The MEDICRIME Convention
La Convention MÉDICRIME

COUNCIL OF EUROPE
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24/7 NETWORK ON COOPERATION AND INFORMATION EXCHANGE CAPACITY REPORT

Countering falsified medical products - Global programme
(CRIMFAMED Project)

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Abbreviations

CoE	Council of Europe
CoP	Committee of the Parties to the MEDICRIME Convention
CENcomm	Customs Enforcement Network Communications Platform (WCO)
CRIMFAMED	Council of Europe Project - Countering falsified medical products - Global programme
EUROPOL	European Union Agency for Law Enforcement Cooperation
GMSM	Global Monitoring and Communications Platform
HMA WEGEO	Heads of Medicines Agencies Working Group of Enforcement Officers
INTERPOL	International Criminal Police Organization
MEDICRIME	Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health
NCB	National Central Bureau (INTERPOL)
PFIPC	Permanent Forum on International Pharmaceutical Crime
UNODC	United Nations Office on Drugs and Crime
WCO	World Customs Organization
WHO	World Health Organization

II. Executive Summary

The Council of Europe (hereinafter CoE) launched the Project “Countering falsified medical products- Global programme” (CRIMFAMED) to assess the current state of 24/7 capabilities of national authorities involved in domestic criminal and other laws to support the prohibition and enforcement against counterfeit/falsified medical products for the purpose of protecting public health.

Bearing in mind the need for building and strengthening institutional and operational capacities to support the MEDICRIME Convention, the CRIMFAMED Survey focused mainly on legislative, strategic and planning measures put in place by States to support those authorities who need to cooperate and exchange information between them, specifically relating to counterfeit medical products and similar crimes. It also included related issues, such as the designation of contact points and their training and resourcing.

It should be noted that the MEDICRIME Convention has been designed to comprehensively deal with threats to public health through criminal law, and it specifically includes the promotion of national and international cooperation in its object and purpose (Article 1.c). It takes into consideration relationships at the domestic level between authorities, including law enforcement, customs, and the health authorities, and internationally between countries, specifically Parties to the MEDICRIME Convention. The survey, therefore, focused on Articles 17 (National measures of co-operation and information exchange) and Article 22 (International co-operation on prevention and other administrative measures) of the MEDICRIME Convention.

Against this background, a questionnaire to establish a baseline assessment on the state of readiness of CoE member States, Parties, and signatories to the MEDICRIME Convention, and other countries, to cooperate and exchange information in combating this type of crime impacting on public health, was drafted, and sent to 31 countries (Annex 1).

This summary report provides an overview of the responses to the questionnaire and is intended to support those countries by indicating their capacity and limitations to cooperate and exchange information specifically relating to counterfeit medical products and similar crimes. It highlights the challenges nationally and internationally where agreed contact points are not designated for such cooperation, and more particularly, where such responsibilities fall under different authorities depending on the subject matter, whether criminal behaviour-related or medical product-related. The responses reveal that information sharing systems often depend on the type of information to be exchanged, whether criminal behaviour-related or medical product-related, and the focus of the authority responsible for its exchange, whether law enforcement, customs, or health product regulatory authority.

The report finds that there is a high level of cooperation and information exchange in practice by national authorities, though this is often based on complex arrangements and not always supported by legislation, is also achieved using informal measures. The report does find, however, that duplication of effort may arise in collecting and transmitting information domestically and internationally and that gaps between systems may go unaddressed.

Collateral issues, that of data collection, and the existence of a database capable of reporting specifically on counterfeit medical product-related criminal behaviour and counterfeit medical products were not the main focus of the survey but were not capable of being separated from the main focus due to the symbiotic relationship between them. The report finds that information-sharing domestically among authorities is generally not being recorded in a structured database such that it may be capable of effective analysis specific to counterfeit medical products and similar crimes.

As it was outside its remit, the report does not recommend whether or not the Committee of the Parties should establish a dedicated 24/7 network specific to the MEDICRIME Convention. Nor does it consider whether the Committee of the Parties should also build a MEDICRIME-specific database to support Parties to the Convention, and other countries, who may wish to contribute to it for the purpose of having a common bank of information on which to cooperate in combating counterfeit medical products and similar crimes to protect public health. The report does raise the issue, in light of its findings, whether existing but often complex cooperation and information exchange arrangements are sufficient to address this type of crime. It is open to the Committee of the Parties to consider establishing a MEDICRIME-specific 24/7 network separate from all other existing networks or to run it in tandem with other similar networks utilising their capacities and experiences and leaving it to States to decide how to do this domestically according to their resources. Regardless of the path taken, the report envisages that structured mechanisms for the collection, analysis, and retrieval of information specific to counterfeit medical product-related crime and the necessary connection to the counterfeit medical products are essential to cooperation and information exchange between authorities at the domestic and international levels.

Finally, the report recognises the commitment of those who contributed to the responses and the challenges arising in collating information from several authorities with different remits involved in addressing counterfeit medical products and similar crimes. This illustrates the extent of cooperation and information needed by authorities to act as one on a national basis, which the report finds is a key indicator of success in the objective of the survey.

III. Introduction

3.1. Context

In the framework of the Project entitled "Countering falsified medical products - Global programme" (CRIMFAMED), the Council of Europe (hereinafter, the CoE) is conducting this **Survey** to assess the current state of 24/7 capabilities of national authorities involved in domestic criminal and other laws support the prohibition and enforcement against counterfeit[1]/falsified medical products as criminal offences for the purpose of protecting public health.

This survey will bring visibility to the legislative procedures and national measures on collaboration between actors (such as justice, health, law enforcement and customs authorities). It will also assess training opportunities for those representatives involved in the MEDICRIME-related criminal proceedings in each state. Finally, participation in other international networks will also be considered.

Please note the object and purpose of the MEDICRIME Convention, as provided Article 1.1, while completing the Survey

Article 1 – Object and purpose

1. *The purpose of this Convention is to prevent and combat threats to public health by:*
   a. *Providing for the criminalization of certain acts;*
   b. *protecting the rights of victims of the offences established under this Convention;*
   c. *promoting national and international co-operation*

This survey takes also into consideration Articles 17 (National measures of co-operation and information exchange) and Article 22 (International co-operation on prevention and other administrative measures) of the MEDICRIME Convention.

3.2. Objective

The purpose of the CRIMFAMED survey is to identify how the Committee of the Parties can best it can support the Parties to the MEDICRIME Convention, and other non-member States build on its preparedness to support cooperation and information exchange within the context of 24/7 networks in combating counterfeit/falsified medical products[2] and similar crimes. The survey aims to identify the strengths and gaps within and between countries in their legislative, regulatory and policy frameworks. It is important to note that the objective does not include a presumption of an outcome that a 24/7 networks either should or should not exist.

[1] See definition of the term 'counterfeit' in Article 4.j), MEDICRIME Convention.

[2] See definition of the term 'medical product' in Article 4.a), MEDICRIME Convention.

3.3. Methodology

The questionnaire was sent to all Parties and Signatories to the MEDICRIME Convention and, in order to obtain a wider range of responses, to a select number of other countries. The report is presented in a horizontal way and not on a country-by-country way, and comments only on the issues of greatest importance.

The areas of focus and the number of questions are split into five main parts: Chapter 1 concerns the General Report; Chapter II concerns issues of National cooperation and information exchange (Questions 1-10); Chapter III contains issues related to training and resources (Questions 10-14); and Chapter IV concerns International Cooperation and Information sharing (Questions 15-20), specifically relating to the combating of medical products-related crime and counterfeit medical products. The conclusions and recommendations are contained in the final part, Chapter V.

Each country was asked to provide a national response rather than by individual authority responses, and they were further asked to: indicate the authorities participating in the response; whether the response was completed as a team or were individual responses that were then consolidated by one authority for submission; if any authority that has a role in combating counterfeit medical products and similar crimes in the country was not involved in responding to the submission; and which authority was making the submission on behalf of all the authorities mentioned in the response. This approach was used to obtain consolidated information and promote cooperation among the authorities who have responsibilities for cooperation and information exchange relating to combating medical products-related crime and counterfeit medical products. The intention being to receive a harmonised picture of national measures and to encourage the true spirit of cooperation and information sharing among those authorities.

If a response to a particular question was not provided, it was assessed that no relevant provision or measure was identifiable. Where a response provided information that was assessed as contradictory to other information provided in the survey response, it was interpreted that the legislative or other measure was made available by at least one national authority and that the latter was the response to be relied upon in the survey.

This approach highlights for the Committee of the Parties and for the country in question that, while gaps can be identified, some legislative or other measures were available to support those persons, units, authorities or services in charge of cooperation and information exchange to work effectively at both the domestic and international levels to specifically combat counterfeit/falsified medical products-related crime and counterfeit medical products for the overall purpose of protecting public health.

As there currently exists no 24/7 network for cooperation and information exchange specific to the MEDICRIME Convention, no obligations in this respect arose for any of the respondents apart from the Parties to the Convention in relation to Articles 17 and 22.

The submissions were accepted in the English and French languages and the assessors, in drafting this report, were in a position to translate and interpret the responses.

3.4. Countries participating

The survey questionnaire was sent to 31 countries from which 15 countries responded (48%) (Annex I). This report's findings are concluded based on the information received in the responses.

The participating CoE member states (all of which are Parties to the MEDICRIME Convention, except where indicated) were: Armenia, Belgium, Bosnia and Herzegovina, Burkina Faso, Croatia, France, Hungary, Ireland (non-Party to the MEDICRIME Convention), Moldova, Portugal, Slovenia, Spain, Switzerland, and Ukraine. The participating non-member State of the CoE was Morocco (Party to the MEDICRIME Convention).

3.5. Limitations

This report is based on submissions made by national focal points agreed, in most instances, by the national authorities who have responsibilities for combating counterfeit medical products and similar crimes. In a small number of instances, the submissions were provided without either consolidation with the other relevant domestic authorities or in their absence.

