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

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;

YES

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;

YES

iii. an investigational medicinal product"?

NO, there is a specific legal framework applicable to investigational medicinal product

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

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

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

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"?

This definition is not totally coincidental with that forseen in Decree Law 176/2006, de 30/08, u), artigo 3º Any constituent of a medicinal product other than the active substance and the packaging material.»

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

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

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"?

There is no such definition In PT internal law

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"?

There is no such definition In PT internal law

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"?

    YES

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"?
In PT we adopted the definition of the falsified medicines directive that comprises a false representation as regards identity and/or source.

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"?

Not provided for in the specific drug legislation.
The provision under the general Portuguese Law, for victim concept, is aplicable

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.

It is prohibited under PT constitutional law.
In accordance with Portuguese law, discrimination is prohibited, the law and its application is the same for all

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; **Please see III k)**

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;

No specific internal strategies were adopted, but within the scope of international cooperation, we share criminal information, considered as an asset to fight this type of practice.

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.

In general, PT criminal law is already prepared to deal with it.
PT only needs specific criminal provisions on medicinal products. At present the applicable sanctions are of administrative nature, unless if there is a real danger to human life, a crime with imprisonment for up 1 to 8 years, (Portuguese penal code, article 282)

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**);

Close collaboration between Polícia Judiciária, ASAE, INFARMED and other police forces and Customs for conducting specific inspections and investigations related to suspicious products.

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**)

NO

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)**);

  Through the contact points established under the Protocol with Customs (public sector)

- 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)**);

  INFARMED shares with relevant national authorities (ASAE and Customs) information received from European and international Competent Authorities regarding the detection of falsified medicinal products.

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**);

   Polícia Judiciária – is the entity responsible for it, the resources are the ones provided by Polícia Judiciária/Justice Ministry and the ones provided by the other agencies as they cooperate with Polícia Judiciária for this kind of matters

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**).

   Polícia judiciária - Mr. Afonso Sales

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.

   NO

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.

At the moment they are all considered administrative offences -

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;

Applicable sanctions under medicinal products legal framework are of administrative nature.

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**).

Portuguese jurisdiction

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 – General criminal law does

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**);

   Temporary or permanent disqualification from exercising commercial activity, judicial winding-up order, seizure and confiscation of products, destruction of confiscated products.
   Natural person responsible for companies can be subject to fine or imprisonment, depending on the gravity of the misconduct. Criminal, civil and administrative sanctions can coexist.

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**).

   Registration in criminal record.

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**).

All of them

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**).

   It has to be qualified as public crime

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**).

   Public Attorney's Office; Judiciary Police, for criminal investigations
   INFARMED – National Authority of Medicines and Health Products, I.P.(expert support in the medicines legislation field

   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**).

   It is only possible according with the Portuguese Law, 25 August 101/2001, and concerning the catalog crimes establisshed
   According with the Portuguese Criminal Law, Polícia Judiciária have the competence for this kind of action.

Question 12: Measures of protection for the victim

According with the Portuguese Law

Whenever the life of the victim or another witness, their physical or mental integrity, their freedom or their property of considerable value are endangered because of their contribution to the investigation and evidence of the crime, they may require application of means of protection.

The following means of protection are of an exceptional nature, and can only be applied if, in particular, they are shown to be necessary and adequate for the protection of people and the realization of the purposes of the process:

concealment: the court may decide, based on circumstances that indicate a high risk of intimidation by the witness, that the rendering of statements that should take place in a public procedural act occurs with concealment of the image, cumulatively or not with distortion of the voice, in order to avoid witness recognition.

teleconference: in relation to the most serious crimes, and whenever strong reasons for protection justify it, it is permissible to use the teleconference, that is, the witness will not give his testimony in the courtroom, but from another public building, preferably in judicial, police or prison facilities, and in the presence of a judge. This testimony can be made with hiding the image and distorting the voice.

reservation of knowledge of the identity of the victim or another witness: the non-disclosure of the identity of the victim or another witness may take place during any or all stages of the process. The victim or witness whose identity is not revealed can give evidence using image concealment (cumulatively or not with voice distortion) or the teleconference.

