COUNCIL OF EUROPE

CONSEIL DE L'EUROPE

MEDICRIME COMMITTEE

Committee of the Parties to the Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health (CETS No. 211)

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

Introduction

1. The Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health (hereinafter "the MEDICRIME Convention" or "the Convention"), which entered into force on 28 October 2011, requires the criminalisation of offences set out in the Convention in Articles 5-8. It sets out that states, in Europe and beyond, shall adopt specific legislation to prevent and combat threats to public health by criminalising certain acts, protecting the rights of victims of the offences established under the Convention, and promoting national and international co-operation.

2. The Committee of the Parties to the Convention (also known as the "MEDICRIME Committee"), established to monitor whether Parties effectively implement the Convention (Rule 25 of the Committee's Rules of Procedure), decided that:

> *"3. The monitoring round shall be initiated by addressing a questionnaire on the implementation of the relevant provisions of the Convention with respect to the selected theme. The Parties shall respond to the questionnaire within the time limit set by the MEDICRIME Committee."*

3. As available data show that offences involving medical products committed during a pandemic target critical funding through fraudulent scams, counterfeiting of vital protective personal equipment and critical medical devices to save lives and to detect the presence of the disease, and attacks on critical infrastructure in the fight against the disease, the MEDICRIME Committee decided that the first monitoring round would focus on "The protection of public health through the MEDICRIME Convention in times of pandemics".[1]

4. On 27 May 2021, the MEDICRIME Committee adopted this thematic questionnaire. Its purpose is to collect specific information on how Parties implement the MEDICRIME Convention with respect to offences involving medical products and similar crimes involving threats to public health and related to a pandemic. The replies to the questionnaire will be assessed against the related background information provided by the Parties when answering the "General Overview" questionnaire on the implementation of the MEDICRIME Convention (hereinafter "Country Profile Questionnaire" or "CPQ") and any other relevant information from reliable sources.

[1] Committee of the Parties of the MEDICRIME Convention, *List of decisions*, 3rd Plenary meeting (1-3 December 2020), T-MEDICRIME-(2020) LD, paragraph 4.5.

5. It is recalled that, in accordance with Rule 26 of the Committee's Rules of Procedure:

> *"(…) 2. The secretariat shall address such questionnaires to the Parties through the member in the MEDICRIME Committee representing the Party to be monitored and who will act as "contact point".*
> *3. Parties shall co-ordinate with their respective domestic authorities to collect replies, which shall be submitted to the secretariat in one of the official languages of the Council of Europe within the time limit set by the MEDICRIME Committee. The replies to the questionnaires shall be detailed, as comprehensive as possible, answer all questions and contain all relevant reference texts. The replies shall be made public, unless a Party makes a reasoned request to the MEDICRIME Committee to keep its reply confidential.*
> *4. The MEDICRIME Committee may also receive information on the implementation of the Convention from non-governmental organisations and civil society involved in preventing and combating the counterfeiting of medical products and similar crimes involving threats to public health, in one of the official languages of the Council of Europe and within the time limit set by the MEDICRIME Committee. The secretariat transmits these comments to the Party or Parties concerned.*
> *5. The secretariat may request additional information if it appears that the replies are not exhaustive or are unclear. Where warranted, with the consent of the Party or Parties concerned and within the limits of budgetary appropriations, the bureau may decide to carry out an on-site visit to the Party or Parties concerned to clarify the situation. The bureau shall establish guidance as to the procedure governing the on-site visits."*

PRELIMINARY REMARKS

6. As in the country profile questionnaire, the provisions of the MEDICRIME Convention have been grouped under different sections in this questionnaire without automatically following the structure of the Convention. This methodological choice in no way intends to prioritise the various provisions of the Convention: equal importance is attached to all rights and principles therein.

7. This thematic questionnaire does not seek to collect information on the general legislative and institutional framework established by Parties to implement the Convention. It focuses only on specific legislative and other measures taken or envisaged to protect public health from counterfeiting of medical products and similar crimes in the context of pandemics.

8. Responses to this thematic questionnaire will be understood against the background information submitted by Parties in reply to the CPQ. Whenever warranted, Parties are invited to refer to such information. Where questions overlap between the CPQ and this questionnaire, the replies to the latter will be assessed by the Committee in order to prepare its implementation reports of the Convention with respect to the monitoring theme.

9. For the purpose of this questionnaire, the notion of pandemic will include the COVID-19 pandemic as well as other major health crises declared by the World Health Organisation as pandemics, epidemics or public health emergencies of international concern (PHEIC), including the Zika virus epidemic in 2015, the Ebola pandemic in 2014, the Middle East Respiratory Syndrome (MERS) in 2012, the H1N1 Influenza

pandemic in 2009, the H5N1 outbreak in 2005, and the severe acute respiratory syndrome (SARS) in 2003.

