The MEDICRIME Convention
La Convention MÉDICRIME

COUNCIL OF EUROPE
CONSEIL DE L'EUROPE

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**)

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

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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

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"?

Yes. In our national law there is a definition for medicines for human use and veterinary use (Law of the 25th of March 1964 on medicines article 1,§1,1)
and a definition for medical devices (Royal Decree of the 18th of March 1999 on Medical Devices article 1,§2,1° ; this Royal Decree refers to the law on Medicines.)

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;
iii. an investigational medicinal product"?

Yes. The point i. and ii. are part of the definition of a medicine for human or veterinary use (See the Law of 25 of March 1964 on medicines article 1,§1,1).The IMPs are considered medicines as well, but are the focus of a different legislation because IMPs usually don't have a authorization to be put on the market. The Law of the 7th of May 2004 concerning experiments refers in article 2, 18° to the definition of a medicine which can be found in Law of 25 of March 1964 on medicines article 1,§1,1.

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

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”?

Yes. The definition of an active substance can be found in the Law of 25th of March 1964 on Medicines in article 1,§1, 2bis.

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”?

Yes. (See article 1,§1,2ter of the Law of the 25th of March 1964 on medicines)

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”?

Yes. (Royal Decree of the 18th of March 1999 on Medical Devices article 1,§2, Royal Decree of the 15th of July 1997 on active implantable medical devices article 1,§1, Royal Decree of the 14th of November 2001 on medical devices for in-vitro diagnostics article 1,§2)

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”?

Yes. (Royal Decree of the 18th of March 1999 on Medical Devices article 1,§2, Royal Decree of the 15th of July 1997 on active implantable medical devices article 1,§1, Royal Decree of the 14th of November 2001 on medical devices for in-vitro diagnostics article 1,§2)

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”?
Yes. (Royal Decree of the 18th of March 1999 on Medical Devices article 1,§2, Royal Decree of the 15th of July 1997 on active implantable medical devices article 1,§1, Royal Decree of the 14th of November 2001 on medical devices for in-vitro diagnostics article 1,§2)

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, labeling, instructions for use, certificate of origin or any other certificate accompanying it, or otherwise directly associated with the manufacturing and/or distribution thereof”?
Yes. In the Law of 25th of March 1964 on Medicines and the Royal Decree of the 14th of December 2006 all documents that are needed are listed.

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;
    Yes. See annex I of the Royal Decree of the 14th of December 2006 (Analytical, pharmacological-toxicological and clinical standards and protocols for the control of medicines) and annex 4 (GMP guidelines)
    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;
    Yes. (Royal Decree of the 18th of March 1999 on Medical Devices article 1,§2, Royal Decree of the 15th of July 1997 on active implantable medical devices article 1,§1, Royal Decree of the 14th of November 2001 on medical devices for in-vitro diagnostics article 1,§2)
    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”?
    Yes. (Royal Decree of the 18th of March 1999 on Medical Devices article 1,§2, Royal Decree of the 15th of July 1997 on active implantable medical devices article 1,§1, Royal Decree of the 14th of November 2001 on medical devices for in-vitro diagnostics article 1,§2)

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”?
We use the term falsified since counterfeit has a tendency to be interpreted as an infraction on IPR. The definition of a falsified medicine in the law of the 25th of March 1964 on medicines is the same as the definition of a falsified medicine in the Falsified Medicines Directive 2011/62 :
“Any medicinal product with a false representation of:
(a) its identity, including its packaging and labelling, its name or its composition as regards any of the ingredients including excipients and the strength of those ingredients;

(b) its source, including its manufacturer, its country of manufacturing, its country of origin or its marketing authorisation holder; or
(c) its history, including the records and documents relating to the distribution channels used".
This definition does not include unintentional quality defects and is without prejudice to infringements of intellectual property rights.';
So we include the falsification of documents in the definition of a falsified medicine.

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"?

In the Belgian Code of Criminal Procedure of 17 April 1878 itself we do not find a definition of the victim. But, It is generally believed that the victim is any person, and their relatives, who have suffered material, physical and / or moral damage as a result of an act that is punishable by criminal law.

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.

Yes, look at:

- Law of 10 May 2007 to combat certain forms of discrimination of 10 May 2007 (Anti-Discrimination Act)
- The Law of 10 May 2007 to combat discrimination between men and women (the Gender Act).
- The Law of 10 May 2007 adapting the Judicial Code to the legislation to combat discrimination and to punish certain acts motivated by racism or xenophobia (Racism Law).
- Belgian Criminal Code of 8 june 1867

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;
    - The Law of the 25th of March 1964 on medicines
    - Belgian Criminal Code of 8 june 1867
    - Belgian Preliminary Title of the Code of Criminal Procedure of 17 April 1878
    - Belgian Code of Criminal Procedure from 17 November 1808

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;

The Pharma-& Food Crime Platform is a platform consisting of representatives from the Federal Agency of Medicines and Health Products, the Federal Agency for the Safety of the Food chain, Customs, the Ministry of Health and the federal police (internal affairs). This is an operational platform where information is shared about different cases. Every 2 weeks they meet and discuss plans of action.

