The MEDICRIME Convention
La Convention MÉDICRIME

GENERAL OVERVIEW QUESTIONNAIRE ON THE IMPLEMENTATION OF THE MEDICRIME CONVENTION

As adopted by the Bureau of the MEDICRIME Committee on 7 July 2020

Replies should be addressed to the MEDICRIME Committee Secretariat by **23 September 2020** **(medicrime@coe.int)**

Switzerland's reply of 9 September 2020

Document prepared by the MEDICRIME Committee Secretariat
Directorate General I – Human Rights and Rule of Law

TABLE OF CONTENTS

I. INTRODUCTION

1. The Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health[1] (hereinafter "the MEDICRIME Convention" or "the Convention"), which entered into force in January 2016, requires criminalisation of the manufacturing of counterfeit medical products, of the supplying, offering to supply and trafficking in counterfeit medical products, of the falsification of documents and of the unauthorised manufacturing or unauthorised supplying of medicinal products and of the placing on the market of medical devices which do not comply with conformity requirements. The Convention provides a framework for national and international co-operation across the different sectors of the public administration, measures for coordination at national level, preventive measures for use by public and private sectors and protection of victims and witnesses. Furthermore, it foresees the establishment of a monitoring body to oversee the implementation of the Convention by the States Parties.

2. The Committee of the Parties to the Convention (also known as the "MEDICRIME Committee"), established to monitor whether Parties effectively implement the Convention, decided that:

> 1. *Following ratification and within six months from the entry into force of the MEDICRIME Convention in respect of the Party concerned, every Party to the Convention shall be required to reply to a questionnaire aimed at providing the MEDICRIME Committee with a general overview of its legislative practice, institutional framework and policies for the implementation of the Convention at the national, regional and local levels. Thereafter, the Parties should regularly inform the MEDICRIME Committee of any substantial changes to the situation described in their replies to the general overview questionnaire.*
>
> 2. *States which have signed the Convention shall be invited to reply to the questionnaire referred to in paragraph 1 of this rule.*
>
> 3. *The secretariat shall compile the replies received and make them public on the Committee's website[2].*

3. In accordance with Rule 26 of the Committee's 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 coordinate 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 questionnaire shall be detailed, as comprehensive as possible, answer*

[1] Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health, CETS No. 211, Article 1, para. 2.
[2] MEDICRIME Committee's Rules of Procedure, Rule 24.

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.

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."*

4. The purpose of this general questionnaire is to collect information to provide the MEDICRIME Committee with an overview of the situation, which will constitute the general framework within which it will assess replies by Parties to the thematic questionnaire for the first monitoring round (see Rule 24 of the MEDICRIME Committee's Rules of Procedure).

II. PRELIMINARY REMARKS

5. The provisions of the MEDICRIME Convention have been grouped under different sections in this questionnaire without necessarily 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.

6. Parties will be invited to update their replies to this general questionnaire when they will receive the next thematic questionnaire. Responses to a thematic questionnaire should therefore be interrelated and combined with the responses provided in the context of this questionnaire.

7. Parties are kindly requested to:

- specify which state body/agency was responsible for collecting the replies to this questionnaire and which state bodies/agencies (and, at the discretion of the country, where relevant, civil society and external contributors) contributed to responding to this questionnaire;

- answer the questions with regard to central, regional and local levels to the extent possible. Federal states may, in respect of their sovereign entities, answer the questions in a summarised way;

- answer the questions from a non-discriminatory perspective (for example, related to gender)[3], i.e. specifying, where relevant, whether and how measures for victims and/or offenders take into account gender-specific requirements;

- bear in mind that when replying to questions related to "internal law" reference should also be made to the relevant case law;

- provide, whenever questions/answers refer to it, the relevant text (or a summary) of legislation or other regulations in English or French;

- if some of the questions below correspond to questions put to Parties by other bodies of the Council of Europe or other organisations (whether or not these are governmental bodies), Parties may refer to their initials answers (by providing a link to the relevant replies or by copying their answers) and update the information where necessary.

- in responding to questions, if you agree, please provide a reference to the legal provision. If you do not agree, please provide an explanation.

III. GENERAL FRAMEWORK

Preliminary remarks:
The Swiss Agency for Therapeutic Products (Swissmedic) is member of the Committee of the Parties to the Council of Europe Medicrime Convention and was responsible for collecting the replies to this questionnaire. Our answers are a joint effort between different departments of the Swiss Agency for Therapeutic Products (Swissmedic) and the Federal Office of Public Health (FOPH). Where necessary, additional authorities were contacted.

Question 1: Definitions

a. Does the understanding of "medical product" under your internal law correspond to that set out in **Article 4, letter (a)**, i.e. "medicinal products and medical devices"?

   Answer:
   Yes, under the TPA the understanding of this term is identical, cf. Article 2, para. 1, letter (a).

b. Does the understanding of "medicinal product" under your internal law correspond to that set out in **Article 4, letter (b)**, i.e. "medicines for human and veterinary use which may be:
   i. any substance or combination of substances presented as having properties for treating or preventing disease in humans or animals;
   ii. any substance or combination of substances which may be used in or administered to human beings or animals either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis;

[3] As envisaged in Art. 2 of the MEDICRIME Convention.

iii. an investigational medicinal product"?

Answer:
Yes, under the TPA the understanding of this term is the same, as it defines medicinal products as products "which are intended to have or are presented as having a medicinal effect on the human or animal organism, in particular in the diagnosis, prevention or treatment of diseases, injuries and handicaps"; cf. Article 4, para. 1, letter (a).

c. Does the understanding of "active substance" under your internal law correspond to that set out in **Article 4, letter (c)**, i.e. "any substance or mixture of substances that is designated to be used in the manufacture of a medicinal product, and that, when used in the production of a medicinal product, becomes an active ingredient of the medicinal product"?

Answer:
Yes, the understanding is the same (cf. Article 2, letter (a) MPLO) although the term "active substance" is not directly listed in the definitions of the TPA. It is covered by the term "medicinal product", which includes "ready-to-use medicinal products" as well as substances which are not yet ready-to-use.

d. Does the understanding of "excipient" under your internal law correspond to that set out in **Article 4, letter (d)**, i.e. "any substance that is not an active substance or a finished medicinal product, but is part of the composition of a medicinal product for human or veterinary use and essential for the integrity of the finished product"?

Answer:
Yes, the understanding is the same although there is no legal definition for "excipient".

e. Does the understanding of "medical devices" under your internal law correspond to that set out in **Article 4, letter (e)**, i.e. "any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software, designated by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, designated by the manufacturer to be used for human beings for the purpose of:
   i. diagnosis, prevention, monitoring, treatment or alleviation of disease;
   ii. diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap;
   iii. investigation, replacement or modification of the anatomy or of a physiological process;
   iv. control of conception;

   and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means"?

