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MEDICRIME COMMITTEE

Committee of the Parties to the Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health (CETS No. 211)

1st Monitoring report:
The protection of public health through the MEDICRIME Convention in times of pandemics

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the Council of Europe Convention
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and similar crimes
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1st implementation report
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through the MEDICRIME Convention
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Executive Summary

1. The 1st monitoring round of the implementation of the MEDICRIME Convention focuses on the **protection of public health through the MEDICRIME Convention in times of pandemics**. The report covers this theme in 13 of the 23 States which were Parties to the Convention at the time the monitoring round report was adopted.

2. The 1st report provides the general framework for the protection of public health in times of pandemics, addressing eight sets of issues: i) Prevention and Training; ii) Education; iii) Victims; iv) Cooperation and Information Exchange; v) Detection; vi) Investigation and Prosecution; vii) Sanctions and Aggravating circumstances; viii) Data collection

3. With regard to the need for prevention and training measures for those with responsibilities for combating counterfeit medical products, the MEDICRIME Committee found that the majority of Parties **have well-developed regulatory authorities that guarantee the quality, safety and efficacy of the medical products that they authorise for marketing**. Although the provision of training for health product regulators, police, and customs services is ongoing, it is not consistent in all these receiving the training and have experienced disruption during the COVID-19 pandemic. The MEDICRIME Committee regrets that the majority of Parties **did not recognise training for procurement programmes and the distribution of medical products as key areas for the effective of counterfeit medical products, especially during a pandemic**. **Review programmes on the effectiveness of training measures, the training of specialised investigation teams on counterfeit medical products with specialised investigation techniques, and the operation of awareness programmes on medical product waste management are largely non-existent**. The MEDICRIME Committee regrets that such deficiencies, in particular during pandemics, weaken the impact of other measures already in place by the Parties to combat counterfeit medical products and similar crimes involving threats to public health.

4. Regarding the identification of measures for the education of civil society on good practices to avoid procuring counterfeit medical products, the Committee found that the Parties provided the general public with information and conducted awareness-raising campaigns, in particular in avoiding procuring from unauthorised online sources and increasing awareness on counterfeit medical products related to the COVID-19 pandemic. Evidence was lacking regarding encouragement by the Parties of civil society to become engaged in delivering awareness-raising campaigns to the public, as was the extent of delivery by civil society of such campaigns. The Parties generally have legal provisions supporting the prohibition of the promotion, advertisement and dissemination of material relating to and the sale of counterfeit medical products, including by online means, generally, which includes during pandemics.

5. Related to the protection of victims the Committee found that **all the Parties have a system of protection for victims of criminal offences which can be applied to those victims arising from the counterfeiting of medical products and similar crimes**. It is relevant to highlight that the majority of the

Parties have adopted different measures to permit victim support and advocacy groups, NGOs and other groups to assist and support victims. Particularly relevant at this stage are the different measures to enable victims to report offences and to receive protection and assistance in respect of offences established in accordance with MEDICRIME Convention. While a majority of the Parties have adopted such measures, no Party has oversight arrangements to assess their effectiveness.

6. As regards the ability and extent to which authorities/bodies may cooperate between them and exchange information in order to facilitate the effective investigation of counterfeit medical products and similar crimes, the Committee noted that **most Parties have systems in place that cover this purpose, even though some were general and not specific to counterfeit medical products**. However, **it is unclear** in the majority of the Parties **the extent to which these activities are supported by enabling legislation regarding counterfeit medical products and similar crimes**. The majority of Parties **do not have a review mechanism to check the effectiveness of these mechanisms**. The designation of a lead authority for cooperation and information exchange remains fluid, depending on the situation. While this may not pose a difficulty for some Parties, there is no review mechanism on the effectiveness of the decision-making on how the lead authority in this respect is made. The Parties have national contact points for information exchange and is supported by legislation on the transfer and receipt of evidence between countries, though it is noted that there is little evidence of the existence of Memorandums of Understanding and Data Sharing agreements either internally between authorities, or internationally with equivalent authorities. The MEDICRIME Committee stresses the **importance of designating contact points**, for both national and international contacts, and **supporting them by enabling information sharing and data exchange, including with civil society, industry, and service providers, as appropriate**.

7. As regards the various measures that may proactively be taken during a pandemic to detect counterfeit medical products and prevent them from reaching patients, **the Committee regrets that the majority of the Parties have systems that were assessed as inadequate for this purpose**. The majority of Parties do not have mandatory or even adequate measures in place for the industry to report counterfeit medical products, notwithstanding that industry is expected in most Parties to proactively make such reports. While the majority of Parties have market sampling programmes for medical products, most of them were focused on regulatory quality defects and mostly on medicinal products only and were not specifically focused on counterfeit medical products. Few Parties included the sampling of medical products in public procurement programmes, and none in private procurement programmes. The Committee noted that a minority of Parties have legislation that enables customs services to detect, detain and act on counterfeit medical products using legislation in line with the Convention and without having to rely upon or be subordinate to intellectual property rights legislation. The **Committee regrets that none of the measures taken by the Parties to proactively detect counterfeit medical products relates to specific additional measures during a pandemic**. The Committee stresses the need to proactively detect instances of counterfeit medical products at all times, in particular during pandemics, and to close any

gaps in the detection system that may allow medical products supply to escape regulatory scrutiny.

8. As regards investigations and prosecutions, the first issue related to this section is to ascertain the correspondence between the domestic laws of the Parties and the definitions of certain concepts included in the MEDICRIME Convention, as well as with the offences set up in Articles 5 to 8 of the MEDICRIME Convention and with the liability of legal persons (Article 11, MEDICRIME Convention). At this point, the Committee noted that **the majority of the Parties have fully implemented at the internal level the definitions of Article 4, the main offences established in Articles 5 to 8, and the liability of legal persons connected with those crimes**. Nevertheless, a minority of Parties have implemented Article 8. b which remains an aspect that needs to be considered. Related to the existence of specialized national investigation services responsible for conducting criminal investigations in the field of counterfeiting of medical products and similar crimes, such specialization is still pending in some of the Parties. One key aspect in the field of investigation and prosecution is the existence of processes used to decide which investigative department is responsible for investigations in general. The Committee noted that all the Parties have either procedural rules or formal criteria in order to decide which investigative service or body is responsible or takes the lead for investigations when they arise. Nevertheless, certain Parties deal with complaints about counterfeiting of medical products and similar crimes involving threats to public health on a case-by-case basis by individual investigative services and bodies while other Parties collate complaints about those offences at a national level. Finally, it is also positive to confirm that in the majority of Parties all prescribed offences in Articles 5-8 and 9 are investigated and not subject to a complaint being made and maintained.

9. As regards sanctions and aggravating circumstances the MEDICRIME Committee noted that all the Parties have internal laws which permit the seizure, confiscation and disposal, including the destruction of medical products and other materials and instrumentalities employed to the commission of the offences established in Articles 5-8, MEDICRIME Convention. Related to the implementation at the internal level of the aggravating circumstances established in Article 13 MEDICRIME Convention, **the majority of the Parties fulfil the obligations established in Article 13**. As regards policies by the Parties for offences in Articles 5-9, either generally or during a pandemic, to be subordinate to other criminal law offences in the case of a prosecution of the same person(s) (such as the trafficking of controlled substances in the same consignment as the counterfeit medical products), it was not possible to make an assessment on this in the majority of the Parties. Finally, a relevant measure consists of the possibility of removing the professional status of a person who abused the confidence placed in them in their capacity as a professional (Articles 12.2 and 13. b) or, including legal persons, as manufacturers and suppliers (Article 13. c). At this point, it is important to highlight that certain Parties have legal provisions to remove the professional status of both natural and legal persons.

10. **As to data collection**, the MEDICRIME Committee found that **this was not a high priority by the Parties**. In the majority of Parties, the data on counterfeit medical products and similar crimes is not collected during or related to

pandemics, or at all, except by a minority of Parties. No specific data collection system is evident in the majority of Parties and focal points are not tasked to collect such data. Some promising practices are evident in one Party that collects data on medical products during the COVID-19 pandemic. The collection of relevant data is necessary for a better understanding of the impacts of counterfeit medical products, on determining the true level of this type of crime, and in order to better support policy development and systems to protect public health through effective investigation and prosecution of offenders. **The designation of focal points tasked with collecting and assessing such data and making the data and analysis available is an urgent need**. The collection of data during times of pandemic, as well as more generally, is required to track the rapid changes in the profile of counterfeit medical products, in particular, those related to the treatment of conditions related to the pandemic.

11. The main recommendations by the MEDICRIME Committee on steps to improve or reinforce the protection of public health through the MEDICRIME Convention in times of pandemics in the areas covered by this report are provided at the end of the Introduction. Specific recommendations are at the end of each chapter. All chapters also highlight a number of promising practices. Cooperation between all relevant stakeholders, and civil society, is essential to ensure that effective measures against the counterfeiting of medical products and similar crimes involving threats to public health are enacted and implemented.

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INTRODUCTION

- 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") provides that a specific monitoring mechanism be set up to ensure effective implementation of its provisions by Parties (Article 25§1 and Rule 25).

- This report is the 1st implementation report developed by the Committee of the Parties to the MEDICRIME Convention (hereinafter "the Committee"). It contains the Committee's evaluation of the implementation by Parties of a selected number of provisions of the MEDICRIME Convention which are relevant to assess the situation in Parties with respect to "the protection of public health through the MEDICRIME Convention in times of pandemics".

Thematic monitoring

- During its 3rd meeting[1], the MEDICRIME Committee decided that its monitoring work (i.e. the assessment of the implementation of the Convention) would be based on a thematic approach.

- As available data show that offences involving medical products committed during a pandemic target critical funding through fraudulent scams, counterfeiting of vital protective personal equipment and critical medical devices to save lives and to detect the presence of the disease, and attacks on critical infrastructure in the fight against the disease, the MEDICRIME Committee decided that the first monitoring round would focus on "The protection of public health through the MEDICRIME Convention in times of pandemics".

- On 27 May 2021, the MEDICRIME Committee adopted this thematic questionnaire. Its purpose is to collect specific information on how Parties implement the MEDICRIME Convention with respect to offences involving medical products and similar crimes involving threats to public health and related to a pandemic. The replies to the questionnaire are assessed against the related background information provided by the Parties when answering the "General Overview" questionnaire on the implementation of the MEDICRIME Convention (hereinafter "Country Profile Questionnaire" or "CPQ") and any other relevant information from reliable sources.

Rule 26 of the Committee of the Parties' Rules of Procedure:

"(…) 2. The secretariat shall address such questionnaires to the Parties through the member in the MEDICRIME Committee representing the Party to be monitored and who will act as "contact point".

3. Parties shall co-ordinate with their respective domestic authorities to collect replies, which shall be submitted to the secretariat in one of the official languages of the Council of Europe within the time limit set by the MEDICRIME Committee. The replies to the questionnaires shall be detailed, as comprehensive as possible, answer all questions and contain all relevant reference texts. The replies shall be made public, unless a Party makes a reasoned request to the MEDICRIME Committee to keep its reply confidential.

[1] Committee of the Parties of the MEDICRIME Convention, List of decisions, 3rd Plenary meeting (1-3 December 2020), T-MEDICRIME-(2020) LD, paragraph 4.5

4. The MEDICRIME Committee may also receive information on the implementation of the Convention from non-governmental organisations and civil society involved in preventing and combating the counterfeiting of medical products and similar crimes involving threats to public health, in one of the official languages of the Council of Europe and within the time limit set by the MEDICRIME Committee. The secretariat transmits these comments to the Party or Parties concerned.
5. The secretariat may request additional information if it appears that the replies are not exhaustive or are unclear. Where warranted, with the consent of the Party or Parties concerned and within the limits of budgetary appropriations, the bureau may decide to carry out an on-site visit to the Party or Parties concerned to clarify the situation. The bureau shall establish guidance as to the procedure governing the on-site visits."

Parties involved in the 1st monitoring round

- The 1st monitoring round concerns the following 13 Parties which ratified the Convention: **Armenia, Belgium, Bosnia and Herzegovina, Croatia, Cyprus, France, Hungary, Morocco, Portugal, Russian Federation, Spain, Switzerland and Türkiye.** 23 countries had ratified the Convention at the time that the MEDICRIME Committee adopted the thematic report to the 1st monitoring round[2]. Five countries ratified the Conventions since the adoption of the questionnaire on 27 May 2021[3]. The thematic questionnaire was circulated to th countries.

- The above 13 Parties were monitored within a timeframe to create momentum around specific aspects of the monitoring theme. The remaining Parties who did not respond to the questionnaire were not monitored for the purpose of this report (**Albania, Belarus, Benin, Burkina Faso, Cote d'Ivoire, Guinea, Moldova, Niger, Slovenia, and Ukraine)[4].** This report, therefore, does not address the situation in each country separately. It presents an overview of the trends which emerge from the comparison of the situation in all Parties.

- Article 25§1 of the MEDICRIME Convention provides that the "Rules of Procedure of the Committee of the Parties shall determine the procedure for evaluating the implementation of this Convention using a multisectoral and multidisciplinary approach". Accordingly, Rule 25 §3 and Rule 26§2 provide that:

> ***"Rule 25§3*** *The monitoring round shall be initiated by addressing a questionnaire on the implementation of the relevant provisions of the Convention with respect to the selected theme. The Parties shall respond to the questionnaire within the time limit set by the MEDICRIME Committee.*
> *"**Rule 26§2*** *The secretariat shall address such questionnaires to the Parties through the member in the MEDICRIME Committee representing the Party to be monitored and who will act as "contact point".*

[2] See Appendix I for the State of signatures and ratifications and Appendix III for the State of play of replies to the Questionnaire.

[3] Cyprus on 05 September 2023; Morocco on 19 April 2022; Niger on 10 March 2022; Slovenia on 01 September 2022; Côte d'Ivoire on 01 November 2023

[4] It is noted that, in accordance with Rule 25§3, all Parties to the Convention have a requirement to respond to the 1st monitoring round questionnaire within the timeframe decided by the MEDICRIME Committee.

The Committee appreciates that all the information submitted by Parties was made public and underlines that the replies to the questionnaire were its main source of information to prepare this report.[5]

Structure of the Report

- The provisions of the MEDICRIME Convention have been grouped under different sections in this report without automatically following the structure of the Convention. This methodological choice in no way intends to prioritise the various provisions of the Convention: equal importance is attached to all rights and principles therein.

- This report does not seek to collect information on the general legislative and institutional framework established by Parties to implement the Convention. It focuses only on specific legislative and other measures taken or envisaged to protect public health from counterfeiting of medical products and similar crimes in the context of pandemics.

- For the purpose of this report, the notion of a pandemic will include the COVID-19 pandemic as well as other major health crises declared by the World Health Organisation as pandemics, epidemics or public health emergencies of international concern (PHEIC), including the Zika virus epidemic in 2015, the Ebola pandemic in 2014, the Middle East Respiratory Syndrome (MERS) in 2012, the H1N1 Influenza pandemic in 2009, the H5N1 outbreak in 2005, and the severe acute respiratory syndrome (SARS) in 2003.

- The Parties were requested to respond to all questions marked **mandatory** as they are essential to the monitoring round. It was also requested, where possible, that all questions marked **optional** could be answered. There were 18 questions marked as mandatory and 22 questions marked as optional.

- This report has eight main chapters

  - The first chapter collects information on policies, strategies, plans and activities to prevent counterfeit medical products and similar crimes involving a threat to public health, in particular during times of pandemics.
  - The second chapter identifies measures aimed at educating civil society on good practices in avoiding the risk associated with counterfeit medical products
  - The third chapter identifies measures focused on the protection of victims' rights.
  - The fourth chapter focuses on the ability and extent to which authorities/bodies may cooperate between them and exchange information in order to facilitate effective investigation
  - The fifth chapter is an appreciation of the various measures that may be proactively taken during a pandemic to detect counterfeit medical products and prevent them from reaching patients.
  - The sixth chapter concerns the ability to investigate and prosecute offenders for intentional crimes related to counterfeit medical products and similar crimes, in particular during a pandemic.

[5] All replies to the questionnaire are online at Appendix IV

- The seventh chapter identifies specific legislative and other measures that have been taken to support the sanctioning of persons in relation to the counterfeiting of medical products and similar crimes in final sentences, in particular relating to offences committed in a pandemic.
- Finally, the 8th and last chapter concerns the effective collection, collation and analysis of data that can support the fight against counterfeit medical products and similar crimes involving threats to public health in a pandemic, and in general.

- Each chapter
  - Provides a comparative overview of the situation in the eight Parties monitored, whilst a country-specific summary of the information is appended to the report in the form of tables[6]
  - Highlights promising practices where identified to effectively implement the Convention
  - Identifies the shortcomings and recommends steps that the Parties should take to improve or reinforce the protection of public health in times of pandemics, using the Convention

- Finally, in its recommendations to Parties, the MEDICRIME Committee decided to use the terms to "urge", "consider" and "invite" to mark different levels of urgency as follows:

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  - "**Urge**": when the MEDICRIME Committee assesses that legislation or policies are not in compliance with the Convention, or when it finds that despite the existence of legal provisions and other measures, the implementation of a key obligation of the Convention is lacking;
  - "**Consider":** when the MEDICRIME Committee agrees that further improvements are necessary for law or in practice to fully comply with the Convention;
  - "**Invite**": when the MEDICRIME Committee believes Parties are on the right track but it wishes to point at one or several promising practices to reinforce the implementation of the Convention

[6] See Appendix IV

I. PREVENTION AND TRAINING

This part aims to collect information on policies, strategies, plans and activities to prevent counterfeit medical products and similar crimes involving a threat to public health, in particular during times of pandemics. The questions concern all those whose responsibilities it is to procure and supply medical products, and those who encounter them or their impact on public health having regard to pandemics.

This part concerns:

- training and awareness programmes aimed at those people in particular, as well as the public in general.
- prevention measures aimed at raising awareness of the availability of counterfeit medical products.

The intention of the Convention is to promote putting in place measures to prevent circumstances whereby counterfeit medical products can infiltrate the supply chain. This means that there need to be regulatory regimes to ensure the quality and safety of medical products from the initial stage of procurement of excipients and active substances, both regarding medicinal products, accessories, and parts and materials, both regarding medical devices (Art 18.1). The regulatory regime extends to the manufacturing process of medical products, excipients and active substances, parts and materials, and accessories (Art 18.1) through to the distribution to the market. The Explanatory Report noted that the terms *supplying and offering to supply* (in Article 4 - Definitions, and Article 6- Substantive Criminal Law Offences) are not specifically defined in the Convention but are understood to cover acts of *procuring*. While not specifically mentioned in the Convention, the regulatory regime necessarily includes procurement programmes, both public and private. Therefore, the procurement and distribution of medical products are recognised by the Convention as a key area for prevention (Art 18.2)

The intention of the Convention is that all activities that result in criminal activities involving threats to public health are considered. To this end, it involves not only the legal supply chain but supplies conducted outside that chain and evades the regulatory supervised chain (Article 18. 3.c). In addition, it intends that Parties take measures to develop arrangements with Internet Service Providers and Domain Registrars to facilitate actions against websites involved in the promotion and selling of counterfeit medical products and similar crimes.
This part of the report focuses on the legislative, policy, and other measures taken by Parties to provide effective preventive measures and train healthcare professionals, providers, police and customs authorities and relevant regulatory authorities.

This part of the report considers prevention and training matters in the context of times of pandemics. This is of particular concern having regard to the global experience

during the COVID-19 pandemic and the expectation that both pandemics and epidemics will continue in times to come[7].

Article 18 – Preventive measures

1. Each Party shall take the necessary legislative and other measures to establish the quality and safety requirements of medical products.
2. Each Party shall take the necessary legislative and other measures to ensure the safe distribution of medical products.
3. With the aim of preventing counterfeiting of medical products, active substances, excipients, parts, materials and accessories, each Party shall take the necessary measures to provide, inter alia, for:
    a. training of healthcare professionals, providers, police and customs authorities, as well as relevant regulatory authorities;
    c. the prevention of illegal supplying of counterfeit medical products, active substances, excipients, parts, materials and accessories

Explanatory Report

113. Paragraphs 1 and 2 of this article provide for two key preventive measures in combating counterfeiting of medical products and similar crimes, namely the introduction, at the national level, of quality and safety requirements of medical products on the one hand, and measures ensuring the safe distribution of such products on the other. The ad hoc committee considered that it should be left to the domestic law of each Party to define the appropriate quality and safety requirements as well as the measures ensuring safe distribution. One example of the latter type of measure, which a Party may consider adopting, the introduction of adequate track and trace systems on medical products could be mentioned. Such track and trace systems can have different features but are essentially ensuring the traceability of a given medical product to its source.

114. As further preventive measures, paragraph 3 requires Parties to provide:

a. training of health care professionals, providers, police, customs and relevant regulatory authorities in order to better prevent and combat the counterfeiting of medical products and similar crimes;

c. to supervise all professional activities within the distribution chain of medical products, as well as to develop agreements with Internet Service Providers and Domain Registrars to facilitate actions against websites involved in the promotion and selling of counterfeit medical products.

115. The actions enumerated in paragraphs 1 - 3 are not to be considered as an exhaustive list.

[7] Imagining the future of pandemics and epidemics: a 2022 perspective. Geneva: World Health Organization; 2022.

61. As in the case of Article 6 above, the terms "supplying" and "offering to supply" are not specifically defined, but understood to cover, in the widest sense, the acts of procuring, selling or offering for free as well as brokering and promoting (including through advertising these products.

1.1. Prevention and Training

1.1.1. Measures to provide training to those in the distribution, wholesale and procurement programmes (Article 18.2)

- While considering the specific wording chosen by domestic legislation to implement Article 18, this should appreciate the intention of the Convention that measures are put in place to ensure that prevention and training are effective and not limited to actions enumerated in Article 18 and that these actions are not considered to be an exhaustive list.

- The Convention does not intend that prevention and training matters be provided and implemented by the Criminal Law alone, or at all. Matters of *quality* and *safety* are scientific standards that are more appropriately dealt with by regulatory laws, as is the case of all the Parties in this report (**Armenia, Belgium, Bosnia and Herzegovina, Croatia, France, Hungary, Morocco, Portugal, Russian Federation, Spain, Switzerland, and Türkiye**).

- Matters of the *distribution* of medical products are, likewise, dealt with by regulatory laws, whilst provisions for training are often not regulated by law but are provided through strategic planning and other measures, such as structured training sessions, awareness-raising programmes, and round table discussions (**Armenia, Belgium, Croatia, Hungary, Morocco, Portugal, Spain, Switzerland, and Türkiye**). Reliance is also placed on the distributors and wholesalers to train their own staff on preventive measures, including measures mandated by Good Wholesale and Distribution Practice Guides (GDP) (**Belgium, France, Spain**).

