I. 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"?

Royal Legislative Decree 1/2015, of 24 July, approving the revised text of the Law on guarantees and the rational use of medicines and health products, does not define a "medicinal product" but does refer to "healthcare products", defining these as "any instrument, device, equipment, computer program, material or other item used alone or in combination, including computer programs intended by their manufacturer to be for specific purposes of diagnosis and/or therapy and that are involved in their appropriate operation, intended by the manufacturer to be used on humans for the purpose of:

1. Diagnosis, prevention, control, treatment or alleviation of an illness;
2. Diagnosis, control, treatment, alleviation or compensation for an injury or deficiency;
3. Investigation, replacement or modification of the anatomy or a physiological process;
4. Regulation of conception, and substances that do not carry out the main action that is desired to be obtained inside or on the surface of the human body by pharmacological, immunological or metabolic means, but whose function these can contribute to".

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"?

According to the Redrafted Text on "medicines for human use", these are understood to be any substance or combination of substances that present with properties for treating or preventing diseases in humans or that can be used on humans or administered to humans in order to restore, correct or modify physiological functions by exerting a pharmacological, immunological or metabolic effect, or to establish a medical diagnosis.

"Veterinary medicines" should be understood to be any substance or combination of substances that presents with curative or preventive properties

with respect to animal diseases or that can be administered to an animal in order to restore, correct or modify its physiological functions by exerting a pharmacological, immunological or metabolic effect, or to establish a veterinary diagnosis. “Veterinary medicines” also include “premixtures for medicated feedingstuffs” prepared for mixing into feed.

Article 8 "Legally recognised medicines" of Royal Legislative Decree 1/2015, of 24 July, which approves the revised text of the Law of Guarantees and Rational Use of Medicines and Health Products, states in section 1 that : “Only those substances listed below will be considered to be medicine: a) Medicine for human use and for veterinary use manufactured industrially or whose manufacture includes an industrial process; b) Pharmaceutical compounds; c) Medicinal preparations; d) The special medicines provided for in this Law”. Likewise, section 2 of the provisions indicates that: "Substances or combinations of substances authorised for use in clinical trials or for research on animals will be legally treated as medicines for the purposes of the application of this Law and its general monitoring."

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”?**

Precisely, in our internal legislation "active ingredient" or "active substance" is understood to be any substance or mixture of substances used for manufacturing a medicine and that, when used in its production, become an active component of this medicine intended to exert a pharmacological, immunological or metabolic effect in order to restore, correct or modify physiological functions, or to establish a diagnosis.

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”?**

According to the Redrafted Text, "excipient" is understood to be any component of a drug other than the active ingredient 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"?

As noted above, Royal Legislative Decree 1/2015, of 24 July, approving the Redrafted Text on guarantees and the rational use of medicines and health products, defines "healthcare products", as "any instrument, device, equipment, computer program, material or other item used alone or in combination, including computer programs intended by their manufacturer to be for specific purposes of diagnosis and/or therapy and that are involved in their appropriate operation, intended by the manufacturer to be used on humans for the purpose of:

1. Diagnosis, prevention, control, treatment or alleviation of an illness;
2. Diagnosis, control, treatment, alleviation or compensation for an injury or deficiency;
3. Investigation, replacement or modification of the anatomy or a physiological process;
4. Regulation of conception, and substances that do not carry out the main action that is desired to be obtained inside or on the surface of the human body by pharmacological, immunological or metabolic means, but whose function these can contribute to".

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"?

According and for the purposes of Royal Decree 9/1996, of 15 January, which regulates the selection of effects and accessories, effects and accessories are defined as those healthcare products of serial manufacture that are obtained on an outpatient basis and are intended to be used for the purpose of carrying out a therapeutic treatment or helping a patient with the unwanted effects thereof.

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 definition of "parts" or "materials" in domestic legislation.

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"?

For criminal purposes, it could be understood that the documentary elements referred to in article 362 ter of our Penal Code constitute documents within the meaning of article 26 of the Penal Code, in other words, any material form that expresses or incorporates data, facts or narrations with evidential efficacy or any other type of legal relevance.

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"?**

Royal Decree 824/2010, of 25 June, which regulates pharmaceutical laboratories, manufacturers of active ingredients for pharmaceutical use and foreign trade of medicines and investigational medicines defines the concept of "manufacturing" as all operations of material and product acquisition, production, quality control, release, storage, distribution of medicines and the monitoring corresponding to these operations.