Answer:
Yes, cf. the legal definitions of “medical device” in Article 4, para. 1, letter (b) and para. 2 TPA in conjunction with Article 1 MedDO.

f. Does the understanding of “accessory” under your internal law correspond to that set out in **Article 4, letter (f)**, i.e. “an article which whilst not being a medical device is designated specifically by its manufacturer to be used together with a medical device to enable it to be used in accordance with the use of the medical device intended by the manufacturer of the medical device”?

Answer:
Yes, cf. the legal definition of “accessory” in Article 3, para. 1, letter (a) MedDO.

g. Do the understanding of “parts” and “materials” under your internal law correspond to that set out in **Article 4, letter (g)**, i.e. “all parts and materials constructed and designated to be used for medical devices and that are essential for the integrity thereof”?

Answer:
Yes, the understanding is the same although there is no legal definition for “parts and materials”.

h. Does the understanding of “document” under your internal law correspond to that set out in **Article 4, letter (h)**, i.e. “any document related to a medical product, an active substance, an excipient, a part, a material or an accessory, including the packaging, labelling, instructions for use, certificate of origin or any other certificate accompanying it, or otherwise directly associated with the manufacturing and/or distribution thereof”?

Answer:
Yes, the understanding of “document” corresponds to that set out in the Convention although there is no legal definition of the term.

i. Does the understanding of “manufacturing” under your internal law correspond to that set out in **Article 4, letter (i)**, i.e.
    i. “as regards a medicinal product, any part of the process of producing the medicinal product, or an active substance or an excipient of such a product, or of bringing the medicinal product, active substance or excipient to its final state;
    ii. as regards a medical device, any part of the process of producing the medical device, as well as parts or materials of such a device, including designing the device, the parts or materials, or of bringing the medical device, the parts or materials to their final state;
    iii. as regards an accessory, any part of the process of producing the accessory, including designing the accessory, or of bringing the accessory to its final state”?

Answer:
Yes. Under the TPA the understanding of “manufacturing” is similar, but in addition to the definition in the Convention it also includes storage and delivery of the end

products, quality controls and batch release. This applies to medicinal products, medical devices and accessories, cf. Article 2, para. 1, letter (c) TPA.

j. Does the understanding of "counterfeit" under your internal law correspond to that set out in **Article 4, letter (j)**, i.e. "a false representation as regards identity and/or source"?

Answer:
Yes, the understanding of "counterfeit" under the TPA corresponds to that set out in the Convention although there is no legal definition of the term. There is no need to complement the TPA accordingly, since counterfeiting includes illegal activities which are already defined in the TPA and are punishable by law, cf. Article 86, para.1, letter (g).

k. Does the understanding of "victim" under your internal law correspond to that set out in **Article 4, letter (k)**, i.e. "any natural person suffering adverse physical or psychological effects as a result of having used a counterfeit medical product or a medical product manufactured, supplied or placed on the market without authorisation or without being in compliance with the conformity requirements as described in Article 8"?

Answer:
Yes, the understanding of "victim" under Swiss law corresponds to that set out in the Convention, cf. Article 124 of the Federal Constitution of the Swiss Confederation ("Victim support").

Question 2: Non-discrimination

Is discrimination, on grounds such as the ones mentioned in the indicative list in **Article 2**, prohibited in the implementation of the Convention, in particular in the enjoyment of the rights guaranteed by it? If so, please specify. If not, please justify.

Answer:
Yes, as the principle of non-discrimination is enshrined in the Constitution, cf. Article 8 paragraph 2. The Constitution is the primary piece of legislation in the Swiss legal system, taking precedence over all the federal, cantonal and communal acts, ordinances and other enactments; these may not contradict the Constitution.

Question 3: Overview of the implementation

Please indicate (without entering into details):

a. the main legislative or other measures to combat counterfeiting of medical products and similar crimes involving threats to public health in accordance with the Convention;

Answer:
The main legislative measure has been an amendment of the TPA which came into force for the most part on January 1, 2019. This amendment was based on two

legislative projects, one of which was a regular revision of the TPA that was passed by the Swiss parliament in 2016, the other being the implementation of the Convention itself that was adopted in 2017. As the criminal provisions of the TPA had already been adapted in the course of the regular revision, in order to implement the Convention the Swiss legislator only had to make some further adjustments to the TPA and the CrimPC, such as granting Swissmedic and the FCA the authority to order certain covert surveillance measures (cf. Art. 90a TPA) as well as amending the respective articles in the CrimPC by inserting references to the criminal provisions of the TPA.
Other measures include prevention (cf. also question 13 and the answer thereto), training of officers of other authorities involved in enforcement against illegal medical products, training of healthcare professionals, public awareness-raising campaigns, regular publications regarding health risks when purchasing drugs from illegal sources, and ad hoc publications regarding specific dangerous illegal medicines.

b. whether your country has adopted a national strategy and/or Action Plan to combat counterfeiting of medical products and similar crimes involving threats to public health. If so, please specify the main fields of action and the body/bodies responsible for its/their implementation;

Answer:
Switzerland aims to be on the forefront of the countries combatting the counterfeiting of medicinal products. Accordingly, in 2002 Switzerland established the Swiss Agency for Therapeutic products (Swissmedic), which has the powers to prosecute counterfeiters of medical products on a national level. Since becoming operational, Swissmedic has not only been an active member of the PFIPC (and is currently represented on its management board), but also been involved in the CD-P-PH/CMED and acted as Chair or Vice-Chair for eight years. Additionally, Swissmedic has contributed to drafting the Convention and has hosted in 2010 an International Conference to promote the Convention.

c. If there has not been any adoption of a national strategy and/or Action Plan to combat counterfeiting of medical products and similar crimes involving threats to public health, whether there is a strategy and /or Action Plan by a particular Ministry or State Agency that leads on this nationally.

Answer:
See the answer to question 3 (b) above.

Question 4: National co-operation and information exchange

a. Please describe how co-operation and exchange of information is ensured between representatives of health authorities, law-enforcement (e.g. police and customs authorities) and other competent authorities in order to prevent and combat effectively the counterfeiting of medical products and similar crimes involving threats to public health (**Article 17, para. 1**);

Answer:

In accordance with the Convention and following the entry into force of the revised TPA on 1 January 2019, Swissmedic became the national SPOC according to Art. 69, para. 4 of the new legislation.

There is close cooperation between this national SPOC division and the Swissmedic penal division, which is responsible for prosecuting perpetrators of violations relating to the manufacture, supply and trafficking of illegal therapeutic products (cf. question 6 et seqq. below and the answers thereto). Violations in connection with the use and dispensing of therapeutic products fall under the jurisdiction of the cantonal prosecution authorities. Swissmedic's Penal Division, the OAG and the cantonal prosecuting authorities have a very close, active and efficient exchange of information, thus ensuring uniform prosecution of violations relating to the TPA throughout Switzerland. This exchange takes place on a case-by-case basis, but also in the form of training events.

