COUNCIL OF EUROPE

CONSEIL DE L'EUROPE

T-MEDICRIME(2021)01
16 June 2021

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

Replies should be addressed to the MEDICRIME Committee Secretariat

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by 30 November 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)?
   Following the implementation of the Falsified Medicines Directive, lectures have been given to raise the awareness of the possibility of falsified medicines to penetrate the legal supply chain.
   All actors in the legal supply chain need to have a procedure in place to detect and prevent falsified medicines from entering the legal supply chain. They need to train there personnel in these procedures.
b. healthcare practitioners, police, customs, and health product regulators?
   The Federal Medicines Agency has a specialised unit to treat cases concerning falsified medicines and illegal distribution. These inspectors also give training to the police.
c. specialised investigation units/bodies in the investigation of counterfeit medical products and similar crimes, in specialised techniques, including financial investigations (Article 16.2)?
   - Training on the job
   - Writing official reports for prosecutors : internal and external trainings
   - Cooperation with the Centre for Police Studies (CPS): depending on their offer

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?
Yes. The strategy in Belgium to vaccinate the population involved the set-up of vaccination centra. A script for the operation of these centra was drawn up and specific guidelines were developed to handle the vaccines and all the waste coming from these vaccination centra. These vaccination centra were put under the supervision of a responsible pharmacist and a manager. The guidelines specified that all waste coming from the vaccines (the vials, the stickers, leaflets, packaging,..) had to be put in a secured area. Labels had to be made illegible. All waste had to be put in special containers in the secured area. Every week there was a videoconference for the responsible pharmacists of all the vaccination centra during which the potential fraud with waste was discussed and best practices were shared. According to Belgium law medicinal waste is high risk waste and specialised firms were put under contract to collect the waste from the vaccination centra.

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?
The vaccination centra were visited to give advice on the proper handling of the vaccines and the waste management. Rapport were made of these visits and if necessary adaption to the way of working were made.

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.

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

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

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.

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)?
In general the Law of the 25th of March 1964 on medicines stipulates that the advertising, promotion and selling of falsified medicinal product is a crime.
A Facebook article was posted by the FAMHP regarding a counterfeit medicine that was distributed via an online shop.
Cooperation with police and justice services: For several months the FAMHP could easily transfer reports about fraudulent websites to the specialized police service to block immediately the access to these websites.

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)?

Several initiatives can be mentioned. We refer to, amongst others:

The Federal Police has within central direction Serious and Organised Crime (DJSOC), the section «i2-IRU» (Internet Investigation) that performs daily patrols on open sources (Internet) looking for websites offering counterfeit and/or non-mainstream products. Every file is communicated to the competent partner services (services of the integrated police, Customs, the Federal Agency for Medicines and Health Products (FAMHP) and/or the Federal Public Service (FPS) Economy, in function of the detected violation and / or the type of product offered).

The Board of Public Prosecutors has designated the «i2-IRU» service as the central point of contact for investigations relating to (see the COL NR. 10/2020 of 2nd of April 2020 concerning CORONAVIRUS – Guidelines of the College of Prosecutors General on the fight against fake webshops and fake news sites):

– online stores that sell counterfeit medicines or products related to Covid-19;

– fake online stores that offer genuine/fake items in the same setting;

– fake news sites (mainly or exclusively related to Covid-19) that can explicitly endanger public health.

There is thus an collaboration between all the competent authorities to tackle theses websites.

The FOD Economie has also developed a webpage containing all the information for victims (preventive measures such as how to recognize these website) and what to do when a person becomes a victim with a referral button to a central reporting point where the victim can report the facts. The website also refers to a film available on Youtube that explains this in a comprehensive and intelligible way.

During criminal proceedings, the regular offer to all victims of crime (see in particular services for judicial victim support and victim support services of the competent authorities of the Communities) is also available to these victims. It is important to mention that during the pandemic, for all victims, the regular services of judicial victim support and victim support were/are not interrupted. Assistance and help however during the lockdowns were given by phone, mail or written information, if necessary, videoconference is also possible.

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)?

Yes. Victims of these facts benefices of the same rights as other victims.

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).

In Belgium, several services are involved in offering assistance to victims in criminal proceedings, all within their own competences. Their interventions are differentiated and complementary. To assure an overall support to victims, these services collaborate on a regular basis and coordinate their actions in a structural way to improve their way of working on a permanent and practical basis.

