the trial, however, the court, the defendant and the public prosecutor agreed to terminate the proceedings without a formal verdict against payment of a sum of money to the public treasury or a charitable institution.

In four cases (all for use of improperly disinfected equipment by doctors or dentists), there were sentences of fines (between 2000 euros and 4000 euros) plus confiscation of the equipment. Three sentences are final. In the fourth case, the accused has appealed.

16 Thuringia

Two preliminary proceedings are reported from Thuringia. In one case, a medical device with an incorrect CE marking was sold to Germany from the Czech Republic. The court imposed a fine of 1500 euros. This became legally binding.

## III. Some Conclusions

In Germany, very few preliminary proceedings are conducted overall for criminal offences under the Medical Devices Act.

As the example of Schleswig-Holstein (small federal state, very high number of proceedings, almost all based on criminal charges filed by the surveillance authorities) shows, this could (among other things) be due to the fact that the surveillance authorities (in the other federal states) do not cooperate optimally with the public prosecutors (or the police), i.e. they do not pass on their findings to the law enforcement authorities.

In most cases where investigations are conducted, charges (indictments) are not brought to court and a verdict is reached.

This could be due (among other things) to the fact that the threatened penalties under the current law are low. If only a very low penalty is threatened anyway, then the public prosecutor's office will often drop the case on grounds of insignificance. The trouble of bringing charges and conducting a trial in court is "not worth it".

**GEORGIA** (prepared by the national consultant Ms Nino AGLEMASHVILI)

| PLEASE COLLECT ONLY RELEVANT CASES ON THE FALSIFICATION OF MEDICAL PRODUCTS OR SIMILAR CRIMES | | |
|---|---|---|
| **DATE AND CASE** | **DESCRIPTION** | **RESULT** |
| 15.12.2017<br>Case №092191017006 | Criminal case into the crime committed on December 15, 2017, in the name of BIOPLIUSI LLC.<br>Investigation revealed that Archil Beradze, Manager of BIOPLIUSI LLC, organized the purchase of falsified medicine (3,520 bpackages) labeled as "Actimax". BIOPLIUSI LLC was supposed to sell the medicine, but the law-enforcement agencies prevented the crime before it was committed. | Manager of the company was charged under Articles 19, 1971 of the Criminal Code of Georgia (attempt to sell a falsified/ forged item knowingly). Under the final decision of the court, the defendant was sentenced to a fine in the amount of GEL 3,000 (three thousand) and the conditional sentence – imprisonment for a term of 2 (two) years and probation for a term of 2 (two) years.<br>Note: Law-enforcement agencies were unable to bring charges against the company, because Article 1971 of the Criminal Code does not provide for the criminal liability of legal entities (please, see document A1, comments to paragraphs 11.1 and 11.2). |
| 04.07.2018<br>N092030818001 | Zviad Grigalashvili, Director of TEST WHOLESALE LLC, with the help of Publishing House Grifoni LLC, manufactured 6,442 units of JSC KEDRION trademark boxes (verbal part of the trademark – "KEDRION") and marked the boxes with the registration number #24280/3 issued by the Georgian National Intellectual Property Center – SAKPATENTI. Furthermore, he used the forged trademark boxes mentioned above for packaging the falsified medicine "EMOCLOT" and on August 2, 2018, put the falsified medicines marked as "EMOCLOT" (with the total value of GEL 523,798.8) in export commodity operation under the customs declaration NC21022/11114. | The defendant was charged under Article 196 (illegal use of trademark) and Articles 19, 214 (attempt to transport goods over the border by entering false data in customs declaration) of the Criminal Code. Under the court decision, the defendant was sentenced to a fine in the amount of GEL 5,000 (five thousand). |

**GREECE** No submission has been received on case law from the national consultant

**GUINEA** (prepared by the national consultant Mr Abdoulaye KPOGOMOU)

| PLEASE COLLECT ONLY RELEVANT CASES ON THE FALSIFICATION OF MEDICAL PRODUCTS OR SIMILAR CRIMES | | |
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| **DATE AND CASE** | **DESCRIPTION** | **RESULT** |
| 02 January 2019<br>Reference: RP<br>No. 001/2019 | Mr Bangaly Traoré, a trader by profession, was arrested with a truck loaded with counterfeit pharmaceutical products from the Federal Republic of Nigeria.<br>He was about to move the goods into the country.<br>He was therefore arrested by the MEDICRIME Brigade and the load was seized and placed under the control of the courts.<br>He was questioned and brought before the prosecutor at Mafanco court of first instance. | Direct summons proceedings were initiated by the prosecution.<br>The case is still pending before the criminal court, which has already considered the case and debated it in several hearings |

**ICELAND** No submission has been received on case law from the national consultant

**IRELAND** (prepared by the national consultant Mr Brian GAGEBY)

| PLEASE COLLECT ONLY RELEVANT CASES ON THE FALSIFICATION OF MEDICAL PRODUCTS OR SIMILAR CRIMES | | |
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| **DATE AND CASE** | **DESCRIPTION** | **RESULT** |
| 22 June 2018, Dublin Metropolitan District Court, Court of First<br>Instance. Common Law jurisdiction<br>HPRA v. Taj Accura Pharmaceuticals<br>Ltd; and two named persons | T aj Accura Pharmaceuticals Ltd ('Taj Accura') was a pharmaceutical wholesale company registered company in Ireland. It was related to Taj Pharmaceuticals Ltd, a company registered in India, which held itself out as a supplier of oncology-indicated medicines. Taj Accura held itself out as being responsible for the sales and marketing of Taj Pharmaceuticals Ltd.<br>Following the receipt of a request for assistance from the Israeli Ministry of Health on 29 February 2016, the Irish Health Products Regulatory Authority (HPRA) launched an investigation into the dealings of Taj Accura between June 2015 and April 2016.<br>The HPRA laid a number of charges against Taj Accura,(Defendant 1, one of its directors, Defendant 2 who acted as the sales and marketing director, and a shadow director, Defendant 3 who held himself out as the Chief Executive and Chairman. These charges were laid under the<br>- Medicinal Products (Control of Wholesale Distribution) Regulations 2007, Regulation 14B (sale and supply by wholesale of 100,000 ampoules of Fluorouracil 50 Injection 250mg to Iran in circumstances where the defendants knew or there were sufficient grounds to suspect that it was a falsified medicinal product);<br>- Medicinal Products (Control of Manufacture) Regulations 2007, regulation 14B (1) (importation into Ireland from outside the EEA where the importation documentation contained the Customs declarations that Ireland was the final country of destination, of Afhlan (Melphalan Injection USP 50mg), the in circumstances where the defendants knew or there were sufficient grounds to suspect that it was a falsified medicinal product (instead relabelled the consignment of Afhlan and exported to Kuwait whilst listing Ireland as the country of origin and Kuwait as the country of destination;<br>- Medicinal Products (Control of Wholesale Distribution) Regulations 2007, Regulation 14B (sale by wholesale of Afhlan (Melphalan Injection USP 50mg) to a UK company claiming the manufacturer to be a UK licensed pharmaceutical manufacturing company on behalf of Taj Accura whilst knowing that this was untrue and in circumstances where the defendants knew or there were sufficient grounds to suspect that it was a falsified medicinal product);<br>- Medicinal Products (Control of Wholesale Distribution) Regulations 2007, Regulation, Reg 39(c) (introduction into Ireland of Afhlan (Melphalan Injection USP 50mg) in circumstances where the defendants knew or there were sufficient grounds to suspect that it was a falsified medicinal product | On 22 June 2018, convictions were recorded against each of the three accused for these charges and the remaining charges were struck out by consent. The three accused were ordered to pay fine of EUR 1000 each. The judge sentenced each defendant to a fine of EUR 1000. In giving such a sentence, the court took into account a number of mitigating factors. These included the fact that this was the first offence for each of the three accused, that there was a low probability of reoffending, that there was a loss of professional standing for both Defendants 2 and 3, a commitment had been made to the court that Taj Accura would no longer trade, and that commitments had been made by Defendants 2 and 3 that they would no longer engage in any business regarding health products regulated by the HPRA. Furthermore, the fact that the three accused had entered guilty pleas was a significant mitigating factor, and the court stated that had the accused not pleaded guilty and had subsequently been convicted at trial, a sentence of imprisonment would have been in order. |

| PLEASE COLLECT ONLY RELEVANT CASES ON THE FALSIFICATION OF MEDICAL PRODUCTS OR SIMILAR CRIMES | | |
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| **DATE AND CASE** | **DESCRIPTION** | **RESULT** |
| | - Medicinal Products (Control of Placing on the Market) Regulations 2007. Regulation 39(c) (introduction into Ireland of Afhlan (Melphalan Injection USP 50mg) in circumstances where the defendants knew or there were sufficient grounds to suspect that it was a falsified medicinal product<br>The charges related to selling and supply by wholesale, brokering by wholesale, importing, exporting, placing into circulation and introducing into Ireland falsified medicinal products indicated for the treatment of cancers. The charges related to medical products sold to pharmaceutical companies in Iran, Kuwait, Israel, and the United Kingdom where the defendants had made misrepresentations about the source of the medical products.<br>The three accused each pleaded guilty to a number of the charges laid against them.<br>Correlation to the MEDICRIME Convention:<br>Substantive Criminal Law: Article 6,7, 8, 11, 13<br>Article 17, | |

**ITALY** (prepared by the national consultant Ms Giuliana GIULANO)

| PLEASE COLLECT ONLY RELEVANT CASES ON THE FALSIFICATION OF MEDICAL PRODUCTS OR SIMILAR CRIMES | | |
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| **DATE AND CASE** | **DESCRIPTION** | **RESULT** |
| *Court of Cassation Section 1*, **judgment** n. 50566 of the 07/11/2013 Cc. (filed 13/12/2013) Rv. 257610 - 01 | The Court of Cassation, Section I, with its judgment n. 50566 del<br>7.11.2013 annulled an order issued by the Court of Rome, in function of a review judge, rejecting the appeals brought by three parties, as managers of the pharmaceutical company, quality assurance and quality control of the same company, to which the precautionary measure of house arrest had been applied by order of the GIP of the Court of Frosinone for the crime referred to in Art. 440 co. 1 and 3 c.p. for adulteration and counterfeiting of medicinal products called Ozopulmin G 80 mg for children and Ozopulmin G 160 mg for adults, placed on the market in the absence of the main component, the active substance so-called P.O.T. and, for this reason, according to the indictment, dangerous to public health. The applicant defences considered that, in the present case, the least serious case referred to in Article 10 of the Directive was configurable. 443 c.p. | The production, depending on the subsequent marketing, of a drug deprived of its active ingredient, replaced with other drugs of minor or no effectiveness, which does not make it dangerous for public health supplements the crime referred to in Art. The production, depending on the subsequent marketing, of a drug deprived of its active ingredient, replaced with other drugs of minor or no effectiveness, which does not make it dangerous for public health supplements the crime referred to in Art. 443 criminal code 443 criminal code because in this way the drug itself is neither adulterated nor counterfeited but made only imperfect. because in this way the drug itself is neither adulterated nor counterfeited but made only imperfect. (In accordance with the principle, the Court annulled the decision of the Review Court which had held that the crime referred to in Article 440 of the Pen. (In accordance with the principle, the Court annulled the decision of the Review Court which had held that the crime referred to in Article 440 of the domestic criminal law) |
| *Court of Cassation Section 6*, **judgment** n. 24242 del 21/04/2015 Cc. (filed 05/06/2015 ) Rv. 264167 - 01 | The Court of Cassation, Section VI, with its judgment n. 24242 del 21.4.2015 rejected the appeal for Cassation brought by the parents of a child, suffering from muscular dystrophy of Duchenne, who had begun treatment with the Stamina method, against the order of the Court of Turin that had confirmed the decree of preventive seizure of materials and products deposited at the stem cell laboratory of the Hospital "Spedali civili di Brescia" in the context of criminal proceedings instituted for crimes of association for delinquency , trade in and administration of imperfect medicines, in a manner dangerous to public health, aggravated fraud, abuse of office, abusive exercise of the profession, and other crimes | The appeal for Cassation was dismissed and the Supreme Court said that "the application of the socalled "stamina method" configures the crime referred to in art. 443 cod. pen., as an activity focused on the administration of preparations and substances considered to be devoid of therapeutic efficacy by the general ity of the international scientific community, and, therefore, as such, attributable to the category of "imperfect medicines". (Conf. sentt. n. 24243/15 and 24244/15, non mass). (Principle affirmed in the context of real pre-trial proceedings). |

| PLEASE COLLECT ONLY RELEVANT CASES ON THE FALSIFICATION OF MEDICAL PRODUCTS OR SIMILAR CRIMES | | |
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| **DATE AND CASE** | **DESCRIPTION** | **RESULT** |
| Cremona, 12 September 2019<br>complex investigation conventionally called "DAWAA", carried out by Carabinieri AntiSophistication and Health Unit of Cremona | On 12 September 2019, at the conclusion of a complex investigation conventionally called "DAWAA", the Carabinieri of the NAS of Cremona carried out 18 precautionary measures, of which 14 custodial and 4 restrictive (obligation to submit to the PG), as well as 34 decrees of searches, against as many subjects under investigation as involved in various capacities in an international trafficking of drugs, mainly oncological, antiviral and intended for particular treatments. Medicinal substances, all characterized by a high therapeutic and commercial value, constitute the proceeds of numerous thefts committed between 2017 and 2018 in hospital pharmacies, local health companies and pharmaceutical warehouses throughout the country.<br>The measures, ordered by the GIP of the Court of Cremona at the request at the request of the local Public Prosecutor's Office, were carried out with the use of a device consisting of 220 military personnel from the NAS and the territorial weapon in the provinces of Cremona, Lodi, Milan, Piacenza, Bologna, Naples and Salerno. The recipients of the measures, who are part of a criminal association based in the Cremasco area, are attributable to various components represented by thieves, fences, couriers and touts, who had set up a dense network of illegal trade in high-cost drugs , all destined for the foreign market.<br>A part of the association was involved in stealing medicines from the pharmacies of local health companies and public hospitals as well as from pharmaceutical logistics, delivering them to the first level of fences made up of subjects of Campania origin who, in turn, gave them to a further level of management , at the head of the entire organization, a role played by two Egyptian citizens who, thanks to the collaboration of supporters and couriers, were involved in the export phases of drugs in France, Germany and especially in North Africa and the Middle East, in particular Egypt, Syria and Saudi Arabia. The medicines exported in air shipments by couriers or passengers departing from Milan Malpensa Airport, upon reaching their destination, were taken into custody by the accomplices who dealt with the logistics of transport and placement in local warehouses or delivery to private individuals such as doctors and patients wealthy.<br>During the investigation 824 packs of medicines were seized for a total amount, based on the high economic value of each single therapeutic unit, of almost 4 million euros. | At present, the outcome of the process is not known |

| PLEASE COLLECT ONLY RELEVANT CASES ON THE FALSIFICATION OF MEDICAL PRODUCTS OR SIMILAR CRIMES | | |
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| **DATE AND CASE** | **DESCRIPTION** | **RESULT** |
| | Of particular investigative importance was the contribution of the AIFA Carabinieri Nucleus (the NAS Nucleus located at the Italian Medicines Agency), whose findings made it possible to reconstruct and identify the illicit origin of the medicines, stolen in the course of burglary and burglary. committed between September 2017 and May 2018 at the internal pharmacies of the San Giovanni Bosco and Ascalesi hospitals in Naples, San Timoteo di Termoli and the Provincial Health Authorities, appointed to distribute medicines to public structures on a territorial basis, in Catanzaro, Caltagirone and Rutigliano as well as at a well-known pharmaceutical logistics company in Lodi. Precisely for the purpose of public health for which the stolen drugs were intended, the investigation represents an important repressive intervention to counter a particularly insidious criminal phenomenon, both for the considerable economic export to the detriment of the public health service and for the theft of pharmacological products. intended for the treatment of important pathologies such as oncological ones and with urgent therapeutic needs.<br><br>The investigations also demonstrated the failure to apply the correct methods of custody of drugs subject to illicit trade: in fact some categories of drugs subject to theft required binding storage at refrigeration temperature, a necessary condition to ensure the efficacy of the active pharmacological principle and therapeutic action. This storage temperature requirement was not maintained, thus making them imperfect and becoming a potential serious danger to the health of unsuspecting patients due, at best, to the ineffectiveness of the curative function. Those arrested, associated in various detention institutions in Northern and Southern Italy, on the instructions of the Cremona Public Prosecutor's Office, will have to answer for the crimes of conspiracy, receiving stolen goods, aggravated theft and trade in broken and imperfect drugs. | |
| International operation "SHIELD" ended in December 2020 | The Carabinieri of the NAS have concluded "SHIELD", a vast international operation aimed at protecting health and combating the cd. pharma crime, which involved 19 Member States of the European Union, as well as Albania, Bosnia and Herzegovina, Colombia, Moldova, Norway, Serbia, the Republic of North Macedonia, Ukraine and the European Anti-Fraud Office (OLAF), under the direction and coordination of Europol. | |

| PLEASE COLLECT ONLY RELEVANT CASES ON THE FALSIFICATION OF MEDICAL PRODUCTS OR SIMILAR CRIMES | | |
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| **DATE AND CASE** | **DESCRIPTION** | **RESULT** |
| | Operation SHIELD, born from the experience of the previous European operations VIRIBUS and MISMED and launched in early 2020 during the kick-off meeting held in Alicante (Spain) at the headquarters of the European Union Office for Intellectual Property (EUIPO), represents the largest activity conducted to protect health and to combat "pharmaceutical crime", a phenomenon now of transactional importance against which they have been developed , within the framework of the guidelines established by Europol, specific law enforcement activities at national level according to an effective organisational model of coordination, cooperation and exchange of information between the States involved, aimed at prosecuting illicit trafficking in doping substances and their use in sports competitions, as well as the production and distribution of counterfeit drugs or the proceeds of illegal activities.<br>The explosion of the COVID-19 pandemic has also led to the development of a targeted law enforcement action, in a synergistic effort among the participating countries that have oriented investigations and investigations also in the delicate emergency sector.<br>Of note was the role played by Italy, and in particular by the NAS military, within "SHIELD".<br>The Carabinieri Command for the Protection of Health was, in fact, entrusted with the delicate role of co-leader of Europol: this position of responsibility allowed the NAS to take its place in the "control room" (also composed of the National Gendarmerie French, the Greek Police and the Finnish Customs) which planned, directed and coordinated the participating countries in the various areas of intervention.<br>The results achieved by the various joints of the Carabinieri Command for the Protection of Health during Operation "SHIELD", held during 2020, saw the execution of 220 inspection and control activities on the national territory, with the opening of 166 judicial and administrative proceedings, for a total of 13 arrests and 485 reports to the competent Authorities.<br>Large seizures of medicines and doping substances, as well as medical devices and products of various kinds related to the COVID-19 emergency: over 62,000 packages and about 1,500,000 units of medicinal products for human use in different pharmaceutical forms (tablets, injectables, powders), containing active ingredients with various therapeutic indications, mainly attributable to anabolic agents, antibiotics, anti-inflammatories, erectile dysfunction and boasting properties for the treatment of COVID-19. Mention should also be made of the seizure of some 3 quintals of various substances in powders and crystals, including cutting material and other allegedly narcotic material, which are being analysed, found during an operation which, last October, led to the discovery of a clandestine printing press of euro banknotes. | |

