

Questionnaire for the 1st thematic monitoring round:

**The protection of public health through the MEDICRIME Convention in
times of pandemics**

As adopted by the MEDICRIME Committee on 27 May 2021

SPAIN

30.11.2021

Question 1. (Mandatory)

Which legislative, policy, strategic and other measures have been taken to provide training with a view to preventing medical products, active substances, substances, accessories, parts and materials to:

- a. those involved in both public and private procurement programmes, Wholesalers, and distributors of medical products to ensure that they are competent to prevent and Detect medical products and conducts which contribute to the Commission of similar crimes interfering with public health, having regard to the impact of a pandemic (Articles 18.1, 2 and 3. a and c)?**
- b. healthcare practitioners, police, customs, and health product regulators?**
- c. specialised investigation units/bodies in the investigation of medical products and similar products, in specialised techniques, including financial investigations (Article 16.2)?**

Within the Strategic Plan 2019-2022 of the Spanish Medicines and Health Products Agency, the strategic objective number 5 is to optimise the training of the resources and capacities of the AEMPS (acronym of “Spanish Medicines and Health Products Agency”, in Spanish language Agencia Española de Medicamentos y Productos Sanitarios) and it is envisaged as a measure to adapt the training of staff to their area of competence, enhancing specialised training.

With regard to the State Security and Corps Forces, cooperation with the AEMPS is envisaged in the specific, continuous and up-to-date training of officials specialising in the fight against falsified and illegal medicinal products and adulterated products within the framework of the cooperation agreement.

The Ministry of Justice of Spain provides for cooperation with the Justice Administration on procedures relating to falsified medicinal products as experts and the drawing up of appropriate reports. Participation in training and awareness-raising activities for judges, magistrates and public prosecutors on the problem and risks posed by falsified medicines is also contemplated.

The AEMPS therefore cooperates in the specific, continuous and up-to-date training of agents specialising in combating falsified, illegal and adulterated medicinal products within the framework of that cooperation agreement. It also works on the proper training of all actors involved and on raising citizens’ awareness and knowledge of this problem. It is also active in the development of specific continuing training activities for pharmaceutical inspectors in relation to falsified medicines.

In the area of distribution entities, it provides the necessary ongoing training in the field of falsified medicinal products to staff responsible for the implementation of good practice in the distribution of medicinal products.

At the level of the Ministry of Justice, it participates in training and awareness-raising activities for judges, magistrates and public prosecutors on the problem and risks posed by falsified medicines.

Attention should also be drawn to the Council of Europe’s HELP programme (European training programme on human rights for legal practitioners) which together with the European

Committee on Criminal Matters has launched the 'MEDICRIME' course in Spain in collaboration with the Spanish Judicial School of the General Council of the Judiciary.

The aim of this course is to expand the capabilities and skills of judges to improve the national implementation of the Council of Europe Convention on the counterfeiting of medical products and similar crimes posing a threat to public health.

Within each Investigation Corps, generic training on financial investigations is also provided.

As regards the Spanish Guardia Civil, the units specialising in the investigation of drug trafficking offences are the Consumer Affairs Section of the Central Operational Unit, the Criminal Analysis Group of the Criminal Police Technical Unit and the Organised Crime Teams (EDOAs as acronym is Spanish language) of the Comandances of the Guardia Civil. The latter share the investigation of drug trafficking with that of other types of crime.

With regard to the strategic plans being developed, there are training days for EDOAs, which include issues related to drug trafficking offences.

Similarly, the Criminal Police Technical Unit produces intelligence products for dissemination to the above-mentioned units, such as documents on specific issues (DARDO) or others where changes in modus operandi, new technologies used by criminal organisations, etc. are reported, information obtained from the operations carried out (RAID).

The Head of the Criminal Police has published a Technical Instruction on trafficking in medicinal products, which is being updated on a regular basis and is a training and consultation document for the units involved in investigating these crimes.

Question 3. (Mandatory)

Are there awareness-raising and training programmes for all of those in question 1a and b call and for persons and entities responsible for cleaning and waste disposal on the disposal of medical product waste at all stages of the process to prevent the recycling of medical products for the further manufacturing of medical products and instruments used in the counting of medical products?

The management of health waste is a very important environmental issue. It is essential to know how to classify health waste, collect and manage it in an optimal way, minimising the risk to both the environment and human health and complying with all legal regulations.

For the management of the health crisis caused by COVID-19, instructions have been issued on the management of household waste, both for domestic handling in homes with patients and for its subsequent management, as well as on the management of waste from hospitals, ambulances, health centres, laboratories and similar establishments in contact with COVID-19.

For this purpose, Order SND/271/2020 of 19 March establishing instructions on waste management in the health crisis caused by COVID-19, published in the Official State Gazette on 22 March 2020 was adopted.

Furthermore, in the area of health waste, it is up to the Autonomous Communities (Regions) to develop their own management legislation.