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.

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**);
The Pharma-& Food Crime Platform : this platform ensures national exchange of information and cooperation between health authorities, Customs and the police.
The Federal Agency for Medicines and Health Products has appointed a focal point for WHO, a SPOC for Medicrime and a SPOC for WGEO. These SPOCs ensure the exchange of information internationally.

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**)
Yes. The FAMHP has created a Rapid Alert system to alert the industry when (suspected or confirmed falsifications of medicines have been found. This system is also used to alert the industry of thefts of medicines.
And the Falsified Medicines Directive has made it mandatory for the industry to put up a system to make it easier to detect falsified medicines within the legal supply chain.

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)**);
     The Rapid Alerts System mentioned under question 4b.

   - 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)**);
     The Pharma-& Food Crime Platform mentioned in point 4a.

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**);
The FAMHP has a Special investigation unit. This unit consist of inspectors with a medical/pharmaceutical degree which are then trained in enforcement.

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**).
Special Investigation Unit

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.

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.

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

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;

Article 5 – Manufacturing of counterfeits ***Yes***

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 Yes

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 Yes

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 Yes

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 Yes

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**).

The Belgian jurisdiction rules can be found in article 3 and 4 of the Belgian Criminal Code of 8 June 1867:

- Art. 3. The crime committed on the territory of the Reich by Belgians or by foreigners is punished in accordance with the provisions of Belgian law.
- Art. 4. The crime committed outside the territory of the Kingdom by Belgians or by foreigners will not be punished in Belgium other than in the cases determined by law.

And the Belgian Preliminary Title of the Code of Criminal Procedure of 17 April 1878:

- Chapter II. Criminal action for crimes or crimes outside the territory of the empire (Art. 6-10, 10bis, 10ter, 10quater, 11-12, 12bis, 13-14)

For example:

Art. 7. § 1. Any Belgian or person with principal residence in the Reich who, outside the territory of the Reich, is guilty of an offense called a crime or offense under Belgian law, can be prosecuted in Belgium if the offense is stipulated by the law of the country where it was committed.

§ 2. If the crime has been committed against a foreigner, the prosecution can only take place at the request of the Public Prosecution Service and, moreover, it must be preceded by a complaint from the aggrieved foreigner or from his family or by an official message to the Belgian authorities. given by the government of the country where the crime was committed.

If the offense was committed in wartime against a national of a country that is an ally of Belgium within the meaning of Article 117, second paragraph, of the Criminal Code, the official message can also be given by the government of the country of which that foreigner is a national. is or was.

Art. 10. A foreigner, except for those referred to in Articles 6 and 7, § 1, can be prosecuted in Belgium if he commits himself outside the territory of the Reich:
5 ° To a crime against a Belgian national, if the offense is punishable under the law of the country where it was committed with a punishment exceeding five years of deprivation of liberty.

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.

Yes. The Criminal Code article 5 says that 'A legal person may be held liable for offences that are either intrinsically linked to its purpose or its interest, or which are committed on its behalf as evidenced by the specific circumstances.

The liability of legal persons does not exclude that of natural persons who are perpetrators of the same acts or who have participated in them.

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**);
   - *Manufacturing of counterfeits : law of the 25th of March 1964 on Medicines article 16 (medicines) and 16bis (medical devices) -> criminal sanction*
   - *Supplying, offering to supply, and trafficking in counterfeits : law of the 25th of March 1964 on Medicines article 16 and 16bis (medical devices) -> criminal sanction*
   - *Falsification of documents : law of the 25th of March 1964 on Medicines article 16*
   - *Similar crimes involving threats to public health : law of the 25th of March 1964 on Medicines article 16 and 16bis (medical devices) -> criminal sanction*
   - *Aiding or abetting and attempt : law of the 25th of March 1964 on Medicines article 19 (the same sanctions as in article 16 and 16bis) -> criminal sanction*
   - *Confiscation : law of the 25th of March 1964 on Medicines article 14*

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**).
   - *law of the 25th of March 1964 on Medicines article 18, §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**).

Article 16ter of the Law of 25th of March on Medicines lists the aggravating circumstances in which cases the sanctions are doubled :

- *the offence caused the death of, or damage to the physical or mental health of, the victim;*
- *the offence was committed by persons abusing the confidence placed in them in their capacity as professionals, manufacturers or suppliers;*

- *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;*
- *the offence was committed in the framework of a criminal organisation;*
- *the perpetrator has previously been convicted of offences of the same nature.*

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**)

See also the answer to question 7.

Article 2 of the Belgian Preliminary Title of the Code of Criminal Procedure of 17 April 1878, states that where the law provides that the exercise of criminal proceedings is conditional on a complaint from the aggrieved party, the proceedings cannot proceed if that party withdraws its complaint before any act of prosecution.