| PLEASE COLLECT ONLY RELEVANT CASES ON THE FALSIFICATION OF MEDICAL PRODUCTS OR SIMILAR CRIMES | | |
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| **DATE AND CASE** | **DESCRIPTION** | **RESULT** |
| | In addition, there are approximately 2 million medical devices and devices seized in connection with the COVID-19 emergency because they do not comply or illegally imported, including masks, gloves, protective kits and PPE, diagnostic tests and sanitizing liquids, for a quantity of 15 tons.<br>The commercial value of all seizures exceeds the figure of 6,500,000 euros.<br>At the same time, targeted control was carried out on the illicit sale and advertising of medicines online. The specific scope of the contrast to the cd. pharmaceutical cybercrime was, in fact, considered particularly sensitive since the citizens' fears especially with regard to the spread of COVID-19, fueling a probable frantic search for "DO IT YOURSELF" remedies on the net, could have been exploited by criminals who feed the illicitly sourced drug market and parallel supply channels. In this context, the military of the Carabinieri Command for the Protection of Health have therefore conducted targeted analyses of the web that have allowed to identify and "obscure", on measures of the Ministry of Health as many as 132 websites all with servers located abroad and with fictitious data of the relative managers. Of these sites, 112 related to medicinal products based on active ingredients (hydroxychloroquine, chloroquine, lopinavir/ritonavir, azithromycin) for which off-label use was authorized only in the context of research and clinical studies related to COVID-19, while 20 offered for sale and advertised medicines with various therapeutic indications, mainly doping, against erectile dysfunction, anti-inflammatories and antibiotics, all subject to prescription.<br>Despite the limitations of sports activities related to the pandemic emergency, 42 anti-doping checks were conducted "in" (36) and "out" (6) competition by the NAS Anti-Doping Investigation Inspectors, which allowed 154 athletes to be checked (135 on the sidelines of races and 21 out of competition), 13 of which were positive (all "in" competition). In this context, the military has made use at national level of the consolidated collaboration of NADO ITALIA, under whose aegis they have also contributed to the controls conducted by the UCI during the 2020 Giro d'Italia, and by the Doping Surveillance Section of the Ministry of Health.<br>The operational opportunity was also fruitful to promote the relations of institutional cooperation between the Carabinieri of the NAS and the Customs and Monopolies Agency in the areas of respective competence, moreover strengthened by the recent signing of a specific memorandum of understanding between the General Command of the Carabinieri And the Same Agency. In this regard, mention should be made of the joint activity that led to the discovery, a few days ago, of an underground laboratory for the production and marketing of doping substances intended to be taken in a dangerous way for health, in the absence of any medical prescription and in the absence of therapeutic needs, with the seizure of large quantities of products of various kinds and packaging material. | |

| PLEASE COLLECT ONLY RELEVANT CASES ON THE FALSIFICATION OF MEDICAL PRODUCTS OR SIMILAR CRIMES | | |
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| **DATE AND CASE** | **DESCRIPTION** | **RESULT** |
| | In total, Operation SHIELD, conducted in the territories of the various acceding countries, has made it possible to dismantle 25 criminal groups, seize thousands of medicines and doping products of various kinds, for a total of over 25 million units and a commercial value of almost 73 million euros, identify and seize 10 clandestine laboratories, launch 95 investigations, arrest 667 people and report a further 1,282 , as well as monitor 4,009 websites by obscuring 453 of them. The antidoping activity, on the other hand, resulted in 536 checks "in" (148) and "out" (388) competition controlling 650 athletes (247 on the sidelines of races and 403 out of competition), 17 of which were positive results (13 following checks "in" competition and 4 during "out" competition checks). Finally, the targeted action on COVID-19 alone led to the seizure of over 32 million masks, tests, diagnostic kits and medical devices, 8 tons between chemicals and active ingredients and 70 tons of hand sanitizing liquid. | |
| "Operation Pharmalab", Arzano June 2014 This operation is part of the activities carried out with the Operation Volcano. The latter operation concerns a number of activities carried out after a German distributor received defective vials of an anticancer medicine Herceptin® 150 mg from a UK wholesaler. Operation Vulcano has allowed the adoption of both ad hoc tools (web platforms for data sharing, databases, "blacklists" of operators) and good practices in the EU Member States in order to prevent the recurrence of similar cases. AIFA, for example, coordinated an important EU-wide verification campaign through the Fakeshare web platform, | The "Operation Pharmalab" is part of the activities carried out with the Operation Volcano. The investigation was launched after the seizure of a large quantity of medicines (58,222 packs of medicines of different types, genera and origins, including hospital drugs, with an estimated market value of EUR 839,530) by the Finance Police of Fiumicino (Roma), in June 2014 at a warehouse located in Arzano. Arzano's warehouse was used by two subjects, one of whom was a pharmacist. The investigations were coordinated by the Public Prosecutor's Office at the Court of Naples Nord and allowed, through checks on seized assets, interception, interrogation, to clear the members of a criminal association that received and then placed on the market stolen medicines. To place stolen medicines on the market, false fiscal documents were prepared that simulated their purchase from Italian suppliers and pharmacies by apparently foreign companies. The criminal activity was organized in several stages: 1) theft or robbery of medicines throughout Italy; 2) placement in warehouses for storage in the Campania; 3) preparation of false documentation attesting to the origin of the stolen medicines; 4) relocation to the market through accomplices (pharmacies, wholesalers, distributors). Following a search, in November 2014, of some premises in the availability of suspects in the provinces of Naples and Caserta, a further 3,117 packages of medicines were seized.<br>The offences alleged against the suspects with the exercise of criminal proceedings were as follows: purchase or receipt of goods of criminal origin - art. 648 c.p.; possession of narcotic drugs (Article 73(1) also relating to paragraph 4 of Italian Republic Presidential Decree No. 309/1990) for certain packages of medicinal products (1191) containing active substances which may appear in the tables included in the Consolidated Text on Narcotic Drugs (in particular Table I, Section A and Table IV), trade and administration of defective or defective medicinal products (Article 443 of the Criminal Code) in relation to expired drugs found ; criminal association finalized to the commission of the above crimes (Art. 416 of the Criminal Code) | Three defendants asked for their position to be defined by a plea bargain. In particular, 4.3.2016, was applied, pursuant to art. 444 code of criminal procedure (plea bargain), from the Court of Naples North to one of the defendants the final sentence of three years and eleven months imprisonment and euro 12,000.00 fine while to another defendant the final oena of years 4 months six imprisonment and euro16,000 fine. One defendant was acquitted and for the other six defendants, in 2019, a first-degree sentence was handed down by the Court of Naples Nord |

**JAPAN** No submission has been received on case law from the national consultant

**LATVIA** (prepared by the national consultant Ms Sanita TIMBARE ZILVESTERE)

| PLEASE COLLECT ONLY RELEVANT CASES ON THE FALSIFICATION OF MEDICAL PRODUCTS OR SIMILAR CRIMES | | |
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| **DATE AND CASE** | **DESCRIPTION** | **RESULT** |
| 29.11.2019.<br>No. 1A68016718* | An official of the Medicines Supervision and Control Division of the Health Inspectorate on 20 March 2018 adopted Decision for calling Company "H" as the pharmaceutical wholesaler administratively liable for the committing an administrative offense regarding distribution of falsified medicinal products (one falsified batch), imposing a fine in the amount of EUR 6070,00.<br>On the decision of the official of the Medicines Supervision and Control Division of the Health Inspectorate Company "H" submitted a complaint to the director of the Health Inspectorate as a higher institution, requesting to cancel and terminate the administrative violation proceedings. The Health Inspectorate on 16 August 2018 made decision - it was decided to leave the appealed decision unchanged, but to reject the Company's "H" complaint.<br>The Company "H" appealed the decision of the Health Inspectorate to the Court.<br>As the last instance the Panel of the Riga City Criminal Court in 29.11.2019. with judgment in case No. 1A68016718 upheld the decision of the Health Inspectorate and rejected the Company's "H" application. | The judgment of the Panel of the Riga City Criminal Court is final and has entered into force. |
| 03.04.2020.<br>No.A420239819* | Information about rapid alert was received by Rapid Alert national contact point in Latvia - Health Inspectorate - on April, 2018 that pharmaceutical wholesaler Company "S" distributes counterfeit medicines "X" (two falsified batches). Latvian Health Inspectorate launched an investigation and performed unscheduled inspections at pharmaceutical wholesaler (WD) premises. During the investigation, the State Agency of Medicines (SAM) and the Health Inspectorate identified that distribution was performed outside medicines "X" manufacturer's approved supply chain and medicinal product "X" was received without supporting quality documentation but nevertheless accepted to saleable stock, sold further to unlicensed company. Company "S" did not take all possible steps to prevent the distribution of falsified medicinal products in the legal supply chain. SAM Licensing board on 18 October, 2018 adopted decision to revoke pharmaceutical WD license of the Company "S". The SAM decision to revoke WD license has been challenged in the Ministry of Health by the Company "S".<br>The Ministry of Health upheld the decision of the State Agency of Medicines.<br>The company "S" appealed the decision of the Ministry of Health to the Administrative District Court.<br>In the first instance, the Administrative District Court in 03.04.2020. in case No. A420239819 upheld the decision of the Ministry of Health and rejected the Company's "S" application. | The judgment of the Administrative District Court as the first Instance has been appealed to the Regional Court and has not entered into force. |

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| 04.09.2020.<br>No.1A30047818* | On 18 July 2018, an official of the Medicines Supervision and Control Division of the Health Inspectorate adopted Decision for calling Company "S" as the pharmaceutical wholesaler administratively liable for the committing an administrative offense regarding distribution of falsified medicinal products, imposing a fine in the amount of EUR 6,070.<br><br>On the decision of the official of the Medicines Supervision and Control Division of the Health Inspectorate Company "S" submitted a complaint to the director of the Health Inspectorate as a higher institution, requesting to cancel and terminate the administrative violation proceedings. The Health Inspectorate on 30 August 2018 made decision - it was decided to leave the appealed decision unchanged, but to reject the Company's "S" complaint.<br><br>The Company "S" appealed the decision of the Health Inspectorate to the Riga City Vidzeme Suburb Court.<br><br>As the second instance the Riga City Vidzeme Suburb Court in 04.09.2020. in case No. 1A30047818 upheld the decision of the Health Inspectorate and rejected the Company's "S" application. | The judgment of the Riga City Vidzeme Suburb Court as the second Instance has been appealed to the Regional Court and has not entered into force. |
| 13.11.2020.<br>No.A420257019* | Information about rapid alert was received by national Rapid Alert contact point in Latvia - Health Inspectorate - on December, 2017 that Company "H" distributes counterfeit medicines "Y" (one falsified batch). Latvian Health Inspectorate launched an investigation and performed unscheduled inspections at pharmaceutical wholesaler premises. During the investigation, the State Agency of Medicines (SAM) and the Health Inspectorate identified that distribution was performed outside medicinal product "Y" manufacturer's approved supply chain and medicinal product "Y" was received without supporting quality documentation but nevertheless accepted to saleable stock, sold further to licensed wholesale distribution (WD) holder. Company "H" did not take all possible steps to prevent the distribution of falsified medicinal products in the legal supply chain. SAM Licensing board on 18 October, 2018 adopted decision to revoke pharmaceutical WD license of the Company "H". The SAM decision to revoke WD license has been challenged in the Ministry of Health by the Company "H". The Ministry of Health upheld the decision of the State Agency of Medicines.<br><br>The company "H" appealed the decision of the Ministry of Health to the Administrative District Court.<br><br>In the first instance, the Administrative District Court in 13.11.2020. in case No. A420257019 upheld the decision of the Ministry of Health and rejected the company's "H" application. | The judgment of the Administrative District Court as the first Instance has been appealed to the Regional Court and has not entered into force. |

*** Court rulings and judgments in Latvia are anonymized.**

**LITHUANIA** (prepared by the national consultant Mr Tautvydas ZEKAS)

| PLEASE COLLECT ONLY RELEVANT CASES ON THE FALSIFICATION OF MEDICAL PRODUCTS OR SIMILAR CRIMES | | |
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| **DATE AND CASE** | **DESCRIPTION** | **RESULT** |
| | Criminal cases regarding **Article 202** („Unauthorised Engagement in Economic, Commercial, Financial or Professional Activities") of the Criminal Code (hereinafter in the text – the CC) | |
| 3 May 2011<br>Criminal case No. 2K-193/2011 | V. N. without establishing a company and without a license for pharmaceutical activities has engaged in prohibited commercial activities: acquired various medicinal products which were illegally imported into Lithuania, transported and distributed prohibited medicinal products through primary health care institutions in rural areas (medical points, outpatient clinics), finally received income from these illegal activities. These medicinal products were not officially registered and did not comply with the labelling requirements.<br>In such a way V. N. violated Paragraph 1 of Article 2 of the Law on Pharmaceutical Activities, which provides that only medicinal products registered in the Republic of Lithuania and the European Community may be imported into the Republic of Lithuania, put into circulation and used for health care. V. N. also violated Article 44 of the Code of Good Practice for the Distribution of Medicinal Products, according to which pharmacies may be supplied with medicinal products registered or otherwise authorized in Lithuania whose packaging text, labelling and information provided to the consumer comply with legal requirements.<br>By these actions mentioned V. N. committed a criminal offence foreseen in Paragraph 2 of Article 202 of the CC. | The Supreme Court of Lithuania dismissed the cassation appeal of the convicted. Thus the sentence of imprisonment for six months which was suspended for one year and six months (with the imposition of penal sanctions) imposed by the Lithuanian Court of Appeal remained in force. |
| 15 September 2014<br>Criminal case No. 1-114-519/2014 | V. M. without having a necessary license for pharmaceutical activities was engaged in commercial activities such as importing licensed medicinal products, trading in licensed medicinal products, systematically selling medicines on the market, bringing and selling medicines to customers at home or elsewhere.<br>In addition, for the purpose of distribution, V. M. held a very large quantity of a psychotropic substance (460 fenazepam tablets) containing a total of 1.15 g of the psychotropic substance fenazepam etc.<br>It should be also noted that at the beginning V. M. was punished for marketing manufactured medicines on the marketplace without having a license for that according to Article 411 of the Code of Administrative Offences (the CAO). This article of CAO provides for liability for activities related to medicinal products for which a license is required, without a license or in another illegal manner, if this has not caused serious consequences or has not been done on a large scale. So according to Article 411 of the CAO, V. M. was punished for a one-time violation of the law – for marketing medicines without a license to trade in them, and according to Article 202 of the CC – for carrying out these activities in a commercial manner, although V. M. also did not have any license required for that. | V. M. was found guilty of the offences under Article 260(3) ("Unlawful Possession of Narcotic or Psychotropic Substances for the Purpose of Distribution Thereof or Unlawful Possession of a Large Quantity of Narcotic or Psychotropic Substances") and under Article 202(1) ("Unauthorised Engagement in Economic, Commercial, Financial or Professional Activities") of the CC and final sentence of 2 years of restriction of liberty was imposed (obliging to work 30 hours free of charge within a year from the date of entry into force of the sentence in health care, care and welfare institutions or non-governmental organizations caring for disabled, elderly or other people in need and during this period of a sentence imposed do not go to <...> (data not available). |

| PLEASE COLLECT ONLY RELEVANT CASES ON THE FALSIFICATION OF MEDICAL PRODUCTS OR SIMILAR CRIMES | | |
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| 17 January 2020<br><br>Criminal case No. 1-102-935/2020 | J. B. was accused of failing to comply with the provision of Paragraph 1 of Article 19 of the Law on Pharmacy which says that "production of medicinal products, investigational medicinal products, import from third countries, wholesale distribution of medicinal products, pharmacy activities are licensed pharmaceutical activities"; also of failing to comply with the provision of Paragraph 2 of the same article according to which "legal persons <…> shall be issued the following types of licenses: production license; wholesale distribution license; pharmacy license and manufacturing pharmacy license"; and of failing to comply with the provisions of Paragraph 9 of Article 35 which declares that "medicinal products shall be sold (issued) to the population in accordance with the procedure established by the Minister of Health".<br><br>Without establishing a legal entity and without having a license for any licensed pharmaceutical activity issued by the State Medicines Control Service, J. B. sent at least 1738 postal items using the services of Lithuania's Post and thus sold medicinal products for at least 10 546 EUR (for example, Kamagra Sildenafil 100 mg, Cenforce-100 Sildenafil Citrate 100 mg, Tadarise 60 Tadalafil 60 mg, Tadacip 20 Tadalafil 20 mg, etc.).<br><br>By these actions, J. B. was accused of having committed a criminal offence provided for in Paragraph 1 of Article 202 of the CC. <…>.<br><br>*(Accusations regarding Article 260(1) and 199(3) of the CC will not be further described in details).* | By a ruling of Vilnius Regional Court, a criminal case in which J. B. is accused of committing criminal offenses provided for in Article 202(1) ("Unauthorised Engagement in Economic, Commercial, Financial or Professional Activities"), Article 260(1) ("Unlawful Possession of Narcotic or Psychotropic Substances for the Purpose of Distribution Thereof or Unlawful Possession of a Large Quantity of Narcotic or Psychotropic Substances") (ten criminal offenses) and Article 199(3) ("Smuggling") of the CC <…> according to the rules of jurisdiction was transferred to Kaunas Regional Court.<br><br>Final decision of the Court is yet to come. |
| | Criminal cases regarding **Article 204** („Use of Another's Trademark or Service Mark") of the CC | |

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| 29 November 2018<br>Criminal case No. 1-83-458/ 2018 | The accused V. V. was charged under Article 204 of the CC by selling the goods bearing the third mark without permission. The accused sent medicines (tablets in sheets) to Italy, Spain, France and other countries. In such a way V. V. marketed goods bearing a third party's brand (medicines Viagra, Cialis, Levitra, the design of which (marking, labels, trademarks and other details) did not meet the requirements of the legitimate manufacturers. | The accused V. V. was acquitted on the ground that no act having the character of a crime or misdemeanor has been committed. According to the charge against him for the crime provided for in Article 204 of the CC, he could not be found guilty on the sole ground that the necessary characteristic of the offense of causing serious harm had not been proved. The amount of goods under the third-party trade mark has also not been proved in this criminal case, and it was not clear why medicinal products such as Cialis and Levitra were listed as not meeting the requirements of the legitimate manufacturer. |
| | Criminal cases regarding **Article 300** („Forgery of a Document or Possession of a Forged Document") of the CC | |
| 4 June 2015<br>Criminal case No. 1A-217-483/2015 | V. L. was accused of falsifying at least 13 prescriptions entitling to obtain medications containing psychotropic substances. In the prescriptions V. L. recorded false data about the persons or placed an invalid imprint on them, and thus passed these prescriptions to various persons, illegally distributing various psychotropic substances on the basis of these false prescriptions. | V. L. was found guilty of the offence under Article 300(1) of the CC, the Court imposed a sentence of 1 year of imprisonment. |

| PLEASE COLLECT ONLY RELEVANT CASES ON THE FALSIFICATION OF MEDICAL PRODUCTS OR SIMILAR CRIMES | | |
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| 7 May 2019<br><br>Criminal case No. 1-147-290/2019 | A. D. falsified 11 prescriptions of Kaunas clinics (hospital) granting the right to purchase medications containing psychotropic substances – "zolpidem", which is allowed to be used for medical purposes – that is, entered in the prescription forms printed by electrographic printing fake data about persons and allegedly prescribed medication. By these actions A. D. committed a crime provided for in Article 300(1) of the CC.<br><br>In addition, A. D. illegally obtained and disposed of a very large quantity of 3.6 g of the psychotropic substance zolpidem, which is authorized for medical purposes, using forged prescription documents. By such actions, A. D. committed a crime provided for in Article 260(3) of the CC. | A. D. was found guilty of the offences under Article 260(3) ("Unlawful Possession of Narcotic or Psychotropic Substances for the Purpose of Distribution Thereof or Unlawful Possession of a Large Quantity of Narcotic or Psychotropic Substances") and under Article 300(1) ("Forgery of a Document or Possession of a Forged Document") of the CC and final aggregate sentence of 2 years of restriction of liberty was imposed obliging during this period to be at home from 24:00 until 06:00, if it is not related to work; after the end of maternity leave, continue working or start working or registering with the Employment Service; continue treatment for dependence on psychotropic substances. |

**MEXICO** (prepared by the national consultant Mr Oscar GUIZAR)

After reviewing several databases of opened official sources from different authorities in Mexico in terms of public information, there are no case-law or relevant cases available to general public for consultation, related to criminal proceedings for crimes of falsified medical product or other similar offenses.