10. If there are differences with the information provided in the responses to the CPQ, Parties are kindly requested to specify which State bodies/agencies and, where relevant, NGOs, contributed to responding to this questionnaire.

11. As with the CPQ, Parties are kindly requested to:

    a. answer the questions regarding central, regional and local levels, to the extent possible. Federal states may, in respect of their sovereign entities, answer the questions in a summarised way;
    b. provide the relevant text (or a summary thereof), in English or French only, whenever questions/answers refer to legislation or other regulations;
    c. respond to all questions marked **mandatory** as they are essential to the monitoring round. It would be appreciated, where possible, if all questions marked **optional** could also be answered.

Prevention and Training

This section aims to collect information on policies, strategies, plans and activities to prevent counterfeit medical products and similar crimes involving a threat to public health, in particular during times of pandemics. The questions concern all those whose responsibilities it is to procure and supply medical products, and those who encounter them or their impact on public health. This section concerns awareness-raising programmes aimed at these people in particular, as well as the public in general. It concerns prevention measures aimed at raising awareness of the availability of counterfeit medical products.

Question 1. **(mandatory)**

Which legislative, policy, strategic and other measures have been taken to provide training with a view to preventing counterfeit medical products, active substances, excipients, 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 counterfeit medical products and conducts that contribute to the commission of similar crimes involving threats to public health, having regard to the impact of a pandemic (Article 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 counterfeit medical products and similar crimes, in specialised techniques, including financial investigations (Article 16.2)?

Decree-Law no. 10-A/2020, of 13 March, and Law no. 1-A/2020, of 20 March, approved exceptional and temporary public procurement and expenditure authorisation measures in response to the epidemiological situation caused by the SARS-CoV-2 coronavirus and COVID-19 disease. They are:
I. Rules applicable to the formation of public works contracts, contracts for the lease or purchase of movable property and the purchase of services, regardless of the nature of the contracting authority, provided that they are part of the public business sector, public administrative sector or, with the necessary adaptations, local authorities, whose object is related to the prevention, containment, mitigation and treatment of epidemiological infection by COVID-19, as well as the restoration of normality following it.

In this context, training has been given to police, customs and National Health Service authorities on how to handle the medical products (e.g. masks, respirators, protective suits and other products) acquired during this phase of COVID.

In addition, the POLÍCIA JUDICIÀRIA has responded to the criminal policy guidelines that, for the 2020 - 2022 biennium, set out a list of crimes that should be a priority, both in terms of prevention and investigation, as stipulated in Law no. 55/2020 of 27 August, which considers that crimes against the health system should be a priority for prevention and investigation. Training has been given and guidance notes have been issued on the investigation of facts that could be crimes of document forgery, qualified fraud, abuse of trust, corruption, abuse of

power, embezzlement and undue receipt of an advantage, without prejudice to further legal classification in accordance with the facts that come to light.

A multidisciplinary team comprising all branches of the National Health Service was also set up (Order no. 11737/2020 of 26 November), which determined the constitution of the aforementioned task force to draw up the "Vaccination plan against COVID-19 in Portugal", comprising a coordination centre and technical support bodies, services and organisations.

In terms of border control, there was increased collaboration between the Medicines Authority (INFARMED) and Customs Authority in order to control products entering PT, either for consumption or for placing on the market.

Also, medicines and veterinary products were taken into account:
Regulation 2019/6, also known as the new veterinary regulation (NVR), legislates for the authorisation, use and monitoring of veterinary medicinal products in the European Union. The legislation came into effect on 28 January 2019, was applied in all EU Member States from 28 January 2022.

Regarding falsified VMPs, the regulation informs:
In Article 93 - Obligations of the holder of a manufacturing authorisation, point i) the holder of a manufacturing authorisation must inform the competent authority and the marketing authorisation holder immediately if the obtains information that veterinary medicinal products which fall within the scope of its manufacturing authorisation are, or are suspected of being, falsified irrespective of whether those veterinary medicinal products were distributed within the legal supply chain or by illegal means, including illegal sale by means of information society services;

In Article 101 - Obligations of wholesale distributors, point 6) the wholesale distributors shall immediately inform the competent authority and, where applicable, the marketing authorisation holder, of veterinary medicinal products they receive or are offered which they identify as falsified or suspected to be falsified.

As mentioned, with the implementation of the new regulation on veterinary medicines Regulation 6/2019, addresses falsified veterinary medicines, and the distributors shall immediately inform the competent authority and, where applicable, the marketing authorisation holder, of veterinary medicinal products they receive or are offered which they identify as falsified or suspected to be falsified.

The Regulation develops further principles set out originally in the Patients' Rights Directive and the Falsified Medicines Directive, with respect to the recognition of veterinary prescriptions and the Common Logo for Internet sites selling veterinary medicines.