- None of the parties, except one (**the Russian Federation)** (and that was not specific to counterfeit medical products alone), reported the structured involvement of procurement programmes in training regimes to prevent the counterfeiting of medical products. This may indicate that there are no measures by the Parties, whether legislative, policy, strategic or other arrangements to either specifically or generally train those in either public or private procurement programmes on the prevention of counterfeiting and similar crimes involving medical products involving threats to public health.

- None of the parties had introduced specific measures for training the distribution sector to combat counterfeit medical products and similar crimes having regard to the impact of a pandemic other than considering their health safety measures of holding training and conferencing events virtually. Specific measures in this context of a pandemic are intended to mean having and implementing preventive

and training measures to take into account the impact of a pandemic on the procurement and distribution of medical products. Such impacts may involve resource challenges due to the diversion of finance and staff to critical pandemic response areas and the absence of staff due to illness and temporary redeployment, all of which leave deficiencies in trained staff in the prevention of counterfeit medical products being procured and distributed in the market, including through procurement programmes.

- It is important, in this context, that Parties are prepared through having and implementing legislative, policy, strategic and other measures to provide training in critical procurement and distribution areas with a view to preventing counterfeit medical products and similar crimes from arising when their systems, resources and priorities are under stress.

Promising Practices

- In Hungary, the National Board Against Counterfeiting (NABC), working under Decree 287/2010, created the Action Plan Against Counterfeiting and has a Working Group on actions against the counterfeiting of medical products. The Action Plan fosters cooperation between the relevant bodies/authorities in organising common training, consultations and the production of information documentation. One such booklet, specifically for customs on identifying falsified vaccines and medical products, was produced by the health product regulator, the National Institute of Pharmacy and Nutrition (OGYÉI), NBAC and pharmaceutical wholesalers.

- In the **Russian Federation**, the Academy of Management of the Ministry of the Interior conducts annual professional development programmes for the improvement of managers in procurement

Recommendations

- Urges **Belgium, Bosnia and Herzegovina, Croatia, France, Hungary, Russian Federation, and Spain** to ensure that policies, strategies and measures are provided for the training of those involved in public and private procurement programmes for medical products.

- Urges **Armenia, Belgium, Bosnia and Herzegovina, Croatia, Cyprus, France, Hungary, Morocco, Portugal, Russian Federation, Spain, Switzerland, and Türkiye** to develop contingency plans, strategies and other measures to provide training in critical procurement and distribution areas of medical products with a view to preventing counterfeit medical products and similar crimes from arising when their systems, resources and priorities are under stress, including during pandemics.

1.1.2. Measures to provide training to healthcare practitioners, police, customs, and health product regulators (Article 18.3.a)

- The Convention does not specify the measures to be taken to provide training. This is left to national authorities to decide within their capacities and structures how training to prevent counterfeiting of medical products and similar crimes should be conducted and the frequency that such training should be provided to healthcare practitioners, police, customs, and health product regulators.

- Training, including online seminars and workshops, involving police, customs, regulatory authorities, and healthcare professionals appear to be ongoing, and with some disruption during the COVID-19 pandemic, in a number of the Parties (**Armenia** (partial), **Belgium, Bosnia and Herzegovina, France, Morocco, Portugal, Spain, Switzerland, and Türkiye).** The training is not uniformly delivered among relevant authorities, with some consistently providing training (**France, Spain**) while others focus mainly on Customs training (**Switzerland)**, or regulatory authorities training only (**Armenia**) or regulatory authorities and healthcare professionals (Croatia)**.** The judiciary and public prosecutors are specifically trained in one Party (**Spain).** Others have strategic plans to conduct training of police and other authorities during the period to 2025 (**Bosnia and Herzegovina and Croatia).** One Party **(Hungary)** has a Working Group on counterfeit medical products, as part of the National Board against counterfeiting, and it coordinates plans among authorities on training in this area. One Party **(Türkiye)** provides training in the area as an adjunct with training of Customs on IPR infringements.

- None of the parties, except three (**France, Portugal, Spain**), consistently provide training to the police, customs, regulatory authority and healthcare practitioners. This results in a fragmented training provision and is not in keeping with the requirements or the spirit of Article 18. 3.a. of the Convention. It does not provide training to all of those who need it on an ongoing basis. This weakens the protections for public health intended by the Convention.

- It is recommended that Parties introduce as a standing item in their policies, strategic plans and arrangements for training on a multi-authority and multi-disciplined basis to include police, customs and regulatory authorities, at a minimum, as well as healthcare practitioners and legal professionals, to appreciate the risks arising with the procurement and distribution of counterfeit medical products and similar crimes. This training should be systematic and ongoing among those mentioned in the Convention as needing the training.

Promising practice

- In **Portugal**, two laws were introduced mandating training of police, customs, and health product regulators on the handling of medical products acquired during COVID-19. A set of crimes against health were identified for the Judicial Police to prioritise actions for prevention and investigation during this period. This highlighted anticipated crimes to be committed during COVID-19 and provided training and guidance notes that included anticipated frauds, embezzlement, abuse of trust, corruption, abuse of power, and undue advantage.

- In **Spain**, The Ministry of Justice includes judges, magistrates, public prosecutors, and selected police officials in training and awareness-raising on the problems and risks posed by counterfeit medical products. The Spanish Judicial School of the General Council of the Judiciary, in collaboration with the Council of Europe (HELP programme and the European Committee on Criminal Matters), has launched the 'MEDICRIME' course to expand the capabilities and skills of judges to improve the national implementation of the MEDICRIME Convention.

Recommendations

- Urges **Armenia, Croatia, Cyprus, Hungary, and the Russian Federation** to develop policies, strategies and other measures to provide training to healthcare practitioners, police, customs and regulatory authorities, to each of the sectors, and not just to some of them, on the prevention of counterfeit medical products, active substances, accessories, parts and materials. This should consider cross-training between the relevant authorities to ensure completeness and sustainability.

- Invites **Armenia, Belgium, Cyprus, Bosnia and Herzegovina, Switzerland and Türkiye to** provide training on a consistent basis, particularly in times of pandemic, to each of the sectors for healthcare practitioners, police, customs and regulatory authorities, and not just to some of them. This should consider cross-training between the relevant authorities to ensure completeness and sustainability.

- Invites **Armenia, Belgium, Bosnia and Herzegovina, Croatia, Cyprus, Hungary, Portugal, Russian Federation, Switzerland** and **Türkiye** to introduce as a standing item in their policies, strategic plans and arrangements for the training of police, customs and regulatory authorities, as well as healthcare practitioners and legal professionals, to appreciate the risks arising with the procurement and distribution of counterfeit medical products and similar crimes to ensure the sustainability of the training.

1.1.3. Measures to provide training to specialised investigation units/bodies in specialised techniques (including financial investigation) (Article 16(2)

Article 16.2 – Criminal Investigations

Each Party shall take the necessary legislative and other measures, in conformity with the principles of its domestic law, to ensure effective criminal investigation and prosecution of offences established in accordance with this Convention, allowing, where appropriate, for the possibility for its competent authorities of carrying out financial investigations, of covert operations, controlled delivery and other special investigative techniques.

Explanatory Report

107. The article provides for the specialised criminal investigation and combating of counterfeiting of medical products and similar crimes by persons, units or services of the competent national authorities of State Parties.

108. Paragraph 2 provides for State Parties to ensure the effective investigation and prosecution of offences established under the Convention in accordance with the fundamental principles of their national law. The notion of "principles of national law" should be understood as also encompassing basic human rights, including those provided under Article 6 of the European Convention on Human Rights (ECHR).

109. "Effective investigation" is further described as including financial investigations, covert operations, controlled delivery and other special investigative techniques. These could encompass electronic and other forms of surveillance as well as infiltration operations. As indicated by the wording "where appropriate", Parties are not legally obliged to apply any or all of these investigative techniques, but if a Party chooses to conduct investigations using these special techniques, the principle of proportionality, as referred to in the Preamble of the Convention, will also apply.

110. The ad hoc committee underlined that "controlled delivery" is one of the most important investigative tools available to authorities in the area of counterfeiting of medical products and similar crimes. The measure of "controlled delivery" is already foreseen by a number of international legal instruments in the field of criminal law, in particular the United Nations Convention Against Transnational Organised Crime and the United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances and the Second 16 Additional Protocol to the European Convention on Mutual Legal Assistance in Criminal Matters (ETS No. 182).

- Article 16, Paragraph 2, provides for State Parties to ensure the effective investigation and prosecution of offences established under the Convention in accordance with the fundamental principles of their national laws. This requires taking into account basic human rights in accordance with Article 6 of the ECHR. That intends to include the application of the principle of proportionality, as referred to in the Preamble of the Convention, where such specialised techniques are applied.

- The Explanatory Report explains that the Convention does not require a Party to use specialised techniques in the investigation of crimes involving counterfeit medical products and similar crimes, and where they do, it must be appropriate

in the circumstances. The type of specialised techniques mentioned in Article 16.2 includes electronic and other forms of surveillance as well as infiltration operations, and controlled deliveries. This is not an exhaustive list and it is open to domestic law to determine which, if any, and the circumstances in which such specialised techniques may be used in relation to the investigation of offences provided by the Convention. The Explanatory Report emphasises that controlled delivery is one of the most important investigative tools available to authorities in the area of investigating the counterfeiting of medical products and similar crimes.

- This part of the report considers the legislative, policy, and other measures taken by Parties to provide effective measures to train specialist investigation bodies that focus on counterfeit medical products and similar crimes with specialist techniques, as mentioned above.

- While it is likely that most Parties have law enforcement specialist units/bodies responsible for the application and training in specialist techniques, as described above, the provision of measures for training in specialist techniques to specialist investigation units in the investigation of counterfeit medical products and similar crimes has been noted to be largely absent, except in two Parties (**France, Spain**). In the absence of a national policy not to implement such techniques relating to the investigation of counterfeit medical products, then the intention of the MEDICRIME Convention has not been met.

Recommendations

- Invites **Armenia, Belgium, Bosnia and Herzegovina, Croatia, Cyprus, Hungary, Morocco, Portugal, Russian Federation, Switzerland, and Türkiye** to consider reviewing their legislation, plans, strategic and other measures to provide training in specialist investigative techniques to specialist units/bodies in the investigation of counterfeit medical products and related crimes, where appropriate.

1.2. Oversight programmes to assess the frequency and effectiveness of training provided (Article 18.1, 2 and 3. a)

- The success and effectiveness of any training are judged by its outputs and outcomes. This can often be challenging to assess other than the taking place of training events and the completion by the relevant officials of the training programme. This part seeks to determine the extent to which the Parties have conducted oversight programmes to assess the frequency and effectiveness of the training provided, as required by Article 18. 1, 2, and 3.a. of the Convention.

- This part also seeks to determine the extent to which revision programmes have been put in place to ensure that remedial actions are addressed by training on any deficiencies observed regarding existing training programmes required by Article 18.1, 2, and 3. a.

- Training programmes conducted in some Parties are assessed for competence and knowledge following the completion of the training programme (**France, Russian Federation**). In one case (**France**) the training is followed in due course by retraining to ensure continued competence by officials. While training validation is a necessary component of training provided, this is considered a different step and process to oversight programmes to assess the effectiveness of the training having regard to the value delivered by officials in the conduct of their duties following the training.

- Two Parties (**Croatia, Hungary**) plans to begin assessment programmes one year after training officials. One Party (**Armenia**) relies on its regulatory quality management system to ensure any remedial actions needed are identified and completed.

- In none of the Parties is it evident that there is an oversight programme to assess the frequency and effectiveness of training already provided. This is, at best, left to retraining programmes (one case only). The frequency of training is not addressed by the Parties, except in one case (**France**) due to its programme of mandatory retraining.

Recommendations

- Urges all parties to the MEDICRIME Convention to train all of the relevant sectors involved in combating the counterfeiting of medical products and similar crimes. This should be followed up by an oversight programme to assess the effectiveness of the training provided.

1.3. Awareness-raising and training programmes for those involved in procurement programmes, wholesalers, distributors, and entities responsible for cleaning and waste disposal on the disposal of medical product waste (Article 18. 1, 2 and 3)

- Waste management and care in the disposal of medical products are crucial elements in the prevention of counterfeit medical products and used or disposed of legitimate medical products being illegally diverted back onto the legitimate supply chain or on unregulated markets.

- While waste management was not specifically enumerated in the Convention or mentioned in the Explanatory report, the Explanatory report emphasised that actions enumerated in paragraphs 1-3 of Article 18 are not to be considered as an exhaustive list. In this context, the Parties are expected to go beyond the wording and give full effect to the spirit and intent of the Convention. While reliance may be placed on domestic environmental laws to satisfy the issues raised in this part of the report, it should be emphasised that the Convention is concerned with the protection of and minimising the risk to public health and compliance with criminal law. This is an added emphasis for all connected to

cleaning and waste disposal of medical products beyond compliance with environmental regulations for environmental purposes.

- Further actions to prevent the recycling of waste and disposed of medical products, whether they are counterfeit or legitimate in nature, are required as part of the end-to-end management of the medical products in the procurement and distribution systems, and in healthcare facilities that consume the medical products and create medical product waste.

- It is expected that seized counterfeit medical products, and the instrumentalities associated with their production and fraudulent diversion would be destroyed by order of a court or otherwise in accordance with domestic laws. They should not be sold or otherwise supplied for any use other than the taking of samples for tests, examinations or analyses undertaken in support of efforts to prevent crime and protect public health. Some seized ancillary equipment associated with medical devices may have alternative uses and may be disposed of by the health product regulator when authorised by the Court while ensuring that there will be no diversion to facilitate further counterfeiting of medical products.

- Within the legal supply chain and in healthcare facilities, large quantities of legitimate medical product waste are produced. This is where the Convention expects end-to-end management of medical product waste control and that everyone connected with waste management of medical products is aware of their responsibilities and the associated health risks and criminal law consequences with deviating from these. Where this is not the case, such loopholes need to be eliminated by approved processes and audited to ensure compliance. For this to happen, a provision for awareness-raising and training programmes for cleaning and disposal staff, and those who manage them, is required. As for other programmes, this should be assured by ongoing oversight to assess the effectiveness and frequency of the awareness-raising.

- Specific awareness-raising programmes for cleaning and waste management of medical products are not conducted as a general measure by any of the Parties. Instead, a more focused application of regulatory licensing requirements is applied to the distribution and wholesale trade in medical products. A similar focus is applied to the retail pharmacy trade (**Croatia**, **France**) where all staff are required to train on the proper disposal of medical product waste to prevent illegal recycling.

- Only one country (**France**) had awareness-raising arrangements for police investigators that focus on medical product-related crime. One Party (Croatia) has established cooperation between police, customs and other regulatory authorities in medical waste management, including in cases of seized counterfeit medical products. It is unclear if the cooperation arrangements are supported by structured awareness-raising programmes or training provided for this purpose. One Party reported that it did not have an awareness-raising campaign for police (**Hungary**) and another (**Croatia**) reported that it did not have such a campaign for cleaning staff or recycling staff, but plans for training

and written instructions to be prepared for this. While one Party (**Portugal**) has a law for the integrated waste management system for the collection of packaging, medical products and medical devices, this is not focused on the prevention of recycling of falsified medical products. One Party (**Croatia**) has a law on the management and disposal of waste medical products, which, while it is not designed specifically to prevent the recycling of counterfeit or disposed of medical products, can contribute to such prevention. It is unclear if the law is supported by structured awareness-raising programmes or training provided for this purpose. One Party (**Türkiye**) requires disposal at certified waste centres to ensure that such products cannot be reused or recycled. This is supported by law and by information to authorities and organisations that no product removed from the supply chain can be used. This presumes that the same regime applies to medical products removed from the illicit supply chain for disposal at certified waste centres. However, there are no structured awareness-raising or training programmes provided for this purpose.

- A greater emphasis was given to awareness-raising in the proper disposal of medical waste during COVID-19 (**Belgium, Portugal, Russian Federation, Spain, Switzerland**). Specific instructions or laws were provided concerning the handling of labelling materials for disposal in Belgium, while a focus was also placed on securing both medical products for disposal in special containers and/or in separate rooms (**Belgium, Croatia, Russian Federation, Spain, Switzerland**). In Belgium, weekly briefings were held for officials in charge of vaccination centres and those responsible for vaccine waste disposal in connection with the potential for fraud with vaccine waste, including associated labelling. In the Russian Federation, regular updating took place of healthcare officials and medical institutions on the turnover and disposal of medical waste, including personal protective equipment. It also updated its instructions on the destruction of seized counterfeit and substandard medicines and drafted similar instructions for medical devices (awaiting adoption). In Spain, special instructions were issued relating to medical waste associated with COVID-19 in domestic dwellings, hospitals, ambulances, health centres and laboratories. In Switzerland, a reference to the MEDICRIME Convention was provided to vaccination centres and supervising authorities regarding waste in the context of the COVID-19 pandemic. It is understood, in all cases, that the reference to medical waste included waste associated with medical products and not just non-medical product medical waste. Greater emphasis on medical product waste could heighten awareness of this aspect of all medical waste.

- The use of authorised waste management entities under specific contracts was in place (**Belgium, Croatia, Portugal, and Türkiye**) for the disposal of waste medical products. It is anticipated, but not specifically noted by other Parties, that such waste disposal arrangements are put in place in many of the Parties and done so for environmental law purposes.

- No Party engaged in awareness-raising campaigns for those involved in the procurement of medical products. This is a clear gap in the protection of public health and creates risks that may remain undetected in breach of criminal law.

- No Party undertook reviews of the effectiveness of the governance and supervision of medical products waste disposal programmes. No party undertook any awareness-raising programmes on the importance of proper disposal and risks associated with disposed of medical product when illegally diverted for re-use.

Promising Practices

- In **Belgium**, during the COVID-19 pandemic, special instructions were issued to public vaccination centres regarding the disposal of waste materials, including vials, labelling, stickers and packaging. Waste labels were required to be made illegible. All waste was required to be put into special containers and stored in a secured area. Every week, videoconferences were held for all vaccination centres during which potential fraud with medical product waste and best practices concerning waste disposal were discussed.

- In **Spain**, during the COVID-19 pandemic, all sectors, including the public, that had the possibility to create and dispose of waste medical products had their awareness raised through instructions to minimise the risk to human health and to comply with all legal requirements, not just environmental requirements, relating to medical waste and COVID-19 pandemic.

Recommendations

- Urge Parties to undertake awareness-raising campaigns for those engaged in the procurement of medical products to close this gap in protecting public health.

- Urges Parties to ensure that arrangements are put in place for all relevant sectors, including those mentioned in Article 18.1, 2, and 3 of the Convention, that handle medical product waste to be included in awareness-raising campaigns.

- Invites Parties to build on their response to the COVID-19 pandemic challenges regarding cleaning and waste disposal and to apply equivalent and enhanced actions in non-pandemic times.

- Invites Parties to ensure that their awareness-raising campaigns on the management and disposal of waste medical products highlight medical product waste and the consequence of illegal diversion associated with public health risks and the consequences flowing from the Criminal Law relating to the illegal diversion of medical products.

- Invites Parties who have not provided information of their national situation, to examine their situation in the light of the foregoing considerations, and urges

them, where appropriate, to bring it into line with the requirements of the Convention.

1.4. Reviews of the effectiveness of the governance and supervision of medical product waste disposal (Article 18.1, 2, 3.c)

- Considering the emphasis placed on waste management and disposal of medical product waste during the COVID-19 pandemic by some Parties, it would be expected that an assessment of the effectiveness of the outcome of those measures, including governance and supervision measures associated with them, would have been undertaken on an ongoing or periodic basis. Only one Party (**Croatia**) was considered to have conducted such assessments as a routine regulatory activity. This was assessed as not having been conducted by any other Party.

- One Party (**Belgium**) could be assessed as having conducted an informal review on a weekly basis through conferences to discuss the measures put in place and best practices on disposal and fraud risks with the public vaccination programme. In addition, physical visits to the vaccination centres were carried out to ensure that any changes to the method of work found necessary were reported on and put in place. However, this is not a formalised effectiveness review of the governance and supervision of medical waste disposal and it is assessed as being restricted to the vaccination programme and not to all medical product waste.

- As there were no reviews of the effectiveness of the governance and supervision of medical product waste disposal, there were no awareness-raising programmes conducted by the Parties on the importance of disposal programmes and the risks that can arise from inadequate governance and supervision.

Recommendations

- Urge the Parties that have not yet achieved this stage to put in place measures to conduct reviews of the effectiveness of the governance and supervision of medical product waste to follow on from the conduct of awareness-raising and training measures on medical waste disposal.

- Urge all Parties to include effectiveness reviews on governance and supervision to the widest possible extent, not only including procurement entities and authorities but also including healthcare facilities that create medical product waste.

1.5. Specific preventive actions targeted at specific medical products involved in a recent pandemic and the results achieved (and not already mentioned above) (Article 18.1, 2, 3)

- One Party (**Hungary**) put measures in place for the police and the *Operational Group for the Protection against the Coronavirus Pandemic*, a Government body, regularly conducted awareness raising among the public about the risks associated with counterfeit vaccines and counterfeit PCR tests. One Party (**Morocco**) implemented special control measures through the Direction Génerale de la Sûreté Nationale related to counterfeit medical products during COVID-19 pandemic. One Party (**Croatia**) implemented new rules, including the requirement for Customs authorities to check whether an importer had an authorisation from the medicinal product and medical device regulatory authority (HALMED), while another rule specifically involved measures to identify importations of COVID-19 vaccines. No Party provided information on any results from the special measures adopted on any specific medical products during any recent pandemic.

II. EDUCATION

This section seeks to identify measures aimed at educating the public and on good practices in avoiding the risks associated with counterfeit medical products.

At this point, MEDICRIME Convention refers specifically to the implementation of awareness-raising campaigns oriented to the public in general in the field of counterfeit medical products and similar crimes.

Article 18 – Preventive measures

(…)

3. With the aim of preventing counterfeiting of medical products, active substances, excipients, parts, materials and accessories, each Party shall take the necessary measures to provide, *inter alia*, for:

(…)

b. the promotion of awareness-raising campaigns addressed to the general public providinginformation about counterfeit medical products;

EXPLANATORY REPORT

Article 18 – Preventive measures

114. As further preventive measures, paragraph 3 requires Parties to provide training of health care professionals, providers, police, customs and relevant regulatory authorities in order to better prevent and combat the counterfeiting of medical products and similar crimes; to promote awareness-raising campaigns with the involvement of relevant non-governmental organisations and the media; to supervise all professional activities within the distribution chain of medical products, as well as to develop agreements with Internet Service Providers and Domain Registrars to facilitate actions against websites involved in the promotion and selling of counterfeit medical products.