However, the Permanent Mission of Mexico to the Council of Europe provided some information on Pangea Operation in 2020, in which Mexican authorities participated in combating medicines falsifying crimes. In addition, some relevant news on this topic were found on the internet. It was considered important to mention them in this document.

| PLEASE COLLECT ONLY RELEVANT CASES ON THE FALSIFICATION OF MEDICAL PRODUCTS OR SIMILAR CRIMES | | |
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| **DATE AND CASE** | **DESCRIPTION** | **RESULT** |
| From March 3rd to 10th, 2020 | Mexican authorities participated in "Pangea XIII Operation". The Guardia Nacional (federal police) carried out cybersecurity actions (to keep the internet under observation), implemented for the Covid-19 pandemic, in order to identify possible crimes. | The result of these activities was the identification of different publications in profiles of Facebook, YouTube and anonymous websites in which falsified medicines, tests and treatments about Covid-19 or other products of Novirsa and Mesofrance were offered and sell illegally. However, there is no information on any criminal proceedings arising from this operation. |
| March 18th, 20218 | In an article published in the newspaper El País; Mexican authorities seized 5,775 fake doses of Sputnik V vaccine at the international airport of Campeche, in the south of the country, which were on a private aircraft bound for San Pedro Sula, Honduras. | There are still no results from the criminal proceedings instituted in this case. |
| March 7th, 20209 | Fifty-five patients undergoing hemodialysis treatment in a public hospital in Villahermosa, Mexico, were administered a contaminated medicine (Heparin Sodium). Three people died and forty-three were hospitalized, six of them in intensive care. | Complaints were filed, but the outcome of the investigations resulting from the criminal proceedings is unknown. |
| January 16th, 201710 | Children suffering from cancer received fake chemotherapy in public hospitals during the administration of Governor Javier Duarte in the Mexican state of Veracruz. Distilled water, instead of medicines, was given to them. | There is still no result on this case in the criminal proceedings initiated for this crime. The information on this proceeding is not available to general public because it is reserved. |

8. This news is available at: https://elpais.com/mexico/2021-03-18/decomisadas-en-mexico-mas-de-5000-dosis-falsas-de-la-vacuna-rusa-sputnik-v.html#:~:text=Las%20autoridades%20mexicanas%20han%20anunciado,V%20con%20destino%20a%20Honduras.
9. This news can be consulted at: https://aristeguinoticias.com/0703/mexico/pemex-confirma-tercera-muerte-por-medicamentos-contaminados/
10. This news is available at: https://www.animalpolitico.com/2017/01/yunes-veracruz-falsas-quimioterapias/

**MONTENEGRO** (prepared by the national consultant Mr Milorad MARKOVIC)

| PLEASE COLLECT ONLY RELEVANT CASES ON THE FALSIFICATION OF MEDICAL PRODUCTS OR SIMILAR CRIMES | | |
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| **DATE AND CASE** | **DESCRIPTION** | **RESULT** |
| 5 March 2020<br><br>Basic Court in Rožaje, Case against N.J. for criminal offense of Unlawful trade under Art. 284. para. 3. in connection with paras. 1 and 2 of the Criminal Code of Montenegro and ML, for the criminal offense of Unlawful trade in aiding under Art. 284. para. 3. in connection with paras. 1 and 2 in conjunction with Art. 25. of the Criminal Code of Montenegro. | On 15 January 2020 in Rožaje, N.J. bought goods - medicines without authorization, whose trade is prohibited pursuant to the provisions of Articles 2 and 3 of the Law on Medicinal Products (Official Gazette of Montenegro No. 56/2011 and No. 6/2013), as follows: 8 boxes of cotton wool (Flaster) "Fucidin Intertulle", 10 boxes of treatment fluid (360 ml) "Renu ", 10 boxes of treatment liquid (120 ml)" Renu ", 8 boxes of tablets (300 ml)" Propaten ", 8 boxes of capsules (600 mg)" Berlithin ", 18 boxes of tablets (15 mg)" Trittico retard ", 10 pieces of eye drops (5 ml), small bottles of Fulucon, 2 boxes of tablets (5 gm / 80 mg) "Exforge", 58 boxes of capsules "Cefaleskin HF", 20 boxes of tablets (4 mg) "Medrol", 19 boxes tablet (300 mg) "Clindamycin MIP", 25 boxes of tablets (600 mg) "Clindamycin" MIP ", 20 boxes (300 mg) ampoules of" Clindamycin ", 50 boxes (4 mg) of tablets" Cintrom ", 10 boxes ) Frisium tablets, 30 boxes (5 mg) Cospot eye drops, 3 boxes (20 mg) Hydrocortisone tablets, 40 boxes (500 mg) Ciprocinal tablets, 29 boxes (50 mg) gel 1 % "Voltaren Emvlegel", 10 boxes (25 mg) tablets "Prazine", 101 boxes (0.5 mg / 1 mg / 10 mg) ointment "Triderm", 5 boxes of food for special honey intentions "Cartlnom", 3 boxes of gel 2% "Voltaren Emulgel", 3 boxes (150 mg) tablets "Irbenida", 106 boxes of fat 0.1% (15 g) "Elocom", 5 boxes of talbet (60 mg) " Dlaaprel MR ", 48 boxes of eye drops (5 ml) 0.2%" Alphagan ", 5 boxes of ampoules" Deposelin ", 9 boxes of tablets (2 mg)" Rissar ", 5 boxes of tablets (75 mg)" Velafax ", 7 boxes of capsules (150 mg) "Diflucan", 2 boxes of tablets (2 mg / 0.03 mg) "Jeanin", 2 boxes of tablets (37.5) "Velafax", 5 boxes of tablets (500 mg) "Sumamed", 10 boxes of tablets (20 mg) "Hpllesta", 10 boxes of eye drops (1 mg / ml) "Nevanac", 14 boxes of tablets (400 mg) "Pance", 100 boxes of tablets (400 mg) "Bactrim", 5 boxes tablets (160 mg / 12.5 mg) "Valsacombi", 13 boxes of tablets (50 mg) "Zoloft", 24 boxes of tablets (35 mg) "Productal MR", 5 boxes of tablets (2.5 mg / 6.25 mg ) "Lodoz", 3 boxes of capsules (75 mg) "Lyrica", 10 boxes of tablets (2 mg) "Rivatril", 5 boxes of tablets (5 mg) "Norvasc", 8 boxes of tablets (10 mg) "Norvasc", 6 box of tablets (40 mg) "Sortis", 6 boxes of tablets (2 0 mg) "Sortis", 29 boxes of solution for inhalation (5 mg / ml) "Spalmotil", 14 boxes of tablets (500 mg) "Orvagil", 40 boxes of capsules (100 mg) "Gabagamma 100",2 boxes of tablets mg) Velafax, 5 boxes of Rowachol capsules, 20 boxes of tablets (30 mg) Calixt, 50 boxes of tablets (5 mg) Xyzal, 8 boxes of Roaccutab capsules, 15 boxes of capsules 20 mg) "Roaccutab", 5 boxes of capsules (120 mg) "Xenical", 6 boxes of tablets (4 mg) "Sirdalud", 4 boxes of ointment (1x50 g) "Bengal", 4 boxes of tablets "Nimulid MD", 10 boxes of tablets (250 mg) Orvagil, 10 boxes of tablets (50 mg) Hemopress, 10 boxes of 1% gel (20 mg) Clindasome, 20 boxes of tablets (60 mg / 2.5 mg) Rinasec, 40 boxes tablet (2 mg) "Clonazepam Remedica", 70 boxes of tablets (20 mg) "Famatidine HF", 40 boxes of eye drops (1 mg / ml 3.5 mg) "Neodexacin", 30 boxes of eye ointment 1% (5 g ) "Chloramphencol", 46 boxes of tablets (5 mg) "Diazepam HF", 40 boxes of ointments (10 ml) "Dexamethason", 10 boxes of tablets (20 mg) "Cialis", 10 boxes of tablets (50 mg) "Imi gran ',20 boxes of tablets (5 mg)' Nebilet ', 18 boxes of nasal sprays (18 g)' Nasonex ', 4 painkillers (59 ml)' Biofreeze ', 5 boxes of nasal sprays' Avamys', 50 box of tablets (5 mg / 25 mg) "Tritace", 11 boxes of tablets (75 mg) "Plavix", 5 boxes of tablets (5 mg) "Vazotal", 15 boxes of tablets (5 mg) "Aerius", | N.J. was sentenced to imprisonment for a term of 3 (three) months.<br><br>M.L. was imposed a Conditional Sentence meaning that the Court sentenced him to imprisonment for a term of 3 (three) months which sentence shall not be executed if the defendant does not commit a new criminal offense within one year.<br><br>The goods of unlawful trade were confiscated. |

| PLEASE COLLECT ONLY RELEVANT CASES ON THE FALSIFICATION OF MEDICAL PRODUCTS OR SIMILAR CRIMES | | |
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| | 40 boxes of tablets ( 100 mg) "Nimulid", 10 boxes of tablets (6.25 mg) "Dilatrend", 5 boxes of tablets (50 micrograms) "Letrox 50", 10 boxes of tablets (200 mg) Febricit, 3 boxes of tablets (300 mg) "Irbenid ", 3 boxes of capsules (22% gamma)" Alanerv ", 5 boxes of tablets (24 mg)" Betaserc ", 9 boxes of eye drops (2.5 ml)" Xalatan ", 80 boxes of tablets (500 mg)" Edemid " , 2 boxes of syrup (0.5 mg / ml) "Aerius", as well as goods in general use (listed in judgment) s for the purpose of selling the same on the territory of Montenegro.<br><br>On 15 January 2020, in Rožaje, M. L., being fully aware of his actions which he willingly committed, knowing them to be prohibited, helped N.J. in the commission of the criminal offense of unlawful trade under Art. 284, para. 3 in connection with paras. 1 and 2 of the Criminal Code of Montenegro, by making available to him a motor vehicle brand "VW", type "P.", registration number RO ..., by which he transported goods that he had previously taken over from an unknown person, and which was bought by N.J. | |
| 11 June 2019<br><br>Basic Court in Bijelo Polje: Case against D.B. for criminal offense of Unlawful trade under Art. 284. Para. 3 in connection with para. 2 of the Criminal Code of Montenegro | On 3 March 2019, in Belgrade, Republic of Serbia, D.B. unauthorizedly bought goods whose trade is prohibited, pursuant to the provisions of Arts. 2 and 3 of the Law on Medicinal Products ("Official Gazette of Montenegro", No. 56/2011 and No. 6/2013), as follows: 17 boxes of 12 tablets and one box of 8 tablets "Kamagre 100 gold", as well as 30 a box of 4 "Kamagra" candies, in the total value of EUR 380.00, for the purpose of sale on the territory of Montenego. | D.B. was found guilty and imposed a Community Service sentence for a period of 180 (one hundred and eighty) hours, which is to be executed in a period of 3 (three) months after the judgment becomes final.<br><br>If the defendant does not serve Community Service sentence, the sentence shall be replaced by imprisonment sentence, by replacing every started 60 (sixty) hours of work in the public interest with a 1 (one) month of imprisonment sentence.<br><br>The goods of unlawful trade were confiscated. |

| PLEASE COLLECT ONLY RELEVANT CASES ON THE FALSIFICATION OF MEDICAL PRODUCTS OR SIMILAR CRIMES | | |
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| 6 June 2019<br><br>Basic Court in Bijelo Polje: Case against A.H. for the criminal offense of Unlawful trade under Art. 284 para. 3 in connection with paras. 1 and 2 of the Criminal Code of Montenegro. | On 16 March 2019, in B. - RS, for the purpose of sale on the territory of the Municipality of B., A.H. unauthorisedly bought drugs of a total value of EUR 5,406.39, as follows: 15 pieces of tape for measuring sugar "AKKYČEK", 58 pieces of drops for eyes "Almagan", 16 pieces "Frisivm" of 10mg, 62 pieces of "Vermox" of 100mg, 10 pieces of "Dieynone" of 250mg, 10 pieces of "Tensec" of 5mg, 5 pieces of "Lioresal" of 25mg, 30 pieces of "Truscopt" 2%, 2 pieces of "Nimulid MD" of 100mg, 5 pieces of "Lioresal" of 10mg, 10 pieces of "Moldamin", 22 pieces of "Nibelet plus" of 5 / 5mg, 20 pieces of "Trimetacor MR" of 35mg, 10 pieces of "Tanakan "of 40mg, 5 pieces of" Letrox "of 50mg, 3 pieces of" Letrox "of 100mg, 15 pieces of" Tanakan 40 "MG / 30, 45 pieces of" Controloc "of 40mg, 25 pieces of" Imigran "of 50mg, 40 pieces of" Seroxat 20mg, 53 pieces "Climara", 10 pieces "Alanerv", 10 pieces "Lodoz" 2,5mg / 6,25mg, 20 pieces "Flasin" of 0,4mg, 30 pieces "Preductal MR" of 35mg, 50 pieces "Nimulid" of 100mg, 20 pieces of "Resocomin", 6 pieces of "Nimulid MD" of 100mg, 20 pieces of "Rivotril" of 2 mg, 20 pieces of "Esperal" of 500mg, 10 pieces of "Trental" of 400mg, 25 pieces of "Tamsol" of 0.4mg, 20 pieces of "Pancef" of 400mg, 20 pieces of "Lata" of 10mg, 15 pieces of "Atoris" of 10mg, 30 pieces of "Concor cor" of 2.5mg, 45 pieces of "Nebilet" of 5mg, 16 pieces of "Letizen S" of 10mg, 4 pieces of "Valsacor" of 160mg, 20 pieces of "Concor" of 5mg, 15 pieces of "Oikamid "of 400mg, 1 piece of" Velafax "of 75mg, 7 pieces of" Xvzal "of 5mg / 10, 6 pieces of" Xvzal "of 5mg / 30, 2 pieces of" Lorista HD "100mg / 25, 40 pieces of" Plavix "of 75mg, 10 pieces of "Lodoz" of 5 mg / 6.25 mg and 20 pieces of "Hemomyein" of 500 mg, trade of which drugs for individuals is prohibited, pursuant to Art. 2 of the Law on Medicinal Products ("Official Gazette of Montenegro" No. 56/11 of 25 November 2011, No. 6/13 of 31 January 2013), and which medicinal products were found in his possession during the control carried out by Border Police officers. | A.H. was found guilty and sentenced for on imprisonment for a term of 3 (three) months.<br><br>The goods of unlawful trade were confiscated. |
| 4 September 2018<br><br>Basic Court in Bijelo Polje: Case against I.S.A for criminal offense of Unlawful trade under Art. 284 para. 3. in connection with para. 2 of the Criminal Code of Montenegro | On 13 June 2018, in N.P., Republic of Serbia, although he knew that his act was prohibited, I.S.A. bought unauthorized goods whose trade is limited, pursuant to the provisions of Art. 2 and 3 of the Law on Medicinal Products (Official Gazette of Montenegro No. 56/2011 and No. 6/12013), various types of medicinal products, as follows: 10 boxes of "Hypolip" 10 mg; 10 boxes of "Hypolip" 20 mg; 5 boxes of Diaprel 60 mg; 5 boxes of Rivotril 2 mg; 5 boxes of '' Alphagan '' 5 ml. 3 boxes of '' Velafax '' 75 mg; 4 boxes of '' Xenical '' 120 mg. 10 boxes of Berlithion 600 mg; 13 boxes of Dilatrend 12.5 mg; 10 boxes "Risar" 2 mg; 9 boxes of "Leponex" 25 mg; 2 boxes of Roaccutan 20 mg; 45 boxes '' Deep Relief '' 50 gr; 5 boxes of "Valsacombi" 80 mg and 30 boxes of "Xyzal" 5 mg, in the total value of EUR 1,084.50, for the purpose of selling it on the territory of Montenegro. | I.S.A. was imposed a Conditional Sentence.<br><br>Court sentenced him to imprisonment for a term of 3 (three) months which sentence shall not be executed if the defendant does not commit a new criminal offense within one year.<br><br>The goods of unlawful trade were confiscated. |