In addition to the notification referred to in Article 101(6) of Regulation (EU) 2019/6, wholesale distributors shall immediately stop the distribution of any veterinary medicinal products they identify as falsified or suspected to be falsified and act on the instructions as specified by the competent authorities. A procedure shall be in place to this effect. The incident shall be recorded with all the original details and investigated.

Any suspected falsified veterinary medicinal products found in the supply chain shall immediately be segregated physically or, if an equivalent electronic system is available, electronically. Any falsified veterinary medicinal products found in the supply chain shall immediately be segregated physically, stored in a dedicated area away from all other veterinary medicinal products and appropriately labelled. All relevant activities in relation to such products shall be documented and records retained

DGAV also haves a public platform where all the authorize literature (SPC/L/PIL) of the Veterinary authorized medicinal products are available. The platform can be found https://medvet.dgav.pt/

Nationally we also have in force administrative offenses established, by law decree, for veterinary medicines that do not comply with the requirements of the legislation, falsified veterinary medicines do not comply with the requirements for a marketing authorization and, in this way, these entities are penalized.

Question 2. **(optional)**

Are there any oversight programmes to assess the frequency and effectiveness of the training provided? If so, are there revision programmes to ensure remedial actions of any deficiencies (Article 18.1, 2 and 3. a)?

Question 3. **(mandatory)**

Are there awareness-raising and training programmes for all of those mentioned in question 1.a and b above 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 manufacture of counterfeit medical products and instrumentalities used in the counterfeiting of medical products?

In Portugal there is a General Regulation for the Management of Hospital Waste approved by Decree-Law no. 102-D/2020 of 10 December, which establishes in its article 9 the principles of waste management responsibility. According to this legal requirement, the initial producer of the waste is responsible for its management, and may ensure the treatment of the waste by using a waste treatment operator. The initial producer's responsibility for waste management is extinguished when it is transferred to a licensed organisation.

According to Order no. 242/96, the producer's management bodies are responsible for enforcing compliance with the provisions of this law, namely in the sorting and packaging of hospital waste. They are also responsible for sensitising and training professionals in general and those working in the sector in particular, namely in aspects related to personal protection and correct procedures.

As part of the integrated waste management system for packaging and medicines (Decree-Law no. 152-D/2017, 11 December), there are procedures for collecting and processing discarded medicines and packaging. Thus, pharmacies have collection points where not only the medicines you no longer use/need and those that have expired should be handed in, but also the materials used to wrap and package the products (empty cartons, information leaflets, bottles, blisters, ampoules, tubes, etc). Likewise, the accessories used to facilitate administration (spoons, cups, dosing syringes, droppers, cannulas, etc.) should also be handed in.

Regarding the WASTE of COVID vaccines: The administration of COVID vaccines has been organised in such a way as to avoid wasting vaccine doses. The following strategies can be considered for this purpose:
a. Prevention of wastage of doses and multidose vials in each vaccination session (one-day period in a given institution):
i. Any (unperforated) vials left over from a vaccination session should be used on the same day.
ii. Vials that have already been punctured may not be transported.
b. To avoid wastage, any eligible person must be vaccinated against COVID-19, respecting, as far as possible, the order of priority defined in the terms of this standard.
c. Vaccine administration is organised in such a way as to avoid wasting doses, so vaccination should continue even if not all people identified as the highest priority within Phase 1 are vaccinated (for example, vaccination should continue for people with comorbidities under 65 years of age even if not all people aged 65 and over are vaccinated).

Regardind medicines for veterinary use:
There are several workshops and meetings with wholesale distributors and retailers of veterinary medicines. There are also frequently asked questions related to good distribution practices (GDP).
Regulation (EU) 2021/1248 of 29 July 2021 as regards measures on good distribution practice for veterinary medicinal products in accordance with Regulation (EU) 2019/6 of the European Parliament and of the Council. This regulation have a consistent approach by all partners in the supply chain is required in order to be successful in the fight against falsified veterinary medicinal products.

Question 4. **(optional)**

Please outline any reviews on the effectiveness of the governance and supervision of medical product waste disposal. Are there any awareness-raising programmes on the importance of proper disposal and the risks that can arise from inadequate governance and supervision?

Question 5. **(optional)**

Apart from the above-mentioned general measures, please briefly describe the details of specific preventive actions targeted at specific medical products involved in any recent pandemic as well as the results achieved.

Education

This section aims at identifying measures aimed at educating civil society on good practices in avoiding the risks associated with counterfeit medical products.

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 counterfeit medical products, in particular those that may be encountered during a pandemic (Article 18.3.b):

a. on purchasing conducts of medical products, including through real world/physical and virtual means, such as online and e-commerce platforms and social media;
b. on promoting good purchasing conduct among the public to encourage rational consumption of medical products and avoiding procurement from sources that are not within your country's authorised supply systems;
c. on developing and delivering risk awareness campaigns regarding counterfeit medical products and similar crimes.

Online educational campaigns and warning campaigns against buying health products online have taken place within the National Health Service (eg. Medicines Authority).