Question 6. (Mandatory)

Please elaborate on the strategies, policies and other measures that have been planned or implemented, with a view to Educating the public on risks associated with certain medical products, in particular that may be regulated during a pandemic (Article 18.3b):

- a. on pure conducts of medical products, including through real world/physical and virtual means, such as online and e-commerce platforms and social media;
- b. promoting good budgeting conduct the public to regulate rational consumption of medical products and Avoiding procurement from sources which are not your country's authorised supply systems;
- c. on speeding and dealing with risk awareness camigns regarding counterfeit medical products and similar crimes.

Are there any reports on the results of these measures? If so, please attach them to your responses to this questionnaire.

The Spanish Agency for Medicines and Health Products ("Agencia Española de Medicamentos y Productos Sanitarios" in Spanish language) together with the Ministry of Health promoted the campaign "No medicines on illegal websites. It is a fatal mistake for your health "to raise citizens' awareness of the health risks of medicines bought on illegal websites. The campaign remains available on the AEMPS website¹.

The AEMPS website provides information on the authorised medicinal products and the conditions of use that are necessary for the medicinal products to offer the guarantees and benefits for which they were authorised.

Furthermore, AEMPS has participated in Operation PANGEA XIII, aimed at the online sale of falsified and illegal medicines and medical devices and led by Interpol together with the Spanish Guardia Civil and the Autonomous Communities (Regions)².

The 2020 report of the Spanish Agency for Medicines and Health Products shows that the AEMPS is part of the European project 11/2020-10/2025 on innovation in digital health, which aims to strengthen and prepare European citizens with information for active management of personal health and adherence to treatments. The aim is to improve access to and understanding of health-related information thus achieving safe use of medicines, risk minimisation and a better quality of life.

In 2020, measures were also taken to plan the information campaign against falsified and illegal medicines and participated in the 'Medicines Safety Week' campaign organised by Uppsala Monitoring Centre.

In January 2021, the International Federation of Pharmaceuticals (FIP), in collaboration with the World Health Organisation (WHO), published a curriculum guide to help trainers ensure that

¹ <https://www.aemps.gob.es/acciones-informativas/campanas-institucionales/campana-contra-la-venta-ilegal-de-medicamentos-en-internet/>

² <https://www.aemps.gob.es/informa/notasInformativas/laAEMPS/2021/docs/memoria-2020.pdf?x44062>

pharmacists are better able to prevent lower-quality or falsified medicines and medical products from reaching patients.

In addition, the AEMPS provides some information on its website:

- I.- Information on the sale of medicinal products via websites and mobile applications³.
- II.- Recalls the risks of buying falsified medicines for the treatment of COVID-19 via illegal websites⁴ and provides information to patients.
- III.- Provide the list of pharmacies registered for distance sales via the internet of medicinal products without medical prescription, which can be found on the AEMPS website, Distafarma: <https://distafarma.aemps.es/farmacom/faces/inicio.xhtml>

For its part, the Spanish Federation of Associations of Pharmaceutical Industry (EFPIA) has called for extreme precautions to be taken when purchasing medicines or medical devices during this health crisis.

No reports on the results of these information measures have been found.

³ <https://www.aemps.gob.es/informa/campannas/medllegales/informacion-sobre-la-venta-de-medicamentos-a-traves-de-sitios-web-y-aplicaciones-para-moviles/>

⁴ <https://www.aemps.gob.es/informa/notasinformativas/medicamentosusohumano-3/medllegales/2020-medllegales/la-aemps-recuerda-los-riesgos-de-comprar-medicamentos-falsificados-para-el-tratamiento-del-covid-19-a-traves-de-webs-ilegales/>

Question 9. (Mandatory)

Which legislative provisions, strategies, plans and preventive measures have been taken to prevent the promotion, warning and dissemination of material, including virtual information and medicinal product offers, when they are contrary to internal laws, during a pandemic and generally (Article 8a, and Article 18. 3. b)?

Law 10/2013 of 24 July 2014 abolished the prior administrative authorisation for advertising of medicinal products for human use not subject to medical prescription, which is subsequently included in Article 80 of Royal Legislative Decree 1/2015 of 24 July 2007 approving the recast text of the Law on guarantees and rational use of medicinal products and medical devices.

In view of the importance of the transmission of information on medicinal products for human use to the public, the Ministry of Health took the view that it was of particular importance that mechanisms should be put in place to control this type of advertising since, in principle, no alternative system of prior control was introduced by this legislative amendment.

For this reason, an agreement was signed in October 2014 between the Ministry of Public Health and the main parties involved in this process, such as the “Association for Self-Care of Health (ANEFP in Spanish language)” and the “Association for the Self-Regulation of Commercial Communication (AUTOCONTROL in Spanish language)” which are the economic operators involved in the advertising of medicinal products for human use to the public, in order to ensure that the advertising messages issued comply with all the conditions imposed by the legal system.

That Convention ceased to be in force in October 2020 and a new agreement between the parties was therefore necessary.

As a result, the Resolution of 26 March 2021 of the State Secretariat for Health published the Agreement with the Association for Self-Care of Health and the Association for the Self-Regulation of Commercial Communication on Advertising Medicinal Products for Human Use addressed to the public (BOE of 7 April 2021⁵).