**MOROCCO** No submission has been received on case law from the national consultant

**NORTH MACEDONIA** (prepared by the national consultant Ms Aleksandra DEANOSKA – TRENDAFILOVA)

| PLEASE COLLECT ONLY RELEVANT CASES ON THE FALSIFICATION OF MEDICAL PRODUCTS OR SIMILAR CRIMES | | |
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| **DATE AND CASE** | **DESCRIPTION** | **RESULT** |
| Public Prosecution Office for Prosecution of Organized Crime and *Corruption*, November 2020 | The Public Prosecution Office for Prosecution of Organized Crime and Corruption (PPOPOCC) took the (below mentioned) case from the Public Prosecution Office as the pre-investigation suggested possible participation of many subjects and in November 2020 seized documents from several drug/medical wholesalers in respect of parallel import of medicinal product and allegations of falsified medicines import. | Ongoing procedure (The pre-investigation procedure is secret according to the law and no details can be disclosed). |
| Public Prosecution Office, December 2017 | The Public Prosecution Office opened a case/investigation in respect of doubts on parallel import of medical products with suspicious quality, possibly falsified medical products. | The case was initiated by the PPO but then taken by the PPOOC and is still in procedure (see explanation above). |
| Customs Administration, 2019 | The Customs Administration office in the annual report for 2019 stated that it has deterred 7 cases of medicines and medical products smuggling and seized 819 pieces of surgical materials and instruments.<br>(Source: Customs Administration Annual Reports, available only in Macedonian Language on: https://customs.gov.mk) | N/A |
| Customs Administration, 2018 | The Customs Administration office in the annual report for 2018 stated that it has deterred 13 cases of medicines and medical products smuggling and seized 41.786 pieces of medicinal products.<br>(Source: Customs Administration Annual Reports, available only in Macedonian Language on: https://customs.gov.mk) | Criminal or misdemeanour reports have been filed respective to the case. 11 |
| Customs Administration, 2017 | 56.000 pieces of medicinal products have been seized in 10 cases by the Customs Administration.<br>(Source: Customs Administration Annual Reports, available only in Macedonian Language on: https://customs.gov.mk) | Criminal or misdemeanour reports have been filed respective to the case. |
| Customs Administration, 2016 | 17.400 pieces of medicinal products have been seized in 17 cases by the Customs Administration.<br>(Source: Customs Administration Annual Reports, available only in Macedonian Language on: https://customs.gov.mk) | Criminal or misdemeanour reports have been filed respective to the case. |

11. *Since there is no specific incrimination for customs related crimes in respect of medicinal products, no follow up information is provided or can be obtained, unless a large – scale research is undertaken covering all the courts and smuggling cases in the country in order to determine how many and which ones include medicinal products. The author of this assessment made interviews and contacts in this respect regarding the biggest criminal court in the country (Criminal Court of Skopje) and no such cases appeared to exist in the ju*dicial practice of this court.)

**NORWAY** (prepared by the national consultant Ms Belinda FORSSTEN)

| PLEASE COLLECT ONLY RELEVANT CASES ON THE FALSIFICATION OF MEDICAL PRODUCTS OR SIMILAR CRIMES | | |
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| **DATE AND CASE** | **DESCRIPTION** | **RESULT** |
| 2015-06-01<br>TGJOV-2015-26193<br>https://lovdata.no/pro/avgjorelse/tgjov- 2015-26193 | Person A was sentenced to community service for the sale and storage of doping substances, as well as the import and sale of melanotan through his<br>own online store. He was also convicted of negligent possession of drugs.<br>Another man was also sentenced to community service for complicity.<br>Violation of ECHR art. 6 (trial within a reasonable time), which was compensated for in the sentencing. Statements about what the normal level of punishment for a similar crime would have been if the ECHR art. 6 had been complied with.<br>A admitted to having sold Melanotan and doping substances for a total of NOK 1,032,975.<br>Gross profits are subject to confiscation, but it is not permissible to confiscate the same amount repeatedly.<br>After a discretionary assessment, where special emphasis is placed on the limited picture of evidence presented to the court regarding the basis for the confiscation, the court has come to the confiscation set in line with the prosecution's proposal of NOK 400,000.<br>Person B admitted to having received money for the services he performed for A and these were a prerequisite for the import and sale of Melanotan. A estimated that the consideration was between NOK 10,000 and 15,000. The court found the conditions for confiscation to be present and the confiscation amount for person B were set to NOK 10,000. | The person A were convicted of violation of the Medicines Act § 31 (1) and (2), cf. (3) and § 16 as well as the Medicines Act § 31 (1), cf. § 13, cf. regulations on the manufacture and import of medicines § 3-2.<br>Person A were sentenced to community punishment for 68 hours with an execution time of 90 days. The subsidiary prison sentence was imprisonment for 75 days.<br>NOK 400,000 which person A acquired from the sales of both drugs and medical products were confiscated.<br>Please note that the person also was convicted of other drug related crimes, which were a part of the punishment as stated above.<br>The person B were convicted of contribution of the violation of the Medicines Act § 31 (1), cf. (3), cf. § 16. T Medicines Act § 31 (1), cf. § 13, cf. regulations on the manufacture and import of medicines § 3-2.<br>Person A were sentenced to community punishment for 30 hours with an execution time of 75 days. The subsidiary prison sentence were imprisonment for 33 days.<br>Person B were sentenced to endure confiscation of NOK 10,000. |

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| **DATE AND CASE** | **DESCRIPTION** | **RESULT** |
| 2014-05-16<br>LG-2014-38884<br>https://lovdata.no/pro/avgjorelse/lg- 2014-38884 | The District Court sentenced the 45-year-old person for violation of the Medicines Act § 31 (1), cf. third paragraph cf. § 16. The Medicines Act § 31 (1), cf. § 13 cf. regulations on manufacture and import of medicines § 3-2, to imprisonment for 90 days.<br>NOK 500,000 were confiscated.<br>The person appealed to the Court of Appeal.<br>The person were sentenced to 60 days probation with the addition of a fine of NOK. 10.000 for illegal import and resale of an unapproved drug, Melanotan, which i.a. was marketed to give users tan.<br>Due to the case's stay with the police, the prison sentence was made conditional, cf. ECHR art. 6 and art. 13.<br>The Court of Appeal rejected the appeal against the district court's confiscation of dividends of NOK 500 000. | The prison sentence were then set at 60 days, which were made conditional on a probationary period of 2 years.<br>In addition, an unconditional fine of NOK 10.000 were imposed, subsidiary imprisonment for 15 days.<br>Otherwise, the appeal is rejected |
| 2014-05-06<br>TSTRO-2013-83021<br>https://lovdata.no/pro/avgjorelse/tstro- 2013-83021 | The case concerns the production, storage and sale of doping substances, doping-related drugs and counterfeit drugs in the period 2005 - 2012, as well as criminal acts committed in connection with this activity. For six of the seven defendants, it is a central issue whether the criminal acts have been committed as part of the activities of an organized criminal group.<br>Serious violation of the doping provision. Organized criminal group. Production and sale of doping substances (approx. 50 kg active substance). The punishment especially sharpened for those with leading roles, also sharpened punishment for the culprit. Imprisonment for a prisoner of 7 years, and confiscation of 3 million. The verdict discusses the Supreme Court's case law on sentencing for doping offenses | Person A were sentenced to prison for 6 months and confiscation of NOK 450.000 in addition to the drugs as listed in the judgment.<br>Person B were sentenced to prison for 7 years and confiscation of NOK 3 000 000 in addition to the drugs as listed in the judgment.<br>Person C were sentenced to prison for 6 years and the confiscation of NOK 2.600.000 in addition to the drugs as listed in the judgment.<br>Person D were sentenced to prison for 5 years and 2 months, and the confiscation of NOK 1.700.000 in addition to the drugs and items related to the crime as listed in the judgment.<br>Person E were sentenced to community punishment for 250 hours. The execution time and the subsidiary prison sentence – imprisonment – were set to 1 year and 6 months. NOK 30.000 in addition to the drugs and items related to the crime as listed in the judgment were confiscated.<br>Person F were sentenced to community punishment for 327 hours. The execution time and the subsidiary prison sentence – imprisonment – were set to 1 year and 4 months. NOK 27.500 in addition to the drugs and items related to the crime as listed in the judgment were confiscated.<br>Person G were sentenced to prison for 2 years. NOK<br>70.000 as week as drugs and items related to the crime were confiscated. |

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| **DATE AND CASE** | **DESCRIPTION** | **RESULT** |
| 2020-07-01<br>LE-2020-11747<br>https://lovdata.no/avgjorelse/le-2020- 11747 | A 23-year-old woman was sentenced by the Court of Appeal to five months in prison for importing a drug that were not on the drug list. The case concerned 81,870 100 mg Tramadol capsules.<br>The District Court ruled in the case in 2019 were the person were sentenced to prison for 1 year. The person were also sentenced to endure the confiscation of 81,870 Tramadol tablets 100 mg. and two suitcases. The person were sentenced to pay legal costs of NOK 5.000. - five thousand - kroner.<br>The person appealed the district court's judgement to the Court of Appeal. A has appealed the district court's judgment.<br>Only the sentence of imprisonment was referred to an appeal hearing. The other grounds for appeal were refused.<br>The Court of Appeal found that imprisonment for 5 moths were the correct punishment. | The person were sentenced to 5 months prison |
| 2012-01-26<br>LB-2011-117686<br>https://lovdata.no/pro/avgjorelse/lb- 2011-117686 | A person were charged for storage of 106.7 grams of methamphetamine, import and storage of between 40 - 50 liters of GBL and GHB, and several other violations of provisions of the Penal Code, the Medicines Act and the Road Traffic Act.<br>Some of the imports of GBL took place before GBL was on the drug list, and these acts were assessed as a violation of the Medicines Act § 31 (1) , cf. section 13 (4).<br>The imports of GBL were considered a continuing criminal offense.<br>The District court sentenced the person to imprisonment for 1 year and 4 months. The person appealed to the Court of Appeal.<br>The Court of Appeal mentioned in the judgement that GBL is converted to GHB by ingestion in the body and which can have an intoxicating effect. Also, that conversion can be carried out relatively easily by means of, for example, caustic soda. | |

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| **DATE AND CASE** | **DESCRIPTION** | **RESULT** |
| | The Supreme Court ruled in a judgment of 12 June 2009 (Rt-2009-780) that GBL cannot be regarded as a derivative of GHB, which is listed on the drug list, determined by the Norwegian Medicines Agency. The Supreme Court therefore concluded that importation and storage of GBL is not affected by the Penal Code. Instead, importation without approval could be punished according to the Medicines Act § 31 (1), cf. § 13 (4). GBL were listed on the drug list a few days later, and it were from that day possible to punish the importation of GLB according to the Penal Code.<br><br>The persons first seven importations of GBL were done before it were listed on the drug list, and the acts therefore were punished as a violation of the Medicines Act § 31 (1). The Medicines Act § 31 opens for penalty with fines or imprisonment for up to 3 months - or both. The circumstances were regarded as aggravating circumstances pursuant to the Penal Code. | The person were sentenced to imprisonment for 1 year and 4 months. The sentence were an additional sentence in relation to the District Court's judgment.<br><br>The person were also regarded as disqualified from driving a motor vehicle subject to a driving license for a period of 6 months as the result of violations of the Road Traffic Act. |
| 2018-06-26<br><br>LB-2017-200514<br><br>https://lovdata.no/pro/avgjorelse/lb- 2017-200514 | A 30-year-old previously punished man were convicted of importing fenazepam from China equivalent to 1.2 million user doses.<br><br>It were assumed that the starting point for punishment was imprisonment for up to 9 years.<br><br>Deductions were given for confession and for long case processing time.<br><br>The sentence was by the District Court. set at 6 years and 6 months, as well as the confiscation of a computer, a mobile phone and a scale used to commit the crime.<br><br>The sentence was set at 6 years in prison by the Court of Appeal.<br><br>The Court of Appeal mentioned that general preventive considerations weigh heavily when dealing with large amounts of narcotic drugs. This applied also to imports from abroad where the motive was profit, even though the profit was relatively limited. Smuggling of such a large quantity and number of user doses entails a particularly extensive spread of drugs and must be considered highly harmful to society. At the same time, this meant that the personal circumstances of the accused came more into the background | The sentence was set at 6 years in prison as well as the confiscation of a computer, a mobile phone and a scale used to commit the crime. |

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| **DATE AND CASE** | **DESCRIPTION** | **RESULT** |
| 2020-03-03<br>LB-2020-1371<br>https://lovdata.no/avgjorelse/lb-2020- 1371 | A 30-year-old person was sentenced by the Court of Appeal to 3 years and 6 months in prison for importing 99,320 tablets containing the narcotic drug diazepam and for violating customs legislation by importing 162.710 Tramadol tablets and violation of the Medicines Act for having imported medicines from states outside the EEA without a permit.<br>Diazepam is listed on the drug list, while tramadol is not. The seizure of the Tramadol tablets were therefore not analyzed or investigated further.<br>However, a quick test taken by the Customs showed that the tablets contained Tramadol.<br>The person received the tablets and the money in Serbia.<br>The starting point for the punishment for the import of diazepam, corresponding to 66,000 drug doses, was, in the opinion of a joint Court of Appeal, imprisonment for about three and a half years.<br>Tramadol is not on the drug list in Norway, but the import of the tablets was a particularly serious customs offense which in isolation entailed a sentence of imprisonment for 1 year and 6 months.<br>After a deduction of approx. 20% for confession and contribution to the reprimand in a case adjudicated in Sweden, the sentence was imprisoned for 3 years and 6 months. | The person were sentenced to imprisonment for 3 years and 6 months.<br>Tramadol tablets, two mobile phones as well as SEK<br>296.000 were confiscated.<br>The person were sentenced to the of the right to drive a motor vehicle subject to a driving license in Norway forever on the basis of the violations of the Road Traffic Act. |

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| **DATE AND CASE** | **DESCRIPTION** | **RESULT** |
| 2011-11-08<br>LG-2010-198774<br>https://lovdata.no/pro/avgjorelse/lg- 2010-198774 | A 49-year-old person woman were sentenced to 30 days in prison on falsification of prescriptions for preparations by the Court of Appeal.<br>The person had been given a total of 400 tablets of Pinex forte and 400 tablets of Valium. In addition, she had been given 150 tablets of Imovane, which is not on the drug list.<br>The Court of Appeal mentioned that according to case law, there must be a strict reaction where prescription counterfeiting is used as a means of illegal acquisition of tablets with narcotic active substances.<br>The person were in the District Court sentenced to imprisonment for 60 days, and to pay legal costs of NOK 3.000. | 30 days in prison. |
| 2015-01-13<br>LF-2014-103657-4<br>https://lovdata.no/pro/avgjorelse/lf- 2014-103657-4 | The so-called «Gilde case».<br>Production and sale of 3.268.800 doping tablets (anabolic androgenic steroids) which were produced from 50 kg of active substance.<br>The Court of Appeal set prison sentences between 4,5 and 6,5 years for the main offenders.<br>The section of the Penal Code on organized criminal groups came into force.<br>The Court of Appeal made certain deductions in the confiscation pursuant to the Penal Code in order to avoid double confiscation. | Person A were sentenced to prison for 4 years and 6 months, as well as confiscation of profits of NOK 650.000.<br>Person B were sentenced to imprisonment for 6 years and 6 months, as well as confiscation of profits of NOK 2.700.000.<br>Person C were sentenced to imprisonment for 6 years, as well as confiscation of profits with NOK 3.100.000.<br>Person D were sentenced to imprisonment for 5 years and 9 months, as well as confiscation of profits of NOK 1.800.000.<br>Person G were sentenced to imprisonment for 1 year and 6 months.<br>The drugs and items used to commit the crimes were confiscated by the judgement of the District Court. |

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| **DATE AND CASE** | **DESCRIPTION** | **RESULT** |
| 2006-10-10<br>Rt-2006-1190<br>https://lovdata.no/pro/avgjorelse/hr- 2006-1728-a | A doctor had received 100 tablets of Hexalid from abroad without permission.<br>According to a conversion table the received tablets corresponded to 12.5 grams of hashish.<br>The import was a violation of procedures laid down in regulations concerning the manufacture and import of drugs of 2004 and the Drugs Regulations of 1978.<br>The Supreme Court concluded that the doctor's circumstances were also affected by the Penal Code for illegal importation of drugs<br>The District court sentenced the person to imprisonment for 20 days and a fined of NOK 5.000, as well as the confiscation of 100 tablets of Hexalid à 5 mg. The person were also sentenced to pay the legal fees of NOK 2.000. | Imprisonment for 20 days, the confiscation of 100 tablets of Hexalid, a fine of NOK 5.000 and legal fees<br>of a total NOK 4.000. |