115. The actions enumerated in paragraphs 1 - 3 are not to be considered an exhaustive list.

2.1 Strategies, policies and other measures planned or implemented, with a view to educating the public on risks associated with counterfeit medical products, in particular, those that may be encountered during a pandemic

This part seeks to determine the strategies, policies and other measures that have been planned or implemented, with a view to educating the public on risks associated with counterfeit medical products, especially those that may be encountered during a pandemic in connection with what is established by Article 18.3.b. In particular, it is intended to obtain information on such education policies related to the following aspects:

i. on purchasing conducts of medical products, including through real-world/physical and virtual means, such as online and e-commerce platforms and social media;
ii. on promoting good purchasing conduct among the public to encourage rational consumption of medical products and avoiding procurement from sources that are not within your country's authorised supply systems;
iii. on developing and delivering risk awareness campaigns regarding counterfeit medical products and similar crimes.

Almost all the Parties (**Armenia, Belgium, Bosnia and Herzegovina, Croatia, France, Hungary, Morocco, Portugal, Russian Federation, Spain, Switzerland, and Türkiye**) have implemented measures with a view to educating the public on risks associated with counterfeit medical products, on purchasing conducts of medical products, including through real-worlds/physical and virtual means, such as online and e-commerce platforms and social media.

- Policies on promoting good purchasing conduct among the public to encourage rational consumption of medical products and avoiding procurement from sources that are not within each Party's authorised supply systems are also generally adopted by the different Parties. One Party (**Türkiye**) has specific awareness-raising activities for this purpose.

- Most Parties have adopted strategies for developing and delivering risk awareness campaigns regarding counterfeit medical products and similar crimes. Only two Parties (**Armenia**, and **Cyprus**) report not having specific programmes in this area.

- It has also to be mentioned that the majority of the Parties **(Croatia, France, Hungary, Morocco, Russian Federation, Spain,** and **Switzerland)** have strengthened those measures, policies and strategies during the COVID-19 pandemic or have implemented specific awareness-raising programmes focused on the counterfeiting of medical products in the context of the pandemic.

- Except for Croatia, no other Party has issued a report on the results of these measures.

Promising Practices

- **Croatia,** includes a report on the results of the measures taken under this point. According to the analysis made by Croatia, systematic media monitoring shows that a significant number of articles about counterfeit medical products and the threat of buying medicines on the internet are published in print publications, as well as on news portals, based on the information the Agency for Medicinal Products and Medical Devices (HALMED) provides. Likewise, national TV and radio stations regularly include reports on the dangers of counterfeit medical products in collaboration with the Agency.

- In **France,** in the context of the crisis, various communications have been sent to the general public by the authorities concerning the risks associated with counterfeit medical products. For example, the National Agency for the Safety of Medicines and Health Products has published on its website:
  - Safety information, opinions and recommendations on medicines in the face of COVID-19,
  - information for buyers, distributors and importers on the qualification of products used during the COVID-19 health crisis,
  - a warning against products presented on the Internet as solutions to COVID-19, including Artemisia annua.
  - In its anti-counterfeiting plan for 2021-2022, the Directorate-General for Competition, Consumer Affairs and Fraud Prevention (DGCCRF) focuses on counterfeit medicines and medical devices in times of health crisis.

- **Portugal**, while not specific to a pandemic situation, has online educational campaigns and warning campaigns on buying medical products online.

- In **Switzerland,** Swissmedic provides a variety of targeted information (factsheets, etc.), primarily on its website (www.swissmedic.ch). Regarding the current pandemic, Swissmedic has issued specific warnings:
  - against purchasing non-conforming and illegal medical devices,
  - against purchasing illegal medicinal products which are used against COVID19, and
  - against purchasing COVID-19 vaccines on a private basis.

  Swissmedic regularly conducts public awareness campaigns (e.g. annual Operation PANGEA, and awareness campaigns within the framework of the Swiss public-private partnership STOP PIRACY), and issues regular publications regarding the health risks of purchasing drugs from illegal sources and *ad hoc* publications regarding specific dangerous illegal medicines.

- One Party (**Türkiye**) has specific awareness-raising activities for this purpose. and to use medical practitioner-prescribed medicines and counselling

services by healthcare professionals. In this context, the Ministry of Health provides advice on Rational Drug Use on social media.

Recommendation

- **URGES Belgium, Bosnia and Herzegovina, France, Hungary, Morocco, Portugal, Russian Federation, Spain, Switzerland, and Türkiye** to issue reports on the measures, policies and strategies taken to the promotion of awareness-raising campaigns addressed to the general public providing information about counterfeit medical products.

- Urges **Armenia** and **Cyprus** to develop strategies, policies and other measures with a view to educating the public on risks associated with counterfeit medical products in the context of purchasing conducts including through real-world/physical and virtual means, promoting good purchasing conduct among the public to encourage rational use of medical products and the avoiding procurement from sources that are not within the Party's authorised supply chain, and on developing and delivering risk awareness campaigns regarding counterfeit medical products and similar crimes

2.2. Policies to encourage or support the involvement of civil society in promoting measures to combat, prevent, detect and respond to counterfeit medical products during a pandemic, or in a more general context.

- This concerns policies by the Parties that encourage or support civil society to become involved in measures to combat, prevent, detect and respond to counterfeit medical products. This was focused on a pandemic period, but also more generally outside of a pandemic. Examples of civil society provided included industries, publishers and academia and include all relevant groups and non-governmental organisations impacted by counterfeit medical products and similar crimes.

- This part was not intended to focus on the actions by authorities in conducting education, training or awareness-raising measures, either to the industry or directly to the public. It is assessed that all the Parties focus on training the industry and raising public awareness among the industry and the public rather than encouraging or supporting civil society to promote such measures to prevent, detect and respond to counterfeit medical products during a pandemic, or in a more general context.

- Two Parties (**Russian Federation, Spain**) may indirectly have such policies. It is not clear if civil society is encouraging awareness-raising to the public as part of public policy or self-driven (**Spain**). For example, Spanish Associations of the Pharmaceutical Industry issued precautions to be taken when purchasing medical products during the COVID-19 pandemic. It is unclear if this has been a result of State policy to encourage the Associations to raise this awareness during the pandemic or an industry initiative. In the Russian Federation, there is

a scheme to recognise civil society, mainly the public, who actively participate in measures to combat, prevent, detect and respond to counterfeit medical products, including during a pandemic. It is not clear if this results from the promotion of a State policy to encourage civil society to make this recognition or if it is a direct State recognition.

Recommendation

- Urges Parties to review their legislation, policies and measures on the promotion of clear supports to encourage the involvement of civil society in conducting awareness-raising activities on combating, preventing, detecting and responding to counterfeit medical products during a pandemic, or in a more general context.

2.3. Active engagement by civil society in raising public awareness of the risks arising from counterfeit medical products (Article 18.3.b)

- The focus of this part is to ascertain whether and to what extent that civil society is engaged in awareness-raising directed to the general public providing information about the risks associated with the consumption of counterfeit medical products.

- None of the Parties, except one Party **(Türkiye)** point to the active engagement by civil society in raising public awareness. This does not mean that such engagement does not take place, only that it is not being recorded by public authorities as part of awareness-raising campaigns addressing the general public on risks associated with the procurement and consumption of counterfeit medical products.

- In one case **(Türkiye)** pharmacy unions and chambers carry out awareness-raising activities to the general public, as well as to healthcare professionals.

- Three Parties (**Croatia, Hungary, Russian Federation**) point to engagements that have the possibility of civil society being involved in awareness raising among the public, though this remains unclear. In Croatia, the brand owners conduct awareness-raising campaigns on counterfeit products more generally but this may also have the possibility of increasing the public's consciousness of the risks arising with counterfeit medical products. In Hungary, the National Board against Counterfeiting (NBAC) engages with civil society, among others, in awareness raising on counterfeit products, including counterfeit medical products. This has the possibility for civil society groups to subsequently become involved in awareness-raising to their respective interest groups or more generally to the public on the risks of procuring and consuming counterfeit medical products. In the Russian Federation, the authentication app available to the public on smartphones requires some promotion for its use and has the possibility of civil society groups being involved in this awareness-raising among

the public to detect and respond to counterfeit medical products. It remains unclear the extent to which civil society is actually involved in such awareness-raising or whether this remains within the domain of the State.

Recommendations

- Urges all Parties to review their legislation, policies and measures on data collection to record instances of the provision by civil society to the general public on awareness-raising campaigns and programmes on the risks arising from procuring and consuming counterfeit medical products.

- Invite all Parties to share with civil society the opportunity to be involved in conducting awareness-raising to the general public on the risks arising from counterfeit medical products.

2.4. Legislative provisions, strategies, plans and preventive measures taken to prevent the promotion, advertisement and dissemination of material, where they are contrary to internal laws, during a pandemic and generally

- The majority of the Parties **(Armenia, Belgium, Croatia, Cyprus, France, Russian Federation, Portugal, Spain, Switzerland,** and **Türkiye)** have legal provisions to prohibit the promotion and selling of falsified medical products.

- Other strategies, plans and preventive measures have been taken by different Parties to prevent the promotion, advertisement and dissemination of material, including virtual information and medicinal product, offers, when they are contrary to internal laws, during a pandemic and generally. One Party (**Morocco**) has two specialised bodies within the Brigade Nationale de la Police Judiciaire dealing with these matters. While the two bodies are mainly focused on crimes associated with new technologies, it is unclear to what extent these also act to prevent the promotion, advertisement and dissemination of material, when they are contrary to internal laws, where new technologies are not involved.

PROMISING PRACTICES:

- In **Spain,** Resolution of 26 March 2021 of the State Secretariat for Health published the Agreement with the Association for Self-Care of Health and the Association for the Self-Regulation of Commercial Communication on Advertising Medicinal Products for Human Use addressed to the public (BOE of 7 April 2021). The purpose of the Convention is to establish the most appropriate mechanisms for the assessment of advertisements addressed to the public concerning medicinal products for human use, in order to ensure that they are produced with the necessary truth, clarity and objectivity and that all the conditions imposed by the relevant legislation are fulfilled. In this regard, the Association for the Self-Care of Health (ANEFP) undertakes to review all draft advertising messages submitted to them on a voluntary basis by pharmaceutical bodies to advertise medicinal products for human use to the public through a Technical Committee for the review of this type of advertising and to inform pharmaceutical bodies of all the incidents noted in the review of the advertising projects submitted and studied. In turn, the Association for the Self-Regulation of Commercial Communication (AUTOCONTROL) undertakes to examine through its Technical Cabinet, and in accordance with its procedures, advertising campaigns sent by ANEFP under the 'ANEFP stamp' and those sent to it on a voluntary basis by advertisers, agencies or media in relation to advertising messages on medicinal products for human use addressed to the public.

- In **Switzerland,** Swissmedic is the central contact point for reports regarding illegal advertisements and illegal offers and takes measures against any such activities contrary to national laws. Together with the national communications authority, Swissmedic has assessed all new websites that included "COVID", "corona" or similar words in their domain name in order to uncover illegal offers or activities. Furthermore, Swissmedic conducts specifically targeted monitoring of illegal virtual information and offers. In order to optimise such monitoring, tools for automated monitoring of illegal medicinal products and non-conforming medical devices are currently being evaluated.

Recommendation

- Urges **Bosnia and Herzegovina** to implement legislative provisions, strategies, plans and preventive measures to prevent the promotion, advertisement and dissemination of material, including virtual information and medicinal product offers, when they are contrary to internal laws, during a pandemic and generally (Article 8. a, and 18. 3. b).

III. VICTIMS

This section aims at identifying measures focused on the protection of victim rights.

In particular, the purpose of this section is to ensure the protection of the rights and interests of victims of counterfeiting of medical products and similar crimes by recognising, by means of legislative and other measures, a set of rights established in Article 19 MEDICRIME Convention. (Those rights relate mainly to access to information relevant to their case and which is necessary for the protection of their health, assistance to victims in their recovery, and the right to compensation from the perpetrators).

This part also aims to ensure the standing of the victims at all stages of criminal investigations and proceedings. Of particular relevance is the protection of some rights and interests of the victims at this stage; i.e., to be informed of their rights and the services at their disposal, right to be heard, to provide them with appropriate support services, measures for their safety, etc.

Article 19 – Protection of victims

Each Party shall take the necessary legislative and other measures to protect the rights andinterests of victims, in particular by:

a ensuring that victims have access to information relevant to their case and which is necessary for the protection of their health;

b assisting victims in their physical, psychological and social recovery;

c providing, in its domestic law, for the right of victims to compensation from the perpetrators.

Article 20 – The standing of victims in criminal investigations and proceedings

1 Each Party shall take the necessary legislative and other measures to protect the rights and interests of victims at all stages of criminal investigations and proceedings, in particular by:

a informing them of their rights and the services at their disposal and, unless they do not wish to receive such information, the follow-up given to their complaint, the possible charges, the general progress of the investigation or proceedings, and their role therein as well as the outcome of their cases;

b enabling them, in a manner consistent with the procedural rules of domestic law, to be heard, to supply evidence and to choose the means of having their views, needs and concerns presented, directly or through an intermediary, and considered;

c providing them with appropriate support services so that their rights and interests are duly presented and taken into account;

d providing effective measures for their safety, as well as that of their families andwitnesses on their behalf, from intimidation and retaliation.

2 Each Party shall ensure that victims have access, as from their first contact with the competent authorities, to information on relevant judicial and administrative proceedings.

3 Each Party shall ensure that victims have access, provided free of charge where warranted, to legal aid when it is possible for them to have the status of parties to criminal proceedings.

4 Each Party shall take the necessary legislative and other measures to ensure that victims of an offence established in accordance with this Convention committed in the territory of a Party other than the one where they reside can make a complaint before the competent authorities of their State of residence.

5 Each Party shall provide, by means of legislative or other measures, in accordance with the conditions provided for by its domestic law, the possibility for groups, foundations, associations or governmental or non-governmental organisations, to assist and/or support the victims with their consent during criminal proceedings concerning the offences established in accordance with this Convention.

Explanatory Report

116. The protection of, and assistance to, victims of crime has long been a priority in the work of the Council of Europe.
117. The horizontal legal instrument in this field is the European Convention on the Compensation of Victims of Violent Crime (ETS No. 116) from 1983, which has since been supplemented by a series of recommendations, notably Recommendation No. R (85) 11 on the position of the victim in the framework of criminal law and procedure, Recommendation No. R (87) 21 on the assistance to victims and the prevention of victimisation and Recommendation Rec (2006)8 on assistance to crime victims.
118. Furthermore, the situation of victims has also been addressed in a number of specialised conventions, including the Council of Europe Convention on the Prevention of Terrorism (CETS No. 196), the Council of Europe Convention on Action against Trafficking in Human Beings (CETS No. 197), both from 2005, and the Council of Europe Convention on the Protection of Children against Sexual Exploitation and Sexual Abuse (CETS No. 201) from 2007.
119. Taking into account the potential grave consequences for victims of counterfeiting of medical products and similar crimes, the ad hoc committee found that it was justified to provide specifically for the protection of such victims, and also to ensure that victims of the crimes established under this Convention are being kept informed about relevant developments in their cases by the competent national authorities and that – subject to the domestic law of the Parties – they are being given the possibility to be heard and to supply evidence.
120. It is recalled that, the term "victim" as defined in Article 4, letter k, of the Convention is limited to natural persons suffering adverse physical or psychological effects as a result of one or more of the conducts criminalised by the Convention. Legal persons are not intended to be covered by the provisions on victims in Chapter VI, nor are persons suffering only financial losses in connection with a conduct criminalised under the Convention.

Article 19 – Protection of victims
121. Article 19 provides for the protection of the rights and interests of victims, in particular by requiring Parties to ensure that victims are given access to information relevant for their case and necessary to protect their health; that victims are assisted in their physical, psychological and social recovery, and that victims are provided with the right to compensation under the internal law of the Parties. As regards the right to compensation, the ad hoc committee noted that in a number of member states of the Council of Europe, national victim funds are already in existence. However, this provision does not oblige Parties to establish such funds.

Article 20 - The standing of victims in criminal investigations and proceedings
122. This article contains a non-exhaustive list of procedures designed to victims of crimes established under this Convention during investigations and proceedings.

These general measures of protection apply at all stages of the criminal proceedings, both during the investigations (whether they are carried out by a police service or a judicial authority) and during criminal trial proceedings.

123. First of all, the article sets out the right of victims to be informed of developments in the investigations and proceedings in which they are involved. In this respect, the provision provides that victims should be informed of their rights and of the services at their disposal and, unless they do not wish to receive such information, the follow-up given to their complaint, the charges, the general progress of the investigations or proceedings, and their role as well as the outcome of their cases. As indicated by the wording "the general progress of the investigation or proceedings", Parties are not always obliged to provide victims with detailed information about aspects of the investigation or the proceedings, as in some situations the proper handling of the case may be adversely affected by the disclosure of information.

124. The article goes on to list a number of procedural rules designed to implement the general principles set out in Article 20: the possibility, for victims, of being heard, of supplying evidence (subject to this being permitted under the domestic law of a Party), choosing the means of having their views, needs and concerns presented, directly or through an intermediary, and of being protected against any risk of retaliation.

125. Paragraph 2 also covers administrative proceedings, since procedures for compensatingvictims are of this type in some states. More generally, there are also situations in which protective measures, even in the context of criminal proceedings, may be delegated to the administrative authorities.

126. Paragraph 3 provides for access, free of charge, where warranted, to legal aid for victimsof counterfeiting of medical products or similar crimes. Judicial and administrative procedures are often highly complex and victims therefore need the assistance of legal counsel to be ableto assert their rights satisfactorily. This provision does not afford victims an automatic right to free legal aid. The conditions under which such aid is granted must be determined by each Party to the Convention when the victim is entitled to be a party to the criminal proceedings.

127. In addition to Article 20 paragraph 3, dealing with the status of victims as parties to criminal proceedings, the States Parties must take account of Article 6 of the ECHR. Even though Article 6, paragraph 3.c. of the ECHR provides for the free assistance of an officially assigned defence counsel only in the case of persons charged with criminal offences, the case law of the European Court of Human Rights (Airey v. Ireland judgement, 9 October 1979) also, in certain circumstances, recognises the right to free assistance from an officially assigned defence counsel in civil proceedings, under Article 6, paragraph 1 ECHR, which is interpreted as enshrining the right of access to a court for the purposes of obtaining a decision concerning civil rights and obligations (Golder v. United Kingdom judgment, 21 February 1975). The Court took the view that effective access to a court might necessitate the free assistance of a lawyer. For instance, the Court considered that it was necessary to ascertain whether it would be effective for the person in question to appear in court without the assistance of counsel, i.e. whether he could argue his case adequately and satisfactorily. To this end, the Court took account of the complexity of the proceedings and the passions involved – which might be incompatible with the degree of objectivity needed in order to pleadin court – so as to determine whether the person in question was in a position to argue his own case effectively and held that, if not, he should be able to obtain free assistance from an officially assigned defence counsel. Thus, even in the absence of legislation affording access to an officially assigned defence counsel in civil cases, it is up to the court to assess whether, in the interests of justice, a destitute party unable to afford a lawyer's fees must be provided with legal assistance.

128. Paragraph 4 is based on Article 11, paragraphs 2 and 3, of the Framework Decision of 15 March 2001 of the Council of the European Union on the standing of victims in criminal proceedings. It is designed to make it easier for victims to file a complaint by enabling them tolodge it with the competent authorities of the state of residence. A similar provision is also found in Article 38, paragraph 2 of the Council of Europe Convention on the Protection of Children against Sexual

Exploitation and Sexual Abuse (CETS No. 201) of 25 October 2007.
129. Paragraph 5 provides for the possibility for various organisations to support victims. The reference to conditions provided for by internal law highlights the fact that it is up to the Parties to make provision for assistance or support, but that they are free to do so in accordance with the rules laid down in their national systems, for example by requiring certification or approval of the organisations, foundations, associations and other bodies concerned.

3.1. Measures for the protection of victims

This part of the report focuses on the existing national laws and policies for the protection of victims of crimes arising from the counterfeiting of medical products and similar crimes, specifically during times of a pandemic due to the increased risks arising. Additionally, and in case of the absence of such laws and policies, it is intended to ascertain what steps are being planned, if any, for the setting of such policy or in the absence of which, for victims of crime relating to counterfeit medical products generally.

- All the Parties (**Armenia, Belgium, Bosnia and Herzegovina, Croatia, Cyprus, France, Hungary, Morocco, Portugal, Russian Federation, Spain, Switzerland, Türkiye**) have a system of protection for victims of criminal offences which can be applied to those victims arising from the counterfeiting of medical products and similar crimes.

- This system of protection of victims emerges either from the Criminal Procedure Code or from a specific Act devoted to the protection of victims of criminal proceedings, depending on the legislative model adopted at this point by each Party. In general, the protection of victims of crime relating to counterfeit medical products includes rights such as the right to protection from intimidation and retaliation, the right to be heard without undue delay after the filing of a criminal report, the right to be informed, etc.

- Most Parties **(Armenia, Belgium, Croatia, Cyprus, France, Hungary, Morocco, Portugal, Russian Federation, Spain, Switzerland, Türkiye)** have established services for the support of victims of criminal offences which are generally at the disposal of victims arising from the counterfeiting of medical products and similar crimes.

- There does not appear to be a focus, except for one Party **(Belgium)** on the introduction of specific measures for the protection of victims of counterfeit medical products and similar crimes having regard to the impact of a pandemic.

Promising Practices

- In the case of **Belgium**, several initiatives can be mentioned.

- The Federal Police Central Directorate for Serious and Organised Crime (DJSOC), section *'i2-IRU'* (Internet Investigation) performs daily checks on open sources (Internet) looking for websites offering counterfeit and/or non-mainstream products. Every file is communicated to the competent partner services (the services of the integrated police, Customs, the Federal Agency for Medicines and Health Products (FAMHP) and/or the Federal Public Service (FPS) Economy, in relation to detected violations and/or the type of product offered.

- The Board of Public Prosecutors has designated the *'i2-IRU'* service as the central point of contact for investigations (COL NR. 10/2020 of 2nd of April 2020 concerning CORONAVIRUS – Guidelines of the College of Prosecutors General on the fight against fake web shops and fake news sites):
  - online stores that sell counterfeit medicines or products related to Covid-19;
  - fake online stores that offer genuine/fake items in the same setting;
  - fake news sites (mainly or exclusively related to Covid-19) that can explicitly endanger public health. This illustrates the collaboration between all the competent authorities to tackle these websites.
  - -The FOD Economie has also developed a webpage containing all the information for victims (preventive measures such as how to recognize these websites), what to do when a person becomes a victim and includes a referral button to a central reporting point where the victim can report the facts. The website also refers to a film available on *Youtube* that explains this in a comprehensive and intelligible way.