This article only deals with complaints about crimes. These are crimes whose prosecution is made dependent on a complaint. These types of crimes do not appear in the Medicrime Convention and therefore fall back on the general rules of criminal prosecution. The principle thereof can be found in article 1 of the Belgian Preliminary Title of the Code of Criminal Procedure of 17 April 1878 and article 28quater of the Belgian Code of Criminal Procedure from 17 November 1808. Crimes under this Convention will therefore be prosecuted independently of a complaint. If a complaint has nevertheless been lodged, its withdrawal will not affect the further prosecution of that crime.

Art. 1 of the Belgian Preliminary Title of the Code of Criminal Procedure of 17 April 1878: The legal claim to apply the penalties cannot be exercised except by the officials charged by law.

Art. 28quater of the Belgian Code of Criminal Procedure from 17 November 1808:
Taking into account the guidelines of the criminal policy, established under Article 143quater of the Judicial Code, the public prosecutor will judge the expediency of the prosecution. He gives the reason for the dismissal decisions he takes in this matter.
He carries out criminal proceedings in the manner determined by law.
The investigation obligation and investigation right of the public prosecutor continue to exist after the criminal procedure has been instituted. However, this duty and right cease to exist for the facts brought before the investigating judge insofar as the criminal investigation would consciously affect his prerogatives, without prejudice to the claim stipulated in Article 28septies, first paragraph, and insofar as the investigating judge charged with the case does not would decide to continue the entire investigation itself.

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**). The FAMHP has a Special Investigations Unit which deals with cases

concerning falsification of medicines and medical devices. The inspectors of this unit all have a pharmaceutical or scientific degree and when they start in this unit are trained to perform investigations. Collaboration with the Federal Police and the Prosecutors (and other agencies when necessary which is evaluated case by case) goes through the PFCP.

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**).

Financial investigation:

See article 46quater of the Belgian Code of Criminal Procedure from 17 November 1808:

Art. 46quater. § 1. When tracing the crimes and offenses, the public prosecutor can, if there are serious indications that the crimes may result in a correctional main imprisonment of one year or a more severe sentence, the necessary information about the products, services and transactions of a financial nature and relating to virtual assets, which are related to a suspect, claim against

1 ° persons and institutions as referred to in Article 5, § 1, 3 ° to 22 ° of the law of 18 September 2017 on the prevention of money laundering and terrorist financing and the restriction of the use of cash;

2 ° persons and institutions that make available or offer services within the Belgian territory with regard to virtual securities that allow regulated means of payment to be exchanged in virtual securities.

§ 2. In the event of offenses referred to in Articles 137 to 141 or 505, first paragraph, 2 ° to 4 °, of the Criminal Code, or in the context of tax fraud as referred to in Articles 449 and 450 of the income taxes 1992, in Articles 73 and 73bis of the Code of Value Added Tax, in Articles 133 and 133bis of the Inheritance Tax Code, in Articles 206 and 206bis of the Registration, Mortgage and Court Tax Code, in articles 207 and 207bis of the Code miscellaneous duties and taxes, in articles 220, § 2, 259 and 260 of the General Law of 18 July 1977 on customs and excise duties, in articles 3.15.3.0.1. and 3.15.3.0.2. of the Flemish Tax Code of 13 December 2013 and in articles 68 and 68ter of the Code of taxes assimilated to income taxes, as well as in the case of the crime referred to in article 4, 23 °, of the law of 18 September 2017 on prevention money laundering and terrorist financing and to limiting the use of cash, the public prosecutor may, upon specific and reasoned request, request information contained in the Central Contact Point held by the National Bank of Belgium, in accordance with the law of 8 July 2018 on the organization of a central point of contact for accounts and financial contracts and on expanding access to the central file of notices of attachment, delegation, transfer, collective debt settlement and protest.

§ 3. If the necessities of the criminal investigation so require, the public prosecutor can also demand that:

1 ° the activities of the suspect are placed under supervision for a renewable period of maximum two months;

2 ° the questioned person or institution may no longer hand over the assets and liabilities relating to the products, services, transactions and values referred to in paragraph 1 for a term that he determines, but which cannot be longer than the term that runs from the moment that

person or institution becomes aware of his claim up to five working days after notification of the information referred to here by that person or institution.

The measure referred to in the first paragraph, 2 °, can only be demanded if serious and exceptional circumstances justify this and only if the investigation relates to crimes or offenses as referred to in Article 90ter, §§ 2 to 4.

§ 4. The public prosecutor can, by written and reasoned decision, demand the cooperation of the persons and institutions referred to in paragraph 1. The institution or person questioned is obliged to cooperate without delay. In his decision, the public prosecutor accurately describes the information he is seeking and the form in which it is communicated to him.

Any person who, by virtue of his ministry, becomes aware of the measure or who cooperates with it, is obliged to observe secrecy. Any violation of secrecy will be punished in accordance with Article 458 of the Criminal Code.

Any person who refuses or fails to communicate the data in real time or, as the case may be, at the time specified in the claim, will be punished by imprisonment from eight days to one year and a fine of twenty-six euros to ten thousand euros. or with one of those penalties alone.