Regarding medicines for veterinary use:
Regulation 2019/06 develops further principles set out originally in the Patients' Rights Directive and the Falsified Medicines Directive, with respect to the recognition of veterinary prescriptions and the Common Logo for Internet sites selling veterinary medicines.
Indeed, the Regulation provides that internet sale of veterinary non-prescription medicines must be authorised in all Member States under conditions which mirror the provisions introduced by the Falsified Medicines Directive for the Internet sale of human non-prescription medicines (i.e. provide certain information, display a common logo, etc.). This makes the Veterinary Medicines Regulation consistent with the rules applying to human medicines.

Regulation (EU) 2021/1248 of 29 July 2021 as regards measures on good distribution practice for veterinary medicinal products in accordance with Regulation (EU) 2019/6 of the European Parliament and of the Council. This regulation have a consistent approach by all partners in the supply chain is required in order to be successful in the fight against falsified veterinary medicinal products.

There are several workshops and meetings with wholesale distributors and retailers of veterinary medicines. There are also frequently asked questions related to good distribution practices (GDP) and several information in DGAV website about:

- *Distribution of VMP*
- *Retail of VMP and also*
- *Authorized online sales of VMPs.*

Our stakeholders also have in the website email addresses for each subject and a dedicated team will respond as soon as possible.

DGAV also haves a public platform where all the authorize literature (SPC/L/PIL) of the Veterinary authorized medicinal products are available. The platform can be found https://medvet.dgav.pt/

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

No.

Question 7. (optional)

Do public authorities have a policy to encourage or support the involvement of civil society (such as industries, publishers, academia, etc.) in the promotion of measures to combat, prevent, detect and respond to counterfeit medical products during a pandemic, or in a more general context? If so, please provide details.

Regardind medicines for veterinary use, DGAV also haves a public platform where all the authorize literature (SPC/L/PIL) of the Veterinary authorized medicinal products are available. The platform can be found https://medvet.dgav.pt/
In the platform there is an email that any stakeholder can communicate with DGAV and send their concerns and requests.

Question 8. (optional)

Is civil society actively engaged in raising public awareness of the risks arising from counterfeit medical products (Article 18. 3, b)? If so, please provide details.

Question 9. (mandatory)

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

None. No more than those that already existed.

Regardind medicines for veterinary use, DGAV applies the legislation in force in Regulation (EU) 2019/6 and Regulation (EU) 2021/1248 of 29 July 2021. Whenever DGAV becomes aware of any action contrary to the provisions of the legislation in force, it takes protective measures provided for by law.
Nationally we also have in force administrative offenses established, by law decree, for veterinary medicines that do not comply with the requirements of the legislation, falsified

veterinary medicines do not comply with the requirements for a marketing authorization and, in this way, these entities are penalized.

Wholesale distributors shall immediately stop the distribution of any veterinary medicinal products they identify as falsified or suspected to be falsified and act on the instructions as specified by the competent authorities. A procedure shall be in place to this effect. The incident shall be recorded with all the original details and investigated.
Any suspected falsified veterinary medicinal products found in the supply chain shall immediately be segregated physically or, if an equivalent electronic system is available, electronically. Any falsified veterinary medicinal products found in the supply chain shall immediately be segregated physically, stored in a dedicated area away from all other veterinary medicinal products and appropriately labelled. All relevant activities in relation to such products shall be documented and records retained

It is the responsibility of the DGAV and the Security Authority Food and Economic Affairs (ASAE), within the scope of their respective competences, ensure the supervision of the compliance with the norms of the legislation, without prejudice to the powers attributed by law to others entities.

Victims

This section aims at identifying measures focused on the protection of victims' rights.

Question 10. (mandatory)

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

There is Law no. 130/2015, of 4 September. Proceeds with the twenty-third amendment to the Code of Criminal Procedure and approves the Victim's Statute, transposing Directive 2012/29/EU of the European Parliament and of the Council of 25 October 2012 establishing rules on the rights, support and protection of victims of crime and replacing Council Framework Decision 2001/220/JHA of 15 March 2001, which applies to any victim of any crime.

Question 11. (optional)

Are measures provided to protect the rights of victims at all stages of the criminal proceedings, in a manner consistent with the procedural rules of internal laws (Article 20. 1 to 4)?

Question 12. **(optional)**

What measures are provided to permit victim support and advocacy groups, NGOs and other groups to assist and support victims, with their consent, during criminal proceeding and outside of proceedings concerning offences related to counterfeiting of medical products and similar crimes involving a threat to public health? Please provide information on any such organisations and groups/bodies. Please provide information on any assessment of the effectiveness of such involvement by such providers (Article 20.5).

Question 13. **(optional)**

Is civil society actively engaged in providing supportive facilities for redress and recovery of victims of counterfeit medical products and similar crimes involving threats to public health (Article 19. b)? If so, please provide details.