The purpose of the Convention is to establish the most appropriate mechanisms for the assessment of advertisements addressed to the public concerning medicinal products for human use, in order to ensure that they are produced with the necessary truth, clarity and objectivity and that all the conditions imposed by the relevant legislation are fulfilled.

In this regard, the Association for the Self-Care of Health (ANEFP) undertakes to review all draft advertising messages submitted to them on a voluntary basis by pharmaceutical bodies to advertise medicinal products for human use to the public through a Technical Committee for the review of this type of advertising, and to inform pharmaceutical bodies of all the incidents noted in the review of the advertising projects submitted and studied.

In turn, the Association for the Self-Regulation of Commercial Communication (AUTOCONTROL) undertakes to examine through its Technical Cabinet, and in accordance with its procedures, advertising campaigns sent by ANEFP under the ‘ANEFP stamp’ and those sent to it on a

⁵ https://www.boe.es/diario_boe/txt.php?id=BOE-A-2021-5468

voluntary basis by advertisers, agencies or media in relation to advertising messages on medicinal products for human use addressed to the public.

Moreover, in view of the proliferation of various websites and associated mobile applications for the sale of medicinal products, both subject to and not subject to prescription, which would be in breach of the legislation in force, the AEMPS has investigated and initiated various measures to ensure that the medicinal products reach the patient with the necessary guarantees of quality, safety and efficacy, accompanied by direct information and ensuring the pharmacist's professional intervention and direct communication with the patient, as provided for in the legislation in force⁶.

The AEMPS has also reported on the risks of buying falsified medicines for the treatment of COVID-19 via illegal websites⁷.

The AEMPS also has a mailbox medicamentos.falsificados@aemps.es to report cases of falsified or suspected medicinal products for human and veterinary use detected in the legal distribution and supply channels. Such notifications may be sent by marketing authorisation holders, manufacturing or importing laboratories, wholesale drug distribution warehouses, and healthcare professionals.

The Strategic Plan 2019-2022 of the Spanish Medicines and Health Products Agency (AEMPS) includes the tactical objective of providing full and reliable information on products to the public, healthcare professionals, industry, authorities and the media (Information Guarantee).

The AEMPS is an information point for both citizens and industry in the various fields in which it has competences. It is therefore responsible for reviewing and authorising the information contained in the technical sheets and package leaflets for medicinal products. This information is made available to the public and healthcare professionals within each medicine package, but is also accessible from multiple platforms. CIMA and C IMA Vet, owned by AEMPS, stand out. Platforms other than CIMA and CIMA Vet consist of third-party information systems (pharmacies, hospitals, etc.) which reuse the information published by the AEMPS.

The AEMPS is responsible for monitoring, with the cooperation of the Autonomous Communities (Regions) and the pharmaceutical services of the Government Delegations and Sub-Delegations, that there are no unauthorised, counterfeit or adulterated products on the market.

⁶ <https://www.aemps.gob.es/informa/campannas/medllegales/informacion-sobre-la-venta-de-medicamentos-a-traves-de-sitios-web-y-aplicaciones-para-moviles/>

⁷ <https://www.aemps.gob.es/informa/notasinformativas/medicamentosusohumano-3/medllegales/2020-medllegales/la-aemps-recuerda-los-riesgos-de-comprar-medicamentos-falsificados-para-el-tratamiento-del-covid-19-a-traves-de-webs-ilegales/>

Question 10. (Mandatory)

Is there any national law and policy for the protection of victims of crime coming from the counting of medical products and similar crimes, specifically during times of a pandemic due to the incriminated risks involved? If yes, please specify it. If not, what steps are planned, if any, for the setting of such policy or in the absence of which, for victims of crime relating to medical products generally (Article 19)?

Victims of crime arising from the counterfeiting of medical products and similar offences are covered by the general provisions of the Statute of Victims of Crime, approved by Law 4/2015 of 27 April.

Law 4/2015 of 27 April on the Status of Victims of Crime establishes the right to information of every victim (Article 3 (1)). Article 5 provides for the right to information from the first contact with the competent authorities. Article 7 specifically provides for the right to receive information about the criminal case and the status of the proceedings. Furthermore, Article 109 of the Code of Criminal Procedure provides for the provision of information on the rights of victims of crime.

As regards assistance and support measures, Article 5 of the Victims' Statute provides for the right to information on the assistance and support measures available to victims, whether medical, psychological or material, and the procedure for obtaining them.

Article 10 governs victims' right of access to assistance and support services provided by public administrations and to those provided by the victim assistance offices.

As regards the reparation of victims, Article 5 of the Victims' Statute provides for the right of victims to receive information on the compensation to which they may be entitled and the procedure for claiming compensation for the damage suffered, as well as the possibility of access to a public compensation scheme. In addition, the Code of Criminal Procedure provides that, by bringing a civil action, injured parties may claim compensation for damage caused by the offence.

The Victims' Statute also regulates the participation of victims in criminal proceedings (Article 11) and provides for measures to support and assist victims through the victim assistance services and offices.

At present, unless mistakenly, there is no planning to establish a specific policy for the protection of victims of crime related to counterfeit medical products and similar offences.