Special investigative techniques

The special investigation methods can be found in articles 47ter to 47undecies of the Belgian Code of Criminal Procedure from 17 November 1808:

Art. 47ter. § 1. The special investigation methods are observation, infiltration, civilian infiltration and informants.
These methods are used by the police forces designated by the Minister of Justice in the context of a criminal investigation or a judicial investigation, under the control of the Public Prosecution Service and without prejudice to Articles 28bis, §§ 1 and 2, 55 and 56, § 1, and 56bis, with the aim of prosecuting offenders, detecting, collecting, registering and processing data and intelligence on the basis of serious indications of criminal offenses to be committed or already committed, whether or not revealed.
Under the same conditions as those that apply to surveillance, infiltration and informant work, these methods can also be used in the context of the execution of punishments or deprivation of liberty, if the person has evaded their execution.
§ 2. The public prosecutor is responsible for permanent control over the application of the special investigative methods by the police services within his judicial district.

1. Surveillance

   Art. 47sexies. § 1. Observation within the meaning of this code is the systematic observation by a police officer of one or more persons, their presence or behavior, or of certain things, places or events.

   A systematic observation within the meaning of this Code is an observation of more than five consecutive days or of more than five non-consecutive days spread over a period of one month, an observation in which technical aids are used, an observation of an international character, or an observation carried out by the specialized units of the federal police.

   A technical aid within the meaning of this Code is a configuration of components that detects signals, transports them, activates their registration and records the signals, with the exception of the technical means used to implement a measure as referred to in Article 90ter.

A device used for taking photos is exclusively considered a technical aid within the meaning of this Code in the case referred to in Article 56bis, second paragraph.

§ 2. The public prosecutor can authorize an observation within the framework of the criminal investigation if the investigation so requires and the other means of investigation do not appear to be sufficient to reveal the truth.

An observation using technical aids can only be authorized if there are serious indications that the criminal offenses may result in a correctional prison sentence of one year or a heavier sentence.

§ 3. The authorization to observe is in writing and states:

1 ° the serious indications of the criminal offense that justify the observation, or, if the observation is part of the proactive investigation as described in Article 28bis, § 2, the reasonable suspicion that it is or has already been committed but not yet at the uncovered offenses, and the special instructions relating to the elements described in this last provision, which justify the observation;

2 ° the reasons why the observation is indispensable to reveal the truth;

3 ° the name or, if not known, a description that is as accurate as possible of the person or persons being observed, as well as of the objects, places or events referred to in § 1;

4 ° the manner in which the observation will be carried out, including the permission to use technical aids in the cases determined by § 2, second paragraph, and Article 56bis, second paragraph. In the latter case, the authorization of the examining magistrate will state the address or the most accurate possible location of the home to which the observation relates;

5 ° the period during which the observation can be carried out, which may not exceed 1 three months from the date of the authorization;

6 ° the name and capacity of the judicial police officer, who is in charge of carrying out the surveillance.

§ 4. The public prosecutor shall at that time state in a separate and written decision the crimes that can be committed by the police forces and the persons referred to in Article 47quinquies, § 2, third paragraph, within the framework of the observation.

This decision is kept in the file referred to in Article 47septies, § 1, second paragraph.

§ 5. In urgent cases, the authorization for observation can be issued orally. The authorization must be confirmed as soon as possible in the form specified in paragraph 3.

§ 6. The public prosecutor can always change, supplement or extend his authorization for observation in a motivated manner. He can revoke his authorization at any time. He verifies with every amendment, addition or extension of his authorization whether the conditions set out in §§ 1 to 3 have been fulfilled and thereby acts in accordance with § 3, 1 ° to 6 °.

§ 7. The public prosecutor is responsible for the enforcement of the authorizations of observation granted by the investigating judge in the context of a judicial investigation in accordance with Article 56bis.

At that time, the public prosecutor will state in a separate written decision the crimes that can be committed by the police forces and the persons referred to in Article 47quinquies, § 2, third paragraph, within the framework of the observation ordered by the investigating judge. The decision is kept in the file referred to in Article 47septies, § 1, second paragraph.

2. Infiltration

Art. 47octies. § 1. Infiltration within the meaning of this code is the permanent contact by a police officer, called an undercover officer, under a fictitious identity, with one or more persons, of whom there are serious indications that they are punishable offenses in the context of a criminal organization, as referred to in Article 324bis of the Criminal Code, or commit or would commit crimes or offenses as referred to in Article 90ter, §§ 2 to 4.

In exceptional circumstances and with the express authorization of the competent magistrate, the undercover officer may, for a specific operation, briefly call on the expertise of a person who is not a member of the police force, if this appears strictly necessary for the success of his task.

§ 2. The public prosecutor can authorize an infiltration in the context of the criminal investigation if the investigation so requires and the other means of investigation do not appear to be sufficient to reveal the truth.

He can authorize the police service to use certain police investigation techniques, within the legal framework of an infiltration and with due observance of its purpose. The King shall determine these police investigation techniques by decree deliberated in the Council of Ministers, on the recommendation of the Minister of Justice and after the advice of the Board of Procurators General. 1 These police investigative techniques can only be used by members of the management of the special units of the federal police and, if necessary, with the additional prior agreement of the federal prosecutor, in cooperation with foreign specially trained and authorized officials.