Swissmedic has been developing and fulfilling the role of national SPOC for many years. Collaboration with the points of contact at the FCA, fedpol, cantonal public prosecutors and other stakeholders is well established. In addition to operational meetings of representatives of the Swissmedic SPOC, penal division, customs and fedpol, which are held bi-monthly, larger "Medicrime Meetings" of the national enforcement authorities are conducted on a yearly basis. Information flow is described in internal documents agreed by these authorities and is regularly re-evaluated.

b. Is any form of cooperation between the competent authorities and the commercial and industrial sectors promoted as regards risk management of counterfeit medical products and similar crimes involving threats to public health? (**Article 17, para. 2**)

Answer:

Yes, cooperation is promoted e.g.:

- by the website www.medicrime.ch (where reference is made to the Convention itself or to the obligation to report suspicion of illegal trading of therapeutic products)
  or
- through targeted presentations at relevant events (for example at the annual meeting of the industry association PSI, where Swissmedic drew attention to the statutory possibility of cooperation between the authorities and the private sector, and in particular to the possible exchange of confidential data on a case-by-case basis in order to uncover or combat suspected illegal trading in therapeutic products).

c. Which legislative or other structured measures have been taken to set up or strengthen mechanisms for:
   - 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? (**Article 17, para. 3, letter (a)**);

Answer:
Based on Article 17 of the Convention, the TPA has been partially amended by the following articles:

- Article 62b TPA ("Cooperation with the private sector"): Following due consideration of the interests concerned, Swissmedic and the FCA are entitled in specific cases to disclose confidential data gathered in accordance with this Act to the holder of an establishment licence or of a medicinal product authorisation or to any person who places a medicinal product on the market, including data enjoying special protection, provided such action is deemed necessary in order to detect and combat suspected illegal trading in therapeutic products.

- Article 59 TPA ("Mandatory notification, notification system and the right to notify"): Para. 3^{bis} of this Article contains a legal obligation to report any suspicion of illegal trading in therapeutic products. A corresponding reporting form has been drafted and is made available by Swissmedic.

- making available the information and data obtained by the health authorities, customs, police and other competent authorities for the co-operation between them? (**Article 17, para. 3, letter (b)**);

  Answer:
  The federal and cantonal authorities responsible for enforcing the TPA ensure mutual disclosure of the data insofar as this is necessary for enforcement within their respective competencies. This data disclosure is enabled by the TPA and other relevant Acts such as the ACLA.

d. Please indicate the persons, units or services in charge of this co-operation and information exchange in the field of the MEDICRIME Convention. Please indicate how they are trained for this purpose and how resources are secured for it/them (**Article 17, para. 4**);

Answer:
Swissmedic is the national central and contact point pursuant to Articles 17, paragraph 3, and 22, paragraph 2 of the Convention.

The contact (email) address is medicrime@swissmedic.ch; 24/7 accessibility by phone is ensured.

Responsibility for medicinal products lies with the Market Monitoring of Illegal Medicines unit and that for medical devices with the Medical Device Surveillance unit.

Regarding Article 17, para. 4, it can be confirmed that, within Swissmedic, the Head of Market Surveillance, who is also a Member of Swissmedic's Management Board, ensures adequate training and resources for these teams.

Question 5: International cooperation

a. Please indicate the national contact point responsible for transmitting and receiving requests for information and/or co-operation in connection with the fight against counterfeiting of medical products and similar crimes involving threats to public health (**Article 22, para. 2**).

Answer:
Swissmedic (with contact [email] address medicrime@swissmedic.ch) is the national central and contact point pursuant to Articles 17, para. 3, and 22, para. 2, of the Convention for medical products. Swissmedic maintains contacts with the designated contact points in other countries.

In case of criminal matters, requests for mutual legal assistance are addressed to the Federal Office of Justice, International Legal Assistance Division, unless there are corresponding international (mostly bilateral) agreements for the direct exchange of information between law enforcement authorities. Furthermore, Switzerland has also acceded to the European Convention on Mutual Assistance in Criminal Matters under which parties agree to afford each other the widest measure of mutual assistance with a view to gathering evidence, hearing witnesses, experts and prosecuted persons, etc.

b. Has your country integrated prevention and the fight against counterfeiting of medical products and similar crimes involving threats to public health in assistance programmes for development provided for the benefit of third states (**Article 22, para. 3**)? Please give examples.

Answer:
In programmes for promoting the development of third states there is no explicit inclusion of prevention and the fight against counterfeiting of medical products and similar crimes involving threats to public health. In Switzerland, this takes place within the framework of international organisations or bilateral relations. Examples are WHO regulatory training sessions hosted by Swissmedic and assistance in projects of the WHO MSM (member state mechanism) on substandard and falsified medical products.

IV. PROSECUTION OF PERPETRATORS OF COUNTERFEIT OF MEDICAL PRODUCTS AND SIMILAR CRIMES INVOLVING THREATS TO PUBLIC HEALTH

Question 6: Criminal Law offences

a. Please indicate whether the intentional conducts in the box below are considered criminal offences in internal law.

Answer:

Ad Article 5:

[1] The intentional manufacturing of counterfeit medical products constitutes a criminal offence in the form of a misdemeanour under Article 86, para. 1, letter (g) of the TPA as adopted by the Swiss Parliament on 18 March 2016. Accordingly, anyone who wilfully and unlawfully copies, falsifies or incorrectly names medicinal products or medical devices or places on the market, uses, imports or exports, or trades in a foreign country, unlawfully copied, falsified or incorrectly named medicinal products or medical devices, commits a misdemeanour and is liable to prosecution. According to Article 86, para. 2 TPA such acts are considered a felony if (letter (a)) the perpetrator knows or must assume that the violation specifically endangers human health or (letter (b)) achieves a high turnover or makes substantial profits through commercial activity. The same applies if the perpetrator acts as member of a gang involved in the illicit trade in therapeutic products, cf. Article 86, para. 3 TPA.

[2] As becomes clear from the wording of Article 86, para. 1, letter (g) TPA ("… copies, falsifies or incorrectly names …"), any adulteration of medicinal products or medical devices is also covered by this provision.

[3] Switzerland has not made a reservation in accordance with Article 5, para. 3, of the Convention.

Ad Article 6:

[1] Almost all of the activities mentioned in Article 6 of the Convention constitute criminal offences covered by Article 86 TPA. For the sake of clarity, however, the Swiss legislator has deemed it useful to specifically mention brokering activities under the term "distribution" as defined in Article 4, letter (e) TPA which itself is a narrower term for the term "placing on the market" mentioned in Article 86, para. 1, letter (g) TPA that, according to the definition in Article 4, para. 1, letter (d) TPA, encompasses "the distribution and dispensing of therapeutic products". With regard to the term "keeping in stock", such "immobile" activities may only be prosecuted in the case of medical products being manufactured (cf. the term "storage" in the definition of "manufacture" in Article 4, para. 1, letter (c) TPA), but not for the finalised products being traded after their initial release. Such activities may, however, be subject to prosecution on the basis of Article 155 SCC (cf. question 6 letter (c) and the answer thereto).