Question 14. **(optional)**

What measures are in place or planned to enable victims to report offences impacting them and to receive protection and assistance in respect of offences established in accordance with this Convention? Is there any oversight to assess the effectiveness of such measures? If so, please briefly describe the results (Article 22.1).

Cooperation and information exchange

This section focuses on the ability and extent to which authorities/bodies may cooperate between them and exchange information in order to facilitate effective investigation.

Question 15. **(mandatory)**

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

At police level, there was an exchange of information between the police and Europol. During the pandemic, working groups were set up at national level between police, military and health authorities to deal with all incidents of crimes or irregularities committed during that period.

There is also a collaboration protocol between INFARMED and the customs authorities that involves the exchange of information to prevent illegal medicines and suspected counterfeits from entering national territory, safeguarding public health.

Portugal, through INFARMED, has also joined the RAPID ALERT System, which operates 24 hours a day, 7 days a week.

Also, regarding complaints, returns, suspected falsified veterinary medicinal products and recalls, Article 29 of regulation (EU) 2021/1248 of 29 July 2021, states that all complaints shall be recorded with all the original details. A distinction shall be made between complaints related to the quality of a veterinary medicinal product and those related to wholesale distribution.

In the event of a complaint about the quality of a veterinary medicinal product and a potential product defect, the manufacturer or marketing authorisation holder shall be informed without delay.

- *Any veterinary medicinal product distribution complaint shall be thoroughly investigated to identify the origin of or the reason for the complaint.*
- *A person shall be appointed to handle complaints and sufficient personnel shall be allocated to support that person.*
- *If necessary, appropriate follow-up actions (including CAPA) shall be taken after investigation and evaluation of the*
- *complaint, including, where required, notification to the national competent authorities.*

Marketing and/or manufacturing authorisation holders are obliged to report to national competent authorities, in Portugal DGAV, any product quality defect, including a suspected defect, of an authorised veterinary medicine which could result in a recall or abnormal restriction on supply. This includes:

- *any prohibition or restriction imposed by the competent authority of any country in which the medicinal product is placed on the market;*
- *any new information that might influence the evaluation of the benefits and risks of the medicine, including systematic information on warnings relating to manufacturing problems issued by competent authorities outside the European Economic Area (EEA);*
- *In addition, marketing authorisation holders should notify the national competent authorities of the Member States or third country authorities where the suspected defective products are distributed or are to be supplied in the event of a restriction to supply.*

If the nature of a product quality defect of a medicinal product presents a serious risk to public and animal health, national competent authorities inform each other through the rapid alert system.

EMA (Agency) is responsible for maintaining a rapid alert list of contact points, which includes national competent authorities in EEA Member States, the European Commission and international partner regulatory authorities and organisations.

Question 16. **(optional)**

a. Is the implementation of such national strategy and/or action plan supported and underpinned by enabling legislation for the transfer and receipt of information and data between authorities/bodies and to and from other jurisdictions (Articles 17.1, 17.3, 21.1, and 21.2)?
b. Are there specific Memorandum of Understanding (MOU) and/or Data Sharing Agreements (DSA) between bodies, at national and international levels, to give effect to arrangements between authorities/bodies in combating counterfeit medical products and similar crimes. Have they been adopted specifically because of the COVID-19 pandemic?
c. Please describe briefly, and without going into detail, the practical measures that ensure the implementation and effectiveness of the MOUs and DSAs, including periodic reviews.

Question 17. **(optional)**

Please state on cooperation arrangements which authority has the lead and which participate in the operation of the plans and what oversight exists on the operation of the plans. Please describe briefly, without going into detail, the main areas of responsibility of the participating authorities.

Question 18. **(optional)**

Do any arrangements involve cooperation arrangements with civil society, with industry or service providers (such as financial and money transfer services, e-commerce, social media platforms providers, logistics – including postal and delivery services, etc.)? If so, please briefly describe these arrangements and whether they took place during or as a result of a pandemic.

Question 19. **(optional)**

Please provide details on the membership or arrangements with bodies/groups dedicated to combating counterfeit medical products and similar crimes, whether investigative or advisory in nature. In your reply, please differentiate bodies/groups that put an emphasis on counterfeit medical products but are not solely dedicated to combating counterfeit medical products and similar crimes involving threats to public health.

Question 20. **(optional)**

Does the national strategy/action plan on counterfeit medical products stipulate or facilitate the establishment of a point of contact for receiving and sending alerts on suspect or confirmed counterfeit medical products between authorities? Is there any oversight of the effectiveness of this process? Please provide information on the effectiveness of this process.

Question 21. **(optional)**

Is there a point of contact specified for the international exchange of information relating to the counterfeiting of medical product, such as product alerts and analytical reports from laboratory investigations, that has different arrangements from other points of contact? Please provide any rationale for this difference.

Question 22. **(mandatory)**

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

Yes.