Recommendation

- Urges **Bosnia and Herzegovina** to proceed to define the term "victim" in criminal and procedural laws (Criminal Code and Code of Criminal Procedure) in accordance with international standards. At present, victims are treated through the terms "injured party" and "witness". This legislative process has already begun at the internal level, taking into account the provisions relating to the protection of victims in accordance with the MEDICRIME Convention.

3.2. Measures to protect the rights of victims at all stages of the criminal proceedings

This part aims to ascertain the measures provided to protect the rights of victims at all stages of the criminal proceedings, in a manner consistent with the procedural rules of internal laws (Article 20. 1 to 4).

- Six Parties **(Bosnia and Herzegovina (**with the limitation that it has not yet defined the term *victim* in its legislation**) Belgium, Croatia, France, Hungary, and Portugal)** highlighted the existence of legal provisions at the internal level that comply with the obligations established at Article 20, MEDICRIME Convention in order to protect the rights of victims at all stages of the criminal proceedings.

- One Party (**Russian Federation**) highlighted the existence of security measures at the internal level oriented to the protection of the victim, witness or other participants in criminal proceedings, as well as their relatives and partners (art. 20.1.d. MEDICRIME Convention).

- Three Parties (**Armenia, Cyprus, Morocco**) provided information on the protection of victims' rights during the criminal proceedings but did not specify if all the rights established in Article 20.1 to 4 MEDICRIME Convention were covered.

- Three Parties (**Spain, Switzerland, Türkiye**) did not provide any information on this matter, having the possibility to do so as the question was optional.

- No Party provided information on the implementation at the internal level of Article 20.4, MEDICRIME Convention.

3.3. Assistance and support to victims by victim support and advocacy groups, NGOs, etc.

This part seeks to ascertain what measures are provided to permit victim support and advocacy groups, NGOs and other groups to assist and support victims, with their consent, during criminal proceedings and outside of proceedings concerning offences related to counterfeiting of medical products and similar crimes involving a threat to public health. It is intended to obtain information on any such organisations and groups/bodies and on any assessment of the effectiveness of such involvement by such providers (Article 20.5).

- Six Parties **(Belgium, Croatia, Hungary, France, Morocco, Russian Federation)** adopted different measures to permit victim support and advocacy groups, NGOs and other groups to assist and support victims.

- Seven Parties (**Armenia, Bosnia and Herzegovina, Cyprus, Portugal, Spain, Switzerland, Türkiye**) did not provide any information on this matter, having the possibility to do so as the question was optional.

Promising Practices

- In **Belgium,** victim support is implemented by the victim support services, recognized and/or subsidized by the Communities, and independent of the police and judicial authorities. The general mission of these services is to

provide social and psychological assistance to victims of crime and their relatives. These services provide free social support aimed at restoring the living conditions of the victim and reintegration into work life or psychological support adapted to the needs of the victims in order to help them find a new life balance. This support can be short or long-term depending on the needs of the victim. The interviews are organized according to the needs and the mobility of the victims: they can be organized in a room that offers guaranteed discretion or, if necessary, in the victim's home or another place (e.g. a hospital) and even via phone. When the victim wishes so, they can be accompanied by a representative/employee of the service when taking certain steps (e.g. doctor's visit, or a visit to a police station). When needed, the victim is referred to more specialized organizations (e.g. for psychotherapeutic support).

- In **Croatia**, the Ministry of Justice and Public Administration RoC has the *Service for Victim and Witness Support*, the central body for coordination of the development of the victim and witness support systems. At court level, *Victim and Witness Support Departments* at the courts exist. The National Committee delivered the National Strategy for Victim and Witness Support 2016-2020 and the Action Plan.

- In **France**, victim support associations approved by the Ministry of Justice offer victims of counterfeit medical products and similar crimes and their relatives, free of charge and in complete confidentiality, guidance, information and assistance in their legal, administrative and social procedures. As part of their missions, these associations, composed of lawyers, psychologists, social workers, provide victims with moral and psychological support to avoid the risk of secondary and repeated victimization. This comprehensive and multidisciplinary care, which is free of charge, is a long-term provision. The offer of services is thus arranged at regular stages and adapted to the victim. Assistance may be provided before any legal proceedings, during the judicial proceedings and beyond them. Where necessary, approved victim support associations provide appropriate referrals to specialized services, such as social and medical-psychological services. This assistance benefits any victim regardless of their nationality and place of residence, including even if they reside abroad.

- In **Hungary**, the regional victim support services, the *Victim Support Centres and the Victim Support Line* provide information and assistance tailored to the individual needs to victims of all crimes. Victim support services cooperate and maintain contact with state bodies, non-governmental organizations and religious communities. As a result of this cooperation, in case a victim support service is unable to provide direct assistance through its services or that a victim needs a kind of service that can better be provided by another organization, the service directs the victim concerned to governmental or non-governmental organizations as well as to religious communities best suited to providing personalized, fast and efficient assistance. For this reason, the

Ministry of Justice has concluded numerous cooperation agreements with organisations.

3.4. Support to victims by civil society

This part seeks to ascertain whether civil society is actively engaged in providing supportive facilities for redress and recovery of victims of counterfeit medical products and similar crimes involving threats to public health (Article 19. b).

- Two Parties **(Croatia, Hungary)** have civil society actively engaged in providing supportive facilities for redress and recovery for victims of crime generally. These are not specific to medical product-related crimes, but to all victims of crime.

- Eleven Parties (**Armenia, Belgium, Bosnia and Herzegovina, Cyprus, France, Morocco, Portugal, Russian Federation, Spain, Switzerland, Türkiye**) did not provide any relevant information on this matter, having the possibility to do so as the question was optional.

PROMISING PRACTICES:

- In **Croatia**, the Network of Support and Co-operation for Victims and Witnesses of Criminal Offences is a network of 10 civil society organizations with 1 coordinator, that is created with the intent of providing assistance and support for victims and witnesses of criminal offences in 17 Counties in Croatia. Network members participated in numerous education and thematic lectures with the aim of improving knowledge and strengthening their capacity to provide support and assistance to victims and witnesses. All members of the Network are continuously participating in educational activities with the aim of providing the highest quality services to victims and witnesses. Coordinator of the Network, Women's Room and member organization, Victim and Witness Support Service are members of Victim Support Europe, a leading European umbrella organization advocating on behalf of all victims of crime, no matter what the crime, no matter who the victim is.

- In **Hungary** the White Ring Public Benefit Association operates alongside the government victim protection system, providing assistance not only to victim of the counterfeiting of medical products and similar crimes.

3.5. Measures to enable victims to report offences. Protection and assistance to victims

This part seeks to determine what measures are in place or planned to enable victims to report offences impacting them and to receive protection and assistance in respect of offences established in accordance with this Convention and whether there is any oversight to assess the effectiveness of such measures.

- Five Parties **(Belgium, Croatia, France, Hungary, Russian Federation)** have put in place different measures to enable victims to report offences and to receive protection and assistance in respect of offences established in accordance with MEDICRIME Convention.

- No Party has oversight arrangements to assess the effectiveness of such measures.

- Two Parties (**Spain, Switzerland**) did not provide any relevant information on this matter, having the possibility to do so as the question was optional.

Promising practices

- In **Croatia**, the Ministry of Justice and Administration has a leading role in the institutionalization of the victim and witness support system within the judicial system and coordinates the victim and witness support system in the Republic of Croatia. Among other measures in place, it is worth highlighting the *National Call Center*, which provides a free service and informs victims of their rights and ways of their realization, emotional support, and refers victims to other institutions and organizations that can provide them with professional assistance. The *National Call Center for Victims of Crime and Misdemeanors 116 006* is available for the entire territory of the Republic of Croatia every working day from 08:00 to 20:00.

- In **Hungary**, the *Victim Support Line* (06 80 225 225), which is available free of charge 24 hours a day, is run by the Ministry of Justice to ensure that citizens who are victims can obtain information outside office hours. By calling the Victim Support Line, victims can obtain legal information and advice on their rights and obligations in criminal proceedings, the types of assistance available, the conditions and procedures for applying for assistance, and the best way to solve the problem they are facing.

Recommendation

- Invites the Parties to establish oversight to assess the effectiveness of the measures in place to enable victims to report offences impacting them and to receive protection and assistance in respect of offences established in accordance with this Convention.

IV. COOPERATION AND INFORMATION EXCHANGE

This section focuses on the ability of authorities/services to cooperate and exchange information in order to facilitate the conduct of effective investigations and the importance of such cooperation and exchanges.

- This part aims to promote the co-operation and information exchange between

the competent authorities in order to prevent and combat the counterfeiting of medical products and similar crimes involving threats to public health.

- Co-operation between public authorities and the commercial and industrial sectors in this field is also a key aspect so as to tackle the counterfeiting of medical products and similar crimes involving threats to public health.

- Although Article 17 MEDICRIME Convention does not oblige Parties to establish new bodies tasked with co-ordination, due to the wide range of authorities involved in the fight against counterfeiting of medical products and similar crimes there is a need to strengthen the existing frameworks for co-operation.

- The MEDICRIME Convention requires that there be adequate training of the persons, units or services in charge of co-operation and information exchange.

Article 17 – National measures of co-operation and information exchange

1 Each Party shall take the necessary legislative and other measures to ensure that representatives of health authorities, customs, police and other competent authorities exchange information and co-operate in accordance with domestic law in order to prevent and combat effectively the counterfeiting of medical products and similar crimes involving threats to public health.

2 Each Party shall endeavour to ensure co-operation between its competent authorities and the commercial and industrial sectors as regards risk management of counterfeit medical products and similar crimes involving threats to public health.

3 With due respect for the requirements of the protection of personal data, each Party shall take the necessary legislative and other measures to set up or strengthen mechanisms for:

a receiving and collecting information and data, including through contact points, at national or local levels and in collaboration with private sector and civil society, for the purpose of preventing and combating the counterfeiting of medical products and similar crimes involving threats to public health;

b making available the information and data obtained by the health authorities, customs, police and other competent authorities for the co-operation between them.

Each Party shall take the necessary measures to ensure that persons, units or services in charge of co-operation and information exchange are trained for this purpose. Such units or services shall have adequate resources.

Explanatory Report
Article 17 – National measures of co-operation and information exchange
111. Networking at national level based on a multidisciplinary and multisectoral approach is a key element in the fight against counterfeiting of medical products and similar crimes. Hence, Article 17 provides for the co-operation and information exchange between the competent authorities in order to prevent and combat effectively the counterfeiting of medical products and similar crimes involving threats to public health. In this context, it should be noted that the involvement of health authorities in the prevention and combat of counterfeiting of medical

products and similar crimes is a key tool for the efficient protection of public health. In addition, paragraph 2 provides for the facilitation of assistance to be provided by the relevant commercial and industrial sectors to the competent authorities as regards risk management, as these sectors have vast product expertise.

112. The ad hoc committee found that the wide range of authorities involved in the fight against counterfeiting of medical products and similar crimes, from law enforcement to health,usually requires a strengthening of the existing frameworks for co-operation. In particular, the Council of Europe model on a network of Single Points of Contact (SPOC) developed by the Committee of Experts on Minimising Public Health Risks posed by Counterfeit Medical Products and Related Crimes (CD-P-PH/CMED) of the Council of Europe served as inspiration for the drafters of the Convention. This Council of Europe SPOC model is already in operation within the EU medicines enforcement sector and has been tabled as a working contact model for the International Medical Product Anti-Counterfeiting Task Force (IMPACT) under the World Health Organization (WHO), by the Permanent Forum on International Pharmaceutical Crime and the International Criminal Police Organization (INTERPOL). However, Article 17 does not in any way oblige Parties to introduce new bodies tasked with co-ordination and information exchange in the field of counterfeiting of medical products and similar crimes.

4.1. Information on national strategies or action plans on cooperation and exchange of information between authorities to combat the counterfeiting of medical products and similar crimes

This part seeks to ascertain whether the Parties has or plan to make a national strategy and/or action plan on cooperation and exchange of information between authorities/services to combat counterfeiting of medical products and similar offences and if these instruments specifically address pandemic situations (Article 17.1).

- Formal systems of exchange of information between public authorities (health authority, customs administration, police) have been established in most of the Parties **(Armenia, Belgium, Bosnia and Herzegovina, Croatia, France, Hungary, Portugal, Russian Federation, Spain,** and **Switzerland).**

- In some Parties, systems (mostly informal, i.e. not based on a legal provision or formally institutionalized) of exchange of information with the private sector (pharmaceutical wholesalers and manufacturers) are already in place **(France, Hungary).**

- No national strategy and/or action plan on cooperation and exchange of information between authorities/services to combat counterfeiting of medical products and similar offences has specifically addressed pandemic situations, except in one Party (**Portugal**).

- Five Parties (**France, Hungary, Portugal, Russian Federation, Switzerland**) established some arrangements in this field in light of the context of a pandemic (COVID-19).

- No other Party has adapted existing systems to take account of the impact of a pandemic.

Promising practices

- In **France**, in terms of public health, all French authorities in charge of these issues have initiated exchanges of information by collaborating directly (ANSM, ANSES (ANMV), National Order of Pharmacists, Orders of Physicians, BNEVP, DIRRECTE, DGCCRF, AFLD, CNAMTS, etc.). Since the outbreak of the pandemic, OCLAESP (Office Central de Lutte Contre les Atteintes à l'Environnement et à la Santé Publique) has largely anticipated the various threats likely to arise from this situation, particularly in view of foreseeable shortages, or drugs presented as remedies or vaccines marketed. This action has prevented or ended many initiatives by criminal organizations seeking to take advantage of this pandemic situation.

- In **Hungary**, cooperation has become more frequent, not only between the public authorities (health, tax and customs administration, police) but also between the pharmaceutical wholesalers and manufacturers concerned. Cooperation is based on legal mandates and also includes informal contacts between the relevant authorities. Police set up an online anti-drugs and anti-counterfeiting task force with representatives of the relevant authorities. This working group will develop recommendations and methodological guidelines in this area.

- In Portugal, working groups were set up during the COVID-19 pandemic between police, Defence, and health authorities to deal with incidents of health-related crime.

- In the **Russian Federation**, the strategy of medicines supply to the population of the Russian Federation for the period up to 2025, approved by the order of the Ministry of Health of Russia, provides for the establishment of a system of effective cooperation of interested federal executive authorities, executive authorities of the constituent entities of the Russian Federation and public organizations to achieve coordinated actions in the implementation of the Strategy's activities. One of the prospects for the implementation of the Strategy is to significantly reduce the existing risks associated with the circulation of falsified and substandard products, as well as with adverse events of medicines for human use.

- In **Switzerland**, within the national network of authorities engaged in enforcement against counterfeit medical products and similar crimes, a scheme on cooperation and information exchange has been adopted at their annual MEDICRIME Meeting. This scheme is promoted, reviewed and adapted annually by the national network. This scheme is valid for non-pandemic and pandemic situations. Additionally, Fedpol (Federal Office of Police) has established a distribution list for all information related to COVID-19 that comes through police networks. The national contact point according to Article 22.2 is included in this distribution list.

Recommendation

- Urges **Cyprus, Morocco, and Türkiye** to continue developing legislative and other measures in order to fully implement MEDICRIME Convention in this field.

4.2. Formal support for the implementation of a national strategy/ action plan to facilitate effective investigation

4.2.1. National Strategy or formal action plan supported by legislation

This concerns the implementation of a national strategy and/or action plan and whether it is underpinned by enabling legislation for the transfer and receipt of information and data between authorities/bodies and to other jurisdictions (Articles 17.1, 17.3, 21.1, and 21.2) in order to facilitate effective investigations.

- As noted above, not all Parties have such a formal national strategy or action plan. In some cases (**Belgium, Switzerland**), it is unclear whether the structures and measures in place result from a formal national strategy or are ad hoc in nature, but recognising that they exist on a continuous basis. In some cases (**Armenia, Croatia, Russian Federation**), there is national legislation that enables cooperation and information sharing but it is unclear whether this follows from a national strategy or action plan, or a recognition of the need to underpin by laws cooperation and information exchange relating to counterfeit medical products and similar crimes. A number of Parties (**Bosnia and Herzegovina, France, Hungary, Morocco, Spain**) either did not have a national strategy that is supported by enabling legislation, notwithstanding that such cooperation and information takes place, or they did not respond on this issue, having the possibility to do so as the question was optional.

- Three Parties (**Cyprus, Portugal, Türkiye**) provided no response to this question, having the possibility to do so as the question was optional.

4.2.2. Memorandums of Understanding and Data Sharing Agreements

Some Parties (**Bosnia and Herzegovina, Croatia, Hungary, Russian Federation**) have in place agreements between authorities/bodies at the national level involving the health authority, Ministries, police and customs administration. It is unclear if these are formal or informal arrangements, except in one Party (**Croatia**) which has a formal Memorandum of Understanding between the regulator (HALMED) and the Ministry of Internal Affairs. In one Party (**Morocco**), informal arrangements exist between law enforcement, including the Customs service, and the Ministry of Health to provide information relating to counterfeit medical products coming to attention from intelligence and investigations activities. In other cases (**Hungary, France**) the agreements relate to crime in general but are not specific to counterfeit medical products and similar crimes and may not include the health authorities. Some Parties

have not indicated whether such agreements are in place (**Armenia, Belgium, Spain, Switzerland**).

- Cooperation and information sharing arrangements at the international level specific to counterfeit medical products and similar crimes are not always clear on whether this is supported by a Memorandum of Understanding or that data can be shared in accordance with a Data Sharing or similar agreement. It is clear that the Parties participate in such activities, for example, from their participation in the INTERPOL-coordinated Operation Pangea on combating falsified medical products trafficking and supply, in particular through the use of online platforms. One Party (**Russian Federation**) has Memorandums of Understanding with countries outside of the MEDICRIME Convention on matters related to the quality, safety and efficacy of medical products and which include counterfeit medical products. It is unclear whether this focus is only on health product-related regulatory matters of product quality or whether it also includes criminal matters relating to the investigation of counterfeit medical products and similar crimes.

- Most Parties (**Armenia, Belgium, Bosnia and Herzegovina, Croatia, France, Hungary, Russian Federation, Spain, Switzerland**) did not illustrate practical measures that ensure the implementation and effectiveness of any Memorandum or Data Sharing Agreement to facilitate effective investigations. One Party (Morocco) actively disseminates information between relevant authorities and services on counterfeit medical products arising from intelligence and investigative activities. One Party (**Russian Federation**) outlined that it reports offending online platforms to the Federal body responsible for online communications and mass media.

- Three Parties (**Cyprus, Portugal, Türkiye**) provided no response to this, having the possibility to do so as the question was optional.

- The use of Memorandums of Understanding and Data Sharing agreements by the Parties, that are specific to or specifically include as part of a wider agreement matters relating to combating counterfeit medical products and similar crimes, is deficient. The support of enabling legislation for national strategies or action plans appears wanting in most of the Parties. No reviews are conducted by the Parties on the effectiveness of measures in the area of cooperation and information exchange to facilitate effective investigations. These deficiencies leave weaknesses in the existence and/or effectiveness of cooperation and information exchange between the authorities/bodies at national and international levels.

Recommendations

- Urges all Parties to put in place a formal national strategy or action plan to enable cooperation and information exchange to facilitate effective investigation to

combat counterfeit medical products and similar crimes involving threats to public health.

- Urges all Parties to have a clear legislative scheme to support a national strategy or action plan to enable cooperation and information exchange to facilitate effective investigation to combat counterfeit medical products and similar crimes involving threats to public health.

- Urges the Parties to make use of Memorandums of Understanding and Data Sharing Agreements to the fullest extent among the relevant national authorities, and where appropriate with equivalent bodies in other countries and with relevant international organizations in combating counterfeit medical products and similar crimes.

- Urges the Parties to conduct periodic reviews on the effectiveness of measures to support cooperation and information exchange in order to facilitate effective investigation.

4.3. Designated lead and participation in the cooperation arrangements among authorities/bodies

- The requirement for the participation of authorities from health, customs, police and other competent authorities in the exchange of information and cooperation in accordance with domestic law in order to facilitate effective investigation is evident from the Convention (Article 17.1, 17.2). For this to be effective, the designation of a lead authority, the participating operational authorities and the lead overview and review authority need to be clear to all authorities.

- Only two Parties (**Croatia, Russian Federation**) have indicated lead responsibilities for authorities, with police and customs services taking the lead depending on the situation and with the health product regulator in both cases being responsible for providing product information, and analysis of suspect medical products. One Party (**Belgium**) has flexible arrangements to assign the lead authority and participating authorities depending on the issue arising. None of the Parties was clear on the circumstances of how the decision on the lead authority may be decided in any case. No Party conducted oversight or review on the effectiveness of arrangements in this regard.

- Nine Parties (**Bosnia and Herzegovina, Cyprus, France, Hungary, Morocco, Portugal, Spain, Switzerland, Türkiye**) did not provide any information on this matter, having the possibility to do so as the question was optional.

Recommendation

- Urges all Parties, where not already achieved, to implement clear measures in relation to cooperation and information exchange to decide on which authority takes the lead and how participation in operational plans is decided.

4.4. Cooperation and information-sharing arrangements involving civil society, industry and service providers.

- The focus of cooperation and information-sharing arrangements involving civil society, industry and service providers in order to facilitate effective investigation is foreseen by the Convention (Article 17.2 and 17.3.a).

- Given the wide range of private sector and non-governmental organizations that may become involved with counterfeit medical products and may interact with authorities in the prevention, detection and investigation of counterfeit medical products and similar crimes, those mentioned by the Convention (Article 17.3.a) should be seen as indicative and not finite. For example, service providers may include financial and money transfer services, and e-commerce, while logistic providers may include postal and delivery services, and others~~.~~

- No Party has established such arrangements with all of the relevant private industry, service providers, civil society and social media platforms.

- Five Parties (**Belgium, Croatia, France, Russian Federation, Türkiye**) have varying cooperation and information-sharing agreements involving either private industry and associations, and logistics. Only Belgium's health product regulator (FAMHP) includes elements of all these, including postal and delivery services, and social media platforms. France's law enforcement on falsified medical products and similar crimes (OCLAESP) has an arrangement with the industry G5 group involving eight industry laboratories that detect online platforms promoting counterfeit medical products. The health product regulators in Croatia, which appears to be a more general arrangement that is not focused on effective investigation, and the Russian Federation have arrangements with the industry and associations. Morocco cooperates with the Union of Internet Service Providers under the Law on the Regulation of Content on the Internet and Combating Crime Committed such content, and two other relevant laws, and with social media platforms on actions to remove content that is contrary to law.