[2] Switzerland has not made a reservation in accordance with Article 6, para. 2, of the Convention.

Ad Article 7:

[1] The falsification of attestations or certificates issued by an authority or a conformity assessment body is covered by Article 28 TBTA, to which Article 88 TPA refers. Counterfeiting of packaging, markings or package leaflets is punishable as unlawful manufacturing, cf. Article 86, para. 1, letter (g) TPA. Pursuant to the TPA, the manufacture of therapeutic products is not limited to the production and composition of the chemical, biological, mechanical or electronic components serving as a basis, but also includes packaging, cf. Article 4, para. 1, letter (c).

[2] Switzerland has not made a reservation in accordance with Article 7, para. 2, of the Convention.

Ad Article 8:

This provision of the Convention concerns criminal offences in the form of intentional violations of national authorisation and compliance systems that endanger public health without referring to counterfeiting. Given that Article 8 does not require the Parties to change their systems of approval and compliance and that it does not contain any additional element compared to Swiss law, the latter did not require any adaptation. The respective activities were already illegal under Swiss Law before the Convention was adopted, cf. Article 86, para. 1, letter (a) TPA (formerly Article 86, para. 1, letter (b) TPA).

Ad Article 9:

The attempt to commit criminal offences under the TPA and ”participation in” (aiding or abetting or inciting) such offences are punishable under Swiss law with regard to felonies and misdemeanours pursuant to Articles 22, 24 and 25 of the Swiss Criminal Code (SCC). As mentioned above (cf. ad Art. 5), Art. 86 TPA, by which the Convention has been implemented, specifies misdemeanours in para. 1 and felonies in paras. 2 and3.

b. Do the offences in your internal laws require intentional conduct? If no, please provide information.

Answer:

Article 86 TPA, by which the Convention has been implemented, is not limited to intentional conduct. Pursuant to Article 86, para. 4 TPA, the perpetrator shall be liable to a monetary penalty or – in minor cases – a fine if he or she acts through negligence. According to Article 12, para. 3 SCC, a person commits a felony or misdemeanour through negligence if he or she fails to consider or disregards the consequences of his or her conduct due to a culpable lack of care. A lack of care is culpable if the person fails to exercise the care that is incumbent on him in the circumstances and commensurate with his personal capabilities.

c. Please highlight whether there are any other offences not included in the box below that involves counterfeit of medical products and similar crimes involving threats to public health in your country? Please provide their definitions and specify in which act these are included;

Answer:

The counterfeiting of goods in general is covered by Article 155 SCC. This states that anyone who, with a view to deceiving another in trade or business, manufactures a product which appears to have a higher commercial value than its true commercial value – in particular by being an imitation or counterfeit version of another product – or imports, stores or markets such a product is liable to prosecution (para. 1; according to para. 2 the perpetrator is liable to more severe punishment if he or she acts for commercial gain). This provision is applicable in addition to Article 86 TPA and Article 88 TPA in conjunction with Article 28 TBTA; however, it does not aim specifically to counter threats to public health but rather the pecuniary losses sustained by the purchase of falsified products.

Article 5 – Manufacturing of counterfeits

1 *Each Party shall take the necessary legislative and other measures to establish as offences under its domestic law, the intentional manufacturing of counterfeit medical products, active substances, excipients, parts, materials and accessories.*

2 *As regards medicinal products and, as appropriate, medical devices, active substances and excipients, paragraph 1 shall also apply to any adulteration thereof.*

3 *Each State or the European Union may, at the time of signature or when depositing its instrument of ratification, acceptance or approval, by a declaration addressed to the Secretary General of the Council of Europe, declare that it reserves the right not to apply, or to apply only in specific cases or conditions, paragraph 1, as regards excipients, parts and materials, and paragraph 2, as regards excipients.*

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

1 *Each Party shall take the necessary legislative and other measures to establish as offences under its domestic law, when committed intentionally, the supplying or the offering to supply, including brokering, the trafficking, including keeping in stock, importing and exporting of counterfeit medical products, active substances, excipients, parts, materials and accessories.*

2 *Each State or the European Union may, at the time of signature or when depositing its instrument of ratification, acceptance or approval, by a declaration addressed to the Secretary General of the Council of Europe, declare that it reserves the right not to apply, or to apply only in specific cases or conditions, paragraph 1, as regards excipients, parts and materials.*

Article 7 – Falsification of documents

1 *Each Party shall take the necessary legislative and other measures to establish as offences under its domestic law the making of false documents or the act of tampering with documents, when committed intentionally.*

2 *Each State or the European Union may, at the time of signature or when depositing its instrument of ratification, acceptance or approval, by a declaration addressed to the Secretary General of the Council of Europe, declare that it reserves the right not to apply, or to apply only in specific cases or conditions, paragraph 1, as regards documents related to excipients, parts and materials*

Article 8 – Similar crimes involving threats to public health

Each Party shall take the necessary legislative and other measures to establish as offences under its domestic law, when committed intentionally, in so far as such an activity is not covered by Articles 5, 6 and 7:

a the manufacturing, the keeping in stock for supply, importing, exporting, supplying, offering to supply or placing on the market of:

i medicinal products without authorisation where such authorisation is required under the domestic law of the Party; or

ii medical devices without being in compliance with the conformity requirements, where such conformity is required under the domestic law of the Party;

b the commercial use of original documents outside their intended use within the legal medical product supply chain, as specified by the domestic law of the Party.

Article 9 – Aiding or abetting and attempt

1 Each Party shall take the necessary legislative and other measures to establish as offences when committed intentionally, aiding or abetting the commission of any of the offences established in accordance with this Convention.

2 Each Party shall take the necessary legislative and other measures to establish as an offence the intentional attempt to commit any of the offences established in accordance with this Convention.

3 Each State or the European Union may, at the time of signature or when depositing its instrument of ratification, acceptance or approval, by a declaration addressed to the Secretary General of the Council of Europe, declare that it reserves the right not to apply, or to apply only in specific cases or conditions, paragraph 2 to offences established in accordance with Articles 7 and 8.

Question 7: Jurisdiction

With regard to the offences referred to in question 6, please indicate which jurisdiction rules apply. Please specify under which conditions, if required (**Article 10, Explanatory Report, paras. 69-78**).