punctual security measures: in relation to the most serious crimes, and whenever strong reasons for protection justify it, the victim or another witness may benefit from punctual security measures, namely transportation in a vehicle provided by the State to be able to intervene in a procedural act, police protection or alteration of the physical place of habitual residence, among others.

special security program: for certain crimes of the most serious nature, the witness, his / her spouse, ascendants, siblings or others close to him / her may benefit, if they so wish, from a special security program, during or after the pending the process, if certain conditions are met. The special security program includes the application of one or more administrative protection and support measures, namely the provision of documents that give the victim or witness a "new identity", the alteration of the physiognomic aspect or the appearance of the victim's body, the concession of new housing, in the country or

abroad, for the time determined or the granting of a subsistence allowance for a limited period.

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.

   Victims and their families are entitled to protection against acts of retaliation, intimidation or the continuation of criminal activity against them. They have the right to be protected from acts that may jeopardize their life, their physical integrity, their emotional and psychological well-being and their dignity when giving statements.

   Whenever the authorities consider that there is a serious threat of acts of revenge or strong indications that the victim's security and privacy may be severely and intentionally disrupted, the victim, as well as his or her family or other close people, must be assured. adequate level of protection.

   If the victim, for security or privacy reasons, does not intend to indicate the address of his residence in the process, he has the right to choose to give another address where he can receive notifications, such as that of his workplace or that of the Office Support to the APAV Victim in which he is being accompanied

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**).

   From the first moment of contact with any authority, whether it is the **Public Prosecution Service** or the **police**, the **victim** is entitled to be informed about the following:

   - what kinds of **support** are available and who can provide them, including medical assistance, psychological counselling, specialised services and, if necessary, accommodation;
   - how and where to file a complaint or **report a crime**;
   - how and under what conditions you may obtain **protection**;
   - how to obtain legal advice and **legal aid**;
   - how and when to seek **compensation** from the offender;
   - in the case of violent or domestic violence crimes, how and when to claim **compensation from the State**;

- how to obtain **interpretation and translation** services;
- if the **victim does not live in Portugal**, what special procedures are in place to defend their rights in this country;
- how to make a complaint if your rights are not respected by the authorities;
- contact details of authorities which the victim should use to give or ask for information about the case;
- which **mediation** services are available;
- how and when to claim **reimbursement of expenses** for participating in the proceedings and when this is applicable.

This information may vary depending on the specific needs and personal circumstances of the victim and on the type of crime. Additional information is available at different stages of the case.

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)**);
During any criminal case, the victim is entitled to be heard and to provide information that may be important for the investigation and submit evidence. When the crime is first reported (if this is done by the victim), he/she has the opportunity to provide as much relevant information and evidence as possible to the authorities receiving the **report**.

Later on in the investigation, the victim will be called on by the **police** or, in some cases, by the **Public Prosecution Service** , to make a statement. At this time, the victim can add details that were not mentioned in the formal report or complaint. If the defendant is charged, the victim will be called upon again to give a statement and to answer the questions of the different participants in the **trial**.

In the case of victims of human trafficking or sexual crimes, the examining judge may, or must when a victim of a sexual crime is a minor, question the victim at the **inquiry stage** or the **examination stage**. This means that their statement may, if necessary, be taken into account during the trial, so as to avoid having them repeat their testimony more than once. The participants in this examination, besides the examining judge, are the public prosecutor, the **defendant** and the **defence lawyer** and the lawyers of the **assistant** and of the civil parties. This statement is known as a statement for future recall and is recorded for use during the trial. However, the trial judge will very often want the witnesses to testify and they may be called and questioned again.

In addition, whenever the victim has information they consider important to

communicate immediately, they can, and should, do so straightaway, preferably in writing, to whichever authority is dealing with the case at the time. The authorities can also, at any time, ask the victim for further information or clarification.

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)**)

Access to justice seeks to ensure that nobody is hindered in or prevented from exercising or protecting their rights because of their social or cultural background, financial means or knowledge.
Victims are entitled to legal aid and advice about their role during the entire procedure.
Victims are also entitled to legal aid when they have the status of **assistant** or of a civil party, or when, as **witnesses**, they would like to be accompanied by a lawyer at any procedure but cannot afford the expenses.