In some instances, responses for particular issues were left unanswered. While relevant information on the issue may exist in the respondent country, the report concluded that the relevant information was not available.

The submissions are technical in nature and should be viewed in that context. Web links are provided by the national authorities in support of the submissions made. These links may not be exhaustive and have not been independently verified. They are provided for information only in this report.

IV. GENERAL REPORT

4.1. Applicable Law and other measures

It is noted that the internal laws and other measures being used in the countries surveyed in this report to address cooperation and information exchange in relation to the counterfeiting of medical products and similar crimes are:

- a mixture of laws and administrative measures
- in some countries it is by formal arrangements between authorities, and in others it is by informal arrangements
- in a small number of countries there are few arrangements, formal or informal, providing for any cooperation or information exchange.

There is no standard, other than in Articles 17 and 22, provided by the MEDICRIME Convention for Parties on what laws or other measures to use to achieve the type of cooperation envisaged by the MEDICRIME Convention to be effective and without having to rely on other general 24/7 networks as matters of general crime.

4.2. Issues analysed

The key issues analysed were on:

- the existence of national measures, whether structured by legislative, policy, strategic plans or informal measures;
- State support through training and resourcing for those responsible for cooperation and information sharing in relation to counterfeit medical products and similar crime;
- the functioning of national authorities in a cohesive and cooperative spirit in domestic and international cooperation and information exchange

4.3. General comment

The MEDICRIME Convention was drafted with the intent that it be a holistic instrument with an interlinking fabric of support between provisions, including national and international cooperation and information sharing. It has been observed in this report that in the absence of specific measures, whether legislative or administrative, such cooperation and information sharing between the domestic authorities, and between countries, may rely on informal arrangements, or none at all, and on other 24/7 networks that may not always be sufficient for the requirements of the MEDICRIME Convention.

4.4. Responding authorities to the Questionnaire

The questionnaire requested information about the responding authorities in order to determine:

- the extent to which the national authorities cooperated with each other in responding to the survey, thus indicating if there was a cooperative spirit in the normal course of combating counterfeit medical products and similar crimes;
- the extent to which they did so either as a team effort or by agreement for one authority to act as a consolidating coordinator for the submission to the questionnaire, thus indicating a cooperative approach and a common understanding and agreement on

how cooperation and information exchange works within the country as regards combating counterfeit medical products and similar crimes;

- which authority, or coordinator is identified as leading nationally in responding to the MEDICRIME Committee on matters related to combating counterfeit medical products and similar crimes.

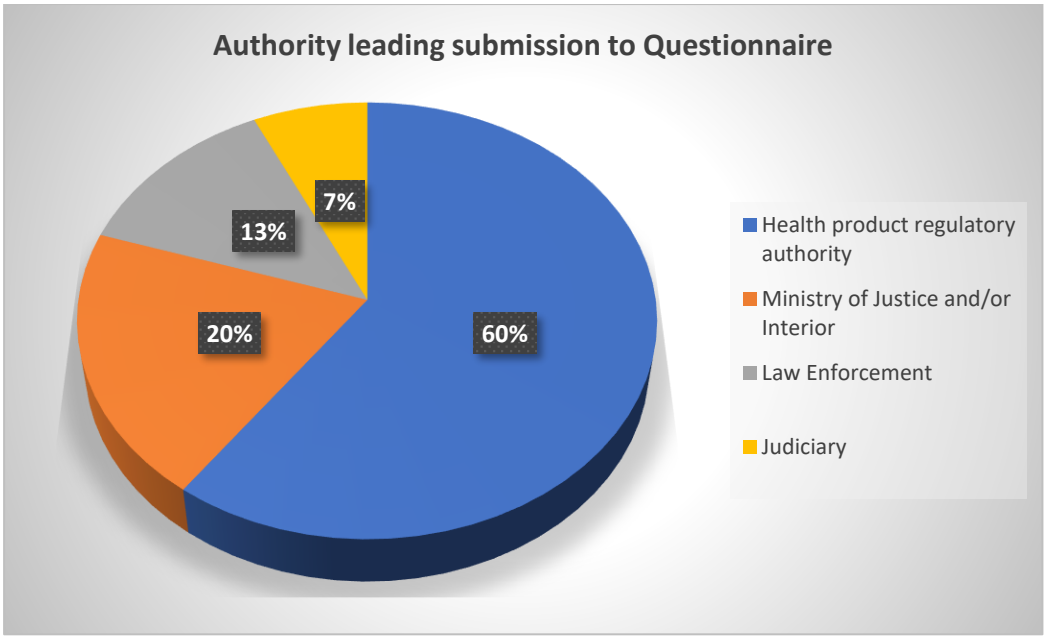
The following information summarises the position regarding the responding authorities:

- Nine countries (60%) (Armenia, Belgium, Bosnia and Herzegovina, Burkina Faso, France, Hungary, Spain, Switzerland, and Ukraine) identified the person making the response submission to the questionnaire to the MEDICRIME Committee as being the country delegate to the MEDICRIME Committee. All responses identified the person and authority making the submission.

- Five countries (36%) (Armenia, Morocco, Moldova, Portugal, and Ukraine) did not provide any information on the participating authorities, whether the response was completed as a team response or any information regarding which authorities have a role to play in combating counterfeit medical products and similar crimes and were not represented in the response to this questionnaire.

- Countries identified the authority leading the submission to the questionnaire as being:

a) **Health product regulatory authority or the Ministry of Health** in nine countries **(60%)** (Armenia, Belgium, Croatia, Ireland, Morocco, Moldova, Slovenia, Switzerland, and Ukraine);
b) **Ministry of Justice and/or Interior** in three countries **(20%)** (France, Hungary, and Spain);
c) **Law Enforcement in two countries (13%)** (Bosnia and Herzegovina, and Portugal).
d) **Judiciary in one country (7%)** (Burkina Faso).
e) One country **(7%)** (Switzerland) reported that it was the **only authority involved** in responding to the questionnaire.
f) Eight countries **(53%)** (Bosnia and Herzegovina, Burkina Faso, Croatia, France, Hungary, Ireland, Slovenia, and Spain) reported **cooperation in compiling the submission of the response from a minimum of the police service, customs service, and health products regulatory authority**.



***Note**: The comments are based on the responses provided and may not reflect the actual position in the country where no information was provided.*

V. NATIONAL COOPERATION

This chapter covers question 1 to 10 of the questionnaire, which included questions on national cooperation and information exchange. Article 17.1 of the MEDICRIME Convention was the focus behind these questions.

Article 17

1. *Each Party shall take the necessary legislative and other measures to ensure that representatives of health authorities, customs, police and other competent authorities exchange information and co-operate in accordance with domestic law in order to prevent and combat effectively the counterfeiting of medical products and similar crimes involving threats to public health.*

5.1. Adoption of a national strategy and/or action plan between State authorities

QUESTION 1	YES	NO
In relation to combating the counterfeiting of medical products and similar crimes, has your country adopted:		
a. A national strategy on cooperation and exchange of information between authorities/services?		
b. A national strategy or, a national action plan on cooperation and exchange of information between authorities/services?		

This question seeks to ascertain whether the Parties/countries have formally put in place a national strategy or formal action plan specifically focused on cooperation and exchange of information between authorities/services to combat counterfeiting of medical products and similar crimes (Article 17.1).

- National strategies and/or national action plans for the formal system of cooperation and exchange of information between authorities/services (health authorities, customs, police, and in some cases, other relevant competent authorities) have been established in six (40%) of the responding countries (Armenia, Burkina Faso, Morocco, Slovenia, Spain, and Ukraine).

- No national strategy or action plan on cooperation and exchange of information between authorities/services to combat counterfeiting of medical products and similar crimes has been specifically put in place by nine (60%) of the responding countries (Belgium, Bosnia and Herzegovina, Croatia, France, Hungary, Ireland, Moldova, Portugal, and Switzerland).

Conclusions

A national strategy or action plan is not evident in just over half (60%) of countries who report that they engage in cooperation and exchange of information between authorities/services in relation to the combating of counterfeiting of medical products and similar crimes. This lack of a strategy or action plan may increase the risk of cooperation and information exchange faltering due to changes in the authorities, including change or absence from appointment in personnel involved in this function. This further a failure of cooperation and information exchange between authorities involved in combating counterfeit medical products and similar crimes.

5.2. National strategy/action plan based on legislation and/or policy

QUESTION 2
Has the national strategy and/or national action plan been put in place based on

a. A legislative requirement	
b. National policy	
c. Other	

This question seeks to ascertain the mechanism by which the national policy and/or action plan has been put in place by those countries responding affirmatively in Q 1 with a view to understanding the compellability for authorities/services to cooperate and exchange information between them.

- Six countries were assessed in Question 1 that they had a national strategy and/or national action plan to combat counterfeit medical products and similar crimes. Of these, national strategies and/or action plans for cooperation and information exchanges were mandated by legislation in three (Slovenia, Spain, and Ukraine). This also means that out of the 15 countries responding to the questionnaire only 20% reported that they had a national strategy and/or action plan that was supported by legislation.

- Two countries out of those six countries, referred to in the preceding paragraph, report having a national policy instead of legislative support for cooperation and information exchange relating to combating counterfeit medical products and similar crimes.

- One country (Spain) had a national policy in addition to a legislative requirement to support the strategy and policy.

- Two countries (Burkina Faso, and Spain) report having other measures in addition to legislation and national policies to support this area. One country (Armenia) reported that, while not having supporting legislation or a national policy, it had informal arrangements for providing training on this topic between law enforcement, customs, and the health product regulatory.