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"?

Article 362.1 of the Penal Code penalises deceptive preparation (simulation or imitation) of documentary elements. In this way, anyone who manufactures a medicine by deceptively presenting it, whether that is in its container, labelling, expiration date, name, composition, authorisation, etc., is committing the crime established in article 362.1 of the Penal Code.

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"?**

We find the concept of "victim" in the Statute of the victim of a crime, approved by Law 4/2015, of 27 April, which defines a victim as "any physical person who has suffered damage or harm to their own person or patrimony, especially physical or psychological injuries, emotional damage or economic damage directly caused by the commission of a crime".

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.

Article 22.4 of the Penal Code regulates the generic aggravating factor of discrimination by establishing what aggravating circumstances are "4. Committing crimes for racist, anti-Semitic or other types of discriminatory motives regarding the ideology, religion or beliefs of the victim, ethnicity, race or nation to which they belong, their sex, sexual orientation or identity, gender, any illnesses they suffer or their disability".

Likewise, in Article 14, the EC establishes that: "Spaniards are equal before the law, without any discrimination based on birth, race, sex, religion, opinion or any other personal or social condition or circumstance."

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;**

Following the ratification of the Medicrime Convention, Spain has made substantial modifications to its Penal Code to align it with the convention, with the aim of having more effective tools to fight these crimes.

The general legal framework is Royal Legislative Decree 1/2015, of 24 July, which approves the redrafted text of the Law of guarantees and rational use of medicines and healthcare products that has incorporated tools to reinforce the protection of the legal channel of medicines and active ingredients as provided for in the European regulations.

The implementing regulations have been updated with the entry into force of Royal Decree 782/2013, of 11 October, on the distribution of medicines for human use. Another administrative protection derived from the transposition of Directive 2011/62/EU is Royal Decree 870/2013, of 8 November, which regulates distance selling to the public, through websites, of medicines for human use not subject to medical prescriptions.

Likewise, the March 2015 reform of the Penal Code is of note, as it affects articles related to crimes against public health, and more specifically with medicines (articles 361, 362, 362 bis, 362 ter, 362 quater and 362 quinquies), as a consequence of the ratification of the Medicrime Convention, which has introduced new criminal conduct, as well as the intensification of penalties.

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 Spanish Agency for Medicines and Healthcare Products (AEMPS) has prepared the 2019-2022 General Strategic Plan[1], which updates the previous 2016-2019 strategy and is a guide to achieving the objective of being a reference point for the population and for health professionals, as well as positioning itself at the forefront of knowledge in medicines and healthcare products. In this four-year period, eleven Action Plans will be deployed, in addition to the processes implemented to achieve the strategic, tactical and operational objectives indicated in the Strategic Plan.

To develop the mission entrusted to it, AEMPS has defined five strategic objectives.

1 Provide guarantees: guarantee citizens the quality, safety, efficacy, availability and information regarding medicines and health products, as well as the quality and safety of cosmetics and personal care products.
2 Customer orientation: increase transparency, accessibility and user satisfaction.
3 Social impact: create value for society, with the AEMPS being recognised as a national and international benchmark by interest groups, and promoting research.
4 Efficiency: improve economic and organisational management.
5 Capacity development: improve AEMPS resources and capacities through the development of people, technology and strategic alliances.

[1] https://www.aemps.gob.es/laAEMPS/planificacion-AEMPS/docs/plan-Estrategico-AEMPS_2009-2012.pdf?x21576

On the other hand, the AEMPS has also prepared the 2020 Annual Work Plan [2].

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.**

Not applicable.

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);**

In relation to the State Security Forces and Bodies, collaboration is foreseen with the Spanish Agency of Medicines and Medical Devices (AEMPS for its acronym in Spanish) in the prevention of the illicit distribution of counterfeit medicines in the national territory and in the investigation of the networks of manufacture and distribution of counterfeit, illegal medicines and adulterated products within the framework of the Cooperation Agreement established between AEMPS and the Secretary of State for Security of the Ministry of the Interior.

Likewise, the formalisation of technical agreements and procedures
for the collection of samples and actions as administrative police are envisaged in order to extend the supervisory actions in non-pharmaceutical establishments open to the public.

In addition, in the framework of the aforementioned collaboration agreement, there is cooperation in the specific, continuous and updated training of the agents specialised in the fight against counterfeit and illegal medicines and adulterated products.