The services of judicial victim support are state services, which depend on the three communities of Belgium. The justice assistants of these services can provide the victims and/or their relatives with specific information regarding their individual penal case, during the entire judicial procedure, from the complaint at the police to the (conditional) release of the offender. They can offer them every necessary support during this procedure (for instance : guiding a victim when given insight in the criminal file, supporting the victim when personal belongings which have been subject to investigation are handed back, supporting the victim during the proceeding before the court). They can also refer victims to other, specialized services or organizations depending on the needs of the victim.

Victim support is implemented by the victim support services, recognized and / or subsidized by the Communities, independent of the police and judicial authorities. The general mission of these services is to provide social and psychological assistance to victims of crime and their relatives. These services provide free social support aimed at restoring the living conditions of the victim and reintegration into work life or a psychological support adapted to the needs of the victims in order to help them find a new life balance. This support can be of short time or long term, depending on the needs of the victim. The interviews are organized according to the needs and the mobility of the victims: they can be organized in a room that offers the guaranteed discretion or, if necessary, in the victim's home or another place (e.g. an hospital) and even via phone. When the victim wishes so, he/she can be accompanied by a representative/employee of the service when effectuating certain steps (e.g. doctor's visit, visit to a police station). When needed, the victim is referred to more specialized organizations (e.g. for psychotherapeutic support).

The intervention of the services of judicial victim support and the victim support services is free of charge.

Court audiences are public, so NGO's and other groups can be present during the court audiences.

Third party reporting in Belgian criminal proceedings is limited to certain offences (see TEH, domestic violence and child sexual abuse images).

On can also refer to our legal aid system. Legal aid may take two forms: primary legal aid and secondary legal aid.

Primary legal aid is granted for “practical information, legal information, an initial legal opinion or a referral to a specialist body or organization”. It takes the form of free consultations, given via a rota service organized by the commissions for legal aid (Article 508/2 of the Judicial Code). These commissions are legal bodies and are organized by each legal district. They are formed as follows: 50% barristers designated by the Law Society for the district concerned, 25% representatives of public welfare assistance centers, and 25% approved legal aid organizations.

Secondary legal aid is defined as aid granted to a natural person for “detailed legal advice or legal assistance within the framework of proceedings”. It is organized by the legal aid offices accountable to the bar associations. Unlike primary legal aid, secondary legal aid is provided exclusively by barristers.

Secondary legal has different financial thresholds which can lead to totally free legal aid or partially free legal aid. In addition to those people who have to prove the insufficiency of their resources, there is another category of people who benefit from a presumption that they do not have sufficient resources (so that they are below the thresholds). They just have to show the documents proving that they belong to the categories defined by the Royal decree. Categories : persons who receive a social integration allowance from the CPAS (public social aid); persons who receive a guaranteed income for elderly persons from the National Pensions Office; persons who receive a disabled replacement income; a detainee, asylum seeker, etc… Minors benefit from a irrebuttable presumption that they have enough resources. Therefore totally free legal aid is granted in every case.

Legal assistance consists of exempting those who do not have sufficient resources to pay the cost of proceedings (not the lawyers’ fees), in full or in part, from paying the relevant costs, which are consequently paid for by the State budget.

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).

See the answer under question 12.

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).
The Pharma-& Food Crime Platform : this platform ensures national exchange of information and cooperation between health authorities, Customs and the police.
The Federal Agency for Medicines and Health Products has appointed a focal point for WHO, a SPOC for Medicrime and a SPOC for WGEO. These SPOCs ensure the exchange of information internationally.
The cooperation with customs services, but also with the FPS Economy (mouth masks) and FPS Public Health was expanded and the communication between the various authorities was optimized during the pandemic.

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)? Yes. The law of the 25th of March 1964 list the competences of the inspectors of the FAMHP and the exchange of information is listed.
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. Depends on the case.

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.
With industry : RAS, was set up before the pandemic
With postal services and logistic firms : putting in quarantine of suspect parcels. Was set up before the pandemic.
Social media: Contacts were established through which reports of infringements can be easily passed on with a good follow-up.

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.