5.3. Strategy/action plan based on legislation and/or policy

QUESTION 3	YES	NO
If there is no legislative provision, national policy, national strategy or action plan in place, is there:		
a) Any State authority (e.g. police, customs, health product regulatory authority, ministry) with a policy, strategy or action plan to ensure that there is provision for cooperation and information exchange between the various authorities who are engaged in combating counterfeit medical products and similar crimes?		
b) Please provide the details of the authority with such provision:		
c) If such a cooperation agreement exists, which authorities/services have signed it or have indicated an intention to sign		

This question addresses those countries that indicated in Question 1 that they did not have legislative provisions, national policy, national strategy, or action plans in place. The question seeks to ascertain in such countries whether any relevant State authority had an individual

policy, strategy, or action plan to ensure that there is provision for cooperation and information exchange between the relevant authorities dealing specifically with combating counterfeit medical products and similar crimes.

- 11 countries (73%) (Armenia, Belgium, Bosnia and Herzegovina, Croatia, Hungary, France, Ireland, Portugal, Spain, Switzerland, and Ukraine) reported as having such State authority-specific arrangements. One country (7%) (Moldova) did not have such arrangements. Three countries (20%) (Armenia, Spain, and Ukraine) already specified that they had national strategies, action plans or policies that addressed this.
- The State authorities who have signed, or plan to sign such cooperation agreements include law enforcement services, customs services, and health product regulatory. This included 10 out of 15 countries (67%) (Armenia, Belgium, Bosnia and Herzegovina, Croatia, France, Hungary, Ireland, Slovenia, Spain, and Switzerland) responding to the questionnaire.

- Other State authorities that are included in such arrangements in some countries include the anti-doping authority in six countries, the food safety authority in five countries, and National INTERPOL NCB in five countries. Only three countries (20%) (Bosnia and Herzegovina, Ireland, and Spain) report having arrangements with all the authorities.

- One country (7%) (Moldova) reported not having any formal arrangements in place but has informal case-by-case arrangements involving law enforcement services, customs services, the health product regulator, the food safety authority, and the INTERPOL NCB.

Conclusion

Taking Questions 2 and 3 together, it is concluded that this result means that all but one country report that there is some measure existing or planned to make specific provisions for cooperation and information exchange between the relevant State authorities involved in combating medical products and similar crimes.

5.4. Measures for cooperation and information exchange between the relevant State authority and the industrial sector

QUESTION 4	YES	NO
Does any of the above measures (legislative provision, national policy, strategy, action plan or other structured measures) (**Article 17, paragraph 2**)		
a. Provide for cooperation between the competent authorities (for the investigation of crime, border surveillance, health product regulation, other relevant authorities) and the industrial sector as regards risk management of counterfeit medical products and similar crimes involving threats to public health		

This question seeks to ascertain if any, and which State authority provides for cooperation between the competent authorities (for the investigation of crime, border surveillance, health product regulation, and other relevant authorities) and the industrial sector as regards risk management of counterfeit medical products and similar crimes involving threats to public health. This question's focus on risk management primarily refers to the health risks and

impacts resulting from a counterfeit medical product. Within the context of this report, the issue is whether there is a system of cooperation and information exchange that is necessary for the function of risk management between the State authorities, normally the regulatory authorities, and the industrial sector that manufactures and/or markets the authentic medical product that is now suspected of being counterfeited.

- Having regard to the health products regulator's licensing/authorisation/registration function of medical products it was expected that in all countries responding to this questionnaire that there is a structured system in place for cooperation and information exchange for risk management of incidents involving counterfeit medical products involving the health product regulator and industry. 11 out of the 15 countries (73%) (Armenia, Belgium, Croatia, France, Hungary, Ireland, Morocco, Portugal, Slovenia, Spain, and Ukraine) indicated that such systems for cooperation for risk management exist. The additional information provided by six out of these 10 countries suggested an interpretation of the question as to cooperation between the authorities themselves, and not between the authorities and the industrial sector. This may invalidate the level of reporting to have cooperation measures between authorities and the industrial sector regarding risk management of counterfeit medical products and similar crimes.

- Four countries (27%) (Bosnia and Herzegovina, Burkina Faso, Moldova, and Switzerland) reported that they do not have such cooperation systems. The absence of such a system in those four countries may result from an alternative interpretation of the question. It is expected, subject to the country's clarification, that some of these may have such a system in place.

5.5. Structured bodies, committees and/systems for the collection and transmission of information and data

QUESTION 5	YES	NO
Are there structured bodies/ committees/ systems in place for the collection and transmission of information and data that are specific to		
a. Combating counterfeit medical products and similar crimes (i.e. concerning crimes and criminal behaviours)		
b. Counterfeit medical products (i.e. concerning the product)		
c. Are not specific to counterfeit medical products but are general in nature and may include counterfeit medical products (i.e., a general criminal law)		

This question seeks to ascertain whether the country's competent authorities have structured bodies, committees or other systems in place for the collection and transmission of information and data that are specific to the criminal behaviours and/or the medical product that are associated with counterfeit medical products and similar crimes.

With regard to combating counterfeit medical products and similar crimes (i.e., concerning crimes and criminal behaviours):

- 10 countries (67%) (Armenia, Belgium, Bosnia and Herzegovina, Hungary, Ireland, Morocco, Portugal, Slovenia, Spain, and Ukraine) report having such measures in place for the collection and transmission of information and data that are specific to counterfeit medical product-related crime.

- 5 countries (33%) (Burkina Faso, Croatia, France, Moldova, and Switzerland) report not having any such measures in place for this purpose specific to counterfeit medical product-related crime.

With regard to counterfeit medical products (i.e., concerning the product)

- 11 countries (73%) (Armenia, Belgium, Bosnia and Herzegovina, Croatia, Hungary, Ireland, Morocco, Portugal, Slovenia, Spain, and Ukraine) report as having such measures in place for the collection and transmission of information and data that are specific to the counterfeit medical product.

- 6 countries (40%) (Armenia, Belgium, France, Hungary, Portugal, and Ukraine) also report having legislation that is more general that also includes these activities that take account of criminal behaviour and counterfeit medical products.

- 3 countries (20%) (Burkina Faso, Moldova, and Switzerland) report not having such measures in place for this purpose relating to counterfeit medical products.

With regard to general law

- 3 countries (20%) (Burkina Faso, France and Switzerland) report having measures of a more general nature that also include counterfeit medical products and similar crimes.

Conclusion

With the exception of Moldova, all countries responding to the questionnaire have some measures, in place for the collection and transmission of information whether specific to the counterfeit medical product-related criminal behaviours and counterfeit medical products, or more generally that include both the criminal behaviours and the counterfeit medical products.

5.6. Provisions and measures supporting the establishment and operation of structured systems for the collection and transmission of information and data

QUESTION 6		
If the answer to 5. a or b is 'Yes', specify the legislative provision, or other policy measures supporting the establishment and operation of structured bodies/ committees/ systems for the collection and transmission of information and data as regards		
a. Combating counterfeit medical products and similar crimes (i.e. concerning crimes and criminal behaviours)		
b. Counterfeit medical products (i.e. concerning the product)		

This question seeks to obtain supporting information in relation to only those 11 countries (Armenia, Belgium, Bosnia and Herzegovina, Croatia, Hungary, Ireland, Morocco, Portugal, Slovenia, Spain, and Ukraine) whose repones in Question 5. a., or 5. b., (Yes) are that they have specific arrangements in place to support their responses.

- There are clear bases in legislation or other structured agreements in six (43%) of the countries responding to this questionnaire (Armenia, Bosnia and Herzegovina, Hungary, Ireland, Portugal, and Spain) to support their establishment of systems for the collection and transmission of information and data relating to the criminal behaviours and the counterfeit medical products. It is unclear what the basis is in three countries (Belgium, Croatia, and Morocco) whose responses indicate that some form of interagency agreements exist for the collection and transmission of information and data. Two countries (Slovenia and Ukraine) did not provide any information on this.

- In all of the 11 countries, points of contact were arranged, and the authorities involved in each case included law enforcement, customs services, and the health products regulator, at a minimum. In two countries (Ireland and Portugal) both the anti-doping and the food product safety authorities were also included.

- Responses received from three countries (France, Moldova, and Switzerland) were not considered for reporting under Question 6 as they had not indicated in Question 5 that they had specific arrangements in place. The response of two of these countries (France, and Switzerland) are considered in this report under Question 7.

Conclusion

11 countries responding to the questionnaire have legislative provisions, or other structured measures supporting the establishment and operation of bodies, committees, or systems for the collection and transmission of information and data specifically relating to the combating of counterfeit medical products and similar crimes (criminal behaviour), and/or the counterfeit medical product. All those 11 countries include law enforcement services, customs services, and the health product authority in their points of contact for these purposes.

5.7. Other arrangements for the collection and transmission of information and data

QUESTION 7	YES	NO
Are there informal or ad hoc arrangements in place, instead of more structured arrangements, between the relevant authorities, for the collection, and transmission of information and data that are specific to		
a. Combating counterfeit medical products and similar crimes (i.e. concerning crimes and criminal behaviours)		
b. Counterfeit medical products (i.e. concerning the product)		

This question seeks to ascertain whether the country's competent authorities have informal or ad hoc arrangements in place where there are no formal or structured arrangements specific to and concerning counterfeit medical product-related criminal behaviour and the counterfeit medical product. This question primarily concerns those countries (Burkina Faso, Moldova, and Switzerland) following their responses to Question 5 a, and/or b. Responses from these countries to Question 6 are also considered here. The question was also available to the other countries that responded with a 'Yes' to Question 5. a, and/or b, to state if they also have in place informal or ad hoc arrangements in addition to structured bodies, committees or other systems relating to the a and b above.

- The responses of four countries (Bosnia and Herzegovina, Burkina Faso, Moldova, and Switzerland) are presented here as they did not have formal structured bodies, committees, or systems in relation to the matters discussed in Questions 5 and 6. Of these.

- 3 countries (Bosnia and Herzegovina, Burkina Faso, and Switzerland) responded that they have informal or ad hoc arrangements in place for this purpose relating to criminal behaviours and counterfeit medical products. This variously included the collection and transmission of information on particular counterfeit medical product-related topics, information and data relating to operational matters with an international focus for reporting, and informal communications mechanisms for sharing information

- One country (Moldova) responded that it does not have informal or ad hoc arrangements in place.