In this sense, the National Police maintains direct contact with the various administrative authorities competent in the matter under investigation, as well

[2] https://www.aemps.gob.es/laAEMPS/planificacion-AEMPS/docs/plan-anual-trabajo-AEMPS-2020.pdf?x21576

as those in charge of the analysis, reception of suspicious products or control of licenses.

Within the scope of the Ministry of Justice, collaboration is foreseen with the Administration of Justice in procedures related to counterfeit medicines in their capacity as experts and the preparation of the relevant reports. Participation in training and awareness-raising activities is also envisaged for judges, magistrates and the Attorney General's Office on the problem and risks posed by counterfeit medicines.

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)

With regard to how to promote cooperation between the authorities involved and the commercial and industrial sector, on most occasions it is those responsible for the investigation who provide, together with other agencies, the information and human resources so that, acting jointly, the common effort benefits the result of the investigation carried out.

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));

- 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));

AEMPS relies on advisory and coordination bodies, including the Technical Committees. These are advisory bodies that guarantee transparency and independence in the actions of AEMPS. The composition of these bodies is mixed, with the participation of AEMPS officials and other experts of renowned prestige, as well as representatives of consumer and user associations or professional associations of doctors, pharmacists or veterinarians.

Among them we also find the coordination committees of AEMPS, with the authorities of the Autonomous Communities and the regional services of pharmaceutical inspection.

However, no contact points or data and information collection systems are detected for a national cooperation between health authorities, customs, law enforcement and other competent authorities, beyond the interpersonal

relations that are woven through a network of contacts created as a result of the implementation of the Medicrime Convention.

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 national cooperation network within the scope of the Medicrime Convention includes representatives of the Directorate General of the Police, the Civil Guard, Customs Surveillance, the Spanish Agency of Medicines and Medical Devices, university professors and the national contact point, in this case, a representative of the Ministry of Justice.

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).

Spain has recently appointed Judge Sonia Nuez Rivera as the national contact point in the Committee of the Parties to the MEDICRIME Convention (Article 22.2 of the Convention). Ms. Nuez Rivera is responsible for receiving and transmitting requests for information and/or cooperation related to the counterfeiting of medical products and similar crimes that pose a threat to public health.

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.

The current Master Plan (MP) of the Spanish Cooperation (SC) 2018-2021, approved by the Council of Ministers on 23 March 2018, and in the framework of the 2030 Agenda, which defines the Sustainable Development Goals (SDGs), does not include any reference to the prevention or fight against counterfeiting of medical products.

SDG 3, which deals with health and well-being and seeks to ensure healthy living and promote well-being at all ages, only addresses access to medicines, vaccines and other essential healthcare products, by supporting specific initiatives of specialised agencies and funds to enhance the functioning of the supply chain and procurement primarily of medicines against communicable diseases.

II. 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.

These are wilful crimes, which require intentional conduct, with eventual wilfulness being sufficient. However, in Article 367 of the Criminal Code, the negligent commission is also criminally punished:

"If the acts provided for in all the foregoing articles are carried out through serious negligence, the lesser penalties shall be imposed, respectively".

However, despite the literal wording of Article 367 CC, the truth is that in some articles the assessment of the negligent form of commission is not very compatible with the definition of the crime, which requires specific intent on the part of the perpetrator.

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

Our Penal Code contemplates the following types of criminal offences, included in the Medicrime convention:

- Article 361 CC, that regulates the entry into circulation of medicines without authorisation, deteriorated, expired or not fulfilling its technical requirements, punishing all the phases of the cycle of distribution of medicines and medical devices. It contains the conducts foreseen in the "Medicrime" convention, that is, to manufacture, import, export, supply, intermediate, market, offer or place on the market, or to store with these purposes.
- Article 362 CC, that regulates the counterfeiting or alteration of medicines or medical devices, that would be produced in the field of the elaboration or manufacture of medicines of bad quality.
- Article 362 bis CC, which regulates the import, export, advertising, publicity, offering, exhibition, sale, facilitation, expedition, dispatch, packaging, supply or intermediation, traffic, distribution or placing on the market of adulterated or counterfeit medicines. That is to say, the illegal traffic of medicines and medical devices, taking into account all the phases of the marketing process of the goods.
- Article 362 ter CC, which regulates the forgery of documents in relation to adulterated or counterfeit medicines.

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).