Detection

This section seeks to understand and appreciate the various measures that may be proactively taken during a pandemic to detect counterfeit medical products and to prevent them from reaching patients.

Question 23. **(mandatory)**

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

Yes, there are legislative measures.

Mainly the Medicines Statute, established by Decree-Law 176/2006 of 30 August, which lays down the legal regime governing marketing authorisations and amendments thereto, the manufacture, import, export, marketing, labelling and information, advertising, pharmacovigilance and use of medicines for human use and their inspection, including homeopathic medicines, radiopharmaceuticals and traditional herbal medicines.

There are no ad hoc procedures or process for reporting.

Regarding veterinary medicines, marketing and/or manufacturing authorisation holders are obliged to report to national competent authorities, in Portugal DGAV, any product quality defect, including a suspected defect, of an authorised veterinary medicine which could result in a recall or abnormal restriction on supply. This includes:

- *any prohibition or restriction imposed by the competent authority of any country in which the medicinal product is placed on the market;*
- *any new information that might influence the evaluation of the benefits and risks of the medicine, including systematic information on warnings relating to manufacturing problems issued by competent authorities outside the European Economic Area (EEA);*
- *In addition, marketing authorisation holders should notify the national competent authorities of the Member States or third country authorities where the suspected defective products are distributed or are to be supplied in the event of a restriction to supply.*

If the nature of a product quality defect of a medicinal product presents a serious risk to public and animal health, national competent authorities inform each other through the rapid alert system.
EMA (Agency) is responsible for maintaining a rapid alert list of contact points, which includes national competent authorities in EEA Member States, the European Commission and international partner regulatory authorities and organisations.

Regulation (EU) 2021/1248 of 29 July 202, states that all records of all significant activities or events should be made and kept to ensure the traceability of the origin and destination of veterinary medicinal products, as well as the identification of all suppliers of, or those supplied with, such veterinary medicinal products. Such records should facilitate the recall of a batch of a veterinary medicinal product, if necessary, as well as the investigation of falsified or suspected falsified veterinary medicinal products.

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 having regard to the additional demands placed on analytical laboratories and testing services by the impact of the pandemic? Are there oversight arrangements to ascertain the effectiveness of these measures?

There is a sampling programme between the Medicines Authority and Customs control.

Regarding veterinary medicines, Wholesale distributors shall immediately stop the distribution of any veterinary medicinal products they identify as falsified or suspected to be falsified and act on the instructions as specified by the competent authorities. A procedure shall be in place to this effect. The incident shall be recorded with all the original details and investigated.
Any suspected falsified veterinary medicinal products found in the supply chain shall immediately be segregated physically or, if an equivalent electronic system is available, electronically. Any falsified veterinary medicinal products found in the supply chain shall immediately be segregated physically, stored in a dedicated area away from all other veterinary medicinal products and appropriately labelled. All relevant activities in relation to such products shall be documented and records retained.

Relevant sections of good distribution practice for veterinary medicinal products should also be adhered to by third party actors involved in the wholesale distribution of veterinary medicinal products and should be part of their contractual obligations. A consistent approach by all partners in the supply chain is required in order to be successful in the fight against falsified veterinary medicinal products.

Records of all significant activities or events should be made and kept to ensure the traceability of the origin and destination of veterinary medicinal products, as well as the identification of all suppliers of, or those supplied with, such veterinary medicinal products. Such records should facilitate the recall of a batch of a veterinary medicinal product, if necessary, as well as the investigation of falsified or suspected falsified veterinary medicinal products.

Question 25. **(mandatory)**

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

Yes.

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 counterfeiting? Do the laws and policies enable customs services to take action without reference to a rights holder notwithstanding that the same medical product may also infringe an intellectual property right?

Yes.

Investigation and Prosecution

This section concerns the ability to investigate and prosecute offenders for intentional crimes related to counterfeit medical products and similar crimes, in particular during a pandemic.

Question 27. **(mandatory)**

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

a. To what extent does the notion of 'medical products' in internal law fully corresponds to the definition in Article 4.a, even if the term is not specifically defined?
It doesn`t

b. To what extent does the notion of 'counterfeiting' in internal law fully corresponds 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?
It doesn´t

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

Given that Portugal has already ratified the Council of Europe Convention on the counterfeiting of medicines and similar offences involving threats to public health, there will certainly be a need to review the criminal legislation on the counterfeiting of medicines.

d. Please outline what steps have been taken to ensure that intentional offences described in Article 8 relating to medical products, as defined in Article 4.a, are criminalised.

Given that Portugal has already ratified the Council of Europe Convention on the counterfeiting of medicines and similar offences involving threats to public health, there will certainly be a need to review the criminal legislation on the counterfeiting of medicines.

e. Please outline what steps have been taken to ensure that intentional offences described in Article 7 relating to documents, as defined in Article 4.h, are criminalised when performed in relation to medical products.