- The Pharma-& Food Crime Platform : this platform ensures national exchange of information and cooperation between health authorities, Customs and the police. They deal with cases on falsified medicines and food fraud.
- Permanent Forum On International Pharmaceutical Crime (PFIPC) : this group is dedicated to the combat of falsified medicines and does this by exchange of information on an international level and stimulating mutual cooperation.
- Member State Mechanism on substandard and falsified medical products (MSMSFM) of the WHO : this group has different working groups which provide advice to protect legal distribution chains, prevent and detect falsified medicines and facilitate access to good quality medicines.
- Working group of Enforcement Officers (WGEO) of the HMA : this group promotes cooperation and the sharing of information concerning falsified medicines, identifies emerging threats and provides training.
- Committee of experts on minimising public health risks posed by falsification of medical products and similar crimes (CD-P-PH/CMED) : this group is dedicated to falsified medical products by looking into threats to public health and sharing of best practices by providing training and publications.

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.
The Federal Agency for Medicines and Health Products has appointed a focal point for WHO, a SPOC for Medicrime and a SPOC for WGEO. These SPOCs ensure the exchange of information internationally.

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.
No.

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. The law of the 25th of March 1964 list the competences of the inspectors of the FAMHP and the exchange of information is listed.

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. The FAMHP has created a Rapid Alert system to alert the industry when (suspected or confirmed) falsifications of medicines have been found. This system is also used to alert the industry of thefts of medicines. If these medicines are found within our supply chain the concerned distributor or manufacturer will contact us so we can investigate further.
And the Falsified Medicines Directive has made it mandatory for the industry to put up a system to make it easier to detect falsified medicines within the legal supply chain.

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 market sampling programme to detect non conformities in medicines, not only for falsified medicines.

Medical Devices: During the lockdown period there was a sampling plan but now it is cancelled because there are no longer laboratories that are able to execute tests on particular medical devices. A sample plan was temporarily developed in response to the introduction of the ATP (Alternative Testing Protocol) for mouth masks.

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?

As mentioned in the answer to question 24 : the market sampling programme detects non conformities in medicines in the legal supply chain (distributors, pharmacies and hospitals.)
The Belgian Law does not allow the purchase of samples of (possible) falsified medicines outside this legal chain. However the legislation will change and in the future it will be possible to do test purchases of (possibly) falsified medicines p.e. through the internet.

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?

The Regulation (EU) 608/2013 concerning customs enforcement of intellectual property rights gives Customs the legal basis to act in cases of counterfeit. They can act on their own initiative if they suspect a counterfeit, but it will only be considered a counterfeit if the rights owner confirms it.
Regulation (EC) 765/2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 gives Customs the possibility to block suspicious shipments for 3 days in which period they can contact the competent authority, the FAMHP in case of medical products, and ask their advice concerning this shipment. Should the shipment contain falsified medicines the case is transferred to the FAMHP who -depending on the severity of the case- will conduct the investigation itself or will contact a Prosecutor.

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

b. 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?
We use the term falsified since counterfeit has a tendency to be interpreted as an infraction on IPR. The definition of a falsified medicine in the law of the 25th of March 1964 on medicines is the same as the definition of a falsified medicine in the Falsified Medicines Directive 2011/62 :
"Any medicinal product with a false representation of:
(a) its identity, including its packaging and labelling, its name or its composition as regards any of the ingredients including excipients and the strength of those ingredients;
(b) its source, including its manufacturer, its country of manufacturing, its country of origin or its marketing authorisation holder; or
(c) its history, including the records and documents relating to the distribution channels used".
This definition does not include unintentional quality defects and is without prejudice to infringements of intellectual property rights.';
So we include the falsification of documents in the definition of a falsified medicine. The notion of counterfeit corresponds with the notion of falsified since the Medicrime Convention does not target IPR infractions.

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. .
    - Manufacturing of counterfeits : law of the 25th of March 1964 on Medicines article 16 (medicines) and 16bis (medical devices) -> criminal sanction
    - Supplying, offering to supply, and trafficking in counterfeits : law of the 25th of March 1964 on Medicines article 16 and 16bis (medical devices) -> criminal sanction

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.
    - Similar crimes involving threats to public health : law of the 25th of March 1964 on Medicines article 16 and 16bis (medical devices) -> criminal sanction

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.