Question 15. (Mandatory)

Please provide information on measures that your country has taken or plans to take to take to adopt a national strategy and/or or formal action plan on cooperation and information between authorities/bodies to combat medical products and similar products and which they specifically make provision for pandemic situations (Article 17.1).

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

As regards the pandemic, at international level, INTERPOL has included in its operation PANGEA on internet drug trafficking, medicines and COVID-19 related crimes. Europol has also included this type of crime through Operation SHIELD on drug trafficking.

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

Question 22. (Mandatory)

Is the exchange of information or transfer and receipt of data and evidence between bodies/countries supported and covered by legislation?

In the case of Customs, there is the Convention concluded on the basis of Article K.3 of the Treaty on European Union on mutual assistance and cooperation between customs administrations (Naples II Convention). The Convention covers mutual assistance and cooperation between national authorities in the field of prevention, investigation and prosecution of certain infringements of national and European Union (EU) customs rules.

The exchange of information and personal data between law enforcement authorities must be subject to the applicable national and international laws and to bilateral or multilateral agreements signed between the respective governments.

Where necessary, intelligence is shared with other countries through channels such as EUROPOL, INTERPOL and police attachés, including joint investigations with those countries.

Thus, the European Union Agency for Law Enforcement Cooperation (Europol) is a central element of the overall internal security architecture of the Union. The Europol Convention establishes the European Police Office as the institution responsible for structuring police cooperation within the European Union.

For its part, the International Criminal Police Organisation—INTERPOL is an international organisation constituted under public international law, facilitating structured police cooperation.

The legal basis is to be found in Articles 33 (customs cooperation), 87, 88 and 89 of the Treaty on the Functioning of the European Union (TFEU).

As regards the pandemic, at international level, INTERPOL has included in its operation PANGAEA on internet drug trafficking, medicines and COVID-19 related crimes. Similarly, EUROPOL through Operation SHIELD on drug trafficking has included this type of crime.

The Spanish Guardia Civil actively participates in PANGAEA and SHIELD.

As regards the transfer and receipt of data and evidence, Directive 2014/41/EU of the European Parliament and of the Council of 3 April 2014 regarding the European Investigation Order in criminal matters, which is based on a single instrument for the taking of cross-border criminal evidence in the European Union, is available at European Union level. The Directive, proposed under the Spanish Presidency as a result of a slow and complex negotiation process, regulates the European Investigation Order, which will be issued for the purpose of obtaining one or more specific investigative measures to be carried out in the executing State, with a view to obtaining evidence or gathering evidence already in the possession of the executing authority.

The Directive was transposed by Law 3/2018 of 11 June, amending Law 23/2014 of 20 November on mutual recognition of criminal decisions in the European Union, to regulate the European Investigation Order.

The European Investigation Order creates a single regime for the taking of evidence and also includes measures involving the taking of evidence in real time, continuously or over a certain period of time, providing that, where necessary, the issuing and executing States may agree

among themselves practical arrangements in order to reconcile the differences between their national laws.

Question 23. (Mandatory)

Are there legislative or other measures to ensure that industry can prominently report suspicions or detections of medical products and similar crimes interfering with others to public health, to any particular authority? Are there established or ad hoc procedures and processes for this reporting?

As mentioned above, the Spanish Medicines and Health Products Agency (Agencia Española de Medicamentos y Productos Sanitarios) has a mailbox medicamentos.falsificados@aemps.es to report cases of medicinal products, both for human and veterinary use, which are falsified or suspected of being falsified, which are detected in the legal distribution and supply channels. Such notifications may be sent by marketing authorisation holders, manufacturing or importing laboratories, wholesale drug distribution warehouses, and healthcare professionals.

As regards information channels, a first channel is the Social Security Investigation Group (GISS) of the Criminal Police Technical Unit. The Ministry of Health forwards to the GISS any reports or suspicions of criminal offences which it is aware of, either directly, from the Autonomous Communities (Regions) or from the international spheres with which it is linked. The GISS studies, analyses and passes them on the basis of the location of the main event to the various investigation units of the Spanish Guardia Civil, which carry out the operational activities necessary for their investigation.

Another way of intelligence (input/output) to the GISS is through Spanish agencies; such as the Spanish Medicines and Health Products Agency (AEMPS), the Spanish Agency for the Protection of Health in Sport (AEPSAD) or the Spanish Food Safety and Nutrition Agency (AESAN), Official Associations and other bodies; At international level, information is shared with EUROPOL, INTERPOL, Police Attachés, other International Agencies and with different countries.

Another channel would be the Spanish Guardia Civil units that are aware, either ex officio or through the various national or international channels, of these crimes. These units would carry out the investigation itself by assuming responsibility of the investigation, or if this is not possible, they would transfer it to another superior or competent unit, but always in the Spanish Guardia Civil.