**POLAND** No submission has been received on case law from the national consultant

**ROMANIA** (prepared by the national consultant Mr Adrian SANDRU)

| PLEASE COLLECT ONLY RELEVANT CASES ON THE FALSIFICATION OF MEDICAL PRODUCTS OR SIMILAR CRIMES | | |
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| **DATE AND CASE** | **DESCRIPTION** | **RESULT** |
| Decision 1315/2014 dated 28 October 2014, passed by the Bucharest Court of Appeal – Final Decision | The criminal investigations found that an organised crime group was conducting itself an activity through a company called Natural Green, which made several imports of counterfeit products, belonging to authorized warehouses for the marketing of pharmaceutical products and/or supplements food, being used herbal stores, drugstores or even pharmacies. The National Sanitary Veterinary and Food Safety Authority started a series of controls and verifications at the headquarters/ warehouses of company AF S.R.L., in view of the alert issued by the Belgian Federal Agency for Food Chain Safety regarding the presence of sibutramine in the composition of several food supplement products. Specifically, the notifications referred to the presence of sibutramine in the product batches "Slimming Capsule" imported by C and sold on the Romanian market by the company AF S.R.L., as well as in the product Super Slim Pomegranate Weight Loss, also imported by C and sold on the Romanian market by the company TEM FS.R.L.<br><br>The inspectors of the Public Health Direction, as result of the inspections they had performed, did not identify the batch of the product Slimming Capsule in the records of company AF S.R.L., thus concluding that this product had not been imported by this company.<br><br>As a safety measure, the Sanitary Veterinary and Food Safety Directorate ordered banned AF S.R.L. to further sale 54 boxes of the Slimming Capsule product.<br><br>In 2009, defendant F I D was found on the highway, transporting, in his car, several slimming products, respectively: 2 boxes of the Chinese slimming tablet and 500 boxes of the AF S.R.L. slimming capsule, without possessing the corresponding legal documents.<br><br>In this case, the "constituting of the group" was done by means of setting up a company, namely Natural Green Life on 18.09.2008, having as associates and administrators the defendants, most of the criminal activity being carried out by the two. Their criminal activity consisted of: the use at the customs authority of some forged commercial documents, the introduction in the country through the places established for customs control, by avoiding customs control of goods to be placed under a customs procedure. Thereafter, the products were being sold on the internet. | All the persons investigated and prosecuted were found guilty of the offence of unfair competition (art. 5 Law no. 11/1991), the offences against intellectual property (art. 52 Law no. 129/1992), the offence of preparing counterfeit food or drink, altered or prohibited for consumption, harmful to health, exposure to sale or sale of such food or beverage, knowing that they are counterfeit or altered or prohibited for consumption (art. 313 para. 1 of the former Criminal Code 1968), the offence of falsifying or substituting other goods or products, if by falsification or substitution they have become harmful to health (art. 313 para. 2 of the former Criminal Code 1968), the offence of tax evasion (art. 9 Law. no. 241/2005), the offence of using falsified transport or commercial customs documents before the customs authority (art. 273 Law no. 86/2006, the offence of introducing goods in the country, through places other than those established for customs control (art. 270 Law no. 86/2006).<br><br>All defendants were each sentenced to a total penalty of 3 years in prison, but the enforcement of the sentence was suspended and a period of probation of 8 years was imposed to the defendants, period in which they had to comply with several obligations established by the court (to go to the Police Station on certain dates, to announce the change of address, etc.). |

| PLEASE COLLECT ONLY RELEVANT CASES ON THE FALSIFICATION OF MEDICAL PRODUCTS OR SIMILAR CRIMES | | |
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| **DATE AND CASE** | **DESCRIPTION** | **RESULT** |
| Sentence no. 614/2018 dated 8 April 2018, passed by the Bucharest Tribunal – Final Sentence | The defendants (G and V) created and implemented a criminal mechanism through which they sought, on the one hand, the introduction to the legal marketing circuit of counterfeit medicinal products for human use (bearing the PEGASYS brand, a protected trademark at Community level), and the evasion of the payment of taxes owed to the state budget by the company VERDAN FARM SRL (in the amount of 945,389 lei). The group also sought the concealing of the real source of origin of the goods (which were purchased, in reality, by defendant G without supporting documents and without paying VAT on the" black market"), creating the appearance that these goods would have been purchased at higher prices (very close to the delivery ones) and with the payment of VAT, from the legal person administered by defendant V. | The defendants agreed to conclude a plea bargaining, pleading guilty for tax evasion offences both in the form of authorship and in the form of complicity (art. 9 Law 241/2005) and trademark criminal offences (art. 90 Law 94/2008). The plea bargaining was approved by the court.<br>G was convicted to a total sentence of 2 years in prison, but the enforcement of the sentence was suspended and a probation period of 4 years was imposed to him, having to comply with several obligations set by the court (to go to the Police Station on certain dates, to announce the change of address, etc.)<br>V was convicted to a total sentence of 1 year and 6 months in prison, but the enforcement of sentence was suspended and a probation period of 3 years and 6 months was imposed for the defendant in which he had to comply with several obligations set by the court (to go to the Police Station on certain dates, to announce the change of address, etc.) |
| Decision no. 46/2011 dated 15 February 2011, passed by the Bucharest Court of Appeal, Final decision | Between the end of 2005 and the middle of 2006, defendant G corresponded with witness A, offering him and delivering to him directly or through intermediaries, several types of medicines, including the product with unmarked inscription, the sign of Cialis.<br>The defendant's statement confirmed this factual situation, the defendant admitting that he acted as an intermediary, in exchange of a fee. | Defendant G was prosecuted and tried for committing trademark crimes and the offence of counterfeiting of medicines (as formerly provided by article of 834 Law no. 95/2006 on the healthcare reform).<br>The defendant was convicted for trademark crimes to a sentence of 3 in prison, but the enforcement of the sentence was suspended and a period of 7 years was imposed for the defendant in which he had to comply with several obligations established by the court (to go to the Police Station on certain dates, to announce the change of address, etc.)<br>Regarding the accusation of counterfeiting of medicines, defendant G was acquitted for the reason that the offence provided by art. 834 of Law 95/2006 is covering only selling counterfeiting medicines on the territory of Romania and the defendant was selling the medicines abroad. |

| PLEASE COLLECT ONLY RELEVANT CASES ON THE FALSIFICATION OF MEDICAL PRODUCTS OR SIMILAR CRIMES | | |
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| **DATE AND CASE** | **DESCRIPTION** | **RESULT** |
| Decision no. 1071/2019 dated 15 March 2019, passed by Cluj Napoca Court – Final by Decision no. 658/2019 dated 31 May 2019, passed by Cluj Court of Appeal. | During 2014-2015 the defendant traded and held for sale counterfeit drugs by registering the trademarks Viagra and Cialis without the consent of the trademark rights holders and he exhibited for sale counterfeit medicines bearing the inscriptions of the trademarks Viagra and Cialis, which are harmful to health given the active substance - sildenafil. The defendant purchased from the website www.viagra100mg.hu products bearing the marks of the registered trademarks Viagra and Cialis, which he knew to be counterfeit and which he decided to further sell, on the grounds that he had initially used them for his own use, and subsequently, finding that they have beneficial effects on him, he decided to increase his income, respectively the disability pension.<br><br>In this context, the defendant posted ads on the websites www.anunturipenet.gsp.ro and www.anuncuri.cere.ro, offering for sale the products with the above-mentioned brands. | The action of the defendant to expose for sale counterfeit drugs bearing the inscriptions of the brands Viagra and Cialis, harmful to health given the active substance (sildenafil), was found to meet the constituent elements of the criminal offence of preparation, offering or display for sale of counterfeit or substituted medicines provided by art. 357 para. 2 of the Romanian Criminal Code. The defendant was convicted for this offence.<br><br>Moreover, the defendant was also convicted for committing the crime of putting into circulation a product bearing an identical or similar trademark with a trademark for identical or similar products in continuous form (2 actions related to the VIAGRA and CIALIS trademarks), provided by art. 90 para. 1) b of Law 84/1998. The defendant was convicted to a total sentence of 1 year and one month in prison, but the enforcement of the sentence was postponed and a probation period of 2 years was imposed to the defendant to comply with several obligations established by the judge (to go to the Police Station on certain dates, to announce the change of address, etc.). |

**SERBIA** (prepared by the national consultants Ms Neda MARKOVIC, Mr Jovan ĆOSIĆ and Mr Božidar BLAGOJEVIĆ)

| PLEASE COLLECT ONLY RELEVANT CASES ON THE FALSIFICATION OF MEDICAL PRODUCTS OR SIMILAR CRIMES | | |
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| **DATE AND CASE** | **DESCRIPTION** | **RESULT** |
| KTO VTK 23/20 | Illicit trade of face masks on the internet | On 25 May 2020 motion to indict submitted – court proceedings underway |
| KTO VTK 18/20) | Illicit trade of face masks on the internet | On 27 March 2020 plea agreement with the defendant concluded<br><br>On 7 April 2020 – the Court accepted the plea agreement and pronounced a conviction |

| PLEASE COLLECT ONLY RELEVANT CASES ON THE FALSIFICATION OF MEDICAL PRODUCTS OR SIMILAR CRIMES | | |
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| KT.No.536/19 | On 17 June 2019, in the vehicle of the suspect, 142 packs of 3 ampoules of blockers each, used for heroin addicts, were found without any accompanying documents on the goods origin and distribution. | On 16 August 2019 the Decision to reject the criminal complaint adopted |
| KTKo No. 539/19 | A criminal complaint against three persons was submitted based on grounded suspicion that during the period of time from 10 December 2015 to 30 April 2019, as responsible persons in a company, they put in circulation medical devices - digital thermometers, which did not conform to basic requirements; also, their conformity assessment in accordance with the law was not performed, they did not bear the CE marking, and they were not registered in the Republic of Serbia. | The procedure is in the investigation phase. |
| Kt 6415/19 | A criminal complaint against one person was submitted on grounded suspicion that on 25 September 2019 he produced significant quantities of medicinal products without the approval of the Ministry of Health, which he then sold through the company he owns. | The procedure is in the investigation phase.<br>The request for the collection of necessary information was submitted to the Sector for the inspection of Medicinal Products and Psychoactive Controlled Substances and Precursors of the Ministry of Health |
| Kt 130/20 | Criminal offence of Production and Putting in Circulation of Harmful Products under Article 256 of the Criminal Code | On 10 June 2020 motion to indict submitted – court proceedings underway |

**SLOVAK REPUBLIC** (prepared by the national consultant Mr Peter KLANDUCH)

| PLEASE COLLECT ONLY RELEVANT CASES ON THE FALSIFICATION OF MEDICAL PRODUCTS OR SIMILAR CRIMES | | |
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| **DATE AND CASE** | **DESCRIPTION** | **RESULT** |
| 2018-2019 | Official data of the Ministry of Justice and the Prosecutor General's Office indicate that only a handful of cases related to pharmaceutical criminal offences (Sections 170, 170a and 170b of the Criminal Code) were tried before Slovakian courts in the two-year period of 2018-2019. Three cases were tried in 2018 and five cases in 2019. No criminal case under Section 170b (Counterfeiting of medicinal products and medical devices) was tried in the reported period. No details concerning the above cases have been found from which to infer the key characteristic features, patterns of this type of criminality or long-term trends. It seems to be hard to determine what are the causes of low level of attention to pharmaceutical criminality (lack of financial and/or human resources, insufficient expertise of law-enforcement authorities, evidentiary problems, etc.?) | The court proceedings resulted in three convictions in 2018 (one conviction under Section 170 and two convictions under Section 170a of the Criminal Code) and five convictions in 2019 (one conviction under Section 170 and four convictions under Section 170a of the Criminal Code). The sanctions included prison sentences, forfeiture of item and protective measures. |

| PLEASE COLLECT ONLY RELEVANT CASES ON THE FALSIFICATION OF MEDICAL PRODUCTS OR SIMILAR CRIMES | | |
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| **DATE AND CASE** | **DESCRIPTION** | **RESULT** |
| 2017 | On 13 September 2017, the Police Force of the Slovak Republic informed on its Facebook page of the case of a 26-year old man charged with the counterfeiting of medicinal product and medical device. During routine police check pills and the packs with unknown medicaments were found. The expert analysis confirmed that three pills were counterfeits of the original medicinal product registered in the country for the ED treatment. The items did not contain the same effective substance as the original. The remaining drugs were not registered in Slovakia nor in any other EU Member State. | Not known. |

**SLOVENIA** (prepared by the national consultant Ms Jasmina ARNUS TABAKOVIC)

Based on available data, obtained by the Centre of Expertise and IT at the Supreme State Prosecutor's Office[12] the prosecution at the state level from year 2005 to 2018 deal with less than 10 cases where the subject of the seizure was counterfeit erectile drugs dysfunction such as *Viagra, Cialis in Kamagra gel.* From the point of view of prosecutorial cases we may define counterfeit medicinal products as medicinal products that deviate from the original in this way in quality as well as in quantity of active substances, they differ from them in serial form numbers and after the date of use, the medicinal products concerned are not registered, etc.

In the period from 2018 to 2020, the state prosecutor's offices in the Republic of Slovenia received a total of 16 criminal complaints in connection with a criminal offense under **Article 183 of the Criminal Code** (KZ-1, 2012) - **Article 183 - Manufacture and Trade in Harmful Remedies.**[13] In 11 cases, the charges were dismissed (mostly on the grounds that the reported act is not a criminal offense prosecuted *ex officio (possession of harmful medicinal product is not punishable, it is not possible to prove manufacturing or sales of harmful medicinal product, the quantity seized does not indicate a sale, no medicinal product as seriously endanger health has been identified*) and because there is no reasonable suspicion), which shows on the shortcomings of incrimination.[14] In 5 cases the prosecution filed an indictment.

The number of proceedings with the police and the prosecution on the basis of the Article 183 of CC-1 does not reflect the actual scope of the problem of counterfeit medicines, if this is necessary for the purpose of **proving harmfulness to health.**[15]

Already in **2016, 2018 and 2019** the police and the state prosecutor's office drew attention to inadequate criminal law legislation and suggested better criminalisation. In 2020, the Ministry of Justice proposed an amendment to the criminal law of the Criminal Code **(amendment to the Criminal Code - KZ-1H)** and in September 2020 a discussion was held on amendments to articles in KZ-1 to implement the provisions of the MEDICRIME Convention[16]. Amendments to KZ-1H, relating to the MEDICRIME Convention, are harmonized at the professional level,[17] which is also one of the objectives of the **Resolution on the National Program for the Prevention and Suppression of Crime for the period 2019-2023.** [18]

12. Centre of Expertise and IT at the Supreme State Prosecutor's Office, available at the following link https://www.dt-rs.si/units-and-departments.
13. Slovenian Criminal Code (Kazenski zakonik KZ-1, Official Gazette RS, no. 50/12, 6/16, 54/15, 38/16, 27/17, 23/20 in 91/20) available at the following link http://www.pisrs.si/Pis.web/pregledPredpisa?id=ZAKO5050.
14. The article cited in the first paragraph provides for only **two forms** of enforcement, i.e. **acts: 1)** the **manufacture** of drugs or other medicinal products that are so harmful to health and **2)** the **placing on the market** of such medicinal products or medicinal products for treatment or in some other way.
15. The crucial for prosecution is the interpretation of the legal sign in Article 183: **harmful to health.**
16. The Republic of Slovenia has already signed the Convention in March 2019, and before ratification - in addition to changes in sectoral legislation - amendments to Criminal Code (CC-1) are needed.
17. Draft of the law: Given the above and the fact that counterfeit medicines certainly pose a threat to public health, although in this particular case it is not possible to prove at least an abstract health threat in criminal law, a new criminal offense of "production and trafficking of counterfeit medicines" must be established. A new criminal offense in proposed in **Article 183.a of the CC-1** (as subsidiary offense) "production and trade in counterfeit remedies for treatment" for medicinal products which are false, forged or falsified and no serious crime has been committed under KZ-1. In Article 183 of the CC-1 new form of acts will be added such as *manufactures, sells or offers for sale or, for sale or placing on the market, buys or stores, or mediates in the sale or purchase, or imports or exports or otherwise.*
18. (Resolution on the national programme for the prevention and suppression of crime 2019–2023, Official Gazette, no. 43/19, available on the website http://www.pisrs.si/Pis.web/pregledPredpisa?id=RESO119).

Criminal legislation of the Republic of Slovenia or the Criminal Code (KZ-1, 2012) contains criminal offenses that could be classified as criminal individual practices in the field of counterfeiting of medical (medicinal) products. To persecute such offenses are the most appropriate offenses: Manufacture and trade in harmful remedies for treatment under Article 183 of the Criminal Code, Unjustified use of a foreign mark or model under Article 233 of the Criminal Code, Smuggling under Article 250 of the Criminal Code, Deceiving costumers under Article 232 of the Criminal Code, Fraud under Article 211 of the Criminal Code or criminal offenses in the field of copyright infringement.

**Regarding Article 183 of the Criminal Code (Article 183 - Manufacture and Trade in Harmful Remedies) we note three (3) final judgements; one from 2013 and two final judgement in 2019 as stated below. Regarding Medicinal Products Act (Zakon o zdravilih, ZZdr-2)19 we note one (1) final administrative judgement.**

| PLEASE COLLECT ONLY RELEVANT CASES ON THE FALSIFICATION OF MEDICAL PRODUCTS OR SIMILAR CRIMES | | |
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| **DATE AND CASE** | **DESCRIPTION** | **RESULT** |
| **Maribor Higher Court no. II Kp 3198/2010, 10. 1. 2013,**<br>available at the following link<br>http://www.sodisce.si/vismb/odlocitve/2012032113060855/<br>**The District State Prosecutor's Office in Maribor (DSPO MB)**<br>**good prosecutorial practice**<br>**first and pilot conviction**<br>**first judgement regarding Article 183 of CC-1** | The District State Prosecutor's Office in Maribor (https://www.dt-rs.si/dspo-maribor) prosecuted the perpetrator of the criminal offense of production and trade of harmful means of treatment under **Article 183 of the Criminal Code (Article 183 - Manufacture and Trade in Harmful Remedies),** which ended with a conviction. As an example of good prosecutorial practice, it represents first and pilot conviction in relation to counterfeit medicines.<br>**Agency for Medicinal Products and Medical Devices of the Republic of Slovenia** (hereinafter **JAZMP,** https://www.jazmp.si/en/) is due to a violation of labor law; sale of medicines illegally, ordered the perpetrator to pay a fine. After re-examining the sale of drugs, a **preliminary analysis** found that the drugs sold by the same perpetrator online were counterfeit, so **JAZMP** filed a complaint to the prosecutor's office, accusing the suspect of selling a counterfeit drug for erectile dysfunction online. | **The Court of First Instance** is in deciding on the criminal sanction took into account that the accused sold counterfeit drugs no more than 26 people and that no customer has been shown to have it because of them health problems, except for one that associated higher blood pressure with taking *Cialis* tablets and nosebleeds, but found no specific aggravating circumstances such as stated in the grounds of the judgment under appeal. The Court found the accused guilty of committing the criminal offense and sentenced him to a suspended sentence, which sentenced him to 7 months in prison with a probation period of 2 years and confiscated his confiscated pills and illegal property.<br>**The prosecutor appealed** against the decision on the criminal sanction, as the sanction of a warning nature was not appropriate in view of the seriously danger that can be caused. It also drew attention to the gravity of the crime, which was indicated by the danger of taking counterfeit medicines, which the defendant's counsel objected to on the grounds that the counterfeits contained fewer harmful substances than the originals.<br>Following the appeal of the prosecution, **the High Court in Maribor changed the criminal sanction by sentencing the convict to 7 months in prison.** |



19. **Medicinal Products Act - MPA** (Zakon o zdravilih, ZZdr-2, Official Gazette RS, no. 17/14 in 66/19) available at the following link http://www.pisrs.si/Pis.web/pregledPredpisa?id=ZAKO6295.