- In relation to responses from countries that responded with a 'Yes' to Question 5, four countries (Armenia, Ireland, Spain, and Ukraine) responded that, in addition to formal structured measures, they also have informal or ad hoc arrangements in place.

Conclusion

This result from Questions 5-7 indicates that all but one country out of 15 countries (93%) responding to the questionnaire report that there are some measures making provisions, whether formal or informal, for the collection and transmission of information and data that are specific to or more generally including combating medical products and similar crimes involving criminal behaviour.

5.8. Structured databases to collect information

QUESTION 8	YES	NO
Are there structured databases to collect information as regards		
a. Combating counterfeit medical products and similar crimes (i.e. concerning crimes and criminal behaviours)		
b. Counterfeit medical products (i.e. concerning the product)		

This question seeks to ascertain whether there are structured databases to collect information in relation to 8. a (concerning criminal behaviour), and/or 8. b (concerning the medical product). The question does not require that the database, where it exists, be under the control of one authority so long as it is structured to collect the relevant information in a consolidated manner on a national basis.

- 8 out of the 15 **(53%)** countries (Armenia, Bosnia and Herzegovina, Ireland, Portugal, Slovenia, Spain, Switzerland, and Ukraine) responding to the questionnaire reported that they have structured databases to collect information as regards both the counterfeit medical product-related criminal behaviours (8. a) and counterfeit medical products (8. b). One country (7%) (Hungary) reported that it had a database regarding counterfeit medical product-related criminal behaviours (8. a), but not for counterfeit medicinal products (8. b). Five countries (33%) (Belgium, Burkina Faso, Croatia,

France, and Moldova) report that they do not have structured databases to collect this type of information. One country (7%) (Morocco) did not respond to this question.

- 4 countries **(27%)** (Armenia, Ireland, Portugal, and Ukraine) report that the database falls within the responsibility of the health products regulator One country (7%) (Hungary) indicated that the database falls within the responsibility of the law enforcement service, and the public prosecutor, while one country (7%) (Ukraine) indicated that it falls within the responsibility of the law enforcement service only. One country (7%) (Bosnia and Herzegovina) reports that the database for criminal behaviours lies within law enforcement, while the database for counterfeit medical products lies within the health products regulatory authority. No information was provided on which authority the database falls in two countries reporting that they have such databases (Slovenia, and Switzerland). One country (Morocco) did not provide a response to this question.

Conclusions

It can be concluded that just over one-third (38%) of countries responding to this questionnaire did not have databases as regards counterfeit medical product-related crime and the counterfeit medical products.

The responses indicate that over half of those responding have structured databases to collect information regarding criminal behaviours and counterfeit medical products. Almost one-third (33%) do not have any structured databases to collect information on the combating of counterfeit medical product-related crime or counterfeit medical products.

5.9. No arrangements for the collection and transmission of information and data

QUESTION 9
Do you consider that there are no arrangements, i.e. neither formal nor informal, in place for the collection and transmission of information and data that are specific to
a. Receiving and collecting information and data, including through contact points, at national or local levels and in collaboration with the private sector and civil society, for the purpose of preventing and combating the counterfeiting of medical products and similar crimes involving threats to public health
b. Making available the information and data obtained by the health authorities, customs, police and other competent authorities for the co-operation between them

This question seeks to clarify that there are no measures existing for the above purposes at national or local levels that include authorities, the private sector, and civil society, and to make the information and data obtained by the authorities for cooperation between the relevant public sector authorities.

- Five countries **(33%)** (Burkina Faso, France, Moldova, Slovenia, and Switzerland) out of the 15 countries responding to the questionnaire reported that there were no specific arrangements, either formal or informal, for receiving information and data at national or local levels and in collaboration with the private sector and civil society. The same five countries reported that there were no arrangements in place for making information

and data obtained by health authorities, customs and police and other competent authorities for cooperation between them.

- The remaining 10 countries (**(67%)** Armenia, Bosnia and Herzegovina, Belgium, Croatia, Hungary, Ireland, Morocco, Portugal, Spain, and Ukraine) reported that such arrangements were in place as regards doing so in collaboration with the private sector and civil society, and for making information obtained from authorities for the cooperation between them

Conclusions from Questions 8 and 9

The indications from the results from Questions 8 and 9 suggest that two-thirds (67%) of the responding countries have arrangements for receiving and transmitting information and data, and in collaboration with civil society and the private sector, and also sharing between the authorities the information collected by them, while just over half of the countries have arrangements for the recording on structured databases information and data (57%). It may be concluded that some of the information and data while being shared among the authorities, is not being recorded in a structured database such that it may be capable of analysis.

5.10. Planned systems for information and data exchange where no systems exist

QUESTION 10	YES	NO
If the answer to any part of question 9 is 'Yes' (that there are no formal or no informal arrangements in place), are there any draft legislation, strategies, plans or other measures contemplated or in the process of development to provide for such formal or informal arrangements		

This question seeks to ascertain whether or not the five countries (Burkina Faso, France, Moldova, Slovenia, and Switzerland) reporting in Q.9 as having no arrangements in place, in relation to a. and b. above, have any draft legislation, strategies, plans or other measures contemplated for making arrangements, such as:

a. Receiving and collecting information and data, including through contact points, at national or local levels and in collaboration with the private sector and civil society, for the purposes of preventing and combating counterfeit medical products and similar crimes involving threats to public health
b. Making available the information and data obtained by the health authorities, customs, police, and other competent authorities for the cooperation between them

- Two of the five countries (Burkina Faso, and Slovenia) reported that they have plans to address the issues raised in this question. In Burkina Faso, a draft law on combating counterfeit medical products commenced in 2017. This included the creation of a National Council to Combat Fake Medicines and Other Medical Products (CONALFAM). This inter-ministerial and multidisciplinary structure is intended to be a coordinating body for the fight against fake medicines and is responsible for developing, coordinating, monitoring, and evaluating national preventive measures adopted to prevent all forms of trafficking in fake medicines and other medical products

and related offences. Slovenia did not provide any information regarding any draft arrangements relative to this question.

- One country (Moldova) reported that it does not have plans in this regard.

- No response was received from two countries (France and Switzerland) in relation to this question.

Conclusion

This result means that all but two countries out of 15 countries responding to the questionnaire report that there are some measures making provisions, whether formal or informal, for the collection and transmission of information and data that are specific to or more generally including combating medical products and related crimes involving criminal behaviour.

VI. NATIONAL CO-OPERATION– TRAINING AND RESOURCING

Article 17

4. Each Party shall take the necessary measures to ensure that persons, units or services in charge of co-operation and information exchange are trained for this purpose. Such units or services shall have adequate resources.

6.1. Specialised Units, offices, groups and designated appointments

QUESTION 11	YES	NO
Are there specialised units, offices, groups, designated appointments, or similar, with the specific responsibility		
A. To combat counterfeit medical products and similar crimes (i.e. concerning crimes and criminal behaviours)		
B. Counterfeit medical products (i.e. concerning the product)		

This question seeks to identify the existing specialised organisations that are responsible for combating counterfeit medical products and similar crimes (concerning criminal behaviour) or counterfeit medical products (i.e., concerning the product), determine their primary competencies and if there is any specialised training in place for the purpose of cooperation and information exchange.

With regard to criminal behaviours:

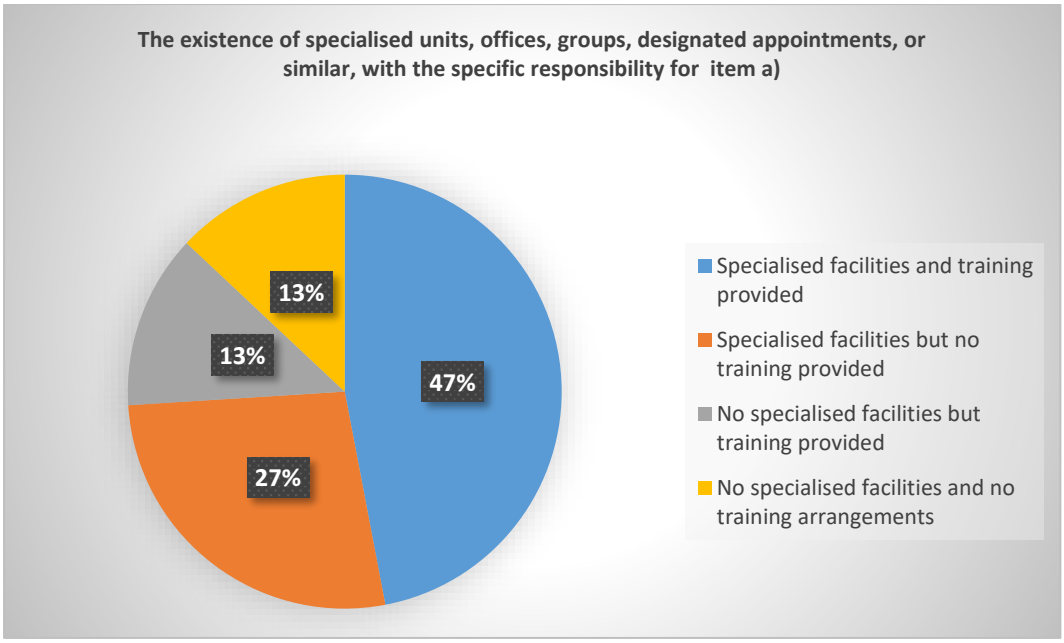
- 11 (73%) countries, (Armenia, Belgium, Burkina Faso, Croatia, France, Ireland, Morocco, Portugal, Spain, Switzerland, and Ukraine) are assessed as having specialised units/organisations that specifically deal with this type of criminal behaviour.

- One of these countries (Switzerland) reports that there is no dedicated unit or training provided, but from the information provided in response to the questionnaire, it is assessed that Switzerland has a dedicated organisation/unit focusing on counterfeit medical product-related crime and also its health product regulatory authority provides regular training to the other authorities combating this type of crime.