Answer:
First, Article 10, para. 1, letter (a)–(c) of the Convention require(s) the Parties to establish their jurisdiction when the criminal offence is committed in their territory, on board a ship flying their flag or on board an aircraft registered in that country. The jurisdiction of the Swiss courts in such cases is derived from Article 3 SCC, Article 4, para. 2 Navigation Act and Article 97, para. 1 FAA, respectively.

Secondly, according to Article 10, para. 1, letter (d), and Article 10, para. 2 of the Convention, each Party shall also establish its jurisdiction where the perpetrator or victim of a crime committed abroad is one of its nationals or a person habitually resident in its territory. The basis for Swiss jurisdiction in the case of the commission of a crime by a Swiss national is Article 7, para. 1, letter (a) SCC. Swiss jurisdiction in the case of a Swiss victim is based on Article 7, para. 1 SCC, to which para. 2 refers. The SCC does not, however, provide for Swiss jurisdiction if the perpetrator or the victim of a crime committed abroad is merely habitually resident in Switzerland. Thus, Switzerland has made use of the possibility to make a

reservation provided for in Article 10, para. 4 of the Convention. For offences not committed in Switzerland, the Swiss courts will, as before, only have jurisdiction in cases where the offence was committed by or against a Swiss national.

Finally, the Parties must establish their jurisdiction when the alleged perpetrator of an offence committed abroad is present in their territory and is not extradited because of his or her nationality (cf. Article 10, para. 3 of the Convention). Switzerland complies with this obligation to prosecute in the event of non-extradition on the basis of Articles 6 and 7 SCC and the European Convention on Extradition of 13 December 1957. The rules for representative criminal prosecution by Switzerland are laid down in Article 85 et seqq. IMAC.

Question 8: Corporate liability

Does your system provide that a legal person may be held liable for an offence established in accordance with **Article 11**? Please specify under which conditions.

Answer:
According to Article 11 of the Convention, a legal person must be able to be held liable for offences under the Convention committed for its benefit by an executive within the company (para. 1). It must also be possible to hold a legal person accountable if lack of supervision or control has made it possible to commit such an offence (para. 2). The company's liability may be of a criminal, civil or administrative nature (para. 3) and does not affect the criminal liability of the natural person who committed the offence (para. 4).
The criminal liability of legal persons has been included in Swiss law since 1 October 2003 in Article 102 SCC. Para. 2 of this Article establishes primary responsibility for a limited number of types of offences if the legal person has not taken all necessary and reasonable organisational measures to prevent the offence. The crimes covered by the Convention, however, are not among the mentioned offences. At the same time, para. 1 provides for a subsidiary criminal liability (fine of up to five million Swiss francs) of a legal person in cases where an offence cannot be attributed to any natural person due to the legal person's organisational shortcomings. This subsidiary criminal liability encompasses all felonies and misdemeanours under Swiss law and, thus, includes all offences covered by the Convention. It concerns offences committed by a person in the course of business activities in the context of the legal person's/company's purpose and goes beyond the offences contained in the Convention, which is limited to offences committed for the benefit of a legal person by its executive personnel as defined in Article 11, para. 1, of the Convention. Taking into consideration that, on the one hand, a legal person may in principle only be punished according to Article 102, para. 1 SCC if the offence cannot be attributed to a natural person, and that, on the other hand, according to Article 11, para. 4, of the Convention, the criminal liability of legal persons must not affect that of natural persons, the question arises whether this provision obliges the states to introduce parallel criminal liability. The Explanatory Report to the Convention does not give any details in this regard. The subsidiary liability of legal persons under Swiss law does not, however, exclude the criminal liability of natural persons: If the conduct and culpability of the perpetrator are established after the conviction of the legal person and the offence could not previously have been attributed to him or her because of the legal person's organisational shortcomings, the punishment of both parties, i.e. the legal and the natural person, is conceivable. Moreover, Art. 7 ACLA provides for a special system of

penalties that applies both in cases that fall within the competence of the federal authorities, cf. Article 90, para. 1 TPA, and in those that fall within the competence of the cantons, cf. Article 89, para. 2 TPA in conjunction with Article 90, para. 3 TPA. Based on Article 89, para. 1 TPA a fine of up to 20,000 Swiss francs may be imposed on a legal person if the investigation of the natural persons working in the company would require disproportionate investigative measures in relation to the expected penalty. In this case, only the company is fined.
In addition to criminal liability, the TPA also provides for administrative liability for preventive purposes. According to Article 66 TPA, Swissmedic and the cantons may, within the scope of their competences, take all administrative measures necessary for the enforcement of the law. This ranges from lodging an objection to the revocation of operating licences or the recall of a therapeutic product from the market. Besides, companies that pursue immoral or illegal purposes cannot obtain legal personality. They are dissolved and their assets are transferred to the community (cf. Articles 52 and 57 of the Civil Code). If an executive commits a criminal offence for the benefit of a company or violates his or her duty of supervision by failing to prevent the commission of such an offence by a subordinate or subordinates, the company may be held liable under civil law.

Question 9: Sanctions and measures

a. Please indicate which sanctions internal law provides for the criminal offences established in accordance with the Convention with regard to both natural and legal persons. Please specify whether the sanctions are criminal, civil and/or administrative sanctions (**Article 12, Explanatory Report, paras. 84-91**);

   Answer:
   Article 12, para. 1, requires Parties to ensure that the offences established in the Convention are punishable by effective, proportionate and dissuasive sanctions, including monetary sanctions and imprisonment, which may give rise to extradition. The misdemeanours contained in Article 86, para. 1 TPA carry a custodial sentence of up to three years or a monetary penalty, whereas the felonies contained in Article 86, para. 2 and 3 TPA may be punished with custodial sentences of up to ten years that may be combined with a monetary penalty. If the perpetrator acts through negligence, Article 86, para. 4 TPA allows for a monetary penalty or – in minor cases – a fine. Accordingly, with the exception of the latter cases, extradition is possible in any event, whether in application of the European Convention on Extradition or other relevant treaties binding on Switzerland.
   Article 12, para. 2, requires that legal persons held liable pursuant to Article 11 shall also be subject to effective, proportionate and dissuasive sanctions, including monetary sanctions. The sanction measures under Swiss law for legal persons have been explained above (cf. question 8 and the answer thereto).
   Article 12, para. 3, of the Convention requires the Parties to permit the seizure and confiscation of the instrumentalities for the commission of the offences and of the proceeds of such offences or of property corresponding to the value of such proceeds. Furthermore, Parties must take the necessary measures to permit the destruction of confiscated objects and to take other appropriate measures to prevent future offences. These measures are all provided for by the SCC. Under Article 69, para. 1, the court orders the confiscation of objects used to commit or produced by an offence if these

objects endanger the safety of persons. The Court of First Instance may order the destruction of confiscated property. Based on Article 70 SCC, assets may be confiscated that have been obtained through a criminal act or that were intended to induce or reward a criminal act. Under Article 71 SCC, the court recognises a governmental claim for compensation for the same amount. In addition, the SCC provides in particular for the possibilities of prohibiting the profession (Article 67), publication of the judgment (Article 68) and entry in the register of criminal convictions (Article 365).

b. Which legislative or other measures have been taken to provide for the possibility of taking into account final sentences passed by another Party in relation to the offences established in accordance with the Convention? Please provide details and describe any good practice resulting from the taking of these measures (**Article 14, Explanatory Report, paras. 100-105**).