Given that Portugal has already ratified the Council of Europe Convention on the counterfeiting of medicines and similar offences involving threats to public health, there will certainly be a need to review the criminal legislation on the counterfeiting of medicines.

f. What steps have been taken to proactively bring to the attention of manufacturers and suppliers of medical products the consequences of actions/inactions by legal persons in relation to their business activities relating to medical products (Art. 11)?
None

As we know from reading Portuguese criminal law, there are divergences between the obligations and impositions arising from the Medicrime convention (which Portugal has ratified) and the Portuguese legal-penal framework. In terms of counterfeiting medical products, this divergence is notorious at various times and on different levels.
In particular:
1. the counterfeiting of medical products that are not considered medicinal or surgical substances has no specific criminal relevance. It can only be criminally relevant through common result offences such as physical harm or homicide.

2. The incrimination of adulteration of medicinal and therapeutic substances takes on much narrower typical contours in the Portuguese system than those presupposed by the convention, both in terms of the legal asset protected and the legislative technique used to construct the incrimination.

3. There is also no specific provision for the forgery of documents relating to medical products, and its criminal relevance is conditional on the mediation of the common offence of forgery of documents, provided for in article 256 of the Penal Code.

4. Similarly, the production, sale or storage of medicines without authorisation or of medical products that do not comply with legal requirements, as well as the improper and illegal use of documents relating to medical products are not criminal offences in our legal system, but rather administrative offences under the various paragraphs of article 181 of the Medicines Statute (Decree-Law 176/2006 of 30 August).

Given that Portugal has already ratified the Council of Europe Convention on the counterfeiting of medicines and similar offences involving threats to public health, there will certainly be a need to review the criminal legislation on the counterfeiting of medicines.

Question 28. Framework for investigation and prosecution **(mandatory)**

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

a. any national specialised investigation 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; *No*
b. any specialised prosecutors and whether they function on a national or local basis. *No*

If neither a or b apply, please describe briefly the framework used for specialised investigations and prosecutions to ensure that the full understanding of the crimes involved are taken into consideration.

In Portugal, there are no investigation units or prosecutors specialised in investigating counterfeit medical products or similar crimes that threaten public health.

The investigation of these types of offences could be delegated by the Public Prosecutor's Office to different criminal police bodies (namely the Judicial Police).

Question 29. (mandatory)

In relation to the investigation of counterfeit 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 investigation unit/body takes responsibility/the lead for investigations in general or as they occur;
b. if there are any different processes or arrangements in place to coordinate crimes related to a pandemic (Article 16.2, 17.1 and 3. b).

In Portugal, there is a criminal policy law that states that crimes against the health system are considered priority investigations - Law 55/2020 of 27 August.

In Portugal, there are no investigation units or prosecutors specialised in investigating counterfeit medical products or similar crimes that threaten public health.

The investigation of this type of crime can be delegated by the Public Prosecutor's Office to criminal police bodies (namely the Judicial Police), under the terms of the law on the organisation of criminal investigation (Law no. 49/2008, of 27 August).

As part of these criminal investigations, the Medicines Authority may be asked to collaborate by the Public Prosecutor's Office

Also It is the responsibility of the DGAV and the Security Authority Food and Economic Affairs (A, within the scope of their respective competences, ensure the supervision of the compliance with the norms of the legislation, without prejudice to the powers attributed by law.
All complaints received are handled and analysed.
The aren´t any different processes or arrangements related to a pandemic, only the urgency of the resolution if public or animal health are in risk.

Question 30. (optional)

Please provide details of any dedicated facility available for the public to report information to investigating authorities (this does not relate to pharmacovigilance or product quality defect

reports). Please provide details of whether the reporting is done by telephone, email, via an online platform, or other means, and whether this is a confidential report system. Is the reporting system reviewed for effectiveness? Please provide your assessment of the effectiveness of such facility.

Question 31. **(mandatory)**

Are complaints on counterfeit 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?

Dealt with on an ad hoc basis by individual investigating authorities/bodies

Question 32. **(mandatory)**

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

Yes. But there is no centralisation of information from the different entities, so there is no concrete data.

Question 33. **(optional)**

In relation to counterfeit medical products and similar crimes involving a threat to public health, is there an indicative list of offences, associated with Articles 5-9, 11 and 13 and other criminal laws, to facilitate investigators in deciding the legal basis and the evidence required for successful investigations, in particular during a pandemic when advisory experts and technical staff may not be immediately available (Article 16)?

Question 34. **(optional)**

Please outline the national approach with regard to investigating bodies/authorities on counterfeit medical products and similar crimes, in a manner consistent with procedural rules of internal laws, on the extent of any discretion on whether to initiate and terminate an investigation without reference to a prosecuting authority or other investigating authorities for medical product counterfeiting?