Article 23 of the Organic Law of the Judiciary determines the jurisdiction of the Spanish criminal courts.

Article 23.

"1. In the criminal field, the Spanish jurisdiction shall be competent to hear cases of crimes and misdemeanors committed in Spanish territory or on board Spanish ships or aircraft, without prejudice to the provisions of international treaties to which Spain is a party.

2. The Spanish jurisdiction will also cover crimes that have been committed outside the national territory, provided that those criminally responsible are Spanish or foreigners who have acquired Spanish nationality after the fact and that the following requirements are met:

a) That the act is punishable in the place of commission, unless, by virtue of an international treaty or a normative act of an international organisation to which Spain is a party, this requirement is not necessary, without prejudice to the provisions of the following paragraphs.

b) That the aggrieved party or the Attorney General's Office file a complaint before the Spanish Courts.

c) That the offender has not been acquitted, pardoned or sentenced abroad, or, in the latter case, has not served the sentence. If they have only served it partially, they will be taken into account in order to reduce proportionally the corresponding one.

4. Likewise, Spanish jurisdiction will be competent to deal with acts committed by Spaniards or foreigners outside national territory that may be classified, according to Spanish law, as any of the following crimes when the conditions expressed are met:
(…)
o) Crimes regulated by the Council of Europe Convention of 28 October 2011 on counterfeiting of medical products and crimes posing a threat to public health, when:

1. the procedure is directed against a Spaniard;

2. the procedure is directed against a foreigner who habitually resides in Spain;

3. the procedure is directed against a legal person, company, organisation, group or any other kind of entity or group of persons having its headquarters or registered office in Spain;

4. the victim had Spanish nationality at the time of the commission of the acts; or

5. the crime was committed against a person who had habitual residence in Spain at the time of the commission of the acts.

Likewise, the Spanish jurisdiction will also have competence to deal with previous crimes committed outside the national territory by foreign citizens who were in Spain and whose extradition was denied by the Spanish authorities, provided that this is imposed by a Treaty in force for Spain.
(…)
6. The crimes referred to in paragraphs 3 and 4 will only be prosecuted in Spain after a complaint has been filed by the aggrieved party or by the Attorney General's Office".

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.

Prior to the reform implemented by Law 1/2015, of 30 March, the criminal liability of legal persons for these crimes was not contemplated, although accessory measures of Article 129 of the Criminal Code could be established. However, the reform of 2015 extends the criminal liability of legal persons to pharmacological crimes, responding to the demand of Article 11 of the Council of Europe Convention on Counterfeiting of Medical Products and Similar Crimes "Medicrime".

In the event that the author or accomplice is a legal person, the provisions of Article 366 of the Criminal Code shall apply:

"Where, in accordance with the provisions of Article 31 bis, a legal person is liable for the crimes set forth in the preceding articles of this Chapter, it shall be liable to a fine of one to three years, or of twice to five times the value of the substances and products referred to in Articles 359 et seq. or of the profit that would have been or could have been obtained, whichever is greater.
Having observed the rules set out in Article 66 bis, judges and courts may also impose the penalties set out in Article 33(7), letters (b) to (g)".

Article 31 bis of the Criminal Code provides that legal persons are criminally liable for crimes committed in their name or on their behalf, and for their direct or indirect benefit, by their legal representatives or by those authorised to take

decisions in their name and for crimes committed in the exercise of social activities and on their behalf and for their direct or indirect benefit.

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);**

Article 361 of the Penal Code establishes prison sentences of six months to three years, a fine of six to twelve months and special disqualification from a profession or trade of six months to three years; articles 362 and 362a PC imprisonment of six months to four years, a fine of six to eighteen months and special disqualification from a profession or trade of one to three years; article 362b PC imprisonment of six months to two years, a fine of six to twelve months and special disqualification from a profession or trade of six months to two years.

When the circumstances of art. 362c PC are met, the sentences that are higher in degree than those indicated in articles 361 to 362b PC are imposed. Art. 372 PC establishes that in addition to the sentences provided for in each case, the employer, intermediary in the financial sector, doctor, public official, social worker, teacher or educator, in the exercise of their post, profession or trade, will be imposed the penalty of special disqualification for public employment or post, profession or trade, from three to ten years; and when the acts are carried out by an authority or agent of the same, in the exercise of their post, the penalty of absolute disqualification from ten to twenty years.

Acts of gross negligence are punishable by lesser sentences.