Answer:
Article 47 SCC enables the Swiss courts to take into account criminal judgments handed down by another Party. Pursuant to this provision, the court determines the sentence according to the culpability of the offender. It takes account of the previous conduct and the personal circumstances of the perpetrator as well as the effect that the sentence will have on her or his life (para. 1). Culpability is assessed according to the seriousness of the damage or danger to the legal interest concerned, the reprehensibility of the conduct, the perpetrator's motives and aims, and the extent to which the perpetrator, in view of the personal and external circumstances, could have avoided causing the danger or damage (para. 2).

Question 10: Aggravating Circumstances

Please indicate which of the circumstances referred to in **Article 13**, 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 internal law, be taken into consideration in your legal system as aggravating circumstances in the determination of the sanctions in relation to the offences established in accordance with this Convention (**Explanatory Report, paras. 92-99**).

Answer:
The circumstances referred to in Article 13 of the Convention must be taken into account by the Swiss courts under Article 47 SCC (cf. also question 9 and the answer thereto). In the event of circumstances according to Article 13, letter (a) (endangerment of life and health), the penalty under the SCC is determined according to the severity of the violation. The abuse of trust according to Article 13, letters (b) and (c), indicates that the perpetrator acted with special knowledge and volition, which must be taken into account when assessing the penalty under Article 47, para. 2 SCC. The use of opportunities for large-scale distribution, Article 13, letter (d), speaks in favour of the intention to conduct business on a large scale and thus endanger a large number of people. This is also an element which increases fault under Article 47, para. 2 SCC. The commission of the offence within the framework of a criminal organisation, Article 13, letter (d), constitutes an offence in itself, which can be taken into account as an aggravating factor when determining the "concurrence of laws" (Article 260ter

SCC). Repeated offences, Article 13, letter (f), have always been taken into account in the assessment of penalties under Swiss law, cf. Article 47, para. 1 SCC.

Question 11: Investigations and criminal measures

a. Which legislative or other measures have been taken to ensure that investigations or prosecutions of offences established in accordance with the Convention shall not be subordinate to a complaint and that the proceedings may continue even if the victim has withdrawn his or her statement? (**Article 15, Explanatory Report, para. 106**).

Answer:
Criminal acts against life and limb under the SCC as well as under Article 86 and Article 87 TPA are prosecuted ex officio (cf. Article 30 et seq. SCC).

b. Please indicate the persons, units or services or other formalised or agreed arrangements in charge of criminal investigations in the field of MEDICRIME Convention. Please indicate how specialisation in this field is achieved and how resources are secured for it/them (**Article 16, para. 1, Explanatory Report, paras. 107-110**).

Answer:
The main actors in criminal proceedings in the therapeutic products sector in Switzerland are currently Swissmedic, the FCA, fedpol and the cantonal prosecution and police authorities. According to Article 20, para. 1 ACLA, the staff of Swissmedic and of the FCA who are entrusted with interrogations, inspections and coercive measures must be specially trained. Swissmedic has the specific expertise in the field of therapeutic products (especially scientific evaluation of preparations, laboratory analyses); should it require specific expertise in IT and financial matters, Article 90c TPA allows for external specialists to be called in as assistants for the safeguarding, evaluation and storage of extensive electronic data stocks. The FCA already has the specialist knowledge required by the Convention in the field of financial investigations and IT, as well as in the securing of assets and electronic data. The cantonal prosecution and police authorities as well as fedpol can rely on their experience in the field of narcotics, since the investigation methods used and problems are similar to those in the therapeutic products sector (search for products, investigation of financial flows). The cantonal authorities can rely on the knowledge of the cantonal health authorities. In addition, the actors involved cooperate and exchange their experiences.

c. Please describe under which circumstances carrying out financial investigations, the use of covert operations, of controlled delivery and of other special investigative techniques by authorities is allowed in relation to the investigation of the offences established in accordance with the Convention (**Article 16, para. 2**).

Answer:
The procedures carried out by Swissmedic and the FCA are subject to the ACLA, while

those carried out by the criminal authorities of the cantons or the Confederation are subject to the CrimPC. These two procedural laws enable the persons responsible for the investigation to use all the classic investigative measures (including interrogations, searches, seizures, requests for information, involvement of experts). They also provide for secret surveillance measures such as observations, fictitious purchases, the monitoring of postal and telecommunications traffic and undercover investigations. Whereas observations and undercover enquiries may be ordered under the premise that there is reason to believe on the basis of specific information that felonies or misdemeanours have been committed and the enquiries would otherwise have no prospect of success or be made unreasonably complicated (observation, cf. Article 282, para. 2 CrimPC; with regard to procedures carried out by Swissmedic and the FCA, cf. also Article 90a, para. 1 TPA)/it is suspected that a felony or misdemeanour has been committed and previous enquiries or investigations have been unsuccessful or the enquiries would otherwise have little prospect of success or would be made disproportionately more complex (undercover enquiries, cf. Article 298b, para. 1 CrimPC; with regard to procedures carried out by Swissmedic and the FCA cf. also Article 90a, para. 1 TPA), covert surveillance measures such as the surveillance of post and telecommunications (cf. Article 269 et seqq. CrimPC) or of banking transactions (cf. Article 284 et seqq. CrimPC) additionally require the authorisation of the compulsory measures by the court. If the procedures are carried out by Swissmedic or the FCA, the OAG must additionally be notified before application to the compulsory measures court, cf. Article 90a, para. 4 TPA. If the court approves the measures, the OAG takes over the proceedings from Swissmedic or the FCA and conducts them on the basis of the CrimPC, cf. Article 90a, para. 5 TPA.

Question 12: Measures of protection for the victim

a. Please describe the measures taken to (**Article 19**):
   - ensure that victims have access to information relevant to their case and which is necessary for the protection of their health;
   - assist victims in their physical, psychological and social recovery;
   - provide for the right of victims to compensation from the perpetrators.

Answer:

Persons injured by counterfeit therapeutic products have the status of victims within the meaning of the CrimPC and the VSA if their physical or psychological integrity has been directly affected.