The public prosecutor can also, if there are grounds to do so, grant permission to take the necessary measures to safeguard the security and the physical, psychological and moral integrity of the undercover officer. This permission is kept in the confidential file referred to in Article 47novies, § 1, second paragraph.

§ 3. The authorization to infiltration is in writing and states:

1 ° the serious indications of the criminal offense that justify the infiltration or, if the infiltration is part of the proactive investigation as described in Article 28bis, § 2, the reasonable suspicion that a criminal has already been committed or has not yet been discovered. facts, and special indications with regard to the elements described in this last provision, justifying the infiltration;

2 ° the reasons why the infiltration is indispensable to reveal the truth;

3 ° if known, the name or otherwise a description as accurate as possible of the person or persons referred to in § 1;

4 ° the manner in which the infiltration will be carried out, including the permission to briefly call on the expertise of a citizen, as determined in § 1, second paragraph, and the admission of police investigation techniques, as determined in § 2, second paragraph, to use;

5 ° the period during which the infiltration can be carried out and which may not exceed three months from the date of the authorization;

6 ° the name and capacity of the judicial police officer who is in charge of carrying out the infiltration.

§ 4. At that time, the public prosecutor shall state in a separate written decision the crimes that can be committed by the police forces and the persons referred to in Article 47quinquies, § 2, third paragraph, in the context of the infiltration. This decision will be kept in the file referred to in Article 47novies, § 1, second paragraph.

§ 5. In urgent cases, the authorization for infiltration can be issued orally. The authorization must be confirmed as soon as possible in the form specified in paragraph 3.

§ 6. The public prosecutor can always change, supplement or extend his authorization to infiltrate in a motivated manner. He can revoke his authorization at any time. He verifies with every amendment, addition or extension of his authorization whether the conditions stipulated in §§ 1 to 3 have been fulfilled and thereby acts in accordance with § 3, 1 ° to 6 °.

§ 7. The public prosecutor is responsible for the enforcement of the authorizations for infiltration granted by the investigating judge in the context of a judicial investigation in accordance with Article 56bis.

At that time, the public prosecutor will state in a separate written decision the crimes that can be committed by the police forces and the persons referred to in Article 47quinquies, § 2, third paragraph, in the context of the infiltration ordered by the investigating judge. This decision will be kept in the file referred to in Article 47novies, § 1, second paragraph.

3. civilian infiltration

Art. 47novies/1. § 1. Civilian infiltration within the meaning of this Code is a permanent and controlled contact by an adult person who is not a police officer, called a civilian infiltrator, if necessary under a fictitious identity, with one or more persons with regard to whom there are serious indications that they commit or would commit one of the offenses referred to in Article 90ter, §§ 2 to 4, with the exception of Article 90ter, § 2, 11 °, provided that they are or would be committed in the context of a criminal organization such as referred to in Article 324bis of the Criminal Code, or one of the offenses referred to in Book 2, Title Iter of the Criminal Code.

In exceptional circumstances and subject to the express authorization of the competent magistrate, the judicial police officer referred to in paragraph 4, 6 ° may, for a specific operation on civilian infiltration, briefly and steadily call on the expertise of a person who is not part of the police services. if this is strictly necessary for the success of the assignment.

§ 2. In the context of the criminal investigation, the public prosecutor can authorize a civilian infiltration if the investigation so requires and if the other means of the investigation, including the infiltration referred to in Article 47octions, do not appear to be sufficient to reveal the truth. bring.

Authorizing or extending the civil infiltration authorization by the public prosecutor or by the investigating judge requires the prior agreement of the federal prosecutor. If this agreement has been given orally, it will be confirmed in writing afterwards, as soon as possible. The agreement is kept in the confidential file referred to in Article 47novies / 3, § 1, second paragraph.

he public prosecutor can, within the legal framework of civilian infiltration and with due observance of its purpose, authorize the police service referred to in Article 47 °, § 2, second paragraph, to carry out the police investigation techniques referred to in Article 47 °, § 2, second paragraph. to have the civilian infiltrator used under the supervision of the counseling officer referred to in the fifth paragraph.

The public prosecutor can, if there are grounds to do so, grant permission to take the necessary measures to safeguard the safety and physical, psychological and moral

integrity of the civilian infiltrator. This permission is kept in the confidential file referred to in Article 47novies / 3, § 1, second paragraph.

Police officers of the directorate of the special forces of the federal police who have received special training for this purpose, called escort officers, accompany the civilian infiltrator in order to carry out his task properly.

Police officers of the Directorate of the Special Forces of the Federal Police, called control officers, ensure the safeguarding of the security and physical, psychological and moral integrity of the civilian infiltrator, as well as the fulfillment of the obligations of the civilian infiltrator. A police officer cannot be simultaneously escort and control officer of the same civilian infiltrator.

§ 3. Without prejudice to the second to the eighth paragraphs, the civilian infiltrator, the guidance and control officers, are prohibited from committing criminal offenses in the context of the civil infiltrator's mission.