A legal person shall be liable to a fine of between one and three years, or of two to five times the value of the substances and products referred to in Article 359 et seq., or of the profit which has been or could have been obtained, whichever is the greater. Subject to the rules set out in Article 66a, the judges and courts may also impose the penalties laid down in Article 33(7) (b) to (g) of the PC.

Art. 376 PC provides in certain circumstances for an attenuation of the penalty by one or two degrees.

Art. 362e CP establishes the confiscation of the substances and products referred to in Arts. 359 et seq. PC, as well as the goods, means, instruments and profits subject to the provisions of Arts. 127 to 128 PC

However, in the administrative sanctioning field there are offences which contemplate the same conducts of Article 361 PC. Thus, Article 101.2 c) of Law 29/2006, of 26 July, which classifies as a very serious offence the placing on the market of medicines of any kind without having obtained the required health authorisation to do so or the distribution of medicines without observing the legally required conditions, in poor condition or expired. It is also considered as serious misconduct the processing, manufacture, import, export, dispensing or distribution of medicines by natural or legal persons not authorised to do so. In addition, there are also offences in relation to medical devices.

In the various administrative infringements that are regulated, it is not required, with a few exceptions, that the conduct generates a risk to the life or health of persons, nor that the conduct necessarily falls on medicines or medical devices that lack authorisation or legally required documentation, be they deteriorated or expired, or which do not comply with technical requirements.

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).

Article 375 of the Penal Code provides for international recidivism based on the convictions of judges or courts for crimes of the same nature whose records have not been or could be expunged under Spanish law.

For this purpose, it is necessary to take into account the Organic Law 7/2014 of 12 November on the exchange of information and criminal records and consideration of judicial decisions in criminal matters in the European Union, which incorporates into our law the framework decisions and directives approved in the field of mutual recognition and criminal decisions. These rules are coordinated with the Penal Code so that the effects of recidivism are applicable under the same conditions when the conviction has been handed down in Spain or in any other Member State of the European Union

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).

The reform implemented by the Organic Law 1/2015, of 30 March, regulates the aggravated rates in an autonomous precept included in the new Article 362c of the Penal Code, reads as follows:

"Penalties higher in degree than those indicated in Articles 361, 362, 362a or 362b shall be imposed when the offence is committed in any of the following circumstances:
1st. That the guilty party is an authority, public official, physician, health professional, teacher, physical educator or sportsman, and is acting in the exercise of his position, profession or trade.
2nd. That the medicines, active substances, excipients, health products, accessories, elements or materials referred to in Article 362:
a) Have been offered through mass media; or
b) have been offered or provided to minors, persons with disabilities in need of special protection, or persons who are particularly vulnerable in relation to the product provided.
3rd. That the offender belongs to a criminal organisation or group whose purpose is to commit this type of crime.
4th. That the acts were carried out in establishments open to the public by those responsible for or employed by them".

Thus, the first case referred to in Article 13(a) of the "Medicrime" Convention, where the offence has caused the death of the victim or impairment of his physical or mental health, is not covered by our domestic legislation as a specific aggravating circumstance.

The second of the aggravating circumstances in Article 13(b) of the Convention, relating to the fact that the offence was committed by a person who abused the trust conferred on them by their professional status, is provided for in the first paragraph of Article 362c of the PC, although the catalogue of subjects in respect of whom that status is conferred is limited.

Spanish legislation has not taken account of the aggravated circumstances referred to in Article 13(c) of the Convention concerning the commission of the offence by a person who abuses the confidence placed in them as a manufacturer or supplier. The reason for such an omission may be that it is usually these persons who commit the crime in question and an attempt is made to avoid a double sanction.

The aggravating factors referred to in Article 13(d) and (e) of the Convention are provided for. Finally, as regards the aggravation referred to in Article 13(f) relating to the fact that the perpetrator has previously been convicted of offences of the same nature, this has not been specifically included in Article 362c PC, although there is nothing to prevent the generic aggravation of recidivism in Article 22.8 PC from being applied in this case.

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).**

These are public offences, prosecutable ex officio, so that the criminal action for the offence giving rise to the ex officio procedure is not extinguished by the resignation of the offended person, as provided for in Article 106 of the Criminal Procedure Act. In this case, criminal proceedings will be brought by the Public Prosecutor's Office. Criminal proceedings may be initiated, even without the will of the injured party, at the instigation of the Public Prosecutor's Office, which, in accordance with Article 105 of the Criminal Procedure Act, is obliged to bring criminal proceedings.