The AEMPS, together with the Ministry of Health, drew up a number of instructions for the purposes set out: [Instructions for reporting suspicions of falsified medicinal products identified by manufacturers in relation to safety features In accordance with Delegated Regulation \(EU\) No⁸2016/161](#), [Instructions for reporting suspicions of falsified medicinal products identified at distribution entities in relation to safety features in accordance with Delegated Regulation \(EU\)⁹No 2016/161](#) and [Instructions for the notification of suspicions of falsified medicinal products identified in pharmacy offices or services in relation to safety features in accordance with Delegated Regulation ¹⁰\(EU\) No 2016/161.](#)

⁸ https://www.aemps.gob.es/industria/dispositivos_seguridad/notifica-sospechas-med-falsificados/docs/instrucciones-notifica-med-falsificados-fabricantes.pdf

⁹ https://www.aemps.gob.es/industria/dispositivos_seguridad/notifica-sospechas-med-falsificados/docs/instrucciones-notifica-med-falsificados-distribuidores.pdf

¹⁰ https://www.aemps.gob.es/industria/dispositivos_seguridad/notifica-sospechas-med-falsificados/docs/instrucciones-notifica-med-falsificados-farmacia.pdf

Contact points have also been established in the Autonomous Communities (Regions) for the notification of suspected falsifications of medicinal products¹¹.

¹¹ https://www.aemps.gob.es/industria/dispositivos_seguridad/notifica-sospechas-med-falsificados/docs/puntos-contacto-CCAA-notifica-med-falsificados.pdf

Question 24. (Mandatory)

Is there a market sampling programme established to Detect counterfeit medical products on the market? If so, which authority is responsible for this? Is this system sustainable in times of pandemic leave to the additional demands made on analytical laboratories and testing services by the impact of the pandemic? Are there oversight arrangements to ensure the effectiveness of these measures?

The AEMPS is responsible for monitoring, with the cooperation of the Autonomous Communities and the pharmaceutical services of the Government Delegations and Sub-Delegations, that there are no unauthorised, counterfeit or adulterated products on the market. There is also a border pharmaceutical control over the external trade of medicines, which would prevent the entry of counterfeits.

The AEMPS has an e-mail address (medicamentos.falsificados@aemps.es) for reporting cases of falsified or suspected medicinal products for human and veterinary use detected in the legal distribution and supply channels. Such notifications may be sent by marketing authorisation holders, manufacturing laboratories or importers, medicines distribution entities and healthcare professionals. This mailbox is continuously followed up in order to allow for rapid intervention by the health authorities when needed.

In addition, the AEMPS has a system for reporting quality incidents of medicinal products for human use via email alertas.calidad@aemps.es which is continuously monitored. These notifications may be made by the pharmaceutical industry, the competent health ministers of the Autonomous Communities (Regions), and by individuals or other entities (hospitals, pharmacies, wholesale warehouses, official pharmacists' colleges, etc.). These communications are assessed by the AEMPS, and in case of suspicion of falsification of medicinal products, appropriate investigations would be carried out to confirm this fact and to take the necessary action to secure its immediate withdrawal.

On the other hand, each year the AEMPS, in collaboration with the Autonomous Communities, develops a programme to monitor medicines on the market to verify that their quality is maintained in the distribution and dispensing chain. The control plan includes the verification of the placing on the market of medicinal products, the monitoring of materials such as labelling and package leaflet or their compliance with the authorised dossier to the analysis of the medicinal product in question, and the inclusion of the medicinal products in that programme is carried out on the basis of risk criteria. The programmes are designed every year, and the risk of falsification of each medicine is a factor taken into account to include medicines in the study. For example, anabolic steroids or PDE-5 inhibitors, which have a higher risk of being affected by counterfeits, have been included. Such a system would also allow for the possible presence of an illegal medicinal product in the distribution chain.

These samples would be analysed by the AEMPS Official Control Laboratory with sufficient technical and human resources to have analytical capacity in relation to tests to detect falsified medicinal products. The laboratories holding the marketing authorisation for medicinal products also collaborate with the AEMPS to determine whether the sample in question is original or falsified.

In medical devices there is no specific sampling programme for the identification of counterfeit products. Given the wide variety of medical devices on the market and their specific

characteristics with product sampling, it is not easy to detect counterfeits. In medical devices, in the vast majority of cases counterfeits are based on the documentation accompanying the device (declaration of conformity, CE marking certificate, instructions, etc.) rather than on the device itself. Companies falsify the documentation relating to the CE marking in order to be able to place the product on our market.

It is through the annual market control campaigns and, in particular, the usual market control activities and border inspection, that medical devices with falsified documentation are more detected.

The Spanish Medicines and Health Products Agency is the competent authority for medical devices. The Autonomous Communities also have competence in the field of market control.

Finally, with regard to the activities of the analytical laboratories, the Agency has no competence to regulate activities and that action has been taken only in respect of non-compliances observed in the products they use.

Question 25. (Mandatory)

Do these sampling programmes, amended in question 24 above, cover public procurement of medical products to Detect medical products used in the public health system, as in hospitals, and not provided for supply by sale to the trade or public? If not, are there arrangements to introduce such a programme?

The vast majority of medicines included in the control programmes are prescription-only medicines which are publicly funded and fall within the pharmaceutical provision of the National Health System. Many are hospital used, but this characteristic has so far not been considered to prioritise the inclusion of medicinal products in the control programmes.