- In all of these countries, with the exception of four (Burkina Faso, Croatia (no information provided), Morocco (no information provided), and Portugal) there are also training arrangements in place for the purpose of cooperation and information exchange for these units/organisations.

- Two countries (13%) (Bosnia and Herzegovina, Hungary) are assessed as not having specialised units/organizations specifically dealing with counterfeit medical products and similar crimes but there are training arrangements in place for law enforcement agencies generally for the purpose of cooperation and information exchange.

- Two countries (13%) (Moldova and Slovenia) are assessed as not having specialised units/organisations specifically dealing with counterfeit medical product-related crime nor are there any corresponding training arrangements in place for this purpose.



With regard to counterfeit medical products:

- 13 countries (87%) (Armenia, Belgium, Bosnia and Herzegovina, Burkina Faso, Croatia, France, Ireland, Morocco, Moldova, Portugal, Spain, Switzerland, and Ukraine) are assessed as having specialised units dealing with counterfeit medical products from the product perspective and there is also training being provided.

- Two of these countries (France and Switzerland) reported that there is no dedicated unit or training to be provided, but from the explanations provided in the questionnaire, it is assessed that France and Switzerland do have dedicated organisations/units focusing on counterfeit medical products and have facilities that provide regular training to the authorities combating counterfeit medical products.

- In all of these countries, with the exception of four (Burkina Faso, Morocco, Portugal, and Ukraine) there are also corresponding training arrangements in place for the purpose of cooperation and information exchange for these units/organisations.

- Two (13%) countries (Hungary and Slovenia) are assessed as not having specialised units/organisations dealing with counterfeit medical products, nor are there any training arrangements in place.

With regard to the identification of the primary authority in respect of focusing on the criminal behaviours and counterfeit medical products

- Five countries **(33%)** (Belgium, Bosnia and Herzegovina, Croatia, France, and Spain) are assessed as being the law enforcement authority. This responsibility as the lead authority was assessed as being the health product regulatory authority in one (7%) country (Ireland).

- In respect of focusing on the counterfeit medical product, seven countries **(47%)** (Belgium, Bosnia and Herzegovina, Burkina Faso, Ireland, Morocco, Moldova, and Ukraine) are assessed as being the health products regulatory authority.

- Seven countries **(47%)** (Armenia, Burkina Faso, France, Morocco, Portugal, Switzerland, and Ukraine) are assessed as having multiple authorities involved, with no discernible lead authority, as regards focusing on the criminal behaviours from counterfeit medical products.

- Five countries **(33%)** (Armenia, Croatia, Portugal, Spain, and Switzerland) are assessed as also having multiple authorities involved, with no discernible lead authority, as regards focusing on the counterfeit medical product.

- Three countries **(20%)** (Hungary, Moldova, and Slovenia) are assessed as providing either insufficient or no information on the primary competence of the lead authority as regards the criminal behaviour, while two (13%) countries (Hungary and Slovenia) are assessed as being in the same position as regards the counterfeit medical product.

Conclusions

It appears that just over three-quarters (74%) of the countries responding to the questionnaire have in place dedicated facilities to specifically focus on counterfeit medical product-related crimes (criminal behaviour focused), while a higher level (86%) have in place dedicated facilities to specifically focus on the counterfeit medical products (product focus).

More than half (53%) of countries are assessed as having both dedicated facilities in place to specifically focus on both criminal behaviours and counterfeit medical products, and the corresponding training for cooperation and information exchange. The remaining countries have arrangements in place covering various elements of the issues raised by this question but not all. Four (29%) countries, although having dedicated facilities specifically relating to criminal behaviours and counterfeit medical products, do not have corresponding training arrangements for cooperation and information exchange.

A minority (13%) of countries do not have in place arrangements for dedicated facilities to specifically focus on either the criminal behaviours or the counterfeit medical products and the same countries have no arrangements for training for cooperation and information exchange specifically relating to counterfeit medical products and similar crimes.

6.2. Other arrangements to ensure cooperation and information exchange to take place

QUESTION 12	
If the answer to Question 11 is that there is no training provided as regards cooperation and information exchange, please state, briefly, what other arrangements are in place to ensure that	
a. This type of cooperation and information exchange takes place, and	

b. What training relating to the combating of counterfeit medical products and similar crimes is provided to them	

This question seeks to identify any other arrangement regarding cooperation and information exchange if there is no training provided for the specialised units dealing with counterfeit medical products.

- Six (40%) countries (Burkina Faso, Croatia, Moldova, Portugal, Spain, and Ukraine) provide responses regarding other arrangements regarding cooperation and information exchange if there is no training being provided. Two countries (Spain and Ukraine) already specified (in Question 11) that arrangements already existed and used this question to clarify those responses.

6.3. 24/7 Network for cooperation and information exchange

QUESTION 13	YES	NO
Does the national legislation, strategy, action plan, or other measure provide for a 24 hours a day, 7 days a week network cooperation and information exchange as regards		
a. Combating counterfeit medical products and similar crimes (i.e. concerning crimes and criminal behaviours)		
b. Counterfeit medical products (i.e. concerning the medical product)		

This question seeks to identify if there is in place any national measure to provide for a 24-hour-a-day-7-days-a-week network for cooperation and information exchange for counterfeit medical products from a criminal perspective and from the medical product perspective.

- Five (33%) countries (Armenia, Bosnia and Herzegovina, Ireland, Morocco, Ukraine) replied that they have in place a 24-hours-a-day, 7-days-a-week network cooperation and information exchange system for counterfeit medical products from both the criminal behaviour perspective and medical product perspective. Three of these countries (Bosnia and Herzegovina, Ireland, and Ukraine) provided information on the measures in place to specifically focus on counterfeit medical products and similar crimes. One country (Belgium) reported the existence of a 24/7 communications and information exchange system in place for counterfeit medical products and public health-related issues only, and this does not extend to criminal behaviour-related matters.

- One country (7%) (France) reports that it does not have in place a 24-hours a day-7 days-a-week network [notwithstanding that it is clear from France's response in Q. 11 that it has a network within the Gendarmerie that includes counterfeit medical product-related crime, but not exclusively or specific to this topic. It is unclear whether this network also includes counterfeit medical products with a focus on the product.

- One country (7%) (Switzerland) reported that it has a Specific Point of Contact (SPOC) network for receiving reports of counterfeit medical products and similar crimes and for the exchange of information by the prosecutors concerning prosecutions.

- One country (7%) (Portugal) did not respond to this question.

- The remaining seven countries (46%) (Belgium, Burkina Faso, Croatia, Hungary, Moldova, Slovenia, and Spain) indicated that they do not have a dedicated 24/7 network for cooperation and information exchange as regards both criminal behaviours and the counterfeit medical product.

Conclusion

10 (67%) countries responding to this question report that they do not have a dedicated 24/7 network for cooperation and information exchange as regards both criminal behaviours and the counterfeit medical product.

6.4. Adequacy of resourcing to ensure training for cooperation and information exchange

QUESTION 14

Please answer this question placing an 'X' to the RIGHT on the option below that you consider is the closest to your view on whether adequate resources are provided to ensure that persons, units or services in charge of co-operation and information exchange are trained for this purpose relating to counterfeit medical products and related crimes.

This question seeks to ascertain whether, in the views of the responders, adequate resources are provided to ensure that persons, units or services in charge of co-operation and information exchange are trained for this purpose relating to counterfeit medical products and related crimes.

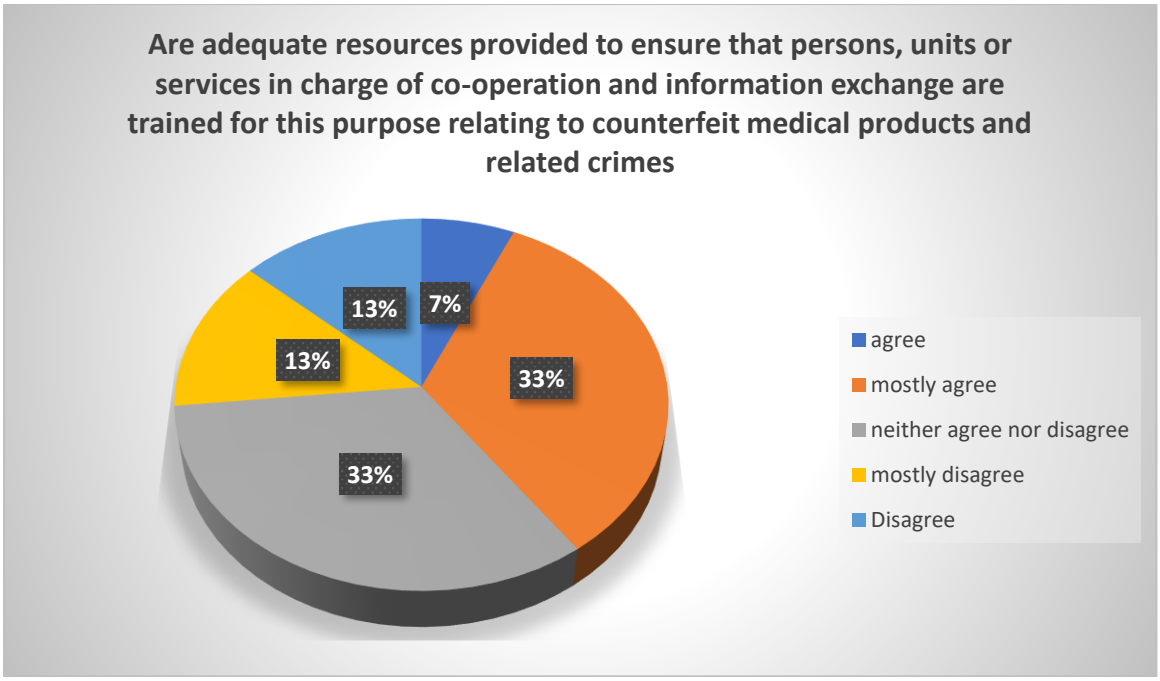
The question posed five areas to consider, selecting only one as the most appropriate for the country. While the responses were provided by the responding authorities, this may not necessarily reflect any official position by the country. However, it is an indication of how this issue is viewed by those who have responsibilities within their countries relating to combating counterfeit medical products and similar crimes.