| PLEASE COLLECT ONLY RELEVANT CASES ON THE FALSIFICATION OF MEDICAL PRODUCTS OR SIMILAR CRIMES | | |
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| **DATE AND CASE** | **DESCRIPTION** | **RESULT** |
| | Based on police initiatives, the prosecutor proposed issuing court orders for **house search and car, inspect phones and computers, and obtain bank account information.** The suspect was seized several boxes of counterfeit medicines and jellies, certificates of delivery, cash in the amount of EUR 25,500,00 and copies of instructions for the use of *Viagra* and *Cialis*. An inspection of the seized mobile phones and a computer revealed that the suspect had recorded customers. At the same time files were found that were used to create websites in Croatian and German, which indicated its operation in foreign markets as well. Based on the obtained bank data, it was established that he sold medicines to at least 19 customers although thousands of addresses were found to which he sent packages.<br><br>The JAZMP carried out an quality control of the seized medicines and found that the content of the active substance in Cialis 20 mg did not correspond to the declared content, as the medicine contained 25 % less tadalafil. Cialis 25 mg was found not to meet the requirements of the original product in terms of purity and quantification and weight, and the tadalafil content was 136% of the declared value, i.e. the product contained 36 % more tadalafil. The conclusion of the analysis concluded that counterfeit medicines could pose a serious threat to human health and life and that the seized medicines were undoubtedly counterfeits, as they differed from the originals in terms of both quality and quantity of active ingredients, by serial number and expiration date.<br><br>Six months later, the prosecutor received a criminal complaint from the police, which was carrying out a secret surveillance measure against another person, with whom the same suspect was on that day, who was stopped and controlled. He suspected was seized: 2 boxes of Cialis 20 mg tablets, a box of *Tadalis* SX20, a box of *Viagra* and 18 mail messages to various people. | The High Court thus agreed with the position of the public prosecutor that the imposition of a suspended sentence, which is a criminal sanction of a purely warning nature, is not substantiated in the case of the accused.<br><br>The Court of First Instance disregarded the high objective risk of sale counterfeit tablets for human health, which is apparent from the expert opinion. The High Court **relied on an expert opinion and took the view that the appeal warns the public prosecutor of the dangers of taking counterfeit medicines** and thus the gravity of the alleged offense to the defendant, and in doing so the allegations advocate that the counterfeits contained fewer harmful substances than the originals, by weight and do not reduce the risk of the alleged offense. **In assessing harmfulness therefore did not only consider the actual amount of substances harmful to health, as it follows from the expert opinion, and the actual potential adverse effects on human health, but also other circumstances.** Considered is that such medications can only be prescribed by a doctor who is taking the appropriateness such medicines according to the patient's state of health and that he can dispense them only a pharmacist on a prescription, and, as is clear from the expert opinion, yes poses a danger to human health, especially the uncontrolled intake of these medicines, not just their composition. According to the expert, it is from the opinion of the expert the courts show that those medicinal products, when used incorrectly or without medical supervision pose an increased risk to the health of the user, which means that **sales and use must be strictly controlled by customers counterfeit medicines** sold by the defendant were not below the relevant level medical supervision and used counterfeits that could pose a serious threat user health. Finding that the witnesses who were heard in the hearing criminal case, did not have health problems, does not reduce the danger and weight the offense in question, nor the circumstance of who carried out the analysis to the defendant of the seized counterfeits.<br><br>**The decision it is based on the fact that such medicines can only be prescribed by a doctor who assesses the suitability of medicines according to the patient's health, that medicines can only be dispensed by a pharmacist and that uncontrolled use of these medicines poses a danger to human health, albeit with a lower content of active substance.** |

| PLEASE COLLECT ONLY RELEVANT CASES ON THE FALSIFICATION OF MEDICAL PRODUCTS OR SIMILAR CRIMES | | |
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| **DATE AND CASE** | **DESCRIPTION** | **RESULT** |
| | After two investigations, the prosecutor's office filed an indictment and the court merged and conducted a single proceeding against the accused for a criminal offense under **Article 183 of the Criminal Code** due to a single hearing. He was accused of selling erectile dysfunction medicines (*Viagra, Cialis* at a price of EUR 54.00/pcs) online, which could only be obtained with a prescription and which differed from the original medicines in terms of quantity and quality of active ingredients, and that thereby endangering the health of at least 27 customers who responded to his offer.<br><br>The **forensic toxicologist** wrote in the opinion that taking **drugs for erectile dysfunction with the active ingredients sildenafil and tadalafil at their own discretion without medical supervision can seriously endanger the health of the use**r, especially when it comes to improper dosing and disregarding contraindications in certain diseases and interactions with other drugs. However, in the case of the use of counterfeit medicines, the risk is even higher. | |
| District Court Kranj, no. I K 47219/2017, 3. 9. 2018 in regard Ljubljana Higher Court no. III Kp 47219/2017, 10. 4. 2019,<br><br>webpage not available<br><br>The District State Prosecutor's Office in Kranj (DSPO KR) | The prosecution filed an indictment against 5 defendants for several crimes. According to Article 211 (Fraud), Article 213 (Blackmail) and **Article 183 of the Criminal Code (Article 183 - Manufacture and Trade in Harmful Remedies).**<br><br>One of the defendants, who was in custody, was also accused, among other things, of selling drugs and medicines that are harmful to health. He sold 120 boxes of *Viagra* tablets to one buyer for EUR 7,200 and 2,780 Cialis tablets, 1,104 Cialis tablets, 1,183 *Kamagra* bags, 172 *Viagra* tablets, 800 *Vizarsin* tablets, 68 *Vizarsin* tablets, 80 *SildeHEXAL* tablets and 1,429 Sildenafil tablets. | According to the **expert opinion of forensic expert** the court found that the active substances sildenafil, which is healthy for the treatment of erectile dysfunction, was found to be essential in all seized items. The seized medicines, except for the manufacturers Viagra Pfizer and Vizarsina manufactured by Krka, **are not registered in Slovenia**. Medicinal products registered in Slovenia are thus registered only as a tablet and are thus only available on a doctor's prescription, as they have the prescription of medicines, certain restrictions or safety measures. The patient's ability to engage in physical activity or sexual activity should be assessed. *Side effects such as headache, redness, indigestion, nasal congestion, urinary tract infections, visual disturbances and diarrhea* can be expected with the prescribed use of sildenafil. At higher doses, there are more digestive and visual disturbances in terms of symptoms than with lower doses. If it is taken healthily in several quantities without the supervision of a doctor, several health complications can occur. |

| PLEASE COLLECT ONLY RELEVANT CASES ON THE FALSIFICATION OF MEDICAL PRODUCTS OR SIMILAR CRIMES | | |
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| **DATE AND CASE** | **DESCRIPTION** | **RESULT** |
| | All of the above tablets and gels contain sildenafil, which is a drug to treat erectile dysfunction as already mentioned. The fact that *Viagra* from *Pfizer* and *Vizarsin* tablets from Krka are not registered drugs in Slovenia at all, and the sale and delivery by unauthorized sellers is thus alleged, is harmful to human health and life without prior approval and a doctor's prescription. The prosecutor proposed that for the first alleged crime 2 years and 6 months imprisonment, for the second 2 years and 2 months imprisonment and for the third 1 year and 6 months imprisonment. He also proposed the revocation of the suspended sentence and the imposition of a total sentence of 7 years in prison. | The concentration of active substances with this possibility of status effects is further altered by a decrease in renal function or impaired liver function. It is clear from all of the above that these medicines are medicines that contain substances that are harmful to health. They can only be prescribed by a doctor (on prescription).<br><br>The prosecutor proposed **a 1 year and 6 months in prison** sentence to the accused for the crime under Article 183 of the Criminal Code. The court sentenced the accused to **1 year and 1 months** in prison and sentenced the defendant to a uniform sentence of 6 years in prison. |
| Maribor Higher Court no. X K 10580/2017, 5. 4. 2019<br><br>webpage not available<br><br>The Specialised State Prosecutor's Office of the Republic of Slovenia | The prosecutor prosecuted several perpetrators of criminal offenses under Articles 113 of the Criminal Code (human trafficking), Article 186 of the Criminal Code (Unjustified production and trafficking of illicit drugs, illicit substances in sport and precursors for the manufacture of illicit drugs) and Article 183 of the Criminal Code (Article 183 - Manufacture and Trade in Harmful Remedies) and Article 187 (Enabling the use of illicit drugs or illicit substances in sports).<br><br>For the offense under Article 183 of the Criminal Code, one perpetrator was charged with selling to an undercover police officer 4 pieces of Kamagra gel containing the active substances Sildenafil to treat erectile dysfunction. In Slovenia medicinal products with sildenafil are allowed only under controlled sale if it is previously prescribed by a doctor and issued on the basis of a prescription by a pharmacist because sildenafil is harmful to human health if consumed uncontrolled. | The opinion of a forensic expert in the field of medicine, doping and laboratory medicine shows that *Kamagra* is a medicine that **is not registered in the Republic of Slovenia and therefore may not be sold in the Republic of Slovenia.** *Kamagra* contains the active substance sildenafil - an PDE5 inhibitor, which is a medicine used to treat erectile dysfunction and which can cause *side effects such as headache, dizziness, nasal condespia, hypertension, facial, ocular hyperaemia.* It can **be harmful to health,** especially when used **uncontrolled and in individuals with previous illnesses**. Wholesale or retail trade of medicinal products must be licensed by the **JAZMP**, and persons wishing to perform this activity in another EU Member State must notify the Agency. Sildenafil should not be taken by people who do not have erectile dysfunction and should therefore only be given with a prescription. In the Republic of Slovenia, sildenafil can only be obtained in pharmacies and on prescription, other sales are not permitted. The forensic expert also explained that sildenafil-containing medicines were registered in the Republic of Slovenia, namely Revatio film-coated tablets, Sildenafil Lek tablets, Sildenafil Teva film-coated tablets, Viagra, Vizarsin film-coated tablets. **They are prescribed on a white prescription, which the patient uses for one year.**<br><br>The prosecutor proposed a 6-month prison sentence to the accused for this crime. The court sentenced **the accused to 5 months in prison.** This same perpetrator was also charged with several criminal offenses under above mentioned articles of the Criminal Code. The court sentenced him to 2 years and 3 months in prison for all criminal offenses. |

| PLEASE COLLECT ONLY RELEVANT CASES ON THE FALSIFICATION OF MEDICAL PRODUCTS OR SIMILAR CRIMES | | |
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| **DATE AND CASE** | **DESCRIPTION** | **RESULT** |
| Judgment of the Administrative Court, III U 63/2018, 21. 3. 2019<br>Administrative procedure<br>Inspection Supervision, health activity<br>available at the following link<br>http://www.sodisce.si/usrs/odlocitve/2015081111431510/ | Criminal investigators from the Criminal Police Sector of the Ljubljana Police Administration seized shipments from Post of Slovenia on suspicion that the consignor's packages from Hong Kong contained illicit drugs or illicit substances in sports, which is a criminal offense under Article 186 of the Criminal Code (KZ-1). A report was drawn up on the seizure. It was found that in all cases there were shipments weighing about 8 kg, in which there were plastic bottles, and in each of them about 20 purple capsules. Due to the large amount of items, a random sample of one of the shipments was taken and examined at the National Forensic Laboratory. The report from this laboratory shows that **sibutramine** was identified in the sample, which is not on the list of illicit drugs or on the list of banned substances in sport, but is an appetite suppressant that the European Medicines Agency has already 2010 from the list of authorized medicines in the European Union. According to the Agency's website, the Committee for Medicinal Products for Human Use of the European Medicines Agency concluded that the benefits of **sibutramine do not outweigh the risks associated with it and therefore all marketing authorizations for medicinal products containing this substance have been withdrawn.** The list of medicinal products in the Republic of Slovenia also shows that **none of the medicinal products containing sibutramine has a valid marketing authorization.** | In view of the volume of the consignment at issue (22 postal items of 8 kg or a total of 176 kg, each containing plastic bottles, each containing 20 capsules), the first instance authority rightly concluded that sibutramine was not intended for personal use, but for further sale. **The order to destroy the consignment in question is justified.** |

| PLEASE COLLECT ONLY RELEVANT CASES ON THE FALSIFICATION OF MEDICAL PRODUCTS OR SIMILAR CRIMES | | |
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| **DATE AND CASE** | **DESCRIPTION** | **RESULT** |
| | A medicinal product may be marketed in the Republic of Slovenia if it has a **marketing authorization (the first paragraph of Article 20 of the Medicinal Products Act (ZZdr-2).** If he does not have such a permit, trade with him **is prohibited (Article 21 of ZZdr-2).** Placing medicinal products on the market means supplying the market with medicinal products for free or free of charge, or making a medicinal product available in the Republic of Slovenia (Item 4 of Article 6 of ZZdr-2), and the arrival of a medicinal product on the market means the first activity. these medicinal products and their availability to the end user (point 73 of Article 6 of ZZdr-2). Trade in medicines can be carried out as wholesale or retail trade. **Wholesale trade** in medicinal products is the activity of purchase, import, storage, export, export, sale of medicinal products, except for the issuance of medicinal products in retail trade to end users (Item 75 of Article 6 of ZZdr-2, also Article 3 of the Rules20), trade in retail medicines, the activities of purchasing, storing and dispensing a medicinal product or using a medicinal product in addition to a health or veterinary service (Item 76 of Article 6 of ZZdr-2). | |

**SWEDEN** No submission has been received on case law from the national consultant

20. Rules on detailed conditions of wholesale of medicinal products and determining of fulfilment of these conditions and procedure of gain the permission for traffic of wholesale of medicinal products, available at the following link http://www.pisrs.si/Pis.web/pregledPredpisa?id=PRAV8757

**TUNISIA** (prepared by the national consultant Mr Yassine YOUNSI)

| PLEASE COLLECT ONLY RELEVANT CASES ON THE FALSIFICATION OF MEDICAL PRODUCTS OR SIMILAR CRIMES | | |
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| **DATE AND CASE** | **DESCRIPTION** | **RESULT** |
| 28-05-2020 | The judges of Ariana Court of First Instance ruling on case number 30929/2017 between Novartis and Taha Pharma (GILENYA / FINGOLINE) deliberated following the hearing of 28 May 2020 and ruled in favour of NOVARTIS. | The court primarily:<br>§ Held that Taha Pharma had infringed a Novartis patent registered and protected in Tunisia<br>§ Ordered Taha Pharma to stop marketing and manufacturing counterfeit FINGOLINE products |
| 25-06-2020 | The judges of Tunis 2 Court of First Instance ruling on case number 5703 between Servier and Théra deliberated following the hearing of 26 June 2020 and ruled in favour of Servier. | 1 - At first instance, the court ordered the defendant, in the person of its legal representative, to refrain from making any use of the process for manufacturing the patented product, perindopril arginine, and from any manufacturing or marketing of that product in the following medicines:<br>▶ Therapril 10 g<br>▶ BI-Therapril (5 mg / 1.25)<br>▶ Bi-Therapril (10 mg / 2.5)<br>And in the event of non-compliance, ordered it to pay a fine of 10 dinars a day (also allowing the complainant to seize and destroy the aforementioned medicines), to publish the judgment in two daily newspapers in Arabic and French for three days at the defendant's expense, and to pay TND 6 000 in compensation for the non-pecuniary damage suffered by the complainant.<br>The court of first instance also ordered the defendant to pay TND 2 000.000 in respect of the cost of expert reports and TND 107 450 in respect of the cost of Record No. 3571; ordered the complainant to pay TND 200 for the costs of the order on application No. 20018 borne by the complainant, TND 64 150 in respect of the costs of recording the service of the order on request; payment of TND 400 000 for legal and lawyers' fees.<br>The court accepted the counterclaim as to form and dismissed it on the merits. |
| 03-2019 | Complaint to the public prosecutor at Ben Arous Court of First Instance against five persons using a warehouse to counterfeit medicines | The case is still under investigation. |

**UNITED KINGDOM** (prepared by the national consultant Ms Muireann QUIGLEY)

Explanatory Notes from the Researcher

It is important to understand the regulators in the UK are very active in their investigation and prosecution of those involved with falsified medicine and similar crimes. However, the nature of legal reporting in this jurisdiction is such that where cases are decided in the lower courts and no appeal is made there is often not a published record of the case. As such, I have included both those cases which are fully reported in the traditional sense and a number of examples of those which have been reported only through the regulator's own websites or by lawyers involved in the case.

In reality, it is likely that there are significantly more of these 'unreported' cases – particularly where it comes to less serious/sizeable instances of offences related to falsified medical products and similar crimes being committed. However, I hope that the information included in this document gives a helpful picture of the active commitment of the regulators in the UK to find and prosecute people involved in such crimes.