Victims within the meaning of the CrimPC, but also other persons (e.g. property owners), can participate in criminal proceedings as criminal or civil private claimants and thus also gain access to information on the proceedings against the perpetrator. With regard to the administrative criminal proceedings conducted by Swissmedic and the FCA, the ACLA does not grant any victims' rights. The reporting person is, however, entitled to take note of the judgement. The FoIA also provides for the possibility of inspecting the files after the conclusion of administrative proceedings (but not of criminal proceedings, to which other rules apply, cf. answer to question 13, letter (c), below).

Under liability law, the injured parties can demand compensation and satisfaction from the perpetrator; the claims can also be asserted as a party in criminal proceedings conducted under the CrimPC. In addition, in administrative criminal proceedings it is possible to have confiscated assets transferred to the aggrieved parties (Article 2 ACLA in connection with Article 73 SCC, also cf. Article 92 ACLA).

The benefits under the VSA (advice and assistance, compensation and satisfaction) are not linked to criminal proceedings or conviction. The perpetrator need not be known. Victim assistance benefits are granted in a subsidiary manner to those provided by the perpetrator, private insurance and social security (Article 4 VSA).

b. Please describe the measures taken to inform victims of their rights, the services at their disposal, the follow-up given to their complaint, the charges, the general progress of the investigation or proceedings, and their role as well as the outcome of their cases (**Article 20, para. 1, letter (a) and para. 2**).

Answer:
Pursuant to Article 305, para. 1 CrimPC, the police and the public prosecutor shall inform the victim in full at their first examination hearing of his or her rights and obligations in the criminal proceedings (the same applies correspondingly for the main hearing, cf. Article 330, para. 3 CrimPC). According to Article 305, para. 2 CrimPC, they shall at the same time inform the victim of (letter (a)) the addresses of and services provided by victim counselling services, (letter (b)) the possibility of claiming various victim support benefits, (letter (c)) the time limit for the filing of claims for damages and satisfaction, (letter (d)) the right under Article 92a SCC to request information on the decisions and circumstances of the execution of penalties and measures in relation to the offender. Article 305, para. 3 CrimPC holds that if the victim agrees, they shall pass his or her name and address on to a counselling service, whereas Article 305, para. 4 CrimPC extends paragraphs 1 to 3 to the relatives of the victim. Finally, Article 305, para. 5 CrimPC determines that confirmation that the provisions of Article 305 CrimPC have been complied with must be recorded in the case file.
With regard to the administrative criminal proceedings conducted by Swissmedic and the FCA, cf. question 12, letter (a), and the answer thereto.

c. Please also indicate which measures have been taken to enable the victim to be heard, to supply evidence and to choose the means of having his/her views, needs and concerns presented, directly or through an intermediary, and considered (**Article 20, para. 1, letter (b)**);

Answer:
Pursuant to Article 107, para. 1 CrimPC, the parties have the right to be heard; in particular they have the right to (letter (a)) inspect case documents, (letter (b)) participate in procedural acts, (letter (c)) appoint a legal agent, (letter (d)) comment on the case and on the proceedings and (letter (e)) request that further evidence be taken. According to Article 107, para. 2 CrimPC, the criminal justice authorities shall notify parties who are unaware of the law of their rights. Parties are the accused, the public prosecutor (in the main hearing and in appellate proceedings) and the private claimant,

cf. Article 104, para. 1, letters (a) to (c) CrimPC. A private claimant is a person suffering harm who expressly declares that he or she wishes to participate in the criminal proceedings as a criminal or civil claimant, cf. Article 118, para. 1 CrimPC.

With regard to the administrative criminal proceedings conducted by Swissmedic and the FCA, cf. question 12, letter (a), and the answer thereto.

d. What kind of support services are provided to victims so that their rights and interests are duly presented and taken into account? (**Article 20, para. 1, letter (c)**)

Answer:
As mentioned above, victims may appoint a legal agent who represents their interests, cf. also Article 127 CrimPC. Additionally, Article 117, para. 1 CrimPC grants victims special rights, in particular (letter (a)) the right to protection of personal privacy, (letter (b)) the right to be accompanied by a confidant, (letter (c)) the right to protective measures, (letter (d)) the right to remain silent, (letter (e)) the right to information and (letter (f)) the right to a special composition of the court.

For support granted based on the VSA, cf. below. With regard to the administrative criminal proceedings conducted by Swissmedic and the FCA, cf. question 12, letter (a), and the answer thereto.

e. Please describe the measures taken to provide the safety of the victims, their families and witnesses from intimidation and retaliation (**Article 20, para. 1, letter (d)**);

Answer:
As has been mentioned, Article 117, para. 1, letter (c) CrimPC grants victims the right to protective measures. The general measures to protect victims are described in Article 152 CrimPC. Pursuant to this provision, the criminal justice authorities shall safeguard the personal privacy of the victim at every stage of the proceedings; cf. para. 1. The victim may be accompanied at all procedural hearings by a confidant in addition to his or her legal agent, cf. para. 2. The criminal justice authorities shall ensure that the victim does not encounter the accused if the victim so requests. In such a case, they shall take account of the accused's right to be heard in some other way. In particular, they may question the victim while applying protective measures in accordance with Article 149, para. 2, letter (b) and (d) CrimPC, cf. para. 3. Article 149, para. 2, letter (b) CrimPC enables the director of proceedings to suitably restrict the procedural rights of the parties by conducting examination hearings while excluding parties or the public, whereas Article 149, para. 2, letter (d) CrimPC allows for modification of the appearance or the voice of the person requiring protection or screening the person from the court. Finally, pursuant to Article 152, para. 4 CrimPC a confrontation hearing may be ordered if (letter (a)) the accused's right to be heard cannot be guaranteed in any other way or (letter (b)) the hearing is essential for the purpose of the prosecution.
With regard to the administrative criminal proceedings conducted by Swissmedic and the FCA, cf. question 12, letter (a), and the answer thereto.

f. Please specify under which conditions victims of the offences established according to the Convention have access to legal aid provided free of charge (**Article 20, para. 3**).