To include these medicinal products, it is not necessary to establish specific agreements; They can be included in the programme and sampled without agreement.

As regards sanitary products, as indicated above, there are no specific sampling campaigns. However, market surveillance campaigns and routine control activities cover all types of products including medical devices for professional use used in the health system.

Question 26. (Mandatory)

Are there laws and policies in place to enable customs services to Detect, detain and act on a counterfeit medical product, as defined in Article 4.j, different to the intellectual property accounting? Do the laws and policies enabling customs services to take action without reference to a rights holder notariing that the same medical product may also infringe an intellectual property right?

Customs makes requirements for the importation of medicinal products, including the provision of different documentation. If those conditions are not met, the customs office refuses to release the goods, that is to say, their importation.

Customs is responsible for all matters relating to smuggling and is covered by Organic Law 12/1995 of 12 December 2015 on combating smuggling in order to treat counterfeits (regardless which product they are of) as a prohibited genus, as defined in the Law itself.

‘Article 1.12. “Prohibited genres”: All those whose import, export, circulation, holding, trade or production is expressly prohibited by a treaty or convention concluded by Spain, by a legislative provision or by a regulation of the European Union. The prohibition shall be limited, in respect of each sex, to the performance of the activity or activities expressly laid down in the prohibition rule and for such period as may be stated therein.”

‘Article 2.2. The crime of smuggling is committed, provided that the value of the goods, merchandises, genres or effects is equal to or greater than EUR 50,000, by any of the following:

(b) Import, export, trade, holding, movement of: Stagnant or prohibited genera, including their production or rehabilitation, without complying with the requirements laid down by law”.

Customs surveillance resolves cases of forgery by requesting the customs administrator to control the exit of goods, in order to make a kind of ‘controlled delivery’ of these counterfeits in order to prosecute the offenders.

With regard to the tools available, risk analysis is used at customs level, based on certain parameters, in collaboration with rights holders and experts.

Question 27. (Mandatory)

Please outline through the following measures how is the criminalisation offences achieved in order to enable effective investigation and prosecution.

(a) To what extent does the concept of ‘medical products’ in internal law fully correspond to the definition in Article 4a, even if the term is not specifically defined?

Article 4 (a) of the Convention provides that ‘medical product’ means medicinal products and medical devices.

The reform of the Criminal Code in 2015 was intended, inter alia, to comply with Article 5 (1) of the Council of Europe Convention on the counterfeiting of medical products and related crimes.

Article 5.1 provides for the obligation of States Parties to adopt the necessary legislative measures to criminalise the intentional manufacture of medical products, active substances, excipients, falsified elements, materials and accessories, as well as adulteration of medicinal products, medical devices, active substances and excipients (Article 5.2), supply, supply or trafficking (Article 6.1) and falsification of documents (Article 7.1).

The 2015 reform of the Criminal Code introduced a number of new developments affecting the definition of the conduct itself and the material object of crime, which now extended to medical devices such as implants and prostheses.

The previous wording of Article 361 referred only to medicinal products as the sole material object.

Therefore, the inclusion stems from the ratification of the MEDICRIME Convention and the concept of “medical products” in our national law corresponds to that of the Convention.

(b) To what extent does the concept of ‘counterfeiting’ in internal law fully correspond with the definition by Article 4.j as regards medical products? What steps have been taken to ensure that this has been or will be achieved?

Article 4 (j) provides that “‘forgery” shall mean the misleading presentation of the identity or source’.

The current Article 362 of the Criminal Code following the reform introduced by Organic Law 1/2015 of 30 March provides that:

‘shall be punished with imprisonment of six months to four years, a fine of six to eighteen months and a special disqualification from one to three years, any person who draws up or produces;

(a) a medicinal product, including a medicinal product for human and veterinary use, and investigational medicinal products; Or an active substance or an excipient of that medicinal product;

(b) a medical device, as well as accessories, components or materials which are essential for its integrity; In such a way as to misrepresent: Their identity, including, where appropriate, the packaging and labelling, the use-by date, the name or composition of any of their components, or, where appropriate, their strength; Its origin, including the manufacturer, the country of manufacture, the country of origin and the holder of the

marketing authorisation or documents of conformity; Data relating to compliance with legal requirements or requirements, licences, documents of conformity or authorisations; Or their history, including records and documents relating to the distribution channels used, provided that they are intended for public consumption or use by third parties, and create a risk to human life or health.'

The second paragraph states that:

'The same penalties shall be imposed on anyone who alters, in the manufacture or manufacture of the product or at a later stage, the quantity, dose, use-by date or genuine composition, as authorised or declared, of any of the medicinal products, substances, excipients, medical devices, accessories, components or materials referred to in the preceding paragraph in such a way as to reduce their safety, efficacy or quality by creating a risk to human life or health'.

Prior to the 2015 reform, the verbs used to describe the crime were imitate and simulate medicines, giving them the appearance of real drugs.

At present, with the reform of 2015, the conduct is in line with the parameters laid down in the Medicrime Convention.