- While not all the authorities in any of the Parties are involved in all of the arrangements with all of the industry, civil society and social media platforms, it may be sufficient for one authority to specialise in the arrangement so long as it provides the benefits of the arrangement to the other authorities.

Recommendations

- Urge the Parties to ensure, in order to facilitate the effective investigation of counterfeit medical products, that cooperation and information-sharing arrangement involve civil society, industry, service providers, e-commerce and social media platforms, at a minimum.

- Urge the Parties to ensure that the arrangements established by authorities benefit all of the authorities involved in the prevention, detection and investigation of counterfeit medical products and similar crimes.

- Urge the Parties to ensure that arrangements for cooperation and information-sharing to facilitate effective investigation are formalised and subject to periodic review for effectiveness.

4.5. Arrangements with and membership with investigative or advisory bodies/groups dedicated to combating counterfeit medical products and similar crimes

- The Explanatory Report (at 112) mentions a number of groups, as examples, that authorities involved in combating counterfeit medical products and similar crimes, including law enforcement and health authorities, usually engage in the strengthening of existing frameworks for cooperation. The focus may vary from regulatory to law enforcement investigation depending on the group. All have a significant focus on building cooperation and information exchange in their chosen area.

- A number of these types of networks involve some of the Parties as members: the Committee of Experts on Minimising Public Health Risks posed by Counterfeit Medical Products and Related Crimes (**CD-P-PH/CMED**) of the Council of Europe[8] providing experts from national authorities (**Belgium, Bosnia and Herzegovina, Croatia, France, Hungary, Spain, Switzerland**); the World Health Organization's Member State Mechanism on Substandard and Falsified Medical Products (**MSMech SF)**[9] (**Armenia, Belgium, Bosnia and Herzegovina, Croatia, Cyprus, France, Hungary, Morocco, Portugal, Russian Federation, Spain, Switzerland, Türkiye**); Permanent Forum on International Pharmaceutical Crime **(PFIPC)** (**Belgium, France, Spain, Switzerland**); Working Group of Enforcement Officers of the EU Heads of Medicines Agencies **(HMA WGEO)**[10] (**Belgium, Croatia, Cyprus, France, Hungary, Portugal, Spain, Switzerland**), the International Criminal Police Organization **(INTERPOL) and EUROPOL**. All of these networks, except for INTERPOL and Europol, are dedicated to combating counterfeit medical products and similar crimes and are mostly advisory and supportive of their members in the areas of cooperation and information sharing. Both INTERPOL and EUROPOL have dedicated groups to focus on counterfeit medical products and similar crimes, but the organisations have overall remits beyond counterfeit medical products and are dedicated to crime in general.

- The groups mentioned are indicative only and other dedicated groups exist regionally and internationally. Parties may also be involved with healthcare, industry and other associations that have overall remits beyond counterfeit medical products.

[8] While Armenia, Cyprus and Portugal provided no response to this topic, it is understood that the Parties provide delegates from their health authorities to attend meetings
[9] While Armenia, Cyprus, Morocco, Portugal and Türkiye provided to response on this topic, it is understood that the Parties provide delegates from their health authorities to these groups
[10] While Cyprus and Portugal provided no response on this topic, it is understood that the Parties provide delegates from their health authorities to these groups

- Nationally, there are structured groups/bodies in place that focus on anti-counterfeiting and related activities that may also go beyond the counterfeiting of medical products and similar crimes (**Belgium, Hungary, France**). In Belgium, this concerns the counterfeiting of medical products and food fraud. In Hungary, this concerns combating the wider trade in counterfeit products and has a specific working group on counterfeit medical products. In France, this concerns a joint law enforcement and industry group on laboratory analysis and the identification of online platforms promoting counterfeit medical products.

Promising Practices

- In **Belgium**, the Pharma-& Food Crime Platform ensures the national exchange of information and cooperation between health authorities, Customs and the police. It deals with cases of falsified medicines and food fraud.

- In **Hungary**, the National Board Against Counterfeiting (NBAC), which was established by Government Decree in 2008, involves the full spectrum of enforcement and commercial interests, including the public administration bodies, public prosecutors, police, National Tax and Customs Administration, trademark and copyright associations, interest groups of commerce and industry, and the enterprises concerned by counterfeiting. The NBAC has an Action Plan Against Counterfeiting and has a working group against the counterfeiting of medicinal products. This Action Plan fosters cooperation between the relevant bodies, and authorities, and organises common training, consultations, and the provision of information leaflets.

- In **France**, OCLAESP (Gendarmerie) and the industry G5 Group, involve an arrangement in which eight French laboratories, that have developed devices for identifying illicit sites of sale on the Internet, focus on information exchanges in detecting the trafficking of counterfeit medical products.

Recommendations

- Invites all Parties to review their legislation, policies and other measures to enhance and increase their ability to engage nationally and internationally with other authorities and bodies that are dedicated to combating counterfeit medical products and similar crimes.

4.6. National contact points for receiving and sending alerts on a suspect or confirmed counterfeit medical products between authorities

- The setting up of national contact points for the sending and receiving of alerts on a suspect or confirmed counterfeit medical product between authorities is in the context of a national strategy that facilitates this.

- Five Parties (**Armenia**, **Belgium, Croatia, Hungary, and Türkiye**) are assessed as having national contact points between at least the health product regulator

and the police. In two Parties (**Belgium, Croatia**) is it clear that this also includes the Customs service. While it is expected that other Parties also include Customs services in the points of contact, this was not stated by those Parties.

- While one Party (**Russian Federation**) has a national strategy, which is general to all industrial products, including medical products, and requires increased interaction between authorities. While this does not address the existence of contact points for the receiving and sending of alerts between authorities, it implies that this is the result of the increased interaction. This needs to be clarified to ensure that alerts are received and sent and involve all relevant authorities in relation to combating the counterfeiting of medical products and related crimes.

- Where it has not already been determined that a Party had a formal national strategy to combat counterfeit medical products and similar crimes, it is important to determine whether contact points for the purpose of receiving and sending alerts exist in any form. This is the case in two Parties (**France, Spain**) where it is evident from other data available that national contact points exist for sending and receiving alerts on counterfeit medical products between the authorities.

- While one Party (**Switzerland**) has not provided information on this issue, having the possibility to do so as the question was optional, it is evident from other data that it has a national scheme to address counterfeit medical products in relation to the MEDICRIME Convention and operates a contact point for the sending and receiving of alerts between national and cantonal authorities.

- It is assessed that in almost all Parties, the health product regulator is a key contact point for all authorities nationally in receiving and sending information and alerts on a suspected and counterfeit medical product, particularly with reference to regulatory quality defect reports, but not necessarily relating to criminal law matters.

- Only in one Party (**Russian Federation**) is there a review scheme, conducted by the State Commission and reporting to the Federal Government, to assess the effectiveness of measures to increase interaction between authorities. However, it is unclear in this case whether this assesses the effectiveness of a national contact point for receiving and sending alerts on counterfeit medical products and similar crimes.

Recommendations

- Urges all Parties to review their legislation and measures to provide within a national strategy or action plan on counterfeit medical products and similar crimes to stipulate the national contact points among all relevant authorities for the receiving and sending of alerts.

4.7. Points of contact specified for the international exchange of information relating to the counterfeiting of medical products that have different arrangements to other points of contact

- This part seeks to ascertain what specific arrangements exist for the international exchanges of information, such as medical product alerts and analytical reports from laboratory investigations. This is in the context that they are dedicated to this type of focus and are not general points of contact, such as for general medical product alerts or general crime alerts, as is the case with INTERPOL National Control Bureaus in the Parties, for the Europol equivalents.

- Five Parties (**Belgium, Croatia, Hungary, Russian Federation, Switzerland)** are assessed as having specified points of contact for the international exchange of information specific to counterfeit medical products and they specify the organizations with whom they engage: WHO MSMech SF, CoE CMED, both primarily focused on public health protection issues, and HMA WGEO (EU).

- Seven Parties (**Armenia, Cyprus, France, Morocco, Portugal, Spain, Türkiye**), whilst not providing information to support the assessment under this heading, are known from other information supplied, to also have contact points for the international exchange of information, though this requires clarification on whether the points of contact are specific or general in nature.

- It is assessed that in almost all Parties, the health product regulator is a key contact point for the international exchange of information relating to the counterfeiting of medical products, albeit focused on public health issues and not primarily on criminal law issues.

- Most Parties are assessed as engaging in the exchange of information relating to the counterfeiting of medical products and similar crimes during international operations, in particular, the INTERPOL coordinated Operation PANGEA. This also arises for Parties engaged with EUROPOL operations specific to this type of crime.

Recommendations

- Urge all Parties to review their legislation and measures to ensure that they have specified points of contact for the international exchange of information relating to the counterfeiting of medical products and similar crimes.

- Invites all Parties to ensure that all relevant authorities, including the health product regulator, police and customs service are involved in supporting the points of contact for the international exchange of information relating to the counterfeiting of medical products and similar crimes, including information on product alerts and the results of laboratory analysis for such products.

4.8. Legal basis for the exchange of information and transfer and receipt of data between bodies/countries

This part seeks to ascertain whether the exchange of information or transfer and receipt of data and evidence between bodies/countries is supported by legislation. The focus of this issue is mainly on the exchanges between countries and those between equivalent bodies in different countries. It may also include federal arrangements within countries. Exchanges in information or transfer and receipt of data and evidence require legal provisions to include all of the relevant authorities, and not be restricted to some authorities having obligations while others do not. It should be a mutual obligation.

- Almost all Parties **(Belgium, Bosnia and Herzegovina, Croatia, Cyprus, France, Hungary, Morocco, Portugal, Russian Federation, Spain, Switzerland, Türkiye)** have legislation to support the exchange of information or transfer and receipt of data and evidence between countries. This does not mean that the legislative basis in all of the Parties enables these activities to take place between all the Parties to the MEDICRIME Convention, including those who are not part of this monitoring report. One Party (**Armenia**) does not have legislation to underpin the existing exchange of information and the transfer and receipt of data and evidence between bodies and/or countries relating to counterfeit medical products, but has a planned Government Decree to cover this.

- The transfer of information between law enforcement on criminal matters of the Parties may be transferred in accordance with protocols established with INTERPOL, EUROPOL, and World Customs Organization.

- The legal basis for the transfer of information and data between authorities internally is clear in some Parties (**Hungary, Morocco, Russian Federation, Spain, Switzerland**), but is not specified by all Parties (**Belgium, Bosnia and Herzegovina, Croatia, Cyprus, France, Portugal, Türkiye**). In **Belgium**, the obligation and legal authority for such activities clearly arises with the regulatory authority (FAMHP) but is not evident that the same obligations arise with the other relevant Belgian authorities providing information and data to FAMHP, notwithstanding that the transfer and sharing may exist in practice. In **Bosnia and Herzegovina**, the legal basis for these obligations and the extent to which they apply is not clear. Such legal obligations need to be clear to all relevant authorities.

Promising practices

- In the **Russian Federation,** in accordance with the Strategy on Combating Illicit Trafficking in Industrial Products in the Russian Federation for the period up to 2025, which includes counterfeit medical products, is supported by legislation. This provides for cooperation with international organizations whose activities are aimed, inter alia, at countering illicit trafficking in industrial

products, including the exchange of experience with foreign countries.

- In **Spain**, the exchange of information and personal data between law enforcement authorities must be subject to the applicable national and international laws and to bilateral or multilateral agreements signed between the respective governments. Where necessary, intelligence is shared with other countries through channels such as EUROPOL, INTERPOL and police attachés, including joint investigations with those countries.

- **In Switzerland,** Swissmedic, the regulatory authority for medical products, became the national specific point of contact (SPOC) in accordance with Article 69, para. 4, Therapeutic Products Act (TPA) on 1 January 2019. Violations in connection with the use and dispensing of therapeutic products fall under the competence of the cantonal prosecution authorities. Swissmedic's Penal Division, the Office of the Attorney General (OAG) and the cantonal prosecuting authorities exchange information, thus ensuring uniform prosecution of violations relating to the TPA throughout Switzerland. The exchange of confidential data between the (federal and cantonal) enforcement authorities in Switzerland and between the federal enforcement authorities and foreign authorities/institutions is enabled by law, cf. Articles 63 and 64 TPA. In the international context, the prosecutor's offices in Switzerland fulfil mutual legal assistance in close cooperation with the Federal Office of Justice. The Federal Office of Police (FEDPOL) is the central agency for police co-operation which builds and maintains contacts between the cantonal police and law enforcement agencies and between them and international partners.

RECOMMENDATIONS:

- Urges **Armenia, and Bosnia and Herzegovina** to review their legislation to ensure that there is a clear legal basis for the exchange of information or transfer and receipt of data and evidence between bodies/countries.

- Invites all parties to review their legislation to ensure that the exchange of information and data relating to counterfeit medical products and similar crimes by all authorities that conduct such exchanges, both within the domestic and in international settings, are supported by legislation.

V. DETECTION

This part of the report considers detection measures in the context of times of pandemics. This is of particular concern having regard to the global experience during the COVID-19 pandemic and the expectation that both pandemics and epidemics will continue in times to come. While detection measures taken during a pandemic may be a development of detection measures already in existence, it is not guaranteed that such measures already exist in the pre-pandemic period or that they will be continued in the post-pandemic period.

The Convention envisages that detection measures will be adequate to the context, but not exclusive to times of crisis, as in pandemics. Therefore, measures taken in this regard are intended to be effective, appropriate, proportionate and sustainable.

Article 18 – Preventive measures 2. Each Party shall take the necessary legislative and other measures to ensure the safe distribution of medical products

- This chapter aims to understand and appreciate the different measures that may be proactively taken during a pandemic to detect counterfeit medical products and prevent them from reaching patients.

- This concerns:

    - Identifying legislative or other measures to ensure that the industry can promptly report suspicions or detections of counterfeit medical products
    - Identifying market sampling programmes to detect counterfeit medical products on the market
    - The application of sampling programmes to cover public procurement programmes of medical products to detect counterfeit medical products in the public health system
    - Identifying legislative measures, that are different and separate to laws on intellectual property rights, to enable customs service to detect, detain and act on counterfeit medical products.

- The focus on detection flows from the Explanatory Report noting that "*The reason for the strong growth of this type of crime is clearly the relatively low risk of detection and prosecution compared with the potential high financial gains"*. In order to prevent and combat threats to public health, the overall purpose of the Convention, as provided by Article 1, the detection element is required as a central action. However, the term is not mentioned in the Convention, and only a few references are made in the Explanatory report. Yet, detection measures are central to the assurance of protecting public health and prosecuting offenders engaged in the counterfeiting of medical products and similar crimes.

- Both the Convention (Articles 17.2 and 3 and 18. 2 and 3) and the Explanatory Report focus on the necessity of cooperation measures between both public authorities and the private sector in preventing and combating the counterfeiting of medical products and similar crimes. The Convention foresees that all action in the detection of such products includes the dissemination of relevant information, including data collection, risk management, sharing of data and ensuring that the appropriate detection powers are available to those who require them. Specific reference is made for customs services in relation to providing powers that are separate and distinct in the protection of public health from intellectual property rights offences that protect individual economic rights.

5.1. Reporting by industry of suspicions and detections of counterfeit medical products and similar crimes (Article 18.2)

- This concerns any legislative or other measures to ensure that the industry can promptly report suspicions or detections of counterfeit medical products and similar crimes involving threats to public health, or to any particular authority. It also concerns whether there are any established or ad hoc procedures and processes in place for this reporting.

- The reporting by industry is not mentioned in either the Convention or in the Explanatory Report. It is a measure required to give effect to the provisions of Article 18.2 to ensure the safe distribution of medical products.

- Reporting of suspected or confirmed counterfeiting of medical products by industry to the regulator for health products arises for several Parties from regulatory licensing requirements (**Armenia, Croatia, Cyprus, France, Hungary, Portugal, Spain, Switzerland, Türkiye**). This mainly applies to medicinal products, active substances and excipients only in such cases, except for Switzerland which explicitly also includes medical devices. The reporting is mandatory in some cases (**Armenia, Cyprus, France, Hungary, Portugal, Switzerland, Türkiye**), although a more general obligation to report any crime coming to notice applies in one Party (**Bosnia and Herzegovina),** while, in only one case, it is an obligation for statutory professional bodies to report where they become aware of a criminal offence in the course of their professional duties **(Hungary).**

- Some Parties **(Belgium, Russian Federation, Switzerland)** focus on processes to push out to industry information concerning suspected or confirmed counterfeit medical products, using a rapid alert system or the regulatory authority website information. In these cases, the same information and alert systems may also facilitate reporting by industry, but this requires clarification.

- In two cases, it is noted that dedicated email addresses are provided to facilitate reporting (**Hungary, Spain**).

- While not specifically noted by the Parties, it is likely in most cases that the health product regulator has a clear and defined reporting system for the industry to report substandard and counterfeit medical products under the label of quality defect reports, while others, as noted above, have dedicated reporting systems for counterfeit medical products and similar crimes.

- It is assessed that in two cases (**Cyprus, France**) there are active reporting systems for reporting to law enforcement.

- In one Party (**France**), there is a system of reporting between law enforcement and certain manufacturing industry whose products have been the subject of counterfeiting. This is to improve the sharing and cross-checking of information to detect trafficking and counterfeiting of medical products.

- Reporting processes and procedures are provided by two Parties (**Spain, and Switzerland**). This may also arise where dedicated reporting email addresses are provided, but this is unclear.

Promising practices

- In **Cyprus**, manufacturers and marketing authorisation holders are obliged to report suspicions of falsified medical products where they obtain information from any source about falsified medical products where the legitimate product is associated with their activities.

- In **France**, the Central Office for the Fight against Environmental And Public Health/Office Central de lutte contre les atteintes à l'environnement et à la santé publique (OCLAESP) established a system with five major medical product manufacturing companies to share and enhance information cooperation to combat the counterfeiting and trafficking of medical products.

- In **Hungary and Spain**, a dedicated email address is provided by the health product regulators to facilitate industry report instances of a suspect and confirmed counterfeiting of medical products.

- In **Spain and Switzerland**, the health product regulator for medicinal products and medical devices (AEMPS and Swissmedic, respectively) in conjunction with the respective Ministry of Health, issues instructions to the industry on the reporting of a suspect or confirmed instance of counterfeiting of medicinal products.

Recommendations

- Urges **Armenia, Belgium, Bosnia and Herzegovina, Croatia, France, Hungary, Morocco, and Spain** to review their legislation in order to establish systems for reporting counterfeit medical devices, accessories, and parts and materials.

- Urges **Bosnia and Herzegovina** to review its legislation in order to establish a system for reporting by industry of a suspect or confirmed counterfeit medical product, active substance, excipient, and for accessories and parts and materials in relation to medical devices.

- Invites Parties, (except for **Hungary**, and **Switzerland** in relation to medicinal products only) to consider reviewing their legislation and measures to enhance the reporting by industry by the introduction of mandatory reporting and specifying to which authority the report be made on a suspect or confirmed counterfeit medical product, active substance, excipient, and for accessories and parts and materials in relation to medical devices.

5.2. Market sampling programmes to detect counterfeit medical products on the market (Article 18.1, 3.c)

- This concerns any legislative or other measures on the establishment of sampling and analysis programmes to detect counterfeit medical products on the market and to ascertain which authority has this responsibility. It seeks to determine whether the sampling and analysis programme is sustainable during times of pandemic having regard to the additional demands placed on analytical laboratories and testing services resulting from the impact of a pandemic. In order to understand the effectiveness of such legislation and measures, it seeks to identify any oversight arrangements of such measures.

- While market sampling programmes are not mandated by the Convention and not mentioned in it, nor in the Explanatory Report, this is a proactive measure to determine the extent, if any, to which counterfeit medical products are available on the market of the Party. This includes the distribution, wholesaling, and retailing levels. The absence of any such programme results in the Party relying on the reported suspect medical products by industry or by the public, and others. If market sampling programmes for risk-bearing medical products are not conducted, or not on a structured basis, then the Party may not be aware of the presence of counterfeit medical products on its market notwithstanding that it has not received any such reports from the market to date.

- It was noted that the absence of a medical device market sampling programme was based on the understanding that it was mainly medical device documentation that was falsified rather than the medical device itself, of which there were large numbers in circulation. While this may have some validity concerning falsified documentation, medical devices can also be falsified and found on the market where the documentation is not checked or where the documentation accompanying a counterfeit medical device is genuine. This lacuna creates a vulnerability for the protection of public health and enables criminal elements to evade detection and criminal prosecution.

- While many Parties, in particular, their medical product regulatory authorities, may already have laboratories available to them to test, examine or analyse the sampled medical product, this will usually be done to determine the quality of the medicinal product as regards sufficiency of active substance and compliance with labelling standards of medicinal products and to ensure compliance with the essential requirements and labelling for medical devices.

- A market sampling programme for both medicinal products and medical devices, including counterfeit products, exists in two Parties (**Russian Federation, and Türkiye**).

- A market sampling programme is assessed to exist for medicinal products only in five Parties (**Belgium, Bosnia and Herzegovina**, **Croatia, Portugal, Spain**), and for medical devices only in one Party (**Switzerland**). Switzerland suspended

its medical device sampling programme during COVID-19 due to the ad hoc testing of the pandemic-related to non-conforming medical devices. One Party (**Portugal**) operated the market sampling programme for counterfeit medical products between the customs service and the health products regulatory authority.

- There was no structured market sampling programme for either medicinal products or medical devices in five Parties (**Armenia, Cyprus, Morocco, France, Hungary**), with France and Hungary relying on participation in international programmes (INTERPOL's Operation Pangea, and World Customs Organization's Operation STOP, respectively) to detect counterfeit medical products in the market, including through unlicensed online outlets.

- One Party (**Switzerland**) has a structured market sampling programme for medical products from a quality perspective and considers that it can identify counterfeit medicinal products from such sampling.

- Outside of the COVID-19 pandemic, Hungary relies on the general market sampling programmes conducted by the Ministry of Innovation and Technology.

Recommendations

- Urges **France and Hungary** to review their legislation in order to implement structured market surveillance programmes for medical products.

- Invites **Armenia, Cyprus, Hungary and Morocco** to review their legislation in order to implement a structured market surveillance programme for medical products.

- Invites **Belgium, Bosnia and Herzegovina, Croatia, and Spain** to review its legislation in order to implement a structured market surveillance programme for medical devices.