Legal aid includes:

- total or partial exemption from the payment of court fees;
- appointment of a lawyer and payment of his/her fees; or
- payment of court fees or legal fees in instalments.

Applications for legal aid are decided by the social security services on the basis of a calculation of the assets, income and expenses of the applicant. Legal aid application forms are provided free of charge by the social security services, and may be submitted in person, by fax, by post or online. **The application must be accompanied by documents proving the applicant's lack of means, and the decision will be given within 30 days.**

The application is free of charge for the victim.

When an application for the appointment of a lawyer is approved, the social security services will ask the **Portuguese Bar Association (Ordem dos Advogados)** to assign a lawyer to represent the victim.

Victims of domestic violence, female genital mutilation, slavery, human trafficking, sexual coercion and rape are exempt from payment of court fees.

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)**);

Protection Measures

During criminal investigations, interviews of **victims** are conducted without unjustified delay after the complaint with regard to a criminal offence has been made to the competent authority.

The number of interviews and medical examinations of victims is kept to a minimum and are carried out only where strictly necessary for the purposes of the criminal investigation.

Victims may be accompanied by their legal representative and a person of their choice, unless a reasoned decision has been made to the contrary

No contact with the defendant
Privacy
Protect the victim and other witness in exceptional situations
Restritive measures

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**).
Victims are entitled to confidential victim support services **free of charge before, during and after the case**.

The Portuguese Association for Victim Support (*Associação Portuguesa de Apoio à Vítima*, **APAV**) provides emotional, psychological, legal, social support and assistance to all those who were or are victims of crime.

Victims are entitled to victim support services even if the crime was not reported.

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**).
Being the victim of a crime in a foreign country places victims in a particularly vulnerable situation, as they do not know how **criminal proceedings** work or what **support services** are available, they have difficulty understanding another language and their stay in the country where the crime was committed is usually a short one, which makes it difficult to participate it and keep abreast of the case.

People who are the victims of a crime in a country other than their country of residence should be able to avail themselves of measures that make it easier for them to participate and, in particular, to be informed about the progress of the case. These measures include the authorities providing all the necessary information and appointing an **interpreter** to ensure the victim fully understands the different procedures in which they participate.

A resident of a European Union Member State who is the victim of a crime in another Member State may report the crime to the authorities in their country of residence, if they have not reported it in the country where the crime was committed.
In this case, the authorities of the victim's country of residence should promptly transmit the complaint to the relevant authorities of the country where the crime was committed.

In the European Union, the victim of a crime that occurred in a country other than their country of residence may make a statement immediately after the crime was committed. In Portugal, a victim who resides in another country may make a statement that can later be used as evidence at the **trial**, thus avoiding the victim having to return to Portugal.

This statement is called a statement for **future recall** (*declarações para memória futura)*.

However, if it is necessary to question the victim again but they are no longer in the country where the crime was committed, they may be questioned in a telephone conference or videoconference call from the country in which they reside.

Victims of a violent crime committed in a European Union Member State who usually reside in another Member State may file their claim for **compensation** with the authority in their country of residence which has the jurisdiction to assess and decide on this kind of request. This authority should transmit the request to the relevant authority of the Member State in which the crime occurred. In Portugal, the authority with the jurisdiction both to receive claims from people who reside in other countries and who were victims of crime in Portugal and to send the claims of persons resident in Portugal who were the victims of crime in other European Union countries is the **Commission for the Protection of Victims of Crime**.

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;

N/D

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**)

All these measures to Ensure quality and safety requirements of medical products are foreseen in Portuguese legislation regarding regulation of medicinal products

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

Measures to ensure the safe distribution of medical products are foreseen in the Portuguese legislation regarding regulation of medicinal 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?

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**);

In 2008, 2009, 2015 and 2019 INFARMED launched several online campaigns (INFARMED's website) to raise awareness on the risk of buying medicines on line. Such campaigns were normally linked to Operation PANGEA to boost its impact.
The most successful campaign was launched in 2009 and repeated in 2010 (Internet: M-REC video, Search Engine Marketing e Microsite)
We have no plans to launch a new campaign in the near future but we continuously raise awareness through communication with the citizen that contact us regarding potentially illegal medicinal products.