The five areas are listed below with the number of responses appropriate to each area.

a. Adequate resources provided – 1
b. Mostly adequate resources provided – 5
c. Neither agree nor disagree – 5
d. Mostly disagree that adequate resources provided -2
e. Disagree that adequate resources provided – 2

Conclusions

26% of respondents do not believe that adequate resources are provided to ensure that those in charge of cooperation and information exchange, as regards counterfeit medical products and similar crimes, are trained for the purpose. While this is below the level of those agreeing that there are adequate resources provided for this purpose (40%), it still leaves a gap of 33% of respondents neither agreeing nor disagreeing with the adequacy of this provision


Are adequate resources provided to ensure that persons, units or services in charge of co-operation and information exchange are trained for this purpose relating to counterfeit medical products and related crimes
7%
33%
33%
13%
13%
agree
mostly agree
neither agree nor disagree
mostly disagree
Disagree

VII. INTERNATIONAL CO-OPERATION

This chapter covers questions 15 to 20 of the questionnaire, which included questions on international cooperation. Article 22.2 of the Medicrime Convention was the focus behind these questions:

> **Article 22**
>
> *2. The Parties shall, without prejudice to their internal reporting systems, designate a national contact point which shall be responsible for transmitting and receiving requests for information and/or co-operation in connection with the fight against counterfeiting of medical products and similar crimes involving threats to public health.*

7.1. Nominated contact point for the transmission and receiving of request for information and cooperation

QUESTION 15	YES	NO
Is there a nominated national contact point responsible for transmitting and receiving requests for information and/or cooperation as regards		
a. Combating counterfeit medical products and similar crimes (i.e. concerning crimes and criminal behaviours)		
b. Counterfeit medical products (i.e. concerning the medical product)		
c. Is the contact point for a and b the same contact point		

Question 15 seeks to identify the relevant nominated national contact points responsible for activities between countries. Having regard to the different responsibilities of the key national authorities, this question also seeks to identify which of these authorities has lead responsibility.

- 13 countries (87%) out of the 15 countries responding to the questionnaire (Armenia, Belgium, Bosnia and Herzegovina, Burkina Faso, Croatia, France, Hungary, Ireland, Moldova, Morocco, Spain, Switzerland and Ukraine) report as having designated national contact points in place for international cooperation and information sharing on counterfeit medical product-related crimes and on counterfeit medical products.

- Nine out of these above 13 countries (Armenia, Belgium, Burkina Faso, France, Hungary, Moldova, Morocco, Switzerland, and Ukraine) have the same point of contact in place for international cooperation and information sharing on counterfeit medical product-related crimes and on counterfeit medical products. The remaining four countries (Bosnia and Herzegovina, Croatia, Ireland, and Spain) have different single points of contact for counterfeit medical product-related crime and for counterfeit medical products.

- While the specification of how countries arrange their international cooperation may appear complex due to the number of relevant national authorities with different remits across different international networks involving aspects of a) and/or b) above, these countries have discernible designated national contact points within law enforcement, customs, ministries, or the health product regulatory authority for this purpose.

- Two countries (20%) (Portugal, and Slovenia) specified that they have no designated contact points.

Conclusions:

The majority of countries (87%) have in place a designated national contact point responsible for transmitting and receiving requests for information and/or cooperation as regards criminal behaviours and associated counterfeit medical products between countries. Of these countries, 60% have the same point of contact.

This indicates a high level of recognition of the need to coordinate communications and information exchange in an orderly manner with counterparts in other countries.

7.2. Arrangements where the contact points are different for criminal behaviours and counterfeit medical products

QUESTION 16	
If the response to Questions 15 a and b is that the contact points are different contact points according to their purpose, please specify, briefly,	
a. Why arrangements do not facilitate having one agreed national contact point that is responsible for all matters of transmitting and receiving requests for information and/or cooperation with other international contact points	
b. What arrangements are in place to coordinate this work to avoid duplication or gaps in transmitting and receiving requests for information and/or cooperation	

Question 16 is a supplemental question to question 15 for items a) and b) and seeks to understand why the arrangements in place are different for 15. a) and b) and how this works to avoid duplications and gaps arising in the transmitting and receiving of information and/or cooperation with other international contact points.

- Three countries (Croatia, Ireland and Spain) responded in Question 15 that they had the same contact point for a. and b. and also indicated separate contact points according to the responsibilities of the authorities. Two of these countries (Croatia and Spain) did not elaborate on how the transmission of requests and the receipt of information and cooperation was coordinated where the contact points were in different authorities. One country (Ireland) did elaborate on this point highlighting that the health product regulatory authority coordinated information relating to counterfeit medical products, while the contact points in the law enforcement, customs, and the health product regulatory authority were each responsible for the transmission and receipt of request for information according to their remit for investigations. One country (Bosnia and Herzegovina) indicated in Question 15 that there was no network for the exchange of information exclusively relating to the MEDICRIME framework.

- Two countries (Portugal and Slovenia) did not provide information on this question

Conclusions

When taking the responses from Questions 15 and 16 together, it can be concluded that all, but two countries have some element(s) of a national contact point which is responsible for transmitting and receiving requests for information and/or co-operation in connection with combating counterfeiting of medical products and similar crimes involving threats to public health as regards the criminal behaviours involved and/or the counterfeit medical products.

Any apparent differences in approach to the designated contact point by countries as to which authorities have competence in international cooperation and exchange of information result from internal legislative and other arrangements based on the remit of the authority (law enforcement, border control, or health product regulation) whether it is on the criminal behaviour associated with counterfeit medical products, or on the physical counterfeit medical product.

An agreed national contact point for both counterfeit medical products and the criminal behaviours associated with counterfeit medical products is considered a vital aspect of international cooperation between countries. If countries do not have contact points in place, it may leave them open to increased risks of cooperation and information exchange failures due to internal systems not being sufficiently robust to avoid gaps arising.

7.3. Measures for training of the National contact points

QUESTION 17	YES	NO
Are there measures taken to provide training to the national contact point responsible for transmitting and receiving requests for information, and/or cooperation as regards		
a. Combating counterfeit medical products and similar crimes (i.e. concerning crimes and criminal behaviours)		
b. Counterfeit medical products (i.e. concerning the medical product)		

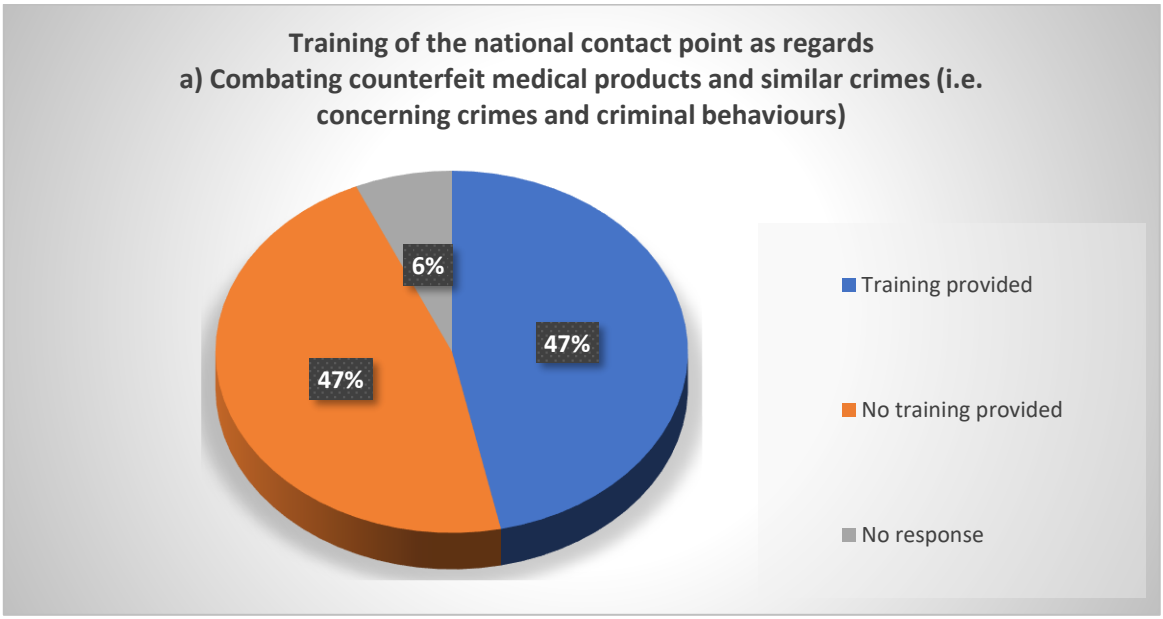
This question seeks to identify existing measures taken to provide this type of training for the national contact points specific to combating counterfeit medical products and similar crimes (i.e., concerning crimes and criminal behaviours) and counterfeit medical products (i.e., concerning the medical product).

In relation to combating counterfeit medical products and similar crimes (i.e., concerning crimes and criminal behaviours):

- Seven (47%) countries (Armenia, Belgium, Bosnia and Herzegovina, Ireland, Hungary, Spain, and Ukraine) report that they have measures to provide training to the national contact point responsible for transmitting and receiving requests for information, and/or cooperation as regards combating counterfeit medical products and similar crimes concerning crimes and criminal behaviours.

- Seven (47%) countries (Burkina Faso, Croatia, France, Moldova, Portugal, Slovenia, Switzerland) replied that they do not have training systems in place relating to criminal behaviours

- No response on this issue was made by one country (6%) (Morocco).