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 complexity of action to prevent and combat counterfeit medicines requires the collaboration of different authorities with a multidisciplinary approach. At national level, both the State Security Forces (National Police and Guardia Civil) and the Tax Agency authorities (Customs) intervene, with the assistance of the health authorities.

Within the National Police Force, the branch specialising in investigating drug trafficking is the Consumer, Environment and Doping Branch of the General Commissariat of Judiciary Police.

As for training, this is done centrally, by attending different forums and courses given by other specialists in the field. Training hours on how the National Police work in this field are also given to both the judiciary and other administrative bodies.

Decentralised training is also envisaged in the various Police Higher Headquarters Likewise, a decentralised training is being implemented (given the increase of crimes of this typology) by moving representatives of the mentioned Branch to give courses or conferences at the Headquarters.

With regard to Customs Surveillance, it is governed by the Organic Law for the Repression of Smuggling 12/95, considering counterfeit medicines as prohibited goods or whose possession (among other conducts) constitutes a crime. However, there is no specialisation in this field.

As for resources to combat this type of crime, they have risk analysis units in ports and airports, which are very useful for detecting the entry of these products at the border.

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 measures can be taken for the investigation and detection of crimes and their perpetrators. Likewise, through the Office for the Recovery and Management of Assets, the Public Prosecutor's Office may approach financial institutions, public bodies and registers and natural or legal persons so that they can provide, within the framework of their specific regulations, a list of the assets or rights of the executed person of which they are aware.

With regard to controlled delivery, this is provided for in relation to toxic drugs, narcotics or psychotropic substances, as well as other prohibited substances (Article 263a of the Criminal Procedure Act), with harmful substances being understood as those that are harmful to health.

Article 282a of the Criminal Procedure Act provides for the undercover agent for crimes against public health provided for in Articles 368 to 373 of the Penal Code. There is no express mention of the offences of counterfeit medicines.

Question 12: Measures of protection for the victim

a. Please describe the measures taken to (Article 19):

- **ensure that victims have access to information relevant to their case and which is necessary for the protection of their health;**
- **assist victims in their physical, psychological and social recovery;**
- **provide for the right of victims to compensation from the perpetrators.**

The Spanish Law 4/2015, of the 27th April, on the Standing of Victims of Crime establishes the victims' right to information (Article 3.1). Article 5 stipulates the right to information from the first contact with the competent authority. Article 7 specifically stipulates the right to receive

information about the criminal case and the state of the proceedings. On the other hand, Article 109 of the Spanish Code of Criminal Procedure stipulates to provide victims of crime with information about their rights.

Article 5 of the Standing of Victims of Crime considers the right to information about available assistance and support measures for the victims, whether medical, psychological or physical and the procedure for obtaining them. Article 10 regulates the right of victims to access assistance or support services provided by the public authorities, as well as those provided by Victim Support Offices.

Article 5 of the Standing of Victims of Crime considers the right of victims to receive information about compensation that they may be entitled to and the procedure for claiming it for any damages suffered, as well as the possibility of accessing a public compensation system. Moreover, the Spanish Code of Criminal Procedure stipulate that by taking civil action the injured party may apply for compensation for damages caused by the punishable act.

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).

As aforementioned, Article 5 of the Standing of Victims of Crime considers the right of victims to receive information from the first contact with authorities and officials, without unnecessary delay, about available assistance, support measures and services. Article 7 stipulates the victims' right to receive information about their criminal case and the state of their proceedings, unless this would prejudice proper conduct of the case. Moreover, the victim shall be informed of the decision concluding the proceedings.

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));

All victims have the right to actively participate in the criminal proceedings. They have the right to report and provide evidence to the authorities responsible for the investigation (Article 5 of the Standing of Victims of Crime). Article 11 stipulates active participation of the victim in criminal proceedings. All victims have the right to pursue criminal and civil proceedings and appear before the authority responsible for the investigation to provide them with any evidence and information they consider relevant to clarify the facts.

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))

They are entitled to access assistance and support services provided by the public authorities, as well as those provided by Victim Support Offices (Article 10 of the Standing of Victims of Crime). Access to support services are regulated, including initial reception, orientation and information and specific measures to protect victims notwithstanding the specific support for each victim.