Falsification of documents : law of the 25th of March 1964 on Medicines article 16 -> criminal sanction

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)?
The Criminal Code article 5 says that 'A legal person may be held liable for offences that are either intrinsically linked to its purpose or its interest, or which are committed on its behalf as evidenced by the specific circumstances.
The liability of legal persons does not exclude that of natural persons who are perpetrators of the same acts or who have participated in them.
This applies to every legal person that is established in Belgium.

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;
   The FAMHP has a Special Investigations Unit which deals with cases concerning falsification of medicines and medical devices. The inspectors of this unit all have a pharmaceutical or scientific degree and when they start in this unit are trained to perform investigations. Collaboration with the Federal Police and the Prosecutors (and other agencies when necessary which is evaluated case by case) goes through the Pharma and Food Crime Platform.

b. any specialised prosecutors and whether they function on a national or local basis.
   There are specialised prosecutors who function on a regional basis.

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.

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;
Depending on the specifics of a case the Prosecutor of the region were the infraction occurs or the FAMPH takes the lead. The Prosecutors have to be notified of all cases

even if they do not lead the investigation. The FAMHP has a Special Investigations Unit which deals with cases concerning falsification of medicines and medical devices. The inspectors of this unit all have a pharmaceutical or scientific degree and when they start in this unit are trained to perform investigations. Collaboration with the Federal Police and the Prosecutors (and other agencies when necessary which is evaluated case by case) goes through the PFCP.

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 the initial phase of the marketing of the vaccines, an ad hoc consultation platform was set up with the following participants : the FAMHP (SIU), Federal Police and Justice. This was to anticipate possible falsified vaccines and to be able to take coordinated actions as quickly as possible.

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?
Cases on falsified medical products and similar crimes are collated by the Special Investigations Unit of the FAMHP.

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. They can be investigated without a complaint. If the investigation is the result of a complaint and the complaint is withdrawn the investigation can continue.

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)?

The Law of the 25th of March 1964 on Medicines stipulates all the offences. The inspectors of the Special Investigation Unit of the FAMHP are specialised in this legislation and they assist police and Prosecutors when working in specific cases.

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. The Law of the 25th of March 1964 on Medicines permits the seizure, confiscation and destruction of falsified medical products, active substances, accessories, parts and materials.

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?
Yes. Because the other offences (p.e. trafficking of controlled substances, criminal organisations) are still more severely punished.

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?

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

- *the offence caused the death of, or damage to the physical or mental health of, the victim;*
- *the offence was committed by persons abusing the confidence placed in them in their capacity as professionals, manufacturers or suppliers;*
- *the offences of supplying and offering to supply were committed having resort to means of large scale distribution, such as information systems, including the Internet;*
- *the offence was committed in the framework of a criminal organization;*
- *the perpetrator has previously been convicted of offences of the same nature.*

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).

For legal persons : the manufacturers and distributors are subject to licensing according to the Law of the 25th of March 1964 on Medicines. The Royal Decree of the 14th of December 2006 (the implementing decree of this law) lists all the obligations of the license holders. If they commit infringements, these licenses can be suspended or revoked. Moreover they can also be prosecuted for these infringements.

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:

The FAMHP (SIU) collects information on 2 levels: the level of research files and the level of postal items:

a. Specify if data is collected in the normal course of activity and for what purpose.
   The data collection is a standard activity of the service for the purpose of risk

management & prioritization of the service.

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?
   During the COVID pandemic, the the period between different internal analyses was shorter with more regular reports. The focus was on the type of drugs found in postal packages & medical devices because this changed drastically.
   Therefore, reports with analyses were made specifically about the COVID-related drugs and medical devices.
c. Specify what mechanisms have been established for data collection.
   In collaboration with the Customs Department 'Risk Management' : creation of a list of external characteristics and parameters (shipper, country of shipment, route of shipment, description of contents, value, weight, etc.) of shipments to target suspicious shipments and collect further data.
d. Provide the relevant data collected, in particular that during the COVID-19 pandemic, and any reports from the analysis of this data.
   This is a very extensive subject and is too extensive to be answered in a single question.
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.
   The reports were shared with Federal Police services, Public Prosecution Service, Customs, where useful Europol and other European competent authorities such as the ANSM in France, IGJ in The Netherlands,…