| PLEASE COLLECT ONLY RELEVANT CASES ON THE FALSIFICATION OF MEDICAL PRODUCTS OR SIMILAR CRIMES | | |
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| **DATE AND CASE** | **DESCRIPTION** | **RESULT** |
| REPORTED COURT CASES | | |
| *R v Patel and another 2009* | This was an appeals case brought by four applicants. The applicants were four of over ten defendants (this is the figure given in the judgement) who had been charged with crimes related to the global supply of counterfeit medicinal products. The charges were brought following a complex investigation by the MHRA, which began in 2003.<br><br>The first two applicants (Hitendra Patel an Shaan Hussain) were granted leave to appeal, and as such their cases were not discussed in this judgement at any length. This case focussed on the appeals of Ashwin Patel and Ketan Metha, which are detailed in turn:<br><br><u>Ashwin Patel</u><br><br>He has been found guilty of:<br>▸ One count of conspiracy to evade the prohibition of an unauthorised use of a trademark in connection with counterfeit Viagra<br>▸ One count of conspiracy to place a medicinal product on the market, contrary to the regulations to which we have just referred, and that related to Sildenafil Citrate | Hitendra Patel & Shaan Hussain<br><br>The court allowed these appeals. The results of the relevant Court of Appeal case are included below.<br><br>Ashwin Patel<br><br>The court did **not** grant Mr Ashwin Patel leave to appeal. They held that the trial court judge had been entitled to find – as he did – that any deficiencies which did exist with regards to the procedural operation of the investigation did **not** amount to a reason to stay proceedings. |

| PLEASE COLLECT ONLY RELEVANT CASES ON THE FALSIFICATION OF MEDICAL PRODUCTS OR SIMILAR CRIMES | | |
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| | ▶ One count of conspiracy to evade the prohibition of the unauthorised use of a trademark in relation to Cialis<br>▶ One count of conspiracy to place a medicinal product on the market, namely Tadalafil<br>He argued that the case for appeal on the following grounds:<br>1. The conviction was unsafe because the minister who delegated the power to prosecute to the MHRA had failed to ensure that the agency had received sufficient resources, training and other help to comply with the various obligations upon those who investigate crime<br>2. That the failure on the part of the MHRA to comply with the obligations imposed upon investigators undermined the safety of the convictions.<br><u>Ketan Metha</u><br>He had initially pled guilty to:<br>▶ Three counts of evading the prohibition on wholesale dealing, contrary to section 8(3)(a) and section 45(1) of the Medicines Act 1968.<br>In appealing the conviction, Metha's lawyer echoed the safety of the convictions as a ground of appeal. He also argued that there had been a miscarriage of justice, due to the fact that the substantive charges to which his client plead guilty had only been added by the prosecution after the jury failed to agree on whether he was guilty for conspiracy to evade prohibition on wholesale dealing. | Ketan Metha<br>The court did **not** grant Mr Metha l leave to appeal. On the safety of the convictions, they echoed what they had said in response to Mr Patel's appeal. On the miscarriage of justice, they held that the prosecution had not done anything that amounted to a miscarriage of justice, noting that it was not uncommon for the prosecution to seek permission to add substantive counts to which the defendant then pleads guilty where the jury are unable to agree on their guilt with regards to a conspiracy. |
| *[2009] EWCA Crim 2311* | <u>Hitendra Patel (pled guilty)</u><br>▶ Two counts of placing a medicinal product on the market, contrary to section 3(1) of the Medicines for Human Use Regulations 1994.<br><u>Shaan Hussain (plead guilty)</u><br>One count of placing a medicinal product on the market, contrary to section 3(1) of the Medicines for Human Use Regulations 1994. | Both convictions were set aside.<br>With regards to the second count for which Patel had pled guilty, the appeal court found that the relevant transactions had neither intended to, nor had the effect of releasing a medicinal product into a distribution system which led to its sale to end users within the European Economic Area. |

| PLEASE COLLECT ONLY RELEVANT CASES ON THE FALSIFICATION OF MEDICAL PRODUCTS OR SIMILAR CRIMES | | |
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| *R v Peter Hugh Gillespie [2011] EWCA Crim 3152* | **The Prosecution's Case**<br><br>The prosecution alleged that through his business in the UK, Peter Gillespie had been had been responsible for importing large quantities of prescription drugs into the UK market between December 2006 and May 2007. These medicines, which were purported to be French medicines, were actually counterfeit medicines which had been manufactured in China and imported into to Europe via Singapore. The included drugs used for the treatment of schizophrenia, prostate cancer and heart disease. It was found that the drugs contained significantly less of the relevant active ingredients than the genuine drugs would have.<br><br>They further contended that the defendant had then been involved in a total of eight transactions to sell this medicine. The prosecution alleged that he labelled the boxes which he knew to contain counterfeit medicine with a specialist sticker used in France intending to cause the purchaser of the to believe they were genuine.<br><br>It was noted that a proportion of the medicine which has been sold had been used on sick patients. Whilst the MHRA were able to recover some of the stock, a significant portion remained unaccounted for.<br><br>**The Defence**<br><br>Mr Gillespie claimed that he had **not** been dishonest, as he had not known that the drugs were counterfeit . He claimed that he had purchased them from the son of a business colleague and believed them to be genuine medicines. While he admitted to altering the packaging, he claimed that this was simply a marketing ploy.<br><br>This case arose out of an investigation run by the MHRA and titled 'Operation Singapore' | Mr Gillespie was found guilty of the following offences:<br><br>▸ One count of conspiracy to defraud<br>▸ Three counts of supplying a medicinal product without marketing authorisation<br>▸ Three counts of selling counterfeit goods<br>▸ One count of acting as a company director when disqualified.<br><br>He was sentenced to a total of 8 years in prison, with the sentencing judge noting that a "genuine deterrent" sentence was required, given the circumstances of the case.<br><br>His appeal of both the convictions and the sentencing was unsuccessful. In his judgement, LJ Elias acknowledged the particular harms associated with counterfeit (this was the terminology used in the case) medicine:<br><br>"On any view these were extremely serious offences. People had been prescribed what they believed to be genuine drugs which may assist them in full recovery when they were not. For the most part the drugs are worthless. In some cases they may be positively damaging. That may depend upon their precise make-up. In any event, the sale of counterfeit drugs undermines public confidence and causes particular grief to those who thought they were taking genuine drugs when they were not" [Lord Justice Elias, at 55] |

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| *R v Martin Hickman [2018] EWCA Crim 2717* | Mr Hickman had been running an online business selling unlicensed and counterfeit Viagra and similar medical products for a number of years. When - following an investigation - MHRA enforcement offices attended his home and searched the premises they found a quantity of the unlicensed medicines and identified large scale movements of money from the United Kingdom to the Isle of Man and then through to Malta.<br><br>At first instance (2009) pled guilty to five counts of supplying unlicensed medicines and one related offence of money laundering, for which he was sentenced to a total of two years imprisonment. In 2012 confiscation order was made requiring him to pay £14,407,850.28 within six months. He failed to do so, at which point the default sentence of ten years was imposed upon in him in his absence. He was then arrested in Spain (where he had been living) under a European Arrest Warrant and returned to custody in the United Kingdom on 13 August 2014.<br><br>He had initially sought leave to appeal the confiscation order and default when it was made in 2012 but was refused. The issue rested until 2018 when he both sought to renew his application for leave to this court and also made an application for an extension of time of approximately five years. | His appeals were dismissed. |
| NO FULL REPORT OF CASE: REGULATORS / POLICE REPORTS ONLY | | |
| *Police Intellectual Property Unit (PIPCU) Report on the Conviction of Frank Ludlow*<br><br>*(9th July 2020)*<br><br>https://www.cityoflondon.police.uk/news/city-of-london/news/2020/template3/pipcu/man-sentenced-for-making-and-selling-fake-covid-19-treatment-kits/ | Mr Ludlow was accused of making counterfeit treatment kits for COVID-19 (labelled 'Trinity COVID-19 SARS: Anti-Pathogenic Treatment) and sending these across the world. This kits are known to have contained hydrogen peroxide concentration of 6.5 %; potassium thiocyanate, an acid, an unknown enzyme as well as bee pollen. He had been making the kits for a number of years, and had previously made unsupported claims about their ability to cure other infections.<br><br>This case originated when the U.S. Customs and Border Protection Agency in Los Angeles intercepted a package from UK, which contained 60 of these treatment kits which were sent from the UK and passed them on to the FDA. The FDA then determined that they were unapproved drugs, based on the labelling and directions for use, raised the issue with the MHRA.<br><br>A joint operation between the MHRA, PIPCU and the US FDA was carried out, the result of which was the discovery of more than 300 kits and 20 litres of the chemicals used to create these in Mr Ludlow's home. | Mr Ludlow pled guilty to the following charges:<br><br>One count to attempting to supply an unauthorised medicinal product<br><br>One count of possessing an unauthorised medicinal product<br><br>One count assembling an unauthorised product<br><br>He was sentenced to a ten month suspended prison sentence, and also ordered to carry out 170 hours of unpaid community service.<br><br>He further faces prosecution in the United States, where he was has been charged with one count of introducing misbranded drugs into interstate commerce. This is a felony charge which carries a maximum sentence of three years in prison. |

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| *MHRA Report on the Conviction of Leonard Cosgrove*<br><br>*(25th July 2019)*<br><br>https://www.gov.uk/government/news/east-london-crook-charged-with-meds-crimes | Mr Cosgrove was part of a network involved with the illegal import and supply of medicines – including Viagra and appetite suppressants. | Mr Cosgrove was found guilty of:<br><br>Conspiracy to supply authorised medical products<br><br>The supply of prescription only medicines<br><br>The supply of Class C drugs.<br><br>He was sentenced to 2 years and 9 months in prison. |
| *MHRA Report on the Conviction David Noakes*<br><br>*(5th June 2020)*<br><br>https://www.gov.uk/government/news/david-noakes-judge-orders-seizure-of-14-million | Mr Noakes owned Guernsey-based Immuno Biotech, through which he sold GcMAF (an unlicensed medicine). GcMAF is a product derived from Human Blood, which Mr Noakes advertised as being a 'miracle cure' for a range of conditions including cancer, HIV and autism. However, these claims were not backed by scientific evidence. Mr Novak profited significantly from the sales of GcMAF, making over £13 million from the period between 2013 and 2015. | In 2019 Mr Noakes pled guilty to the following charges:<br><br>Four charges relating to the manufacture, sale, and supply of an unlicensed medicine<br><br>One count of money laundering<br><br>He was sentenced to a total of 15 months in prison. In 2020 he was further subject to a confiscation order, totalling just under £1.4 million. |
| *Convictions Related to MHRA Operation Calla*<br><br>*See also*: https://www.5pb.co.uk/print/pdf/node/67 (p3). | Industry partners submitted a referral to the MHRA regarding a mail forwarding company in the UK, who they believe were acting as an importer and distributer of medicines entering the UK illegally. On this basis, the MHRA started Operation Calla – during the course of which they identified a criminal network was identified. This included both UK individuals, and those residing outside of the UK who were responsible for fulfilling demand from European customers via overseas websites. The UK aspect of the operation involved five individuals who were arrested in 2016.<br><br>MHRA 2016 Board Meeting – Item 06 Criminal Enforcement Report | "Trials were held at Southwark crown court in 2018 and 2019...Following deliberation, four defendants were found guilty of offences of importation, sale and supply of unlicensed medicines, including controlled drugs. These defendants were subsequently sentenced to imprisonment totalling nine years."<br><br>MHRA 2016 Board Meeting – Item 06 Criminal Enforcement Report |

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| *Convictions Related to MHRA Operation Daniel*<br><br>https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/652376/Item_10__2017-OB-11__Operation_Pangea_2017.pdf<br><br>https://rusi.org/sites/default/files/201412_whr_on_tap.pdf (p63) | A large group of individuals were involved with the sale of unlicenced medicinal products for treating erectile disfunction and impotence over the internet and the 'face-to-face' sale of counterfeit medication (namely Viagra and Valium). These products originated from a variety of sources in Hong Kong, India, and China.<br><br>A number of front companies had been set up – two of which did some legitimate trade in cosmetics as well as the illicit medicinal trading, and their names and details were used to rent three storage units and two distribution centres.<br><br>The activity lasted from 2004 – 2012. In that time the group's sales of illicit medicines are suspected to have generated over £11 million.<br><br>[The facts of this operation were reported in a 2014 Report by the Think Tank: Royal United Services Institute for Defence and Security Studies (p63)] | "Operation Daniel resulted in the conviction of 12 suspects at the Central Criminal Court originated from the activity during the week of action some years ago. Six suspects were together sentenced to over twenty-five years imprisonment and six defendants received suspended sentences totalling over four years for the sale of counterfeit and unlicensed drugs including Viagra."<br><br>[MHRA Open Board Meeting, October 2017 – Item 10, p2] |
| Dilbar Dishad<br><br>https://www.dentistrytoday.com/news/todays-dental-news/item/914-man-arrested-for-selling-counterfeit-drills#:~:text=Authorities%20in%20the%20United%20Kingdom,(about%20%24110)%20on%20eBay | Mr. Dishad had been selling fake dental drills on ebay. He used stickers to make them appear as though they were legitimate drills from a reputable brand. He was purchsing the drills for about £10 each from a Chinese company, and selling them for £75; far less that the legitimate drills which retailed at about £335. He had purchased them for about £10 (about $15) from a Chinese company and using stickers to make them appear legitimate. He was caught because a potential customer realised what was happening, and contact the actual manufacturer.<br><br>Note that this has only been reported by industry sources, but is included because it is one of the few reported examples of someone being charged with crimes related to counterfeit **medical devices.** | Mr Dishad was found guilty of the illegal sale and supply of counterfeit dental drills (specific charges not known) and was sentenced to a 9 months prison sentence, suspended for 2 years. He was also required to complete 200 hours of unpaid work within 12 months, and was disqualified from being a company director for 5 years |

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| MRG Court Report<br><br>Case Concerning Christopher Noel Logan (18th November 2015)<br><br>https://www.health-ni.gov.uk/news/cloughmills-man-receives-suspended-sentence-supplying-illegal-veterinary-medicines | Mr Logan was accused of having a long-term involvement (5 years) in a large scale illegal veterinary medicines supply network. He allegedly sold the prescription only medicines, worth upwards of £681,000, illegally from his hardware shop. | Mr Logan was found guilty of the following offences:<br>▸ Four counts of supplying veterinary medicinal products other than in accordance with the Veterinary Medicines Regulations 2008<br>▸ Two counts of possession of criminal property<br><br>He was sentenced to 8 months imprisonment suspended for five years on each of the six charges (to run concurrently) and the proceeds of his criminal activity were confiscated by relevant division of the Police Service of Northern Ireland. |
| MRG Report<br><br>Case Concerning Karl Spencer Hewitt (6 December 2016)<br><br>https://www.health-ni.gov.uk/news/lurgan-man-receives-suspended-sentence-importation-and-possession-illegal-veterinary-medicines | Illegal prescription-only veterinary medicines were found during a search of Mr Hewitt's home and further investigation by the MRG established that these has been illegally imported from Australia, Europe and the USA between 2013 and 2015. The primary purpose of these drugs was deemed to be the greyhound market, but it was noted that they also had wider veterinary use. | Mr Hewitt was found guilty of the following offences:<br><br>3 counts of importation of unauthorised veterinary medicinal products other than in accordance with the Veterinary Medicines Regulations 2013<br><br>4 counts of possession of unauthorised veterinary medicinal products other than in accordance with the Veterinary Medicines Regulations 2013<br><br>He was sentenced to 2 months imprisonment, suspended for 12 months on each of the seven charges (to run concurrently). |

**UNITED STATES OF AMERICA** No submission has been received on case law from the national consultant

## Appendix 5 - Links to country laws by National Consultants

**Links to country laws provided by National Consultants**

**Armenia:**
http://www.pharm.am/attachments/article/89/Law%20on%20Medicines_ENG_%2027.06.2017_2.pdf
https://www.legislationline.org/download/id/6358/file/Armenia_CPC_1998_am2016_en.pdf
https://www.legislationline.org/documents/section/criminal-codes/country/45/Armenia/show
www.arlis.am (in Armenian)

**Austria:**
Medicinal Product Act
https://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=10010441
Medical Device Act
https://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=10011003
Austrian Ordinance on Good Manufacturing Practices - AMBO 2009
https://www.ris.bka.gv.at/eli/bgbl/ii/2008/324/P2/NOR40200821
Criminal Procedures Code – https://www.ris.bka.gv.at/eli/bgbl/1975/631/P65/NOR40181026
Criminal Code - https://www.ris.bka.gv.at/eli/bgbl/1974/60/P12/NOR12029553
Association Responsibility Act (Verbandsverantwortlichkeitsgesetz) https://www.ris.bka.gv.at/eli/bgbl/i/2005/151/P0/NOR30004820

**Azerbaijan:**
Criminal Code of the Republic of Azerbaijan http://e-qanun.gov.az/code/11
Code of Administrative Offences of the Republic of Azerbaijan http://e-qanun.gov.az/code/24
Code of Criminal Procedure of the Republic of Azerbaijan http://e-qanun.gov.az/code/14

**Bulgaria:**
Criminal Code https://www.lex.bg/bg/laws/ldoc/1589654529
Law on medicinal products in human medicine https://www.lex.bg/bg/laws/ldoc/2135549536
Law on Medical Devices https://www.lex.bg/bg/laws/ldoc/2135555444.
Penal Procedure Code https://www.lex.bg/bg/laws/ldoc/2135512224

**Canada:**
Medical Devices Regulations Medical Devices Regulations (justice.gc.ca)
Food and Drugs Act R.S.C., 1985 Food and Drugs Act (justice.gc.ca)
Food and Drug Regulations C.R.C., c. 870 Food and Drug Regulations (justice.gc.ca)
Medical Devices Regulations (SOR/98-282) Medical Devices Regulations (justice.gc.ca)
Criminal Code R.S.C., 1985, c. C-46 Criminal Code (justice.gc.ca)

**Cyprus:**
The Medicinal Products for Human Use (Control of Quality, Supply and Prices) Law of 2001 to 2020.
http://www.cylaw.org/nomoi/enop/ind/2001_1_70/section-sc3044b5e3-3656-00a4-d678 0e86756ba83c.html
The Veterinary Medicinal Products (Control of Quality, Registration, Circulation, Manufacturing,
Providing and Use) Law of 2006 to 2011.
http://www.cylaw.org/nomoi/enop/ind/2006_1_10/section-scac1a3190-0888-89d4-636e-b6b29b46e04c.html
The Basic Requirements for Specific Products Categories Law of 2002 to 2013
http://www.cylaw.org/nomoi/enop/ind/2002_1_30/section-sc9b7b8dbb-a26b-d812-aeee-c64361e72320.html

**Denmark:**
The Medicines Act www.retsinformation.dk/eli/lta/2018/99
Law on Medical Devices www.retsinformation.dk/eli/lta/2016/139
https://www.retsinformation.dk/eli/ft/201012L00118
Executive Order on the manufacture, import and distribution of active substances for the manufacture of medicinal products no. 1360 (18 December 2012) https://www.retsinformation.dk/eli/lta/2012/1360

**Estonia:**
Medicinal Products Act https://www.riigiteataja.ee/en/eli/518052020005/consolide#para10b1
Medical Devices Act https://www.riigiteataja.ee/en/eli/528052020007/consolide
Code of Criminal Procedure https://www.riigiteataja.ee/en/eli/518052020007/consolide
Penal Code https://www.riigiteataja.ee/en/eli/515072020011/consolide#para1

**Finland:**
Medicines Act https://www.fimea.fi/documents/160140/765540/18580_Laakelaki_englanniksi_paivitetty_5_2011.pdf
Medical Devices Act
https://finlex.fi/fi/laki/ajantasa/2010/20100629?search%5Btype%5D=pika&search%5Bpika%5D=laki%20terveydenhuollon%20laitteista%2A
Criminal Code https://finlex.fi/en/laki/kaannokset/1889/en18890039_20150766.pdf

**Germany:**
Medicinal Products Act (Arzneimittelgesetz – AMG) 2019
http://www.gesetze-im-internet.de/englisch_amg/
German Criminal Code (Strafgesetzbuch – StGB)
https://www.gesetze-im-internet.de/englisch_stgb/englisch_stgb.html

**Georgia:**
Law of Georgia on Medicines and Pharmaceutical Activities https://matsne.gov.ge/en/document/download/29836/21/en/pdf
Criminal Procedure Code of Georgia https://matsne.gov.ge/ka/document/download/90034/64/en/pdf

**Iceland:**
Medicinal Products Act No 100/2020
https://www.government.is/library/01-Ministries/Ministry-of-HealTh/PDF-skjol/Lyfjal%c3%b6g%20nr.%20100.2020%20%20ensk%20%c3%be%c3%bd%c3%b0ing.pdf

Act on Medical Devices No 16/2001 https://www.government.is/media/velferdarraduneyti-media/media/acrobat-enskar_sidur/Act_on_Medical_Devices_No_162001.pdf
RegulationonMedicalDevicesNo934/2010https://www.government.is/media/velferdarraduneyti-media/media/Reglugerdir-enska/Regulation-on-Medical-Devices-No-934-2010.pdf
General Penal Code No 19/1940 https://www.government.is/library/01-Ministries/Ministry-of-Justice/Generlal%20Penal%20Code,%20No.19%201940.pdf