The civilian infiltrator and the escort and control officers who, in the context of the civilian infiltrator's mission and with a view to its success or to ensure their own safety or that of other persons involved in the operation, remain free from punishment. commit criminal offenses, with the explicit prior agreement of the public prosecutor.

Those offenses must not be more serious than those for which the civilian infiltration is being used, must necessarily be proportionate to the aim pursued and must not affect the physical integrity of persons.

The magistrate, with due observance of this Code, shall remain free from punishment, authorizing a civilian infiltrator, guidance and control officers and persons who do not belong to the police services but whose expertise is called upon to commit punishable facts in connection with the implementation of civilian infiltration.

The officer of the judicial police referred to in paragraph 4, 6 °, reports in writing to the public prosecutor the crimes referred to in the second paragraph that the civilian infiltrator and the guidance and control officers or the persons referred to in the fourth paragraph may have to commit. .

The civilian infiltrator immediately communicates his conduct and observations to the escort officers, who in turn report this to the officer of the judicial police referred to in paragraph 4, 6 °. The latter notifies the public prosecutor of this in accordance with Article 47novies / 3, § 1.

The first three paragraphs also apply to the persons who provided necessary and direct help or assistance in the performance of this assignment and the persons referred to in paragraph 1, second paragraph.

The Minister of Justice and the Minister of the Interior shall, on a joint proposal of the Federal Prosecutor and the Attorney General, who is responsible within the College of Prosecutors General for the special investigation methods, the special measures that are strictly necessary to protect the identity and security of civilian infiltrators and guidance and control officers at all times in the preparation and execution of their assignments. There can be no crime when acts in that regard are committed.

§ 4. The authorization for civilian infiltration is in writing and states:

1 ° the serious indications of the criminal offenses that justify the civilian infiltration or, if the civilian infiltration is part of the proactive investigation as described in Article 28bis, § 2, the reasonable suspicion of a criminal offense to be committed or already committed but not yet discovered facts, and special indications with regard to the elements described in this last provision, justifying civilian infiltration;

2 ° the reasons why civilian infiltration is indispensable to reveal the truth, and in particular the reasons why the infiltration referred to in Article 47 ° does not seem sufficient to reveal the truth;

3 ° if known, the name or otherwise a description as accurate as possible of the persons in respect of whom there are serious indications that they commit or would commit one of the offenses referred to in Article 90ter, §§ 2 to 4, with the exception of Article 90ter, § 2, 11 °, on condition that they are or would be committed within the framework of a criminal organization as referred to in Article 324bis of the Criminal Code, or one of the offenses referred to in Book 2, Title Iter of the Criminal Code;

4 ° the manner in which civilian infiltration will be carried out, including the permission to use police investigation techniques referred to in paragraph 2, third paragraph;

5 ° the period during which the civilian infiltration can be carried out, which may not be longer than three months from the date of the authorization;

6 ° the name and capacity of the officer of the judicial police referred to in Article 47ter, § 2, fourth paragraph, who is in charge of carrying out the civilian infiltration;

7 ° the identity of the citizen infiltrator in the form of a code;

8 ° the agreement of the federal prosecutor to authorize or extend civilian infiltration.

§ 5. If necessary, the public prosecutor shall state in a separate written decision the crimes that can be committed by the civilian infiltrator, the guidance and control officers and the persons referred to in paragraph 3, paragraph 4, in the context of civilian infiltration. This decision is kept in the file referred to in Article 47novies / 3, § 1, second paragraph.

§ 6. In urgent cases, the authorization for civilian infiltration can be issued orally. The authorization will be confirmed as soon as possible in the form specified in paragraph 4.

§ 7. The public prosecutor can always amend, supplement or extend his authorization for civilian infiltration in a reasoned manner. He can revoke his authorization at any time. He verifies with each change, addition or extension of his authorization whether the conditions set out in paragraphs 1, 2 and 4 have been fulfilled and thereby acts in accordance with paragraph 4, 1 ° to 8 °.

§ 8. The public prosecutor is responsible for the enforcement of the civil infiltration authorizations granted by the investigating judge in the context of a judicial investigation in accordance with Article 56bis.

If necessary, the public prosecutor shall state in a separate written decision the crimes that can be committed by the civilian infiltrator, guidance and control officers and the persons referred to in paragraph 3, paragraph 4, in the context of the civilian infiltration ordered by the investigating judge. This decision is kept in the file referred to in Article 47novies / 3, § 1, second paragraph.

4. Informants

Art. 47decies. § 1. Working with informants within the meaning of this code is the maintenance of regular contact by a police officer with a person, called an informant, who is suspected of having close ties with one or more persons, of whom there are serious indications that they are committing criminal offenses. or would commit, and who provides the police officer with information and data about this, whether or not requested. This police officer is called a liaison officer.

§ 2. Within the directorate, which is part of the general directorate of the judicial police of the federal police and which is charged with the task referred to in article 102, 5 °,

of the law of 7 December 1998 organizing an integrated police service Structured on two levels, an officer in charge of the national management of the informant work within the integrated police service is structured on two levels. This officer, referred to as the national informant manager, may be assisted in the performance of his duties by one or more officers of the judicial police.