In relation to counterfeit medical products (i.e., concerning the medical product):

- Seven (47%) countries (Armenia, Belgium, Bosnia and Herzegovina, Croatia, Ireland, Slovenia and Ukraine) are assessed as having measures to provide training to the national contact points responsible for transmitting and receiving requests for information, and/or cooperation as regards counterfeit medical products (i.e., concerning the medical product).

- Two countries (13%) (Hungary and Switzerland) also reported that they rely on participation at specified international groups that focus on combating counterfeit medical products and similar crimes to obtain this type of training and by this measure, they may consider that this provision is adequate for the purpose.

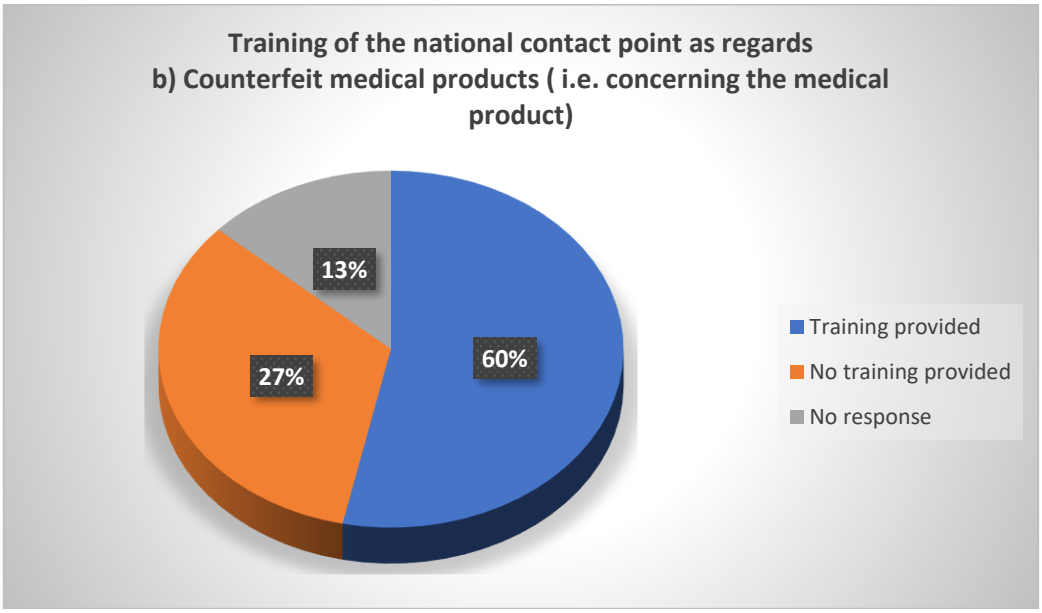
- Four countries (27%) (Burkina Faso, France, Portugal, and Spain) report that they do not have training systems in place relating to the counterfeit medical product.

- No response on this issue was made by two (13%) countries (Moldova and Morocco).

Conclusions:

Nine countries (60%) indicated that they provide training for international contact points, either internally or externally though attendance at international events. The remaining six (40%) do not appear to provide any training.

Cross-training and continuous training of designated contact points for international cooperation and exchange of information would facilitate a greater understanding by the contact points of both the counterfeit medical product crime-related matters and the counterfeit medical products. This could enable effective and efficient national contact points for international cooperation and information exchange regarding counterfeit medical products and similar crimes.



7.4. Other 24/7 networks used to transmit and receive information and cooperation requests relating to counterfeit medical products and related crimes

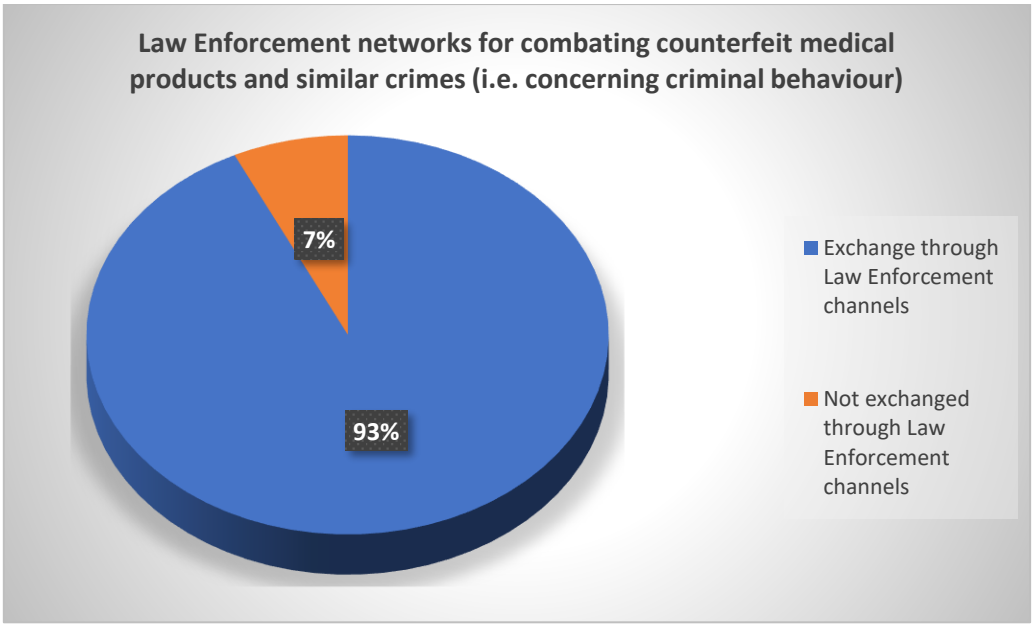
QUESTION 18
Please list below any other 24/7 networks that your authority/service/office, or similar organization, participates in transmitting and receiving of requests for information and/or cooperation as regards a. Combating counterfeit medical products and similar crimes (i.e. concerning crimes and criminal behaviours) b. Counterfeit medical products (i.e. concerning the medical product) Each listed 24/7 network, by authority/service/similar organisation, should specify the purpose as mentioned in a, or b, or both above (Please insert your response in place of the example below)

This question seeks to ascertain what, if any 24/7 networks are used by countries to transmit and receive requests regarding the criminal activity involved with counterfeit medical products and any that focus only on the medical product. It seeks to identify whether some authorities are engaged in these activities with dedicated 24/7 networks in isolation from other authorities who may also have a responsibility concerning falsified medical products and similar crime.

These issues include the parameters of the national structure, the selection process of national focal points and the operational role of focal points, national measures for the exchange of information, including evidence, between competent authorities regarding networking among law enforcement authorities, judicial authorities, customs authorities and the health product regulatory authority when it comes combating counterfeit medical products and similar crimes (i.e., concerning crimes and criminal behaviours) and counterfeit medical products (i.e. concerning the medical).

- In relation to the 24/7 networks that the authorities participate in transmitting and receiving requests for information and/or cooperation as regards a) and b), i.e., combating counterfeit medical products and similar crimes (concerning criminal behaviour) and counterfeit medical products (concerning the medical product), 14 countries (93%) (Armenia, Belgium, Bosnia and Herzegovina, Burkina Faso, Croatia, France, Hungary, Ireland, Morocco, Moldova, Portugal, Slovenia, Spain, and Switzerland) are assessed as having a network system in place in order to exchange of information and cooperation.

- These countries indicated that the operational information exchange relating to the trafficking of counterfeit medical products and similar crimes are exchanged through the law enforcement channels i.e. secure channel, such as the INTERPOL NCB 24/7, and/or EUROPOL networks.



- With regard to the exchange of information relating to counterfeit/falsified medical products and other illicit medical products, (i.e. focusing on the medical product rather than on the criminal behaviour), all countries reported that these exchanges are conducted by the health products regulatory authorities.

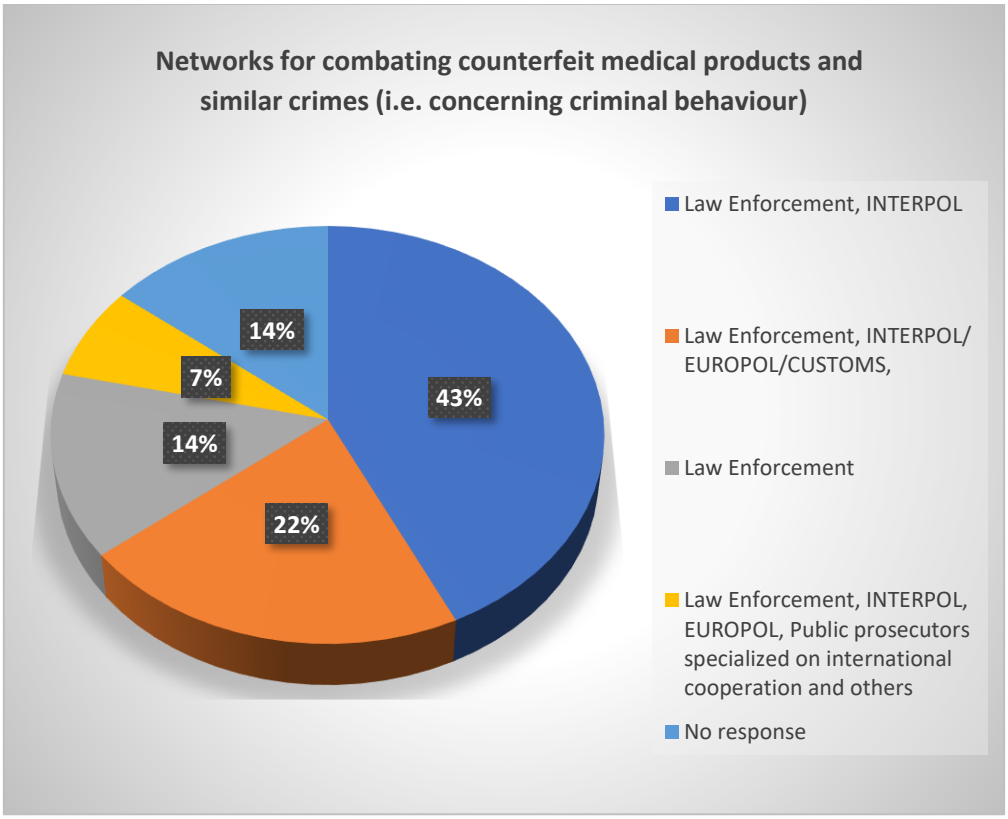
- In addition, seven (47%) countries (Bosnia-Herzegovina, France, Hungary, Ireland, Portugal, Spain, and Switzerland,) reported using several specialised networks in addition to the INTERPOL NCB 24/7 and the EUROPOL networks. These networks include the World Health Organization's (WHO) network on substandard and falsified medical products network, Global Surveillance and Monitoring System (GMSM), the World Customs Organization's (WCO) communications network, CENcomm, The EU Heads of Medicines Agencies Working Group of Enforcement Officers (HMA WGEO) network, the Permanent Forum on International Pharmaceutical Crime (PFIPC) network.