5.3. Market sampling programmes for public procurement programmes of medical products to detect counterfeit products being used in the public health system (Article 18.2)

- This concerns legislation and measures established to provide for market sampling programmes for public procurement of medical products being used in the public health system and whether this includes sampling for counterfeit medical products. This is in the context of those medical products not being procured for supply or sale to the trade or public. It seeks to determine, in the absence of such programmes, whether there are arrangements to introduce them.

- Public procurement programmes are not specifically mentioned in either the Convention or in the Explanatory Report. As noted above in relation to the terms

'supplying' and 'offering to supply' (Article 6), these terms are understood in their widest sense and include the act of procuring.

- Procurement programmes intended for the public health systems that are not intended for supply or sale to the trade or public may escape the scrutiny of the medical product regulator's oversight. This increases the risk of counterfeit medical products infiltrating the public health system.

- Two Parties (**Portugal and Türkiye**) were assessed to have a specific inclusion for the sampling of the public procurement programme that excluded sale or supply to the trade or the public. While market sampling programmes exist in a number of the Parties (**Croatia, Spain**) that could facilitate the inclusion of the public procurement programmes without the need to adjust legislation or provide additional measures, they did not conduct such public procurement programmes sampling. In Spain, some medical devices used by healthcare practitioners in the public health system were routinely sampled for conformity with the essential requirements of the device.

- As there is no market sampling programme for medical products in five Parties (**Armenia, Cyprus, France, Hungary,** and **Morocco**), the inclusion of the public procurement programmes is not possible at this time. Switzerland plans to conduct a medical device sampling programme.

- The sampling programmes, as and where they currently exist, are conducted by the health product regulator of the Parties. They check for quality defects and not specifically for counterfeit medical products. Parties may consider that as counterfeit medical products contain quality defects then instances of counterfeiting of medical products would be detected in market sampling. This approach relies on the intensity of the sampling programme regarding the frequency of sampling and depts of checks conducted on the product. It is noted that medical products may only be sampled by the Parties once in five years, or more routinely 'for cause'.

Recommendations

- Urges **Armenia, Cyprus, France, Hungary,** and **Morocco** to review their legislation and measures in order to establish market sampling programmes on a sustainable basis that include public procurement programmes to detect counterfeit medical products that are not intended for sale or supply to the trade or the public.

- Invites Parties to ensure that market sampling programmes are extended to medical products to include a focus on detecting counterfeit medical products and not only on medicines or for quality defects generally.

5.4. Laws and policies to enable customs service to detect, detain and act on counterfeit medical products, as defined in Article 4. j of the Convention (Articles 1.a, 4.j, 18.3.a, c)

- This concerns legislation and measures established to enable the customs service to detect, detain and act on counterfeit medical products within the meaning of the Convention (Article 4.j definition) without having to rely on intellectual property rights whose focus is on the protection of private economic rights rather than public health. The Explanatory Report (paragraphs 20 and 26) clarifies that the Convention does not cover any issues related to the infringement of intellectual property rights in relation to the counterfeiting of medical products, active substances, excipients, parts and materials.

- Article 1 of the Convention provides for the criminalisation of certain acts. These are different and distinct from acts criminalising for different purposes. As the meaning of counterfeit in Article 4. j of the Convention is different from that of intellectual property meaning of counterfeit, this report seeks to understand whether the laws and policies of the Parties enable the customs service to take action without reference to a rights holder notwithstanding that the same medical product may also infringe intellectual property rights.

- Five Parties (**Hungary, Portugal, Russian Federation, Switzerland, Türkiye**) have legislation that empowers customs services to detect, detain and act on counterfeit medical products, as defined in Article 4. j of the Convention. In Hungary, this power is applicable to medicinal products and does not include medical devices.

- In three cases (**Belgium, Bosnia and Herzegovina, Croatia**), reliance is placed on general legislation, one of which is assessed as limited and inadequate for the customs service action as intended by the Convention.

- In Belgium, reliance is placed on the EU regulations (765/2008/EC) on accreditation and conformity regulations to control health and safety matters and the protection of consumers from risk-bearing products. While this is not specific to counterfeit medical products, Belgium uses this non-intellectual property approach for the customs service to act on counterfeit medical products. While this mechanism permits the customs service to act to protect public health, it is assessed as not using the meaning of counterfeit medical products as defined in Article 4. j of the Convention and inappropriate for the purposes intended by the Convention in this regard. As Belgium ratified the Convention in 2016, more specific legislation, policies and measures should be available to protect public health from counterfeit medical products.

- Reliance is placed in Bosnia and Herzegovina on the Basil Convention to control the transnational movement of hazardous waste (in this case, pharmaceutical waste, drugs and medicines). This is assessed as an inadequate and inappropriate response to the requirements of the MEDICRIME Convention to detect, detain and act on counterfeit medical products. As Bosnia and

Herzegovina ratified the Convention in 2020, more specific legislation, policies and measures should be available to protect public health from counterfeit medical products.

- In Croatia, reliance is placed on EU Regulation (952/2013, Article 47) laying down the Union Customs Code. This regulation enables Customs to cooperate with other competent authorities that have control functions relating to goods and with a view to having those controls performed, wherever possible, at the same time and place as customs controls. While this is not specific to counterfeit medical products, Croatia uses this general approach for the customs service to act on counterfeit medical products. While this mechanism permits the customs service to act to protect public health, it is assessed as not using the meaning of counterfeit medical products as defined in Article 4. j of the Convention and inappropriate for the purposes intended by the Convention in this regard. As Croatia ratified the Convention in 2020, more specific legislation, policies and measures in line with the Convention should be available to protect public health from counterfeit medical products.

- Two Parties (**Cyprus, France**) did not respond on this issue, having the possibility to do so as the question was optional.

Recommendations

- Urges all Parties, except the **Portugal, Russian Federation, and Türkiye** to review their legislation, policies and measures to enable their customs service to detect, detain and act on a counterfeit medical product, as defined by Article 4.j, different to the intellectual property meaning of counterfeit, without the need to refer to the rights holder, and specific to the offences intended by the MEDICRIME Convention.

VI. INVESTIGATION AND PROSECUTION

This section focuses on the ability to investigate and prosecute perpetrators of intentional offences related to the counterfeiting of medical products and similar offences, particularly during a pandemic.

- From a procedural perspective, it is established that investigations and prosecutions in this field are not subordinate to a complaint or may continue even in case of withdrawal of the complaint.

- It is relevant to highlight the importance of the specialisation and adequate training of persons, units and services in charge of criminal investigations in the area of counterfeiting of medical products and similar crimes involving threats to public health.

- A key aspect in the investigation and prosecution of offences related to the counterfeiting of medical products and similar crimes involving threats to public health is the concept of effective investigation which includes financial investigations, covert operations, controlled delivery and other special investigative techniques.

Article 15 – Initiation and continuation of proceedings

Each Party shall take the necessary legislative and other measures to ensure that investigations or prosecution of offences established in accordance with this Convention should not be subordinate to a complaint and that the proceedings may continue even if the complaint is withdrawn

Article 16 –Criminal investigations

1 Each Party shall take the necessary measures to ensure that persons, units or services in charge of criminal investigations are specialised in the field of combating counterfeiting of medical products and similar crimes involving threats to public health or that persons are trained for this purpose, including financial investigations. Such units or services shall have adequate resources.

2 Each Party shall take the necessary legislative and other measures, in conformity with the principles of its domestic law, to ensure effective criminal investigation and prosecution of offences established in accordance with this Convention, allowing, where appropriate, for the possibility for its competent authorities of carrying out financial investigations, of covert operations, controlled delivery and other special investigative techniques.

Explanatory Report

Article 15 – Initiation and continuation of proceedings

106. Article 15 is designed to enable the public authorities to prosecute offences established in accordance with the Convention ex officio, without a victim having to file a complaint. The purpose of this provision is to facilitate prosecution, in particular by ensuring that criminal proceedings may continue regardless of pressure or threats by the perpetrators of offences towards victims.

Article 16 – Criminal investigation

107. The article provides for the specialised criminal investigation and combating of counterfeiting of medical products and similar crimes by persons, units or services of the competent national authorities of State Parties.
108. Paragraph 2 provides for State Parties to ensure the effective investigation and prosecution of offences established under the Convention in accordance with the fundamentalprinciples of their national law. The notion of "principles of national law" should be understood as also encompassing basic human rights, including those provided under Article 6 of the ECHR.
109. "Effective investigation" is further described as including financial investigations, covert operations, controlled delivery and other special investigative techniques. These could encompass electronic and other forms of surveillance as well as infiltration operations. As indicated by the wording "where appropriate", Parties are not legally obliged to apply any orall of these investigative techniques, but if a Party chooses to conduct investigations using these special techniques, the principle of proportionality, as referred to in the Preamble of the Convention, will also apply.
110. The ad hoc committee underlined that "controlled delivery" is one of the most important investigative tools available to authorities in the area of counterfeiting of medical products andsimilar crimes. The measure of "controlled delivery" is already

foreseen by a number of international legal instruments in the field of criminal law, in particular the United Nations Convention Against Transnational Organised Crime and the United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances and the Second Additional Protocol to the European Convention on Mutual Legal Assistance in CriminalMatters (ETS No. 182).

6.1. The criminalisation of offences in order to enable effective investigation and prosecution

- This part seeks to ascertain the level of correspondence between the domestic laws of the Parties and the definitions of certain concepts included in the MEDICRIME Convention (Article 4).

- Additionally, this part aims to establish the correspondence between the internal criminal law of the Parties and the offences set up in Articles 5 to 8 of the MEDICRIME Convention.

- Finally, the section is oriented to specify the measures taken to sensitize manufacturers and suppliers of medical products to the consequences of the activities of legal persons related to medical products having regard to Article 11, MEDICRIME Convention.

6.1.1. Correspondence of the concept of "medical products" in domestic law to the definition in Article 4. a, MEDICRIME Convention

- In the majority of Parties **(France, Hungary, Russian Federation, Switzerland, Türkiye)** the concept of “medical products” in domestic law corresponds to the definition in article 4. a.

- In some Parties (**Belgium, Croatia, Spain**) the concept of “medical product” is not specifically included in domestic law. This results in having to integrate this concept by means of two different legal terms (medicinal products and medical devices).

6.1.2. Correspondence of the concept of "counterfeiting" in domestic law to the definition in Article 4. j, MEDICRIME Convention with regard to medical products.

- In the majority of the Parties **(Armenia, Belgium, Croatia, Cyprus, France, Hungary, Morocco, Russian Federation, Spain, Switzerland)** the concept of “counterfeiting” in domestic law corresponds to the definition in article 4.j.

- Nevertheless, the concept of “counterfeiting” is not used by any of the Parties in the field of defining the offences related to medical products and similar crimes involving threats to public health. Most of the Parties **(Belgium, Croatia, France, Hungary, Russian Federation, Switzerland),** refer to the concept of “falsification” in this field.

- The reason for this preference for the concept of « falsification/falsified » instead of « counterfeit, as defined by the Convention » in most Parties emanates from the association in many countries of the notion of « counterfeiting » with the protection of Intellectual Property Rights (IPR), and the influence of the WHO definition of falsification of medical products.

6.1.3. Measures taken to ensure that offences related to the counterfeiting of medical products, as defined in Articles 4. a. and 4. j, MEDICRIME Convention, are criminalised in accordance with Articles 5 and 6.

- In the majority of the Parties **(Armenia, Belgium, Croatia, France, Hungary, Russian Federation, Spain, Switzerland, Türkiye),** the internal laws provide for the criminalisation of the conducts included in Articles 5 and 6, MEDICRIME Convention.

- Nevertheless, in one Party **(Cyprus)** the criminalisation of such conducts has not been verified.

- In one Party **(Portugal)** the substantive criminal law provides for offences connected with Articles 5 and 6 MEDICRIME Convention but further actions are needed to achieve full compliance by the internal legislation with Articles 5 and 6 MEDICRIME Convention.

- The internal legal model for the criminalisation of these conducts varies from country to country. In some Parties **(Croatia, Hungary, Russian Federation, Spain)**, this is established exclusively via the Criminal Code while in others **(Belgium, France, Switzerland),** it is based on different domestic legislations with specific criminal law provisions.

6.1.4. Measures taken to ensure the criminalization of intentional offences referred to in Article 8 MEDICRIME Convention relating to medical products, as defined in Article 4. a.

- Most of the Parties **(Armenia, Belgium, Croatia, France, Hungary, Russian Federation, Spain, Switzerland, Türkiye)** have implemented at the internal level Article 8. a. of the MEDICRIME Convention.

- Two Parties **(Croatia, Hungary)** have also implemented at their internal level Article 8.b., MEDICRIME Convention (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).

- Some Parties **(Cyprus, Portugal)** have not achieved full compliance with Article 8 MEDICRIME Convention from the criminal law perspective.

6.1.5. Measures taken to ensure the criminalisation of intentional offences referred to in Article 7, MEDICRIME Convention relating to documents, as defined in Article 4. h, when committed in connection with medical products

- In the majority of the Parties **(Armenia, Belgium, Croatia, France, Hungary, Portugal, Russian Federation, Spain, Switzerland)**, the internal laws provide for the criminalisation of the conduct included in Article 7 MEDICRIME Convention.

- The internal legal model for the criminalisation of these conducts varies from country to country. In some Parties (**Belgium, Croatia, Russian Federation, Spain),** a specific criminal offence has been created in the Criminal Code referring to the falsification of documents related to medical products or the use thereof while in others it is the general crime of falsification of documents already existing in the Criminal Code which applies **(Hungary** that made a reservation on the basis of Article 7.2 MEDICRIME Convention, **Portugal).**

6.1.6. Measures taken to proactively sensitize manufacturers and suppliers of medical products to the consequences of intervention/non-intervention by legal persons in the course of their activities related to medical products (Article 11).

- In the majority of the Parties **(Armenia, Belgium, Croatia, France, Hungary, Russian Federation, Spain, Switzerland),** the internal laws implement Article 11 MEDICRIME Convention.

- Some countries **(Cyprus, Türkiye)** have not implemented Article 11 MEDICRIME Convention.

PROMISING PRACTICES

- In the **Russian Federation**, during the pandemic, on the basis of Federal Law № 95-FZ dated 01.04.2020, Article 238.1 of the Criminal Code of the Russian Federation was supplemented with part 1, which provides for liability for "circulation of falsified, substandard and unauthorized medicines, medical devices and circulation of falsified nutritional supplements using the mass media or information and telecommunication networks, including the Internet". These changes are due to the fact that in the context of the pandemic, online stores experienced an increased demand, which is vulnerable to being used by counterfeiters of medicines, offering medicines at a lower price, as well as medicines that are claimed to be effective in the treatment or prevention for a new coronavirus infection.

- In **Switzerland**, in administrative procedures in cases of the illegal manufacture and/or supply of medical products, it is regularly underlined that in the case of a further breach of the Therapeutic Products Act, a penal procedure will follow. Moreover, Swissmedic mentions in media releases, in

regular newsletters to media professionals (listing penalties which entered into force) and in specific answers to the media that infringements of the Therapeutic Products Act may be punishable.

Recommendations

- Urges **Bosnia and Herzegovina** to transpose the provisions of the MEDICRIME Convention into its internal criminal law as required by the Convention. Considers positive the establishment by the Ministry of Justice of **Bosnia and Herzegovina** of a working group to find adequate solutions that will eliminate the identified gaps and improve the current provisions of the Criminal Code of **Bosnia and Herzegovina** and the Code of Criminal Procedure of Bosnia and Herzegovina in order to harmonize criminal legislation in **Bosnia and Herzegovina**.

- Urges **Cyprus** and **Portugal** to ensure that offences related to the counterfeiting of medical products, as defined in Articles 4. a. and 4. j, MEDICRIME Convention, are criminalised in accordance with Articles 5 and 6.

- Urges **Cyprus** and **Türkiye** to guarantee that intentional offences described in Article 7 relating to documents, as defined in Article 4.h, are criminalised when performed in relation to medical products.

- Urges **Cyprus and Portugal** to criminalise the conducts established in article 8 MEDICRIME Convention.

- Urges **Armenia, Belgium, France, Hungary, Marocco, Russian Federation, Spain, Switzerland, and Türkiye** to analyse the level of implementation by the domestic law of Article 8. b, MEDICRIME Convention (« *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: (…), b. the commercial use of original documents outside their intended use within the legalmedical product supply chain, as specified by the domestic law of the Party*").

6.2. Investigation and Prosecution Framework

6.2.1. Dedicated National specialised investigation units

This part seeks to obtain information specifically related to the counterfeiting of medical products and similar offences involving threats to public health, on specialized national investigation services responsible for conducting criminal investigations, and/or coordinating and/or supervising criminal investigations conducted by other services/authorities (Article 16), including formal or informal inter-institutional commissions or structures.

- Certain Parties **(Belgium, Croatia, France, Morocco, Spain, Switzerland, Türkiye)** have established specialized national investigation services responsible for conducting criminal investigations, coordinating, supporting, and supervising criminal investigations conducted by other services/authorities.
- Other Parties **(Armenia, Bosnia and Herzegovina, Cyprus, Hungary, Portugal, Russian Federation)** have no specialized or specifically designated unit in this area in the police services.

RECOMMENDATIONS:

- Considers that **Armenia, Bosnia and Herzegovina, Cyprus, Hungary, Portugal,** and the **Russian Federation** take the necessary measures to ensure that persons, units or services in charge of criminal investigations are specialised in the field of combating counterfeiting of medical products and similar crimes involving threats to public health or that persons are trained for this purpose, including financial investigations. Such units or services shall have adequate resources.

6.2.2. Specialised prosecutors in the field of counterfeiting of medical products and similar crimes involving threats to public health

This part seeks to ascertain information on the existence of specialised prosecutors, specifying whether they intervene at the national or local level.

- Related to specialised prosecutors in the field of counterfeiting of medical products and similar crimes involving threats to public health, the general finding is that there is a lack of specialisation in this area, for investigation or prosecution **(Armenia, Bosnia and Herzegovina, Croatia, Cyprus, France, Morocco, Portugal, Russian Federation, Spain, Türkiye)**

Promising Practices

- **Belgium** has specialised prosecutors in this area who function on a regional basis.
- **Switzerland** has specialised prosecutors at the federal level who support with guidance to cantonal prosecutors in this field.

Recommendations:

- Invites **Armenia, Bosnia and Herzegovina, Croatia, Cyprus, France, Morocco, Portugal, Russian Federation, Spain, and Türkiye** to consider the opportunity of establishing specialized prosecutors in the field of counterfeiting medical products and similar crimes involving threats to public health.

6.3. Leadership and processes for coordinating the investigations

This part seeks to ascertain, with regard to investigations into counterfeit medical products and similar crimes involving threats to public health, the existing or planned process used to decide which investigative department/body is responsible or takes the lead for investigations in general or when they arise. Additionally, it is aimed to determine whether there is a different process or mechanism for coordinating the investigation of pandemic-related offences (Articles 16.2, 17.1 and 3. b)

6.3.1. Existing or planned process used to decide which investigative service/body is responsible or takes the lead for investigations

- The different Parties **(Belgium, Bosnia and Herzegovina, Croatia, France, Hungary, Morocco, Portugal, Russian Federation, Spain, Switzerland, Türkiye)** have either procedural rules or formal criteria in order to decide which investigative department or body is responsible or takes the lead for investigations in general or when they arise.

- In certain Parties **(Belgium, Croatia, France, Morocco, Spain, Switzerland)** specialized units to conduct criminal investigations, and/or coordinate and/or supervise criminal investigations conducted by other services/authorities or even the presence of specialized prosecutors in this field (only in the cases of **Belgium and Switzerland**) do exist.

Promising practices

- In **Belgium**, depending on the specifics of a case, the Prosecutor of the region where the infraction occurs or the Federal Agency for Medicines and Health Products takes the lead. The Prosecutors have to be notified of all cases even if they do not lead the investigation. The Federal Agency for Medicines and Health Products' Special Investigations Unit (SIU), investigate falsification of medicines and medical devices. The SIU inspectors are qualified with pharmaceutical or scientific degrees and are trained to perform investigations. Collaboration with the Federal Police and the Prosecutors (and with other agencies, which is evaluated on a case-by-case basis) goes through the Pharma and Food Crime Platform.

- In **Switzerland**, the investigation body that takes responsibility for investigations of counterfeit medical products depends on the criminal jurisdiction to prosecute the case. The Swissmedic Penal Division is responsible for prosecuting perpetrators of violations relating to the manufacture, supply (including the import and export) and trafficking of counterfeit medical products, whereas violations in connection with the use and dispensing of counterfeit medical products fall under the jurisdiction of the cantonal prosecution authorities. If the import/export of counterfeit medical products also involves a violation of the Customs Act or the Value Added Tax Act, the Federal Customs Administration will prosecute and judge the offences (cf. Article 90, para. 1 Therapeutic Products Act). The Therapeutic Products Act provides for the possibility of combining the proceedings under either federal or cantonal jurisdiction if both federal and cantonal jurisdiction applies

in a criminal matter that falls within the scope of the Therapeutic Products Act's application (cf. Article 90, para. 4 TPA).

6.3.2. Processes or mechanisms for coordinating the investigation of pandemic-related offences

- Related to the processes or arrangements in place to coordinate crimes related to a pandemic (Articles 16.2, 17.1 and 3. b, MEDICRIME Convention) the majority of the Parties (**Armenia, Bosnia and Herzegovina, Croatia, Cyprus, France, Hungary, Portugal, Russian Federation, Switzerland, Türkiye**) did not establish any particular adaptation at this level.

- Only three Parties **(Belgium, Morocco, Spain)** have made special arrangements oriented to coordinate crimes related to pandemics.

PROMISING PRACTICES

- In **Belgium**, in the initial phase of the marketing of the vaccines, an ad hoc consultation platform was set up with the following participants: the Federal Agency for Medicines and Health Products (Special Investigation Unit; SIU), Federal Police and Justice. This was to anticipate possible falsified vaccines and to be able to take coordinated actions as quickly as possible.

- In Morocco, a special service order was established at the beginning of the COVID-19 pandemic to be supervised by an ad-hoc command post to monitor and coordinate the actions of all operational units and to centralise the data reported for analysis and guidance of the responses required according to the developing trends. This was aimed at improving the investigation of pandemic-related offences.

- In **Spain**, in relation to the coordination of investigations between different police forces, all operations, including those related to pandemic offences, are recorded in the Spanish Guardia Civil databases, which are crossed through the Intelligence Centre against Terrorism and Organised Crime (CITCO) with the databases of other police or customs forces. If there are overlaps between the entities under investigation, this body informs the units involved so that they can be coordinated.