**Ireland:**
Irish Medicines Board Act, 1995 http://www.irishstatutebook.ie/eli/1995/act/29/enacted/en/html
Irish Medicines Board (Miscellaneous Provisions) Act 2006 http://www.irishstatutebook.ie/eli/2006/act/3/enacted/en/html
Medicinal Products (Control of Manufacture) Regulations, S.I. No. 539/2007 - Medicinal Products (Control of Manufacture) Regulations 2007
European Communities (Medical Devices) (Amendment) Regulations 2009 S.I. No. 110/2009 - European Communities (Medical Devices) (Amendment) Regulations 2009
European Communities (Medical Devices) Regulations, 1994 S.I. No. 252/1994 - European Communities (Medical Devices) Regulations, 1994.
Animal Remedies Act 1993 Animal Remedies Act, 1993, Section 1
Criminal Justice (Victims of Crime) Act 2017Criminal Justice (Victims of Crime) Act 2017, Section 2
Medicinal Products (Control of Wholesale Distribution) Regulations, 2007 S.I. No. 164/2013 - Medicinal Products (Control of Wholesale Distribution) (Amendment) Regulations 2013
Criminal Justice (Theft and Fraud Offences) Act 2001 Criminal Justice (Theft and Fraud Offences) Act, 2001
Medicinal Products (Control of Placing on the Market) Regulations 2007 S.I. No. 540/2007 - Medicinal Products (Control of Placing on the Market) Regulations 2007
European Communities (Animal Remedies) (No. 2) Regulations, 2007 S.I. No. 786/2007 - European Communities (Animal Remedies) (No. 2) Regulations 2007
Petty Sessions Act 1851 Petty Sessions (Ireland) Act, 1851
Criminal Law Act 1997 Criminal Law Act, 1997

**Japan:**
Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (SQESPM) (japaneselawtranslation.go.jp)
Basic Act on Crime Victims Japanese Law Translation - [Law text] - Basic Act on Crime Victims
Penal Code http://www.japaneselawtranslation.go.jp/law/detail/?printID=&re=2&dn=1&x=45&y=15&co=1&ia=03&ja=04&yo=&gn=&sy=&ht=&no=&bu=&ta=&ky=penal+code&page=10&vm=02
http://www.japaneselawtranslation.go.jp/law/detail/?printID=&ft=1&re=2&dn=1&x=51&y=8&co=01&ia=03&ja=04&ky=%C3%A7%C2%89%C2%B9%C3%A5%C2%AE%C2%9A%C3%A9%C2%9B
Act on Specified Commercial Transactions Japanese Law Translation - [Law text] - Act on Specified Commercial Transactions
Act on Punishment of Organized Crimes and Control of Proceeds of Crime http://www.japaneselawtranslation.go.jp/law/detail/?printID=&ft=2&re=2&dn=1&yo=Act%20on%20Punishment%20of%20Organized%20Crimes%20and%20Control%20of%20Proceeds%20of%20Crime%20&x=43&y=5&ia=03&ja=04&ph=&ky=&page=1&vm=02
Companies Act http://www.japaneselawtranslation.go.jp/law/detail/?printID=&ft=2&re=2&dn=1&yo=Companies%20Act&x=66&y=12&ia=03&ja=04&ph=&ky=&page=4&vm=02
Civil Code http://www.japaneselawtranslation.go.jp/law/detail/?printID=&ft=2&re=2&dn=1&yo=Civil%20Code&x=46&y=8&ia=03&ja=04&ph=&ky=&page=2&vm=02

**Latvia:**
Pharmaceutical Law https://likumi.lv/ta/en/en/id/43127-pharmaceutical-law
Medical Treatment Law https://likumi.lv/ta/en/en/id/44108-medical-treatment-law
Regulations Regarding Procedures for Registration, Conformity Assessment, Distribution, Operation and Technical Supervision of Medical Devices https://likumi.lv/ta/id/295401-medicinisko-iericu-registracijas-atbilstibas-novertesanas-izplatisanas-ekspluatacijas-un-tehniskas-uzraudzibas-kartiba
Regulations Regarding Procedures for the Labelling of Medicinal Products and the Requirements to Be Set for Package Leaflets of Medicinal Products https://likumi.lv/ta/en/en/id/126348-regulations-regarding-procedures-for-the-labelling-of-medicinal-products-and-the-requirements-to-be-set-for-the-package-leaflet-of-medicinal-products

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Law on Administrative Liability https://likumi.lv/ta/en/en/id/303007-law-on-administrative-liability
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**Lithuania:**
Law on Pharmacy of the Republic of Lithuania https://e-seimas.lrs.lt/portal/legalAct/lt/TAD/TAIS.280067/asr
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Criminal Code of the Republic of Lithuania https://www.legislationline.org/download/id/8272/file/Lithuania_CC_2000_am2017_en.pdf
Civil Code of the Republic of Lithuania https://www.e-tar.lt/portal/lt/legalAct/TAR.8A39C83848CB/asr

**Morocco:**
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**North Macedonia:**
Law on Healing and Medical Means https://malmed.gov.mk/%d0%b7%d0%b0%d0%ba%d0%be%d0%bd%d0%b8/
Norway
The Medicines Act https://lovdata.no/lov/1992-12-04-132/

The Medicines Regulations) § 1-2 https://lovdata.no/forskrift/2009-12-18-1839/§1-2
Regulations on the manufacture and import of medicines § 1-2 https://lovdata.no/forskrift/2004-11-02-1441/§1-2
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Regulations on the manufacture and import of medicines https://lovdata.no/forskrift/2004 -11 -02 -1441/§1 - 2
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The Penal Code § 361 https://lovdata.no/lov/2005-05-20-28/§361
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The Health Personnel Act § 4 (https://lovdata.no/lov/1999-07-02-64/§4

**Poland:**
Pharmaceutical Law 2001 Akt prawny (sejm.gov.pl)
Act on Medical Devices 2010 Akt prawny (sejm.gov.pl)
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**Serbia:**
Law On Medical Devices
https://www.alims.gov.rs/eng/regulations/law-on-medicines-and-medical-devices/
Law On Medicinal Products And Medical Devices https://www.alims.gov.rs/eng/files/2012/10/Law-on-Medicines-and-Medical-Devices-teacher2010.pdf
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Law on The Liability of Legal Entities For Criminal Offences https://www.ohchr.org/Documents/Issues/Mercenaries/WG/Law/Serbia/LawOnLiability.pd

**Slovak Republic:**
Law on Medicinal Products and Medical Devices
362/2011 Z.z. - Zákon o liekoch a zdravotníckych po... - SLOV-LEX
Criminal Code 300/2005 Z.z. - Trestný zákon - SLOV-LEX
Victims of Crime and amending certain laws 2017
274/2017 Z.z. - Zákon o obetiach trestných činov a ... - SLOV-LEX
Code of Criminal Procedure 301/2005 Z.z. - Trestný poriadok - SLOV-LEX
Law on criminal liability of legal persons and on amendments to certain laws 2016
91/2016 Z.z. - Zákon o trestnej zodpovednosti práv... - SLOV-LEX

**Slovenia:**
Slovenian Criminal Code http://www.pisrs.si/Pis.web/pregledPredpisa?id=ZAKO5050 (in Slovenian) or available at www.wipo.int › edocs › lexdocs › laws

Medicinal Products Act http://www.pisrs.si/Pis.web/pregledPredpisa?id=ZAKO6295
Medical Devices Act http://www.pisrs.si/Pis.web/pregledPredpisa?id=ZAKO5503
Criminal Procedure Act http://www.pisrs.si/Pis.web/pregledPredpisa?id=ZAKO362
Liability of Legal Persons for Criminal Offences Acts http://www.pisrs.si/Pis.web/pregledPredpisa?id=ZAKO1259

**Sweden:**
Medicinal Products Act https://www.riksdagen.se/sv/dokument-lagar/dokument/svensk-forfattningssamling/lakemedelslag-2015315_sfs-2015-315
Medical Devices Act (https://www.riksdagen.se/sv/dokument-lagar/dokument/svensk-forfattningssamling/lag-1993584-om-medicintekniska-produkter_sfs-1993-584
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Act on Penalties for Smuggling ( https://www.riksdagen.se/sv/dokument-lagar/dokument/svensk-forfattningssamling/lag-20001225-om-straff-for-smuggling_sfs-2000-1225
Medicinal Products Trading Act ( https://www.riksdagen.se/sv/dokument-lagar/dokument/svensk-forfattningssamling/lag-2009366-om-handel-med-lakemedel_sfs-2009-366

**United Kingdom:**
Medicines and Medical Devices Act 2021
https://www.legislation.gov.uk/ukpga/2021/3/contents/enacted
The Human Medicine Regulations 2012 https://www.legislation.gov.uk/uksi/2012/1916/regulation/2
The Veterinary Medicine Regulations 2013 https://www.legislation.gov.uk/uksi/2013/2033/regulation/2
Human Medicines (Amendment) Regulations 2013/1855
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Medical Devices Regulations 2002 https://www.legislation.gov.uk/uksi/2002/618/regulation/2
Trade Marks Act 1994 https://www.legislation.gov.uk/ukpga/1994/26/section/92
Fraud Act 2006 https://www.legislation.gov.uk/ukpga/2006/35/section/2
Criminal Justice and Licensing (Scotland) Act 2010 https://www.legislation.gov.uk/asp/2010/13/section/49
Medicines Act 1968 https://www.legislation.gov.uk/ukpga/1968/67/section/67
Serious Crime Act 2007 https://www.legislation.gov.uk/ukpga/2007/27/schedule/1
Forgery and Counterfeiting Act 1981 https://www.legislation.gov.uk/ukpga/1981/45/section/1
Criminal Attempts Act 1981 https://www.legislation.gov.uk/ukpga/1981/47
The Criminal Attempts and Conspiracy (Northern Ireland) Order 1983
https://www.legislation.gov.uk/nisi/1983/1120/part/II?wrap=true&view=extent
Criminal Procedure (Scotland) Act 1995 https://www.legislation.gov.uk/ukpga/1995/46/section/294
Crown Prosecution Service Guidance on Corporate Prosecutions
https://www.cps.gov.uk/legal-guidance/corporate-prosecutions
Coroners and Justice Act 2009 https://www.legislation.gov.uk/ukpga/2009/25/section/118
Criminal Justice and Licensing (Scotland) Act 2010 https://www.legislation.gov.uk/asp/2010/13/section/1

**United States of America:**
Chapter 9 – Federal Food, Drugs and Cosmetic Act 21 USC [USC02] 21 USC CHAPTER 9, SUBCHAPTER II: DEFINITIONS (house.gov)
Code of Federal Regulations Title 21 Electronic Code of Federal Regulations (eCFR)
18 USC – Crimes and Criminal Procedure [USC02] 18 USC 2320: Trafficking in counterfeit goods or services (house.gov)

## Appendix 6 – List of National Consultants

**GAP ANALYSIS SURVEY- NATIONAL CONSULTANTS**

LIST OF 36 COUNTRIES PARTICIPATING

**CoE member States**: Andorra, Armenia, Austria, Azerbaijan, Bulgaria, Cyprus, Czech Republic, Denmark, Finland, Estonia, Greece, Georgia, Germany, Iceland, Italy, Latvia, Lithuania, Montenegro, North Macedonia, Norway, Poland, Romania, Serbia, Slovak Republic, Slovenia, Sweden, United Kingdom.

**Observer States**: Canada, Japan, Mexico, United States of America.

**Other 3rd countries**: Ecuador, Guinea, Morocco, Tunisia

| COUNTRIES SELECTED | SELECTED NATIONAL CONSULTANT | PROFESIONAL TITLE |
|---|---|---|
| ANDORRA | Mr Oriol GIRÓ CANTURRI | Partner and corporate lawyer at Emindsetlaw |
| ARMENIA | Ms Alvina GYULUMYAN | Former judge of the Constitutional Court of Armenia and the European Court of Human Rights |
| AUSTRIA | Ms Martina HOFMANN | Lawyer at the Austrian Medicines and Medical Device Agency (AGES) |
| AZERBAIJAN | Ms RUHIYYA ISAYEVA | Legal expert/ Member of the Azerbaijani Bar Association |
| BULGARIA | Ms Momiana GENEVA | Tenured professor of Criminal Law, head of department at the Burgas Free University |
| CANADA | Mr David LIPKUS | Lawyer at Kestenberg Siegal Lipkus LLP |
| CYPRUS | Ms Dena Maria ERGATOUDI | Counsel for the Law Office of the Republic of Cyprus |
| CZECH REPUBLIC | Ms. Barbora ŠVÁCHOVÁ | Senior Legal Counsellor, Legal Department, Ministry of Justice |
| DENMARK | Ms Katharina Ó CATHAOIR | Assistant Professor in Health Law, Centre for Legal Studies in Welfare and Market Integration (Welma)<br>Faculty of Law, University of Copenhagen |

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| **ECUADOR** | Ms María Fernanda ROMÁN FERRAND | Director of the Legal Commerce Project of the Universidad de los Hemisferios |
| **ESTONIA** | Dr Kärt PORMEISTER | Lecturer of Private Law at Tallinn University and owner of KP Holding OÜ |
| **FINLAND** | Ms Anna-Riikka RUUTH | Specialized prosecutor, Prosecutor's Office of Eastern Uusimaa, Vantaa (from 1.10.2019 National Prosecution Agency, Southern Prosecution District) |
| **GERMANY** | Mr Alexander ROTH | Public prosecutor at the Office of the Prosecutor General of the Land Brandenburg |
| **GEORGIA** | Ms Nino AGLEMASHVILI | Head of the Unit for Effective Support of State Prosecution in Jury Trial Cases And invited lecturer at Tbilisi State University, Tbilisi European University and Caucasus University |
| **GREECE** | Mr Nikos PASSAS | Professor of Criminology and Criminal Justice at Northeastern University |
| **GUINEA** | Mr Abdoulaye KPOGOMOU | Magistrate, 1st Deputy Public Prosecutor at the Court of Kaloum, Republic of Guinea |
| **ICELAND** | Mr Sindri KRISTJÁNSSON | Senior legal advisor and Special advisor to Executive Director of the Icelandic Medicines Agency |
| **IRELAND** | Mr Brian GAGEBY | Barrister in the Law Library specialise in criminal and regulatory law |
| **ITALY** | Ms Giuliana GIULANO | Public Prosecutor's Office at the Court of Naples |
| **JAPAN** | Dr. Kazuko KIMURA | Professor of the Medi-Quality Security Institute and Professor Emerita at Kanazawa University |
| **LATVIA** | Ms Sanita TIMBARE ZILVESTERE | Head of Legal Unit, State Agency of Medicines |
| **LITHUANIA** | Mr Tautvydas ZEKAS | Senior advisor to the Group of Criminal Justice of the Ministry of Justice |
| **MEXICO** | Mr Oscar GUIZAR | Legal consultant and lawyer in the field of health law |
| **MONTENEGRO** | Mr Milorad MARKOVIC | Legal advisor in the field of countering serious crime in the Western Balkans IPA and long-term experience in education in the field of Criminal Procedure Law and International Criminal Law |
| **MOROCCO** | Mr Abdelhnine TOUZANI | Attorney General at the Court of Cassation and trainer specialising in criminal law |
| **NORTH MACEDONIA** | Ms Aleksandra DEANOSKA - TRENDAFILOVA | Professor in medical criminal law, Faculty of Law "Iustinianus Primus", "Ss.Cyril and Methodius" University, Skopje |

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|---|---|---|
| **NORWAY** | Ms Belinda FORSSTEN | Lawyer at the law firm of BFF |
| **POLAND** | Ms Joanna PILEWSKA | Lawyer at Misiewicz, Mosek & Partners, Office of Legal Advisers |
| **ROMANIA** | Mr Adrian SANDRU | PhD candidate in Criminal Procedure Law<br>School of Advanced Studies of the Romanian Academy |
| **SERBIA** | Ms Neda MARKOVIC,<br>Mr Jovan ĆOSIĆ,<br>Mr Božidar BLAGOJEVIĆ | Ministry of Justice of the Republic of Serbia |
| **SLOVAK REPUBLIC** | Mr Peter KLANDUCH | Legal adviser for the Ministry of Justice |
| **SLOVENIA** | Ms Jasmina ARNUS TABAKOVIC | State Prosecutor at the District State Prosecutor's Office |
| **SWEDEN** | Mr Tomas NILSSON | Assessor, Swedish Medical Products Agency<br>and Delegate in Committee of Experts CD-P-PH/CMED |
| **TUNISIA** | Mr Yassine YOUNSI | Attorney at law - Partner at YOUNSI & YOUNSI International Law Firm |
| **UNITED KINGDOM** | Ms Muireann QUIGLEY | Professor of Law, Medicine, & Technology, Birmingham Law School, University of Birmingham |
| **UNITED STATES OF AMERICA** | Mr Nikos PASSAS | Professor of Criminology and Criminal Justice at Northeastern University |

The multiregional Council of Europe project entitled "Needs assessment– Falsified Medical Products" (NA-FAMED) supports Council of Europe member States and other countries, Parties to the MEDICRIME Convention, to fight against the falsification of medical products and similar crimes involving threats to public health. It is a preparatory project that aims at establishing a baseline for future projects aimed at promoting and implementing the MEDICRIME Convention.

The MEDICRIME NA-FAMED project's Gap Analysis report aims to support Council of Europe member States and other countries by identifying technical gaps that need to be addressed to implement and ratify the MEDICRIME Convention. It also aims to improve and strengthen legal, regulatory and policy frameworks of those countries by assessing the level to which current national criminal law and other relevant laws support the prohibition of the falsification of medical products as criminal offences, for the purposes of protecting public health.

36 countries have been targeted by the NA-FAMED project. The following 28 Council of Europe member States participated in the project: Andorra, Armenia, Austria, Azerbaijan, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, Georgia, Germany, Greece, Iceland, Ireland, Italy, Latvia, Lithuania, Montenegro, North Macedonia, Norway, Poland, Romania, Serbia, Slovak Republic, Slovenia, Sweden and United Kingdom. The following 8 non-Council of Europe member States also participated in the study: Canada, Ecuador, Guinea, Japan, Mexico, Morocco, Tunisia and the United States of America.

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The Council of Europe is the continent's leading human rights organisation. It comprises 47 member states, including all members of the European Union. All Council of Europe member states have signed up to the European Convention on Human Rights, a treaty designed to protect human rights, democracy and the rule of law. The European Court of Human Rights oversees the implementation of the Convention in the member states.

COUNCIL OF EUROPE

CONSEIL DE L'EUROPE