(c) Please outline which steps have been taken to ensure that offences relate to medical products, as defined in Articles 4a and 4.j, are criminalised in accordance with Articles 5 and 6.

New criminal offences and penalties have been introduced in public health offences (Articles 361 to 362c of the Criminal Code) in order to comply with Articles 5 to 8 of the MEDICRIME Convention. Article 361 CC punishes conduct relating to illegal sale of medicinal products; Article 362 CP criminalises the simulation and alteration of medicinal products or medical devices; Article 362a CC punishes conduct relating to trafficking in or the placing on the market of falsified medicinal products or medical devices and Article 362b CC punishes documentary falsifications.

The material object of the crime has been extended to include medicinal products for human and veterinary use, active substances and excipients, investigational medicinal products, medical devices, their accessories, elements or materials essential to their integrity.

Terminology and definitions have also been adapted to the requirements of the Convention. Article 4 of the MEDICRIME Convention.

(d) Please outline which steps have been taken to ensure that intentionally offenses described in Article 8 relating to medical products, as defined in Article 4a, are criminalised.

Article 361 of the Criminal Code punishes the production, placing on the market and disposal of illegal medicinal products and medical devices, punishing all stages of the cycle or chain of distribution of medicinal products and medical devices, including the deposit or storage for any of those purposes, where the required authorisation is not available or the necessary documentation is not available, or the elements are in poor condition, either because they have expired, because they have been altered or deteriorated.

Article 361 of the Criminal Code is an intentional offence of abstract danger which requires that human life or health be endangered.

(e) Please outline which steps have been taken to ensure that intentional uses described in Article 7 relating to documents, as defined in Article 4.h, are criminalised when related to medical products.

Article 362b of the Criminal Code punishes the conduct of forgery of documents relating to the various documentary elements of medicinal products or medical devices simulated or imitated, the production of which is an offence under Article 362.1 CC.

(f) What steps have been taken to proactively increase to the involvement of manufacturers and suppliers of medical products the consequences of actions/inactions by persons in relation to their business activities relating to medical products (Art. 11)?

Article 11 of the MEDICRIME Convention lays down the obligation for States Parties to take the necessary legislative measures to enable legal entities to be held liable for offences under the Convention committed on their behalf by a natural person acting on their behalf or for having failed to fulfil the duty of supervision or control over natural persons acting under its authority, in terms similar to those of Article 31a (1) of the Criminal Code.

Organic Law 1/2015 of 30 March 2007 completely reformed the wording of Article 366 CC, extending to pharmacological offences the criminal liability of legal entities in accordance with the provisions of the Convention.

Question 28. Framework for investigation and pursuit (mandate)

Please provide information, specifically in relation to counterfeit medical products and similar crimes involving threats to public health, on:

- a. any national specialised research units dedicated to:
 - 1) conducting criminal investigations, and/or**
 - 2) coordinating and/or supervising criminal investigations by other units/authorities (Article 16), including inter-agency formal or informal committee or structure;****
- b. any specialised practitioners and whether they function on a national or local basis.**

If neither a nor b apply, please describe briefly the framework used for specific investigations and prosecutions to ensure that the full understanding of the crimes involved are taken into consideration.

In the field of criminal investigation of matters governed by the MEDICRIME Convention, the Spanish Guardia Civil, the National Police and Customs Surveillance are responsible.

The Technical Unit of the Judicial Police of the Spanish Guardia Civil investigates offences related to the material scope of the Convention.

Within the National Police, at central level, the specialised section responsible for investigating drug trafficking is the Environment and Doping Consumer Affairs Section of the General Police Station of the Judicial Police.

Other decentralised units are also being implemented, which also carry out the same work in the various Jefaturas Superiores o Senior Police Offices.

With regard to Customs Surveillance, as part of the judicial police, it is governed in this area by Organic Law on the Repression of Contraband 12/95, considering falsification of medicinal products as prohibited genres or whose possession (among other forms of conduct) constitutes a criminal offence.

As far as the ~~prosecution~~ Public Prosecutor's Office is concerned, there is no specialisation in this area, either for investigation or for prosecution. Although there is an interest in creating specialisation, for the time being there is no specialised prosecution office at either national or regional level.

Question 29. (Mandatory)

In relation to the investigation of medical products and similar crimes involving a threat to public health, please indicate, without entering into detail:

- a. the process in place, or planned, for deciding which research unit/body takes responsibility/the lead for investigations in general or as they have;**
- b. if there are any different processes or arrangements in place to coordinate crimes related to a pandemic (Articles 16.2, 17.1 and 3. b).**

(a) In the Spanish Guardia Civil there are several channels for entering and exit of events related to this type of crime.

A first channel is the Social Security Investigation Group (GISS) of the Criminal Police Technical Unit. The Ministry of Health forwarded to the GISS any reports or suspicions of criminal offences which he is aware of, either directly, from the Autonomous Communities or from the international spheres with which it is linked. The GISS studies, analyses and passes them on the basis of the location of the main event to the various investigation units of the Guardia Civil, which carry out the operational activities necessary for their investigation.