- As well as actively participating in Operations PANGEA and SHIELD, when the pandemic began, a Service Order was drawn up to coordinate and enhance the investigation of offences linked to it, among all units.

6.4. Mechanisms for the public to transmit information to the investigation services

This concerns the mechanisms for the public to report information to the investigation services relating to the counterfeiting of medical products and similar crimes (this does not apply to pharmacovigilance reports or to product quality defects reports). This part also seeks to determine whether the report is made by telephone, email, online

platform or other means and whether it is a confidential notification system and if the effectiveness of this system is monitored.

- In **Armenia**, reporting is done by telephone, email, via an online platform, or other means, and this is a confidential report system.

- In **Croatia**, in order to report any suspicion of a quality defect, adverse drug reaction or counterfeit medicinal product, contact numbers and email addresses for the Rapid alert system are available on HALMED's website.

- In **France**, the National Gendarmerie set up a number of reporting tools aimed at the public allowing the latter to transmit any kind of information (digital platform, online pre-complaint, social networks ...). These tools are monitored and are subject to regular evaluations.

- In **Hungary**, an online reporting platform is available through police.hu, which is anonymous. In addition, the police receive notifications from the public by letter and e-mail. The Police have no information on the effectiveness of these systems. There is a dedicated email address for the purpose of reporting but information may be sent in any way and all methods are accepted. Mostly, the dedicated email address (hamisgyogyszer@ogyei.gov.hu) is used but there is a more confidential facility using electronic forms submitted by the official gateway. Email communication is more considered effective although less confidential as reports are mostly sent via unprotected email services.

- In the **Russian Federation**, citizens can leave a report in the appropriate section of the official website of Roszdravnadzor, as well as contacting the hotline by phone, or sending a complaint through the Unified Portal of Public Services (https://www.gosuslugi.ru/). Such reports, in accordance with the Federal Law "On the procedure for considering appeals of citizens of the Russian Federation" dated 02.05.2006 N 59-FZ, must be considered. Compliance with the requirements of federal legislation is monitored by the Prosecutor General's Office. Citizens' reports and the timely response to them are recorded and monitored in a special closed subsystem of the Automated Information System of Roszdravnadzor.

- In **Türkiye**, complaints concerning counterfeit medicinal products and medical devices and similar crimes are received by the Presidential Communications Center (*CİMER*), Ministry of Health Communications Center (*SABİM*) and the official accounts of the Ministry of Health. Applicants are informed on their complaints within the framework of the relevant provisions. On the request of the applicant, personal information can remain confidential in applications made through the CİMER and SABİM systems. The registry systems for medicine and medical devices also have mobile applications through which people are able to check all such products purchased.

6.5. Collection of complaints about counterfeiting of medical products and similar offences at the national level

This part seeks to ascertain whether complaints about counterfeiting of medical products and similar offences are collected at the national level with a view to being

effectively registered, analysed and investigated or if they are dealt with on a case-by-case basis by individual investigative services/bodies.

- Five Parties **(Bosnia and Herzegovina, France, Portugal, Russian Federation, Spain)** deal with complaints about counterfeiting of medical products and similar crimes involving threats to public health on a case-by-case basis by individual investigative services and bodies.

- Six Parties (**Armenia**, **Belgium, Croatia, Morocco, Switzerland, Türkiye**) collate complaints about those offences at a national level.

Promising Practices

- In **Croatia**, the Agency for Medicinal Products and Medical Devices (HALMED) is responsible for the evaluation and processing of each report/information on suspected quality defects and counterfeited/falsified medicinal products received. Records are kept within the Agency's databases and archives. Handling of quality defects, suspicions of counterfeited/falsified medicinal products, adverse reactions and GMP non-compliances is implemented in HALMED's quality system and periodically evaluated through HALMED's internal audits and external audits (e.g. Joint Audit Programme, BEMA). In addition, the key performing indicators (KPIs) are set by HALMED for the mentioned systems and regularly monitored in order to confirm the efficiency of the processes. As per regular assessments performed by HALMED and external audits, the system was considered to be in compliance with the defined legal requirements and set procedures.

- In **Switzerland**, reports on counterfeit medical products and similar crimes are collated on a national basis. Swissmedic maintains databases of reports regarding counterfeit medical products and similar crimes. Records of investigations and measures are kept. If a local authority is dealing with a case of a crime regarding a medical product in their own jurisdiction, the case will also be reported to Swissmedic.

6.6. Investigation of offences

This part seeks to ascertain whether all the offences set out in Articles 5 to 8 and Article 9 are investigated and whether they are subject to the lodging of a complaint and its maintenance (Article 15).

- In the majority of the Parties **(Armenia, Belgium, Croatia, France, Hungary, Morocco, Portugal, Russian Federation, Spain, Switzerland, Türkiye)** all prescribed offences in Articles 5-8 and 9 are investigated and not subject to a complaint being made and maintained.

- In all the aforementioned Parties if the investigation is the result of a complaint and the complaint is withdrawn the investigation can still continue.

- In these Parties, the criminal offences implemented at the internal level on the basis of (or equivalent to) Articles 5-8 and 9 MEDICRIME Convention are public offences which are prosecuted *ex officio*. Criminal proceedings may be initiated, even without the wishes of the injured parties, on the initiative of the Public Prosecutor.

Recommendation

- Urges **Bosnia and Herzegovina** to put in place the necessary measures in order to guarantee that all the offences set out in Articles 5 to 8 and Article 9 are investigated and that they are not subject to the lodging of a complaint and its maintenance.
- Urges Cyprus to ensure that investigations or prosecution of offences set out in Articles 5 to 8 and Article 9 MEDICRIME Convention are not subordinated to the lodging of a complaint.

6.7. Existence of an indicative list of offense with regard to the counterfeiting of medical products and similar offences involving threats to public health

- This part seeks to ascertain, with regard to the counterfeiting of medical products and similar offences threatening public health, if there is at the national level an indicative list of offences, taking into account Articles 5 to 9, 11 and 13 and other criminal legislation, to assist investigators in determining the legal basis and evidence necessary for the completion of investigations, in particular in times of pandemic when technical staff may not be immediately available (Article 16).

- In one Party **(Belgium),** the inspectors of the Special Investigation Unit of the Federal Agency for Medicines and Health Products (FAMHP) are specialised in this legislation and they assist police and Prosecutors when working in specific cases.

6.8. Discretion of the services/bodies responsible for investigating counterfeiting of medical products and similar offences to initiate and close an investigation without reference to a prosecuting authority or other authorities responsible for investigating counterfeiting of medical products, in accordance with the procedural rules of domestic law

- Only five Parties (**Armenia, Croatia, France, Hungary, Türkiye**) provided information on the discretion of the services responsible for investigating counterfeiting of medical products and similar offences to initiate and close an investigation without reference to a prosecuting authority or other authorities responsible for investigating the aforementioned crimes.

- Seven Parties (**Bosnia and Herzegovina, Cyprus, Morocco, Portugal, Russian Federation, Spain, Switzerland**) did not provide information on this point, having the possibility to do so as the question was optional.

Promising practices

- In **Croatia** in all cases, according to the Criminal Procedure Law, investigating bodies must notify the prosecuting authority that a criminal investigation has begun. After completing the criminal investigation, investigating bodies also have to notify the prosecuting authority of the outcome of the criminal investigation.

- In **France,** the services and bodies responsible for investigations have the possibility of conducting investigations on their own initiative, but must automatically report to the judicial authority on the outcome of the investigation so that the Public Prosecutor can assess the follow-up to be given to it: initiate proceedings, implement an alternative procedure to prosecution in accordance with the provisions of articles 41-1, 41-1-2, or 41-2 of the Code of Criminal Procedure or dismiss the proceedings if the particular circumstances relating to the commission of the facts justify it (Article 40-1 of the Code of Criminal Procedure).

- In **Hungary** on the basis of Section 4(1) of CCP (Code of Criminal Procedure), the prosecution service or investigating authority shall launch a criminal proceeding *ex officio* if it becomes aware of a criminal offence subject to public prosecution. Furthermore, a member of an authority, a public officer, and, if required by law, a statutory professional body shall be obliged to file a crime report regarding a criminal offence subject to public prosecution if they becomes aware of it in their official competence or in their official capacity, respectively [Section 376(2) of CCP]. All grounds for dismissing the crime report (Section 381 of CCP) or for terminating the proceeding (Section 398 CCP) are determined by the CCP.

VII. SANCTIONS AND AGGRAVATING CIRCUMSTANCES

This section aims at identifying what specific legislative and other measures have been taken to support the sanctioning of persons in relation to the counterfeiting of medical products and similar crimes in final sentences, in particular relating to offences committed in a pandemic.

According to Article 12, MEDICRIME Convention sanctions corresponding to the offences established by the Convention shall be effective, proportionate and dissuasive including criminal or non-criminal monetary sanctions. It is particularly relevant to point out that sanctions corresponding to offences created on the basis of Articles 5 and 6 MEDICRIME Convention shall include penalties involving deprivation of liberty that may give raise to extradition.

Particularly relevant is the precision, included in the Explanatory Report, related to article 8 MEDICRIME Convention, according to which “offences under Article 8 (manufacture and supply without authorisation or without the product being in compliance with regulatory requirements) cover a wide range of behaviour from more

formal violations of national administrative requirements to organised acts seriously affecting the health of individuals. While the seriousness is comparable to the behaviour criminalised by Articles 5, 6 and 7, minor violations of regulatory legal requirements (which may be of quite different nature and structure in Parties) may not always necessitate criminal sanctions in the technical sense. Fines of a non-criminal (i.e. regulatory or administrative) nature may therefore be considered sufficient in view of the overall context and structure of domestic law and penal sanctions."

Additionally, the internal laws of the Parties shall permit the seizure, confiscation and disposal, including destruction, of medical products, active substances, accessories, parts and materials, and other instrumentalities used to commit the offences described in Articles 5-8 (Article 12. 2. a. and b. MEDICRIME Convention).

Related to the aggravating circumstances, Article 13 MEDICRIME Convention indicates six circumstances that, 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 in determining the sanctions in relation to the offences established in accordance with the Convention.

Finally, Article 14 MEDICRIME Convention provides for the possibility to take into account final sentences passed by another Party in relation to offences of the same nature when determining the sanctions according to the offences established in accordance with the Convention.

Article 12 – Sanctions and measures

1 Each Party shall take the necessary legislative and other measures to ensure that the offences established in accordance with this Convention are punishable by effective, proportionate and dissuasive sanctions, including criminal or non-criminal monetary sanctions, taking account of their seriousness. These sanctions shall include, for offences established in accordance with Articles 5 and 6, when committed by natural persons, penalties involving deprivation of liberty that may give rise to extradition.

2 Each Party shall take the necessary legislative and other measures to ensure that legal persons held liable in accordance with Article 11 are subject to effective, proportionate and dissuasive sanctions, including criminal or non-criminal monetary sanctions, and may include other measures, such as:

a temporary or permanent disqualification from exercising commercial activity;
b placing under judicial supervision;
c a judicial winding-up order.

3 Each Party shall take the necessary legislative and other measures to:

a permit seizure and confiscation of:

i medical products, active substances, excipients, parts, materials and accessories, as well as goods, documents and other instrumentalities used to commit the offences established in accordance with this Convention or to facilitate their commission;

ii proceeds of these offences, or property whose value corresponds to such proceeds;

b permit the destruction of confiscated medical products, active substances, excipients, parts, materials and accessories that are the subject of an offence established under this Convention;

c take any other appropriate measures in response to an offence, in order to prevent futureoffences.

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:

a the offence caused the death of, or damage to the physical or mental health of, thevictim;

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 organisation;

f the perpetrator has previously been convicted of offences of the same nature.

Article 14 – Previous convictions

Each Party shall take the necessary legislative and other measures to provide for the possibility to take into account final sentences passed by another Party in relation to the offences of the same nature when determining the sanctions.

Explanatory Report

Article 12 – Sanctions and measures

84. This article is closely linked to Articles 5 to 8, which define the various offences that should be made punishable under domestic law. In accordance with the obligations imposed by those articles, Article 12 requires Parties to match their action to the seriousness of the offences and lay down sanctions which are "effective, proportionate and dissuasive". 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. It should be noted that, under Article 2 of the European Convention on Extradition (ETS No. 24), extradition is to be granted in respect of offences punishable under the laws of the requesting and requested Parties by deprivation of liberty or under a detention order for a maximum period of at least one year or by a more severe penalty. Offences under Article 8 (manufacture and supply without authorisation or without the product being in compliance with regulatory requirements) cover awide range of behaviour from more formal violations of national administrative requirementsto organised

acts seriously affecting the health of individuals. While the seriousness is comparable to the behaviour criminalised by Articles 5, 6 and 7, minor violations of regulatory legal requirements (which may be of quite different nature and structure in Parties) may not always necessitate criminal sanctions in the technical sense. Fines of a non-criminal (i.e. regulatory or administrative) nature may therefore be considered sufficient in view of the overall context and structure of domestic law and penal sanctions.

85. Legal entities whose liability is to be established under Article 11 are also to be liable to sanctions that are "effective, proportionate and dissuasive", which may be criminal, administrative or civil in character. Paragraph 2 requires Parties to provide for the possibilityof imposing monetary sanctions on legal persons.

86. In addition, paragraph 2 provides for other measures which may be taken in respect of legal persons, with particular examples given: exclusion from entitlement to public benefits or aid; temporary or permanent disqualification from the practice of commercial activities; placingunder judicial supervision; or a judicial winding-up order. The list of measures is not mandatory or exhaustive and Parties are free to apply none of these measures or envisage other measures.

87. Paragraph 3 requires Parties to ensure that measures concerning seizure and confiscation of certain documents, goods and the proceeds derived from offences can be taken. This paragraph has to be read in the light of the Council of Europe Convention on Laundering, Search, Seizure and Confiscation of the Proceeds from Crime (ETS No. 141) as well as the Council of Europe Convention on Laundering, Search, Seizure and Confiscation ofthe Proceeds from Crime and on the Financing of Terrorism (CETS No. 198), which are based on the idea that confiscating the proceeds of crime is an effective anti-crime weapon.

As all of the offences related to the counterfeiting of medical products and similar crimes are undertaken for financial profit, measures depriving offenders of assets linked to or resulting from the offence are clearly needed in this field as well.

88. Paragraph 3 a provides for the seizure and confiscation of medical products, active substances, excipients, parts, materials and accessories, as well as goods, documents and other instrumentalities used to commit the offences established in accordance with the Convention or to facilitate their commission. Moreover, proceeds of the offences, or property whose value corresponds to such proceeds may be seized or confiscated.

89. The Convention does not contain definitions of the terms "confiscation", "instrumentalities", "proceeds" and "property". However, Article 1 of the Convention on Laundering, Search, Seizure and Confiscation of the Proceeds from Crime provides definitions for these terms which may be used for the purposes of this Convention. By "confiscation" is meant a penalty or measure, ordered by a court following proceedings in relation to a criminal offence or criminal offences, resulting in final deprivation of property. "Instrumentalities" covers the whole range of things which may be used, or intended for use, in any manner, wholly or in part, to commit the criminal offences. "Proceeds" means any economic advantage or financial saving from a criminal offence. It may consist of any "property" (see the interpretation of that term below). The wording of the paragraph takes into account that there may be differences of national law as regards the type of property which can be confiscated after an offence. It can be possible to confiscate items which are (direct) proceeds of the offence or other property of the offender which, though not directly acquired through the offence, is equivalent in value to its direct proceeds ("substitute assets"). "Property" must therefore be interpreted, in this context, as any property, corporeal or incorporeal, movable or immovable, and legal documents or instruments evidencing title to or interest in such property.

90. Paragraph 3 b allows for the destruction of medical products, active substances, excipients, parts, materials and accessories that are the subject of an offence established under the Convention.

91. Paragraph 3 c, addresses in general wording the various administrative measures that Parties may undertake in order to prevent future offences, including re-offending. The permanent or temporary ban on a perpetrator to carry on a commercial or professional activity in connection with which the offence was committed, or the withdrawal of professional licenses from perpetrators are

examples of what such measures could include.

Article 13 – Aggravating circumstances

92. Article 13 requires Parties to ensure that certain circumstances (mentioned in letters a.to f.) may be taken into consideration as aggravating circumstances in the determination ofthe sanction for offences established in this Convention. These circumstances must not already form part of the constituent elements of the offence. This principle applies to cases where the aggravating circumstances already form part of the constituent elements of the offence in the national law of the State Party.

93. By the use of the phrase "may be taken into consideration", the ad hoc committee highlights that the Convention places an obligation on Parties to ensure that these aggravating circumstances are available for judges to consider when sentencing offenders, although there is no obligation on judges to apply them. The reference to "in conformity with the relevant provisions of national law" is intended to reflect the fact that the various legal systems in Europe have different approaches to address those aggravating circumstances and permits Parties to retain their fundamental legal concepts.

94. The first aggravating circumstance (a) is where the offence caused the death of, or damage to the physical or mental health of, the victim. Given the inherent difficulties in linking the consumption of a medicinal product or the use of a medical device directly with the occurrence of a death, the ad hoc committee considered that in such cases, it should be up tothe national courts of the State Parties to assess the causal link between the conducts criminalised under the Convention and any death or injury sustained as a result thereof.

95. The second aggravating circumstance (b) is where the offence was committed by personsabusing the confidence placed in them in their professional capacity. This category of personsis in the first line obviously health professionals, but the application of the aggravating circumstance is not restricted to health professionals.

96. The third aggravating circumstance (c) is where the offence was committed by persons abusing the confidence placed in them as manufacturers and suppliers.

97. The fourth aggravating circumstance (d) is where the offences of supplying and offering to supply are committed through the use of large-scale distribution, including through informationtechnology systems. The ad hoc committee found that the use of information systems,including the Internet, for supplying counterfeit medicinal products and the supply and offering to supply thereof without authorisation is one of the most worrying and serious aspects of counterfeiting of medical products and similar crimes today. Given the immense outreach provided by the Internet, counterfeit, and hence dangerous, medical products are now being spread all over the world at an alarming rate, At the same time, due to problems of jurisdiction, it has become increasingly difficult to get at the criminals behind various Internet sites, offering cheap (i.e. mostly counterfeit) medicines or other medical products.

98. The fifth aggravating circumstance (e) is where the offence involved a criminal organisation. The Convention does not define "criminal organisation". In applying this provision, however, Parties may take their line from other international instruments which define the concept. For example, Article 2(a) of the United Nations Convention against Transnational Organised Crime defines "organised criminal group" as "a structured group of three or more persons, existing for a period of time and acting in concert with the aim of committing one or more serious crimes or offences established in accordance with this Convention, in order to obtain, directly or indirectly, a financial or other material benefit". Recommendation Rec(2001)11 of the Committee of Ministers to member states concerning guiding principles on the fight against organised crime and the EU Council Framework Decision 2008/841/JHA of 24 October 2008 on the fight against organised crime give very similar definitions of "organised criminal group" and "criminal organisation".

99. The sixth aggravating circumstance (f) is where the perpetrator has previously been convicted of offences of the same nature as those established under the

Convention. By including this, the ad hoc committee wanted to signal the need to make a concerted effort to combat recidivism in the low risk – high gain area of counterfeiting of medical products and similar crimes.

Article 14 – Previous convictions

100. Counterfeiting of medical products and similar crimes are more often than not perpetrated transnationally by criminal organisations or by individual persons, some of whom may have been tried and convicted in more than one country. At domestic level, many legal systems provide for a different, often harsher, penalty where someone has previous convictions. In general, only conviction by a national court counts as a previous conviction. Traditionally, previous convictions by foreign courts were not taken into account on the grounds that criminal law is a national matter and that there can be differences of national law, and because of a degree of suspicion of decisions by foreign courts.
101. Such arguments have less force today in that internationalisation of criminal-law standards – as a pendent to internationalisation of crime – is tending to harmonise different countries' law. In addition, in the space of a few decades, countries have adopted instrumentssuch as the ECHR whose implementation has helped build a solid foundation of common guarantees that inspire greater confidence in the justice systems of all the participating states.
102. The principle of international recidivism is established in a number of international legal instruments. Under Article 36 paragraph 2 (iii) of the New York Convention of 30 March 1961 on Narcotic Drugs, for example, foreign convictions have to be taken into account for the purpose of establishing recidivism, subject to each Party's constitutional provisions, legal system and national law. Under Article 1 of the Council Framework Decision of 6 December 2001 amending Framework Decision 2000/383/JHA on increasing protection by criminalpenalties and other sanctions against counterfeiting in connection with the introduction of the euro, European Union member states must recognise as establishing habitual criminality final decisions handed down in another Member state for counterfeiting of currency.
103. The fact remains that at international level there is no standard concept of recidivism andthe law of some countries does not have the concept at all. The fact that foreign convictions are not always brought to the courts' notice for sentencing purposes is an additional practical difficulty. However, in the framework of the European Union, Article 3 of the Council Framework Decision 2008/675/JHA of 24 July 2008 on taking account of convictions in the member states of the European Union in the course of new criminal proceedings has established in a general way – without limitation to specific offences – the obligation of taking into account a previous conviction handed down in another (EU Member) state.
104. Therefore Article 14 provides for the possibility to take into account final sentences passed by another Party in assessing a sentence. To comply with the provision Parties may provide in their domestic law that previous convictions by foreign courts are to result in a harsher penalty. They may also provide that, under their general powers to assess the individual's circumstances in setting the sentence, courts should take those convictions into account. This possibility should also include the principle that the offender should not be treated less favourably than he would have been treated if the previous conviction had been anational conviction.
105. This provision does not place any positive obligation on courts or prosecution services totake steps to find out whether persons being prosecuted have received final sentences from another Party's courts. It should nevertheless be noted that, under Article 13 of the European Convention on Mutual Assistance in Criminal Matters (ETS No. 30), a Party's judicial authorities may request from another Party extracts from and information relating to judicial records, if needed in a criminal matter. In the framework of the European Union, the issues related to the exchange of information contained in criminal records between member states are regulated in two legal acts, namely Council Decision 2005/876/JHA of 21 November 2005on the exchange of information extracted from the criminal record and Council Framework Decision 2009/315/JHA of 26 February 2009 on the organisation and

content of the exchangeof information extracted from the criminal record between Member states.

7.1. Seizure and confiscation

This part seeks to determine whether the internal laws of the Parties permit the seizure, confiscation and disposal, including destruction, of medical products, active substances, accessories, parts and materials, and other instrumentalities used to commit the offences described in Articles 5-8 (Article 12. 2. a and b).

- In all Parties **(Armenia, Belgium, Bosnia and Herzegovina, Croatia, Cyprus, France, Hungary, Morocco, Portugal, Russian Federation, Spain, Switzerland, Türkiye),** the internal laws permit the seizure, confiscation and disposal, including the destruction of medical products and other materials and instrumentalities employed to the commission of the offences established in Articles 5-8, MEDICRIME Convention.