Answer:
Legal aid may be provided free of charge if the private claimant does not have the means to pursue her or his civil claims and the civil action is not hopeless; cf. Article 136, para. 1 CrimPC. If these requirements are met, the private claimant is released from advance payments and security deposits as well as from procedural costs; cf. Article 136, para. 2 letter (a) and (b) CrimPC; for the cases of bail and security deposits, cf. Article 125, Article 184, para. 7, Article 313, para. 2, Article 316, para. 4 and Article 383 CrimPC. If she or he is in need of support for the enforcement of civil claims, legal aid is also granted. The application is dealt with by the director of the respective proceedings, in preliminary proceedings (criminal investigation) by the public prosecutor's office, and in court proceedings by the president of the instance dealing with the case, cf. Article 137 in conjunction with Articles 133 and 61 CrimPC. As a general rule, the costs of free representation are borne by the State, which may pass them on to the accused if the latter has the financial means to bear them, cf. Article 426, para. 4 CrimPC. If the private claimant is awarded damages at the expense of the accused (cf. Article 433 CrimPC), these must be refunded to the Confederation or the canton to the extent that the Confederation or the canton has compensated the legal aid, cf. Article 138, para. 2 CrimPC. An additional claim for the costs of legal aid against the private claimant is possible, provided that the latter is ordered to pay the costs under Article 427 CrimPC and her or his financial situation has improved, cf. Article 138 in conjunction with Article 135, para. 4 CrimPC.
Additionally, the VSA also grants the right to support, cf. Article 1, para. 1. The victim's spouse, children, parents and other persons who are similarly close to the victim are also entitled to victim support as relatives, cf. Article 1, para. 2 VSA. According to Article 14, para. 1 VSA, financial victim support includes, among other things, appropriate legal assistance that has become necessary as a result of the offence. Legal fees can be paid either as immediate assistance (cf. Article 13, para. 1 VSA) or as cost contributions for longer-term assistance from third parties (cf. Article 13, para. 3 in conjunction with Article 16 VSA).
With regard to the administrative criminal proceedings conducted by Swissmedic and the FCA, cf. question 12, letter (a), and the answer thereto.

g. Which legislative or other measures have been taken to ensure that victims of an offence established in accordance with the Convention in the territory of a Party other than the one where they reside may make a complaint before the competent authorities of their state of residence? (**Article 20, para. 4, Explanatory Report, para. 128**).

Answer:
There is no legally binding possibility to make a complaint before Swiss authorities if the offence has been committed outside of Switzerland.

There are, however, victim counselling services in every Swiss canton that provide support and advice to victims of crime abroad on questions of victim assistance. In any

case, the victim counselling services will inform the victims where and how they can get help.

Furthermore, Swiss citizens who have been victims abroad receive immediate support from the Swiss representation abroad (consulate/embassy). A helpline of the Federal Department of Foreign Affairs (FDFA) guarantees immediate support (24/7).

h. Please describe how your internal law allows for groups, foundations, associations or governmental or non-governmental organisations assisting and/or supporting victims to participate in legal proceedings (for example, as third parties) (**Article 20, para. 5**). Please specify under which conditions, if so required;

Answer:
As under Swiss law parties to criminal proceedings conducted under the CrimPC are the accused, the public prosecutor (in the main hearing and in appellate proceedings) and the private claimant (cf. Article 104, para. 1, letters (a) to (c) CrimPC), groups, foundations, associations or governmental or non-governmental organisations assisting and/or supporting victims cannot participate in legal proceedings as third parties. A representative of such a group may, however, act as the victim's legal agent (if he or she is an attorney registered in a cantonal attorney's register or as an EU lawyer) or accompany her or him as a confidant in addition to her or his legal agent (cf. Article 152, para. 2 CrimPC).

With regard to the administrative criminal proceedings conducted by Swissmedic and the FCA, cf. question 12, letter (a), and the answer thereto.

V. PREVENTION OF COUNTERFEITING OF MEDICAL PRODUCTS AND SIMILAR CRIMES INVOLVING THREATS TO PUBLIC HEALTH

Question 13: Ensure quality and safety requirements of medical products, awareness raising and training

a. Which legislative or other measures have been taken to establish the quality, efficacy and safety requirements of medical products? (**Article 18 para. 1, Explanatory Report, para. 113**)

Answer:
The main legislative measure is the TPA itself, which in Article 1, para. 1, defines as its purpose to protect human and animal health and to guarantee that only high quality, safe and effective therapeutic products are placed on the market. The TPA and its accompanying ordinances constitute a comprehensive regulatory framework which includes manufacturing and market surveillance of medical products.

b. Which legislative or other measures have been taken to ensure the safe distribution of medical products? (**Article 18 para. 2**)

Answer:
The main legislative measure is, once again, the TPA itself (cf. above). The TPA and its accompanying ordinances constitute a comprehensive regulatory framework covering the supply chain, including distribution, dispensing and advertising of medical products.

c. Which measures have been taken to provide for (**Article 18 para. 3 letters a and c, Explanatory Report, para. 114**):
   - training of healthcare professionals, providers, law-enforcement (including police and customs authorities), as well as other relevant authorities and civil society?
   - the prevention of illegal supplying of counterfeit medical products, active substances, excipients, parts, materials and accessories?

   Answer:
   Swissmedic provides a variety of targeted information primarily on its website www.swissmedic.ch (fact sheets etc.). Furthermore, presentations are given to targeted groups, e.g. healthcare professionals or law-enforcement officials. Close cooperation is ensured with customs authorities to conduct targeted market surveillance campaigns (incl. training) and regular training of customs officers is provided. Regulations are in place for ensuring a strong and properly controlled legal supply chain. Furthermore, market surveillance and inspection procedures have been established to verify that the manufacture, distribution, dispensing and presentation of therapeutic products are in accordance with the TPA.

d. Which policies or strategies have been implemented to promote or conduct awareness-raising campaigns targeted at the general public where the focus is directed especially towards the risks and realities of the counterfeiting of medical products and similar crimes involving threats to public health? Please describe the material used for the campaign/programme and its dissemination. If possible, please provide an assessment of the impact of the campaign/programme. If there are currently plans for launching a (new) campaign or programme, please provide details (**Article 18, para. 3 letter b**);

Answer:
Swissmedic is a member of the Swiss public-private partnership STOP PIRACY. Within the framework of this association, regular public awareness-raising campaigns are implemented with financial support from Swissmedic and other members. Often intelligence and data of seizures of illegally imported medicines are used for such campaigns. Campaigns are launched regularly. An example of such a campaign can be found under www.shady-past.ch . Currently a digital campaign on social media is being planned by STOP PIRACY (including other branches suffering from falsifications and piracy) and a media event with destruction of illegally imported medicines and other goods is planned for 2021. Switzerland (FCA and Swissmedic) has participated in all 13 PANGEA operations and plans to do so in the future (these operations are

conducted worldwide with the aim of protecting public health, raising public awareness and disrupting the activities of organised criminal networks distributing illicit pharmaceuticals online). Furthermore, Swissmedic implements targeted market surveillance actions followed by awareness campaigns or other appropriate information for the general public. Measures to combat the illegal supply of medical products are published in specific cases in order to prevent and deter other potential illegal suppliers.

Pursuant to Article 30, para. 3, of the Constitution, delivery of judgments must be public. According to the Federal High Court of Switzerland, this constitutional rule also applies to written orders of punishments, i.e. access to such orders must be given to every interested individual. Prosecutors (especially Swissmedic) grant the possibility of inspecting such orders that have been rendered on the basis of the criminal provisions of the TPA (but not the file of the cases itself) on a regular basis after these orders have either become final or have been brought to court. Journalists frequently make use of this service and publish articles in media about such cases of pharmaceutical crime. This may raise public awareness of the problem of counterfeit medical products.