Another way of intelligence entry/exit (input/output) to the GISS is through Spanish agencies such as the Spanish Medicines and Health Products Agency (AEMPS), the Spanish Agency for the Protection of Health in Sport (AEPSAD) or the Spanish Food Safety and Nutrition Agency (AESAN), Official Associations and other bodies; At international level, information is shared with EUROPOL, INTERPOL, Police Attachés, other International Agencies and with different countries.

Another channel would be the Spanish Civil Guard units that are aware, either ex officio or through the various national or international channels, of these crimes. These units would carry out the investigation itself by assuming responsibility for the investigation, or if this is not possible, they would transfer it to another superior or competent unit, but always in the Spanish Guardia Civil.

Generally, investigations by the Spanish Guardia Civil are led, at national level, by the central units, and at provincial or Autonomous Community level by the territorial units.

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

As regards the pandemic, at international level, INTERPOL has included in its operation PANGAEA on internet drug trafficking, medicines and COVID-19 related crimes. Similarly, EUROPOL through Operation SHIELD on drug trafficking has included this type of crime.

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

In the area of Customs Surveillance, there are no specialised units and therefore, the operational unit of the region where the infringement is presumed to have committed the infringement is competent. A Security and Safety Area has recently been set up under Customs Surveillance, which would be responsible for these issues, at least at the level of coordinating investigations. At central level, there is a database of smuggling, in which medicines could probably be filtered.

Question 31. (Mandatory)

Are complaints on medical products and similar crimes collated on a national basis for record keeping, analysis, and effective investigation or dealt with on an ad hoc basis by individual investigating authorities/bodies?

Complaints are not collected at national level in any register. Each Spanish Guardia Civil Unit, when it becomes aware of these crimes, recorded them on the bases of the Corps, where they are available internally for consultation, analysis or investigation, but without being shared with other bodies.

Notwithstanding the above, the Guardia Civil in investigations which, because of their importance, novelty or relevance, carry out various intelligence products which they disseminate to their own units and to other bodies or countries.

Similarly, in those investigations that require it, intelligence is shared with other countries through channels such as EUROPOL, INTERPOL, police attachés, among others, leading to joint investigations with those countries.

Question 32. (Mandatory)

Are all prescribed offences in Articles 5-8, and Article 9 investigated? Are they subject to a complaint made and maintained (Article 15)?

The investigation covers all offences referred to in Articles 5 to 8 and Article 9 of the Convention without prior complaint. The investigation is not subject to reporting, as these are crimes which may be prosecuted ex officio. In other words, they are public offences, which may be prosecuted ex officio, in such a way that criminal proceedings for an offence giving rise to ex officio proceedings are not extinguished by the surrender of the offender, in accordance with Article 106 of the Code of Criminal Procedure. In this case, the prosecution will be brought by the Public Prosecutor's Office.

Criminal proceedings may be initiated, even without the wishes of the injured party, on the initiative of the Public Prosecutor, which, according to Article 105 of the Code of Criminal Procedure, is obliged to bring criminal proceedings.

Question 35. (Mandatory)

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

The reform implemented by Organic Law 1/2015 of 30 March 2007 introduced a new Article 362 sexies into the Criminal Code, which provides for the confiscation of substances, objects, products, assets, media, instruments and gains, of all the previous articles of the Chapter, in the following terms:

‘In respect of the offences referred to in the preceding articles of this Chapter, the substances, objects and proceeds referred to in Article 359 et seq., as well as property, means, instrumentalities and proceeds, subject to Articles 127 and 128, shall be subject to confiscation.’

This reflects the requirements of Article 12 (3) (a) of the Council of Europe Convention on the counterfeiting of medical products and related crimes, which requires signatory States to adopt the necessary legislative measures to allow freezing and confiscation.

On the other hand, Article 127 of the Criminal Code lays down the conditions under which confiscation may be ordered, while Article 128 of the Criminal Code deals with cases in which confiscation is not to be ordered, or ordered to a limited extent.

Question 38. (Mandatory)

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

The 2015 reform of the Criminal Code criminalises the aggravated rates in an autonomous provision. Thus, Article 362 quater of the Criminal Code provides:

‘Penalties higher than those referred to in Articles 361, 362, 362 bis or 362 ter shall be imposed where the offence is committed in one of the following circumstances:

1^a. The guilty person is an authority, a public official, a medical practitioner, a medical practitioner, a teacher, a physical or sporting educator, and obtains himself in the exercise of his or her duties, profession or trade.

2^a. That the medicinal products, active substances, excipients, medical devices, accessories, elements or materials referred to in Article 362:

(a) have been offered through large-scale means of dissemination; Or

(b) were 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.

3^a. The offender belonged to a criminal organisation or group for the purpose of committing such offences.

4^a. The facts were carried out in establishments open to the public by the persons responsible or their employees’.

This new regulation, stems from Article 13 of the Council of Europe Convention on the counterfeiting of medical products and related crimes, which requires Parties to take the necessary legislative measures to regard certain cases as aggravating elements of the offences referred to in the Convention, with the exception that these aggravating elements already form part of the very substance of the offence.

No specific aggravating circumstance is foreseen in case the crime occurred during a pandemic.

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