Sanctions and aggravating circumstances

This section aims at identifying what specific legislative and other measures have been taken to support the sanctioning of persons in relation to the counterfeiting of medical products and similar crimes in final sentences, in particular relating offences committed in a pandemic.

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 instrumentalities used to commit the offences described in Articles 5-8? (Article 12. 2. a and b).

Yes

Criminal Procedure Code:
Article 178
Object and assumptions of seizure
1 - Instruments, products or advantages related to the commission of a typical illicit act shall be seized, as well as all animals, things and objects left by the perpetrator at the scene of the crime or any others that may serve as evidence.

Article 185
Seizure of worthless, perishable, dangerous or deteriorable things
1 - If the seizure concerns things that are worthless, perishable, dangerous, deteriorable or whose use implies loss of value or qualities, the judicial authority may order, depending on the case, their sale or allocation to a public or socially useful purpose, the necessary conservation or maintenance measures or their immediate destruction (...)

Penal Code
Article 109
Forfeiture of instruments
1 - Instruments of a typical unlawful act shall be declared forfeited in favour of the state when, due to their nature or the circumstances of the case, they endanger the safety of persons, morals or public order, or offer a serious risk of being used for the commission of new typical unlawful acts, all objects that have served or were intended to serve for their commission being considered instruments of a typical unlawful act.
2 - The provisions of the previous paragraph shall apply even if no specific person can be punished for the offence, including in the event of the perpetrator's death or when the perpetrator has been declared contumacious.
3 - If the instruments referred to in paragraph 1 cannot be appropriated in kind, the forfeiture may be replaced by payment to the State of the respective value, which may be substituted at any time, even at the enforcement stage, subject to the limits provided for in article 112a.
4 - If the law does not set a special destination for the instruments forfeited under the terms of the previous paragraphs, the judge may order that they be totally or partially destroyed or put out of business.

Article 110
Forfeiture of products and benefits
1 - The following shall be declared forfeit in favour of the State:
a) The proceeds of a typical unlawful act, considering as such all objects that have been produced by its commission; and

b) The advantages of a typical unlawful act, considering as such all things, rights or advantages that constitute an economic advantage, directly or indirectly resulting from that act, for the perpetrator or for others.
2 - The provisions of subparagraph b) of the preceding paragraph shall include rewards given or promised to the perpetrators of a typical unlawful act, already committed or to be committed, for them or for others.
3 - The products and advantages referred to in the preceding paragraphs shall be forfeited even if they have been the object of any subsequent transformation or reinvestment, and shall also include any quantifiable gains that have resulted from them.
4 - If the products or advantages referred to in the preceding paragraphs cannot be appropriated in kind, the loss shall be replaced by payment to the State of the respective value, which may be replaced at any time, even during the enforcement phase, subject to the limits set out in article 112a.
5 - The provisions of the previous paragraphs shall apply even if no specific person can be punished for the offence, including in the event of the perpetrator's death or when the perpetrator has been declared contumacious.
6 - The provisions of this article shall not affect the rights of the offended party.

Question 36. (optional)

Are there policies facilitating the prosecution of offences in Articles 5-9 along with other criminal law offences arising from the same set of facts on counterfeit medical products, such as intentional offering, for gain, of medical products to prevent or treat the pandemic disease and without the intention to supply such products, also referred to as scamming?

Question 37. (optional)

Is there a policy for offences in Articles 5-9, either generally or during a pandemic, to be subordinate to other criminal law offences in the case of a prosecution of the same person(s), such as the trafficking of controlled substances in the same consignment as the counterfeit medical products?

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 offence occurred during a pandemic is considered as an aggravating circumstance?

In Portugal, according to article 282 of the Penal Code (Corruption of food or medicinal substances), this offence is only punishable if it creates a concrete danger to the life or physical integrity of another person. If death or physical harm results, the penalties are increased.

Question 39. (optional)

Please specify if and to what extent internal law provides for the possibility of removing the professional status of a person who abused the confidence placed in them in their capacity as a professional (Articles 12.2 and 13. b) or, including legal persons, as manufacturers and suppliers (Article13. c).

Data Collection

This section concerns the effective collection, collation and analysis of data that can support the fight against counterfeit medical products and similar crimes involving threats to public health in a pandemic, and in general.

Question 40. (optional)

Please indicate whether data is collected for the purpose of observing and evaluating the phenomenon of counterfeit medical products or for another purpose (Article 17.3.a and b). Please:

a. Specify if data is collected in the normal course of activity and for what purpose.
b. Indicate whether they were collected specifically during the COVID-19 pandemic. If not, can data for the period of the pandemic be separated from that collected in the normal course of activity?
c. Specify what mechanisms have been established for data collection.
d. Provide the relevant data collected, in particular that during the COVID-19 pandemic, and any reports from the analysis of this data.
e. Indicate if the data and relevant reports based on such data were shared with all the relevant authorities/bodies. Please list the authorities/bodies that compiled the data, produced the reports and those who received them.