He supervises compliance with the regulations applicable in or pursuant to this article.

The National Informant Administrator acts under the authority of the federal attorney.

§ 3. Within each devolved judicial directorate, as referred to in article 105 of the law of 7 December 1998 organizing an integrated police service structured on two levels, an officer, called the local informant manager, is charged with the district management of the informant work within the devolved judicial (management) and local police forces of the district.

To this end, he exercises permanent control over the reliability of the informants and supervises compliance with the regulations applicable in or pursuant to this article and the proper functioning of the liaison officers.

The local informant manager acts under the authority of the public prosecutor.

In each local police force, within which informant work is carried out, an officer is appointed to assist the local informant manager in his assignment.

§ 4. On the recommendation of the Minister of Justice and after advice from the Board of Procurators General and the Federal Prosecutor, the King determines the operating rules of the national and local informant administrators and of the liaison officers, with due observance of a permanent control over the reliability of the informants, the protection of the identity of the informants and the safeguarding of the physical, psychological and moral integrity of the liaison officers.

§ 5. The local informant manager will at his request and at least quarterly report to the public prosecutor on the informant activities within the devolved judicial (management) and local police forces of the district.

The national informant manager submits to the federal prosecutor at his request and at least quarterly general report on the informant activities within the integrated police service structured at two levels.

§ 6. Contrary to Article 28ter, § 2, last sentence, the local informant manager, if the informant team reveals serious indications about committed or yet to be committed criminal offenses, immediately and in writing to the public prosecutor accurately, fully and report truthfully.

The public prosecutor can also, if there are grounds to do so, prohibit the local informant manager by written decision to continue working on certain information provided by an informant.

The public prosecutor keeps these confidential reports in a separate file. He is the only person who has access to this file, without prejudice to the right of inspection of the investigating judge referred to in Article 56bis. The content of this file is covered by professional secrecy.

He decides whether, depending on the importance of the information provided and taking into account the safety of the informant, an official report is drawn up. If this official report relates to an ongoing criminal investigation or judicial investigation, the public prosecutor is responsible for attaching it to this criminal file.

§ 7. When an informant has close ties with one or more persons, of whom there are serious indications that they commit or would commit criminal offenses that constitute or would constitute a crime as referred to in Articles 137 to 141, as referred to in Articles

324bis and 324ter or as referred to in Articles 136bis, 136ter, 136quater, 136sexies, 136septies of the Criminal Code or as referred to in Article 90ter, § 2, 4 °, 7 °, 7 ° bis, 7 ° ter, 8 °, 11 °, 14 °, 16 ° and 17 °, provided that the latter offenses referred to in Article 90ter, § 2, have been or would be committed within the framework of a criminal organization as referred to in Article 324bis of the Criminal Code, the public prosecutor can allow the informant to commit crimes that are strictly necessary to maintain his information position.

These crimes must necessarily be proportionate to the interest of preserving the informant's position as information and must in no case involve direct and serious violations of the physical integrity of persons.

The local informant manager, referred to in § 3, first paragraph, informs the public prosecutor in advance of the criminal offenses that the informant intends to commit. The public prosecutor shall specify in a separate written decision the crimes that could be committed by the informant, and which must not be more serious than those he intended to commit. This decision is kept in the file referred to in § 6, third paragraph.

A magistrate who, with due observance of this article, allows an informant to commit crimes, remains free from punishment.

Question 12: Measures of protection for the victim

General comment to all following questions:

1. Information to victims about their rights in criminal proceedings:

From a legal point of view, the victim is any person, and their relatives, who have suffered material, physical and / or moral damage as a result of an act that is punishable by criminal law.

Article 3bis of the Preliminary Title of the Code of Criminal Procedure of 17 April 1878 further elaborated by, among others, the COL 5/2009, revised version 13 November 2014 (see www.om-mp.be) whereby persons who file a complaint, a certificate of filing a complaint must be provided with information about their rights in criminal proceedings.

Article 3bis. Crime victims and their relatives should be treated with due care and attention, in particular by making the necessary information available and, where appropriate, establishing contact with the specialized services, and in particular with judicial assistants.

(Victims receive in particular the useful information about the detailed rules for the civil party declaration and the declaration of the injured person.)

Justice assistants are staff members of the Department of Justice Houses of the Ministry of Justice who assist the competent magistrates in guiding persons involved in legal proceedings.

For each jurisdiction of the Court of Appeal, officials from the Department of Justice Houses of the Ministry of Justice are engaged to assist the Attorney General in implementing criminal policy on the reception of victims, for evaluation, coordination and supervision. to the application of victim reception in the various prosecution offices and to assist the officials referred to in the second paragraph, who are responsible for the reception of victims. They work closely with the Attorney General.

In addition, there are also brochures and victim reception at the courts and the public prosecutor's offices (competence of the Communities), see the Joint circular of the Minister of Justice and of the Board of Procurators General at the courts of appeal regarding the reception of victims at the public prosecutors' offices and courts 16/2012.