The Victim Support Offices provide assistance which includes general information regarding their rights, available specialised services which can assist victims, emotional support for victims, advice on financial rights related to the proceedings and advice on how to prevent secondary victimisation. Support functions in relation to restorative justice and out-of-court disposals are also provided.

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));

The Standing of Victims of Crime stipulates measures to protect victims, particularly when they make a statement or have to testify in court and to avoid the risk of secondary or repeat victimisation. The right to avoid contact between the victim and offender and the protection of the victim during criminal investigations are considered. It regulates the right to protect the privacy of all victims and their families and, in particular, to prevent the disclosure of any information which could identify victims who are minors or victims with disabilities in need of special protection.

During the trial phase, measures are stipulated to guarantee that the victim can be heard without being present in the courtroom, to hold a private oral closed-door hearing, etc. Furthermore, one or more of the protection measures provided in Article 2 of the Spanish Organic Law 19/1994, of the 23rd of December, on the protection of witnesses and experts in criminal cases, may also be ordered for the protection of victims.

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).

Citizens involved in any type of criminal proceedings or who wish to initiate them but do not have sufficient assets to litigate may apply for free legal aid. Article 6.3 of the Spanish Law of Free Legal Assistance establishes that the right to free legal assistance includes free defence and representation by a lawyer and prosecutor in legal proceedings, when the intervention of these professionals is legally required or, in any case, expressly requested by the

Court or Tribunal by means of a reasoned order to guarantee the equality of the parties in the process.

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).

Article 17 of the Standing of Victims of Crime establishes that victims resident in Spain may lodge complaints before the Spanish authorities regarding criminal acts committed in the territory of other countries of the European Union.

In the event that Spanish authorities decide not to proceed with the investigation due to lack of jurisdiction, they will immediately send the complaint to the competent authorities of the state in whose territory the acts were committed and the complainant will be notified by the designated procedure.

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;

Article 109 of the Spanish Code of Criminal Procedure stipulates that criminal proceedings may be exercised by victims' associations and by legal entities which are recognised by law as having the right to defend the rights of victims, provided that this is authorised by the victim of the crime.

III. 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)

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

The Spanish Royal Legislative Decree 1/2015, of the 24th July, which approves the consolidated text of the Law on guarantees and rational use of medicines and medical devices, aims to consolidate, in a single text, the subsequent amendments that have been incorporated into the

Spanish Law 29/2006, of the 26th July, on guarantees and rational use of medicines and medical devices, which is the legal framework of reference in the Spanish legal system with regard to the assessment, authorisation, registration, manufacture, storage, distribution, prescription, dispensing and monitoring the risk-benefit balance of medicines, in order to establish guarantees of security, quality and effectiveness.

Title IV of the Consolidated Text deals with the guarantees required in the manufacture and distribution of medicines and regulates the guarantees of accessibility and availability of medicines, administrative control of wholesale distribution, operational requirements, among other things.

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?**

The Spanish Agency for Medicines and Medical Devices (AEMPS, in its Spanish acronym) cooperates in the specific, continuous and up to date training of agencies specialised in the fight against counterfeit and illegal medicines and adulterated products within the framework of the aforementioned collaboration agreement. In addition to this, they work on the adequate training of any person involved and on the increase of the population's knowledge and awareness of this problem. They also take part in the development of the continuous, specific training activities for pharmaceutical inspectors in regard to counterfeit medicines.

Within the framework of distribution entities, it provides continuous necessary training, in the field of counterfeit medicines, to all of those responsible for the application of good practices in the distribution of medicines.

Within the framework of the Spanish Ministry of Justice, it participates in training activities and raising awareness of the problem and the risks associated with counterfeit medicines among judges, magistrates and the Prosecution Service.

Within the framework of State Security Forces and Agencies, they collaborate with the AEMPS to prevent the illegal distribution of counterfeit medicines in the national territory and investigate counterfeit and illegal drug and adulterated product manufacturing and distribution networks within the framework of the aforementioned collaboration

agreement established between the AEMPS and the Secretary of State for the Ministry of the Interior.

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);

The campaign “Don’t buy medicines on illegal websites. It could be fatal for your health” is a campaign being promoted by the Spanish Agency for Medicines and Medical Devices and the Spanish Ministry of Health, Social Services and Equality to raise awareness of the health risks associated with medicines obtained from illegal websites among the population. The campaign provides advice about how to recognise illegal websites and warns of the health risks involved.

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