- Some Parties **(Belgium, Russian Federation, Spain)** have legal dispositions which specifically refer to the seizure, confiscation and disposal, including destruction, of medical products and other instrumentalities used to commit the offences described in Articles 5-8, MEDICRIME Convention. In the rest of the aforementioned Parties which have provided information on this topic (**Bosnia and Herzegovina, Croatia, France, Hungary, Portugal, Switzerland, Türkiye)** seizure, confiscation and disposal in connection with offences established in Articles 5-8, MEDICRIME Convention falls under general dispositions of the respective Criminal Codes or other laws of the Parties, which allow those measures for a wide range of criminal offences.

Promising Practices

- In **Spain** the reform implemented by Organic Law 1/2015 of 30 March 2007 introduced a new Article 362 sexies into the Criminal Code, which provides for the confiscation of substances, objects, products, assets, media, instruments and gains, of all the previous articles of the Chapter ("On felonies against Public Health", where the offences transposing to the internal law Articles 5-8, MEDICRIME Convention are included). This reflects the requirements of Article 12 (3) (a) of the MEDICRIME Convention which requires the Parties to adopt the necessary legislative measures to allow freezing and confiscation.

7.2. Policies facilitating the prosecution of offences in Articles 5-9 along with other criminal law offences arising from the same set of facts on counterfeit medical products

This part seeks to ascertain whether there are, at the internal level, policies facilitating the prosecution of offences in Articles 5-9 along with other criminal law offences arising from the same set of facts on counterfeit medical products, such as intentional offering,

for gain, of medical products to prevent or treat the pandemic disease and without the intention to supply such products, also referred to as scamming.

- No Party provided information about the existence of particular policies intended to address such matters, having the possibility to do so as the question was optional.

7.3. Subordination of offences in Articles 5-9 MEDICRIME Convention to other criminal law offences

This part seeks to explore whether there is a policy for offences in Articles 5-9, either generally or during a pandemic, to be subordinate to other criminal law offences in the case of a prosecution of the same person(s), such as the trafficking of controlled substances in the same consignment as the counterfeit medical products.

- Eight Parties **(Bosnia and Herzegovina, Cyprus, Morocco, Portugal, Russian Federation, Spain, Switzerland, Türkiye)** did not provide information on this aspect, having the possibility to do so as the question was optional.

  - In three Parties, (**Armenia, Croatia, France**), there is no subordination at this level.

  - In two Parties (**Belgium, Hungary**) such subordination can exist. In **Belgium**, such subordination can exist when the other offences (for example, trafficking of controlled substances, and criminal organisations) are still more severely punished. In **Hungary**, subordination can exist depending on the circumstances of the special case. Usually, the concurrence of criminal offences can be determined, e.g. counterfeit medicines and intellectual property offences.

7.4. Specific sanctioning policy in the field of offences related to counterfeit medical products and similar crimes

This part seeks to determine whether there is a specific sanctioning policy in the field of offences related to counterfeit medical products and similar crimes generally, with specific reference to Article 13 circumstances in so far as they do not already form part of the constituent elements of the offence, and if so, whether the fact that the offence occurred during a pandemic is considered as an aggravating circumstance.

- The majority of the Parties **(Armenia, Belgium, Croatia, France, Hungary, Russian Federation, Spain, Switzerland, Türkiye)** have implemented at the internal level the obligations set up by Article 13, MEDICRIME Convention that indicates six aggravating circumstances which, 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 in determining the sanctions in relation to the offences established in accordance with the Convention.

- Different models of implementation of the aggravating circumstances established by Article 13, MEDICRIME Convention do exist. In certain Parties, (**Belgium, Spain, France**) specific aggravating circumstances for the offences related to counterfeit medical products and similar crimes are legally set; in other Parties (**Croatia, Hungary**), some of these circumstances give raise to qualified forms of offences and therefore are constituent elements of the respective offences and only the rest of the circumstances work specifically as aggravating circumstances. Finally, in another Party (**Switzerland**) the reference to the general aggravating circumstances (applicable to the different offences included in the Criminal Code) is considered sufficient in order to cover the spectrum of Article 13, MEDICRIME Convention.

- No Party reported the existence of a legal disposition at the internal level considered as an aggravating circumstance the commission of the offences related to counterfeit medical products and similar crimes during a pandemic. In one case (**Russian Federation**), and in accordance with paragraph "L" of Part 1 of Article 63 of the Criminal Code of the Russian Federation, an aggravating circumstance is the commission of a crime in a state of emergency, natural or other public disaster, as well as during mass riots, in conditions of an armed conflict or in case of war.

Recommendation

- Urges **Bosnia and Herzegovina, Cyprus, Morocco, and Portugal** to implement at the internal level the aggravating circumstances referred in Article 13, MEDICRIME Convention in so far as they do not already form part of the constituent elements of the offences.

7.5. Removal of professional status

This part seeks to ascertain whether and to what extent internal law provides for the possibility of removing the professional status of a person who abused the confidence placed in them in their capacity as a professional (Articles 12.2 and 13. b) or, including legal persons, as manufacturers and suppliers (Article 13. c).

- Seven Parties (**Armenia, Belgium, Croatia, France, Hungary, Russian Federation, Türkiye**) have legal provisions to remove the professional status of both natural and legal persons.

- Six Parties **(Bosnia and Herzegovina, Cyprus, Morocco, Portugal, Spain, Switzerland)** did not provide information on this matter, having the possibility to do so as the question was optional.

Promising practices

- In **Belgium**, related to legal persons, the manufacturers and distributors are subject to licensing arrangements according to the Law of the 25th of March 1964 on Medicines. The Royal Decree of the 14th of December 2006 (the implementing decree of this law) lists all the obligations of the license holders. If they commit infringements, these licenses can be suspended or revoked. Moreover, they can also be prosecuted for these infringements.

- In **Croatia**, the removal of professional status is provided for by various Acts: Articles 7 (termination of the right to practice medicine) and 8 (unworthiness to perform medical activity) Act on Medicine; Article 29, Act on Pharmacy (revocation of the master's degree in pharmacy from independent work); and Article, 80 Medicinal Products Act (cancellation of the manufacturing authorization).

- In **France**, for natural persons, Article 131-6 15° of the Criminal Code provides, as an alternative penalty to imprisonment (including the conduct referred to in the MEDICRIME Convention), that there can be, at the court's discretion, a prohibition for a period of up to five years, from exercising a commercial or industrial profession, from directing, administering, managing or controlling in any capacity, directly or indirectly, on their own account or on behalf of others, a commercial or industrial enterprise or a commercial company. Where the law so provides, natural persons may also incur the additional penalty of prohibition, in accordance with the procedures laid down in Article 131-27 of the Criminal Code, either from exercising a public function or from exercising the professional or social activity in the exercise of or in connection with the exercise activity of which the offence was committed, or from exercising a commercial or industrial profession, from directing, administering, managing or controlling in any capacity, directly or indirectly, for their own account or on behalf of others, a commercial or industrial enterprise or a commercial company. Similarly, legal persons declared criminally liable, under the conditions laid down in Article 121-2 of the Criminal Code and as provided for by law, may also be sentenced to an additional penalty of dissolution and a prohibition mentioned in 2 ° of Article 131-39 of the Criminal Code relating to the activity in the exercise or on the occasion of the exercise of which the offence was committed.

- In **Hungary**, disqualification from a profession (Section 52-53 of CC) is another punishment which can be imposed next to imprisonment. In connection with legal persons, according to Section 3 of Act CIV of 2001 on the criminal measures applicable against legal persons if the court imposes punishment on the person committing the criminal offence defined in Article 2 or applies reprimand or probation against this person,

orders confiscation or forfeiture of assets, it may apply the following measures against the legal person:

a) winding up the legal person,
b) limiting the activity of the legal person,
c) imposing a fine.

- In the **Russian Federation**, one of the criminal punishments provided (as an additional one), *inter alia* for the circulation of falsified, substandard and unauthorized medicines, medical devices and the circulation of falsified nutritional supplements (Article 238.1 of the Criminal Code of the Russian Federation), is deprivation of the right to hold certain positions and be engaged in certain activities, prohibition to hold positions in the public service, in local self-government authorities, or to be engaged in certain professional or other activities.

VIII. DATA COLLECTION

8.1 Data Collection for the purpose of observing and evaluating counterfeit medical products or for another purpose (Article 17.3.a. and b)

This chapter concerns the effective collection, collation and analysis of data that can support combating counterfeit medical products and similar crimes involving threats to public health in a pandemic, and more generally.

The Convention or the Explanatory Report do not directly deal with the issue of data collection. Article 17 provides the direction required for the need to receive and collect information and data at all levels and in cooperation with the private sector and civil society. It also requires the sharing and exchange of data between the authorities, health authorities, customs, police and other competent authorities.

Article 17

3 With due respect for the requirements of the protection of personal data, each Party shall take the necessary legislative and other measures to set up or strengthen mechanisms for:

a. receiving and collecting information and data, including through contact points, at national or local levels and in collaboration with the private sector and civil society, for the purpose of preventing and combating the counterfeiting of medical products and similar crimes involving threats to public health;

b. making available the information and data obtained by the health authorities, customs, police and other competent authorities for the co-operation between them.

OMCL Network[11] of the Council of Europe: General Document PA/PH/OMCL (09) 87 R5

[11] OMCL Network is a network of official medicines control laboratories funded by the Council of Europe and the European Union and implemented by the Council of Europe through its European Directorate on the Quality of Medicines and HealthCare (EDQM). OMCL Network - European Directorate for the Quality of Medicines & HealthCare (edqm.eu)

- The OMCL Network supports the implementation of this Article (Article 17) at a practical and technical level because it has functioning information-sharing tools already in place that facilitate the rapid dissemination of information and data on falsified medicines between OMCLs and Competent Authorities.

- The Competent Authorities in turn make such information available to local law enforcement, customs and other governmental agencies, when necessary, and this leads to a more co-ordinated and collaborative approach between these key stakeholders in relation to dealing with falsified medicine.

The stipulated aim of Article 17, cooperation, is dealt with separately in Chapter II of this report. It does not mention data collection for the purpose of analysis and the Explanatory Report does not provide an indication as to why data needs to be collected in a systematic manner.

In order for policy formulation relative to legislative drafting, and the development of measures leading to the effective prevention, detection and investigation of counterfeiting of medical products and similar crimes, data must be available, collected in a systematic and standard form, reliable and useful. It supports the health products regulatory authority to ensure the continued development in maintaining a safe distribution of medical products and the protection of the public health system.

8.1.1. The collection of data in the normal course of activity and its purpose

- Data collection relating to falsified medical products and similar crimes has been assessed not to be of a high priority among the Parties included in this report, except for three (**Armenia, Belgium, Russian Federation**). **Armenia** collects data in the normal course of business. Such data is published and all data is archived. It is unclear from the information provided to what extent this includes data on counterfeit medical products or whether it concerns medical products generally. This requires clarification. Belgium collects the data for risk management purposes and the health product regulator's decision-making. The Russian Federation's Ministry of the Interior collects data on all crimes for law enforcement purposes and sharing with other relevant authorities.

- One other Party (**Croatia**) has made inroads into data collection in relation to counterfeit medical products and similar crimes. It includes the routine collection of both unanalysed medical products from law enforcement operations and those medical products analysed by the health product regulator, and this is done for the purpose of public health protection.

- One Party (**Hungary**), the Police service maintains a database recording all criminal activities, including data on analysis.

- Eight Parties (**Bosnia and Herzegovina, Cyprus, France, Morocco, Portugal, Spain, Switzerland, Türkiye**) did not submit any information on any aspect of data collection under this heading, having the possibility to do so as the question was optional.

- It is stressed, in this context, that in the absence of data collection, decision-making and policy formulation toward the protection of public health and the

assignment of resources for the investigation and prosecution of offences cannot be based on empirical evidence. This results in weakening efforts to combat counterfeit medical products and similar crimes and may fail to convince policymakers and the legislature of the need for action in this area of crime.

8.1.2. The collection of data specific to the COVID-19 pandemic period

- Two Parties (**Belgium, Russian Federation**) collected data and developed reports specifically during the pandemic specific to medical products. Belgium generated these reports on a more regular basis due to the rapid change in the profile of the medical products observed in postal packages during this period. In both cases, the focus was on the protection of public health by the health product regulator. One Party (**Armenia**) collected data irrespective of the COVID-19 pandemic.

- No other Party provided any information in this context relating to data collection, having the possibility to do so as the question was optional.

Promising Practice

- **Belgium** recorded data and generated COVID-19-related analyses and reports on a more regular basis due to the rapid change in product profile of counterfeit medical products observed in the postal system.

8.1.3. Mechanisms established for data collection

- Two Parties (**Belgium, Russian Federation**) established mechanisms that record counterfeit medical products. Belgium included the creation of external characteristics and parameters relating to the trafficking of counterfeit medical products in conjunction with Customs.

- One Party (**Hungary)** specified that the police database contains the mechanism for data collection relating to all crimes and not specifically to counterfeit medical products and similar crimes.

- One Party (**Armenia**) specified that data is collected by the health product regulatory authority by Government Decree. One Party (**Türkiye**) specified that it collected data based on Rapid Alert System and Drug Alert System. This does not clarify whether this includes counterfeit medical products or if it does, whether it classifies the data as counterfeit products or as quality defects. This requires clarification.

- No other Party provided any information in this context related to the mechanism established for data collection, having the possibility to do so as the question was optional.

8.1.4. Availability of relevant data collected, reports and analysis made, in particular, that relating to the COVID-19 pandemic

- One Party (**Armenia**) reported that the data is available but did not provide it.

- No Party provided relevant data collected, in particular, that relating to the COVID-19 pandemic, having the possibility to do so as the question was optional.

- No reports or analyses were conducted in this context.

8.1.5. Sharing with relevant authorities of data and relevant reports based on such data

- Four Parties (**Armenia, Belgium, Russian Federation, Türkiye**) share data and reports based on them between law enforcement and the health products regulator. Belgium, where relevant, also shares with EUROPOL, and other EU regulatory competent authorities for medical products.

- One Party (**Croatia**) shares data and reports with the Council of Europe (EDQM/OMCL/CMED), in particular during the COVID-19 pandemic.

- Eight Parties **(Bosnia and Herzegovina, Cyprus, France, Hungary, Morocco, Portugal, Spain, Switzerland**) provided no relevant data in this context, having the possibility to do so as the question was optional.

Recommendations

- Urges the Parties that have not reached this stage to review their legislation, policies and measures ensuring designated mechanisms exist or adapt existing data collection systems to take account of the need to collect and analyse data that can support the combating of counterfeit medical products and similar crimes involving threats to public health in a pandemic, and in general.

- Invites Parties, where specific mechanisms are not already in place, to ensure that existing data collection mechanisms used for other purposes are able to produce accurate and reliable data on the phenomenon of counterfeit medical products and related crimes.

- Invites Parties that have not reached this stage, for the purpose of analysis, evaluation and reporting related to counterfeit medical products and similar crimes during the COVID-19 pandemic period, to ensure the separation from data already collected in the normal course of activity.

- Invites Parties to establish a comprehensive system of reporting of cases of counterfeit medical products, as described in Article 4.j of the Convention, and similar crimes to ensure completeness of data collected

- Invites Parties to review their legislation, policies and other measures to make the reporting to a specified central authority of suspect counterfeit medical products mandatory by authorities and the industry for the purpose of data recording, incident recording, and for public health and criminal investigation.

- Invites Parties to ensure that the terminology contained in the MEDICRIME Convention, and that contained in other legislation where relevant data is already collected, is compatible in meaning. This will ensure that data may be used to measure the incidence of counterfeit medical products and similar crimes as intended by the MEDICRIME Convention.

- Invites Parties to share data collected and analysed among their domestic authorities and with relevant authorities of other Parties and with the relevant international organizations.

- Invites Parties to appoint a national authority with providing periodic reports on aggregated data and recording of counterfeit medical products, in accordance with the meaning of counterfeit in Article 4.j of the Convention, and similar crimes, as intended by Article 8 of the Convention.

- Invites Parties to contribute to and make use of the General European Official Medicines Control Laboratories Network (GEON) of the Council of Europe/EDQM to support the pooling of technical data in relation to counterfeit medical products which will support the fostering of the exchange of data and results of analysis of counterfeit and other illicit medicines.

IX. CONCLUSIONS AND RECOMMENDATIONS

a) Conclusions

- The majority of the Parties made efforts in particular areas to give effect to the MEDICRIME Convention during the COVID-19 pandemic, in particular, in increasing awareness among the public of counterfeit medical products related to COVID-19 and the risks associated with procuring medical products from unauthorised online sources.

- The challenges posed by a pandemic were evident in the preparedness of Parties in some areas such that it disrupted their continued ability to detect and prevent counterfeit medical products and similar crimes. This arose, in particular, in disruptions to training facilitation to all those who required it. The challenges were exacerbated by the Parties not recognising that public and private procurement of medical products not intended for the trade or sale to the public was a weak link in the protection of public health from counterfeit medical products, in particular, during times of pandemics.

- While the Parties have developed legislation and measures in place in several critical areas, which apply equally to a pandemic and non-pandemic situations alike, such as the protection of victims, prohibitions on the online sale of counterfeit medical products, and areas related to cooperation, both for information sharing and investigations, the absence of review mechanisms challenges the effectiveness of the measure in place to address the protection of public health and the investigation of counterfeit medical products and similar crimes. This becomes more critical in times of major crises, such as a pandemic.

- The absence of coordinated data collection and analysis systems is a weak point that hampers the ability of policymakers to assess the extent of incidences of counterfeit medical products and similar crimes. This area was not well responded to by the Parties in this monitoring round, but could have resulted from this being an optional question for Parties.

- In general, the conducts included in Articles 5-8 MEDICRIME Convention have been criminalised in the majority of Parties. Nevertheless, to guarantee this level of protection in all Parties is key in order to ensure a sanctioning policy at this stage coherent with the articles of MEDICRIME Convention and to establish a certain homogeneity in the criminal framework applicable to these offences. Only on this legislative basis, further steps in the fight against the counterfeit of medical products and similar crimes can be reached.

- The MEDICRIME Committee noted concerns that the Parties did not always in their responses either interpret the monitoring round questions in the questionnaire as intended or did not apply these to times of pandemics.

- Furthermore, the Committee noted that optional questions were responded to by some Parties. For other Parties, it was considered that the legislation and measures were in place by the Party that would enable it to respond, should they have chosen to do so. These matters weaken the ability of the monitoring

round to report comprehensively on the protection of public health through the MEDICRIME Convention in times of pandemics.

b) Recommendations

Main recommendations emerging from the report concerning the majority of Parties:

As to the policies, strategies, plans and activities to prevent counterfeit medical products and similar crimes involving a threat to public health, in particular during times of pandemics.

The MEDICRIME Committee:

- Urges the Parties to ensure that policies, strategies, and measures are provided for the training of those involved in public and private procurement programmes for medical products.

- Urges the Parties to develop contingency plans, strategies, and other measures to provide training in critical procurement and distribution areas of medical products with a view to preventing counterfeit medical products and similar crimes from arising when their systems, resources, and priorities are under stress, including during pandemics.

- Urges the Parties to implement legislation, plans, strategic and other measures to provide training in specialist investigative techniques to specialist units/bodies in the investigation of counterfeit medical products and related crimes, where appropriate.

- Urge Parties to undertake awareness-raising campaigns for those engaged in the procurement of medical products to close this gap in protecting public health.

- Urges Parties to ensure that arrangements are put in place for all relevant sectors, including those mentioned in Article 18.1, 2, and 3 of the Convention, that handle medical product waste to be included in awareness-raising campaigns.

As to identifying measures aimed at educating civil society on good practices in avoiding the risks associated with counterfeit medical products

The MEDICRIME Committee:

- Urges the Parties to issue reports on the measures, policies, and strategies taken to the promotion of awareness-raising campaigns addressed to the general public providing information about counterfeit medical products.

- Urges all Parties to review their legislation and measures to record instances of the provision by civil society to the general public on awareness-raising campaigns and programmes on the risks arising from procuring and consuming counterfeit medical products.

As to the ability and extent to which authorities/bodies may cooperate between them and exchange information in order to facilitate effective investigation

The MEDICRIME Committee:

- Urges all Parties to put in place a national strategy or action plan to support cooperation and information exchange to enable the effective investigation to combat counterfeit medical products and similar crimes involving threats to public health.

- Urges all Parties to have a clear legislative scheme to support a national strategy or action plan that enables cooperation and information exchange for the effective investigation of counterfeit medical products and similar crimes involving threats to public health.

- Urges the Parties to make use of Memorandums of Understanding and Data Sharing Agreements to the fullest extent among the relevant national authorities, and where appropriate with equivalent bodies in other countries and with relevant international organizations in combating counterfeit medical products and similar crimes.

- Urges the Parties to ensure, in order to facilitate the effective investigation of counterfeit medical products, that cooperation and information-sharing arrangement involve civil society, industry, service providers, e-commerce, and social media platforms, at a minimum.

- Urges Parties to implement clear measures in relation to cooperation and information exchange to decide on which authority takes the lead and how participation in operational plans are decided.

As to the understanding and appreciation of the various measures that may be proactively taken during a pandemic to detect counterfeit medical products and to prevent them from reaching patients

The MEDICRIME Committee:

- Urges the Parties to review their legislation and measures in order to establish systems for reporting suspect or actual counterfeit medical devices, accessories, and parts and materials.

- Urges all Parties to review their legislation, policies, and measures to enable their customs service to detect, detain and act on a counterfeit medical product, as defined by Article 4. j, different to the intellectual property meaning of counterfeit and without the need to refer to the rights holder.

As to the ability to investigate and prosecute offenders for intentional crimes related to counterfeit medical products and similar crimes, in particular during a pandemic

The MEDICRIME Committee:

- Urges the Parties to analyse the level of implementation by the domestic law of Article 8.b MEDICRIME Convention (« 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: (…) 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").

As to the effective collection, collation, and analysis of data that can support the fight against counterfeit medical products and similar crimes involving threats to public health in a pandemic, and in general

The MEDICRIME Committee:

- Urges the Parties to review their legislation, policies, and measures to designate mechanisms to set up or adapt existing data collection systems to take account of the need to collect and analyse data that can support the combating of counterfeit medical products and similar crimes involving threats to public health in a pandemic, and in general.

- Urge the Parties to conduct effectiveness reviews on legislation and measures deployed to protect public health through the MEDICRIME Convention in times of pandemics and generally.