2. Compensation:

The compensation of victims of intentional acts of violence is regulated by the law of 1 August 1985 containing tax and other provisions:

A committee for financial assistance for victims of deliberate acts of violence and for occasional rescuers is set up to decide on applications for emergency aid, financial aid or additional aid. This committee can receive financial aid, among other things persons who suffer serious physical or psychological harm as a direct result of an intentional act of violence.

The financial aid is granted under the following conditions:

1 ° The act of violence was committed in Belgium.

This is equated with an intentional act of violence committed abroad, of which a person referred to in Article 42, § 3, is the victim in an ordered service.

2 °

3 ° If the perpetrator is unknown, the petitioner must have lodged a complaint, assumed the status of injured party or brought himself a civil party.

If the criminal file is dropped for that reason, submitting a complaint or assuming the status of injured person is sufficient.

The request was submitted within three years. The time limit runs, as the case may be, from the day of the first dismissal decision for unknown perpetrator or from the day on which an investigating court has issued a decision to suspend prosecution for unknown perpetrators that has become final.

Equivalent to a decision to dismiss the prosecution for unknown perpetrators is a decision of a civil or criminal court which relieves the suspect or the defendant of the guilt of an intentional act of violence, or of the responsibility for the adverse consequences thereof, in so far as this decision does not the reality of the deliberate act of violence and of its consequences without any doubt, without attributing responsibility for it to any person.

The assistance may also be granted if more than a year has passed since the filing of a complaint, assuming the status of injured person or the date of the civil party claim and the perpetrator remains unknown.

4 ° If the perpetrator is known, the applicant must seek compensation by means of a civil party claim, a direct summons or an action in a civil court.

The application may only be made, as the case may be, after a final decision on the criminal procedure or after a final decision by the civil court on the attribution or compensation of the damage.

The request was submitted within three years.

The period runs, as the case may be, from the day on which a final judgment is given on the criminal action by a final decision by an investigative or judgment court, the day on which a criminal court gives judgment on a final decision. made on the civil interests after the decision on the criminal procedure, or the day on which a civil court judgment was given by a final decision on the attribution of or on compensation for the damage.

5 ° The damage cannot be adequately repaired by the offender or the civil liable party, on the basis of a system of social security or private insurance, or in any other way.

6 ° If, due to circumstances completely beyond his control, the applicant could not file a complaint, could not assume the status of injured party, could not file a civil party, could not institute a claim or obtain a judgment or if the filing of a claim or In view of the insolvency of the perpetrator, obtaining a judgment seems manifestly unreasonable, the committee may consider that the reasons given by the applicant are sufficient to discharge him from the conditions provided for in 3 ° and 4 °.

For the granting of assistance to the persons referred to in Article 31, 1 °, the Commission relies exclusively on the following components of the damage suffered:

1 ° the moral damage;
2 ° medical and hospital costs, including prosthesis costs;
3 ° temporary or permanent disability;
4 ° a loss or reduction in income as a result of temporary or permanent incapacity for work;
5 ° the aesthetic damage;
6 ° the procedural costs, including the trial fee;
7 ° the material costs;
8 ° the damage resulting from the loss of one or more school years.

In addition, there is also the option of civil party filing in the context of criminal proceedings or through civil proceedings.

Art. 63 of the Belgian Code of Criminal Procedure from 17 November 1808:

A person who claims to have been disadvantaged by a crime or an offense can lodge a complaint about this with the competent investigating judge and submit a civil action.

Any victim who takes civil action may, upon simple request, be heard at least once by the investigating judge responsible for the case.

3. Physical, mental and social recovery

With regard to “helping with their recovery on a physical, mental and social level”, this is a competence of the communities with regard to recovery on a mental and social level. At the Flemish side there are for example the centers for general welfare work. The physical recovery is an aspect of Public Health.

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.

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**).

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)**);

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)**)

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)**);

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**).

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**).

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;

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**)

- Law of the 25th of March 1964 on Medicines
- Royal Decree of the 14th of December 2006 on Medicines for Human and Veterinary Use
- Royal Decree of the 18th of March 1999 concerning Medical Devices
- Royal Decree of the 15th of July 1997 concerning active implantable Medical Devices
- Royal Decree of the 14th of November 2001 concerning Medical Devices for in vitro diagnostics

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

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 Special Investigations Unit provides training for the Police and Customs on demand.
   - the prevention of illegal supplying of counterfeit medical products, active substances, excipients, parts, materials and accessories?
     - The legal supply chain is guarded through the legal framework described in the Laws and Royal Decrees under points a and b. Inspections of all the manufacturers and distributors are carried out according to a risk-assessment based plan.
     - For the illegal supply chain there is a cooperation between the FAMHP and Customs to control incoming goods.

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**);
   - Information for the public : how to recognise an authorized medicine-> on the website of the FAMHP
   - Campaign 'Medicines through the internet : don't surf with your health'-> on the website, brochures and posters
   - EDQM publication 'Open minds, free minds' to be translated. Ongoing.