- Two countries (13%) (Moldova and Ukraine) report using only one network.

- Ukraine uses the "State Enterprise Government Contact Center for Citizens".

- Moldova reports using only the WHO network.

- While international cooperation in criminal matters under Article 21 of the MEDICRIME Convention is out of the scope of this survey, some countries also included a reference to using such specialised networks for prosecutors in international cooperation on criminal matters.



Conclusions

The results from Question 18 suggest that the majority of countries (93%) use a selection of domestic arrangements for selecting national contact points. These arrangements include consideration of the responsibilities and the operational role of the authorities of those contact points (law enforcement services, customs administrations, and health products regulatory authorities), and the subject matter of the exchange, whether crime-related or counterfeit medical product related.

Despite the existence of several international cooperation networks, the cooperation between all the authorities involved in international cooperation and information exchange are sometimes based on complex, if not fragmented, and not fully coordinated systems. The cooperation networks used are primarily operational and do not make provision for prosecutor network involvement to specifically deal with matters concerning counterfeit medical products and similar crimes.

7.5. Recording of requests for information or data exchange

QUESTION 19	YES	NO
If the data is unavailable for inclusion in the response to this questionnaire due to		
a. Not recorded in a retrievable manner relating to counterfeit medical products and similar crimes (relating to crimes and criminal behaviours)		
b. Not recorded		

This question seeks to identify the existence of a database, whether it be held by one of the relevant authorities or a notational database, and whether it specifically records requests for information or data exchange, including those emanating from the policing services, the customs service, the national health products regulatory authority, and others, as regards the combating of medical products and similar crimes. It also seeks to ascertain whether the requests are recorded in a retrievable manner specific to counterfeit medical products and similar crimes or not recorded at all.

- With regard to the number of requests for information or data exchange, including those emanating from the policing services, the customs service, the national health products regulatory authority, and others, as regards the combating of medical products and similar crimes, six (40%) of the 15 countries (Bosnia and Herzegovina, Burkina Faso, Hungary, Moldova, Spain, Ukraine) report as recoding such data and in a retrievable manner.

- Three (20%) countries (Croatia, Ireland, and Switzerland) report not having such data in a retrievable manner.

- Six (40%) countries (Armenia, Belgium, France, Morocco (no response), Portugal, and Slovenia) report as not recording any data

Conclusions:
The reports from Question 19 indicates 40% of countries responding to the questionnaire have databases which are capable of producing retrievable statistical data specific to requests made or received relating to counterfeit medical products and similar crimes. A further 20% of countries indicate that whilst they record such statistical data, it is done so in a retrievable manner.

The remaining countries (40%) do not appear to record statistical data specific to requests made or received relating to counterfeit medical products and similar crimes.

7.6. Types of requests to be exchanged

QUESTION 20	YES	NO
Please identify what are the types of requests to be exchanged over a 24/7 network between countries:		
a. Rapid access to evidence in criminal proceedings		
b. Preservation of evidence in another jurisdiction		
c. Exchange of investigative information		

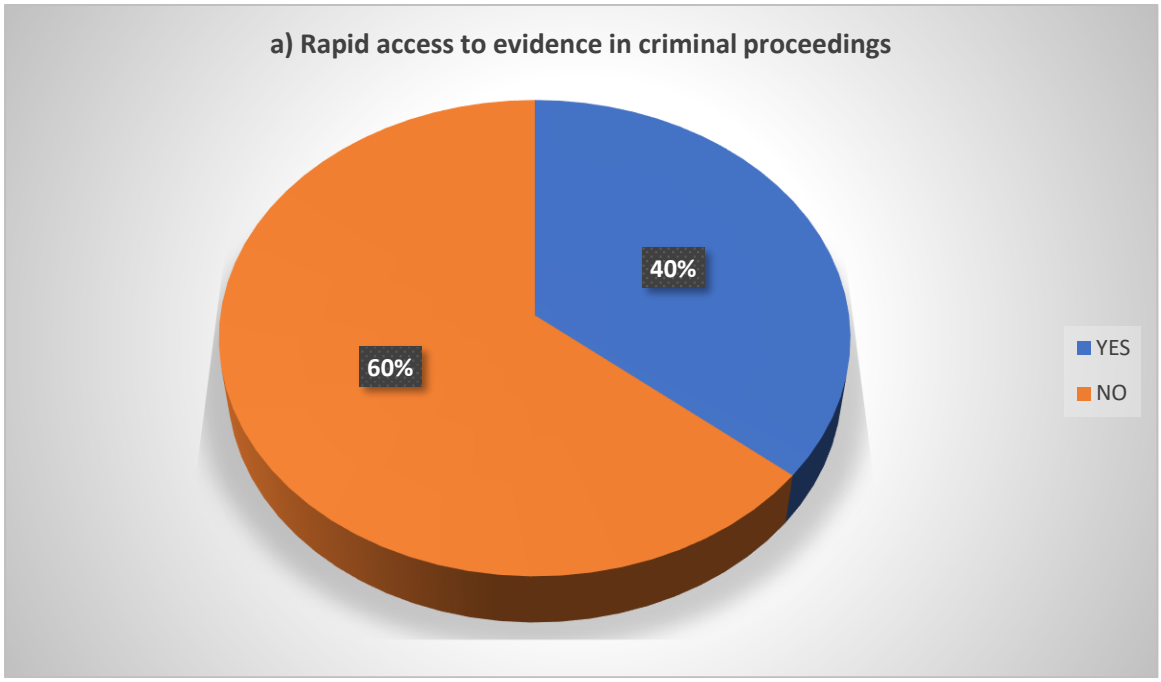
d. Information about counterfeit medical products		
e. Technical advice		
f. Other (please briefly describe)		

This question seeks to ascertain the types of requests to be exchanged over a 24/7 network between countries.

- Three countries (20%) (Burkina Faso, Ireland, and Spain) reported that they can and do make and receive requests for the exchange of information over a 24/7 network between countries concerning all categories listed from categories a. to e., above.

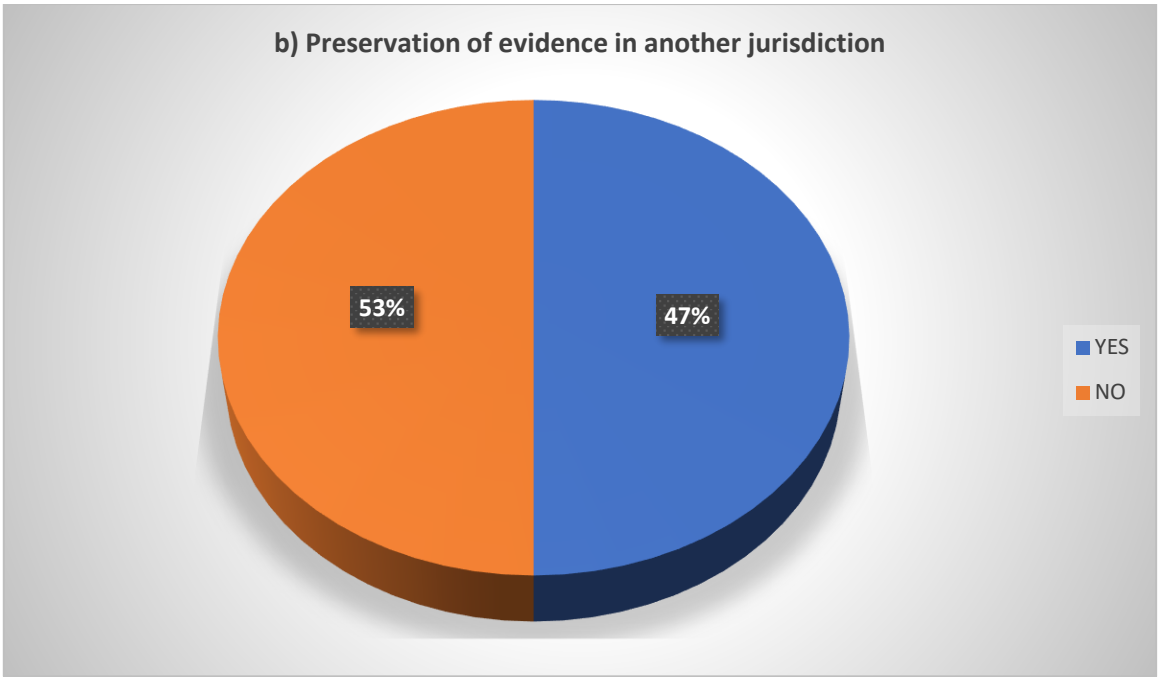
a. Rapid access to evidence in criminal proceedings

- Nine (60%) countries (Armenia, Belgium, Burkina Faso, Croatia, Ireland, Slovenia, Spain, Switzerland and Ukraine) report that they make and receive requests for the exchange of information concerning the category a) (*Rapid access to evidence in criminal proceedings*). Six (40%) countries (Bosnia and Herzegovina, France, Hungary, Moldova, Morocco and Portugal) report that they do not make or receive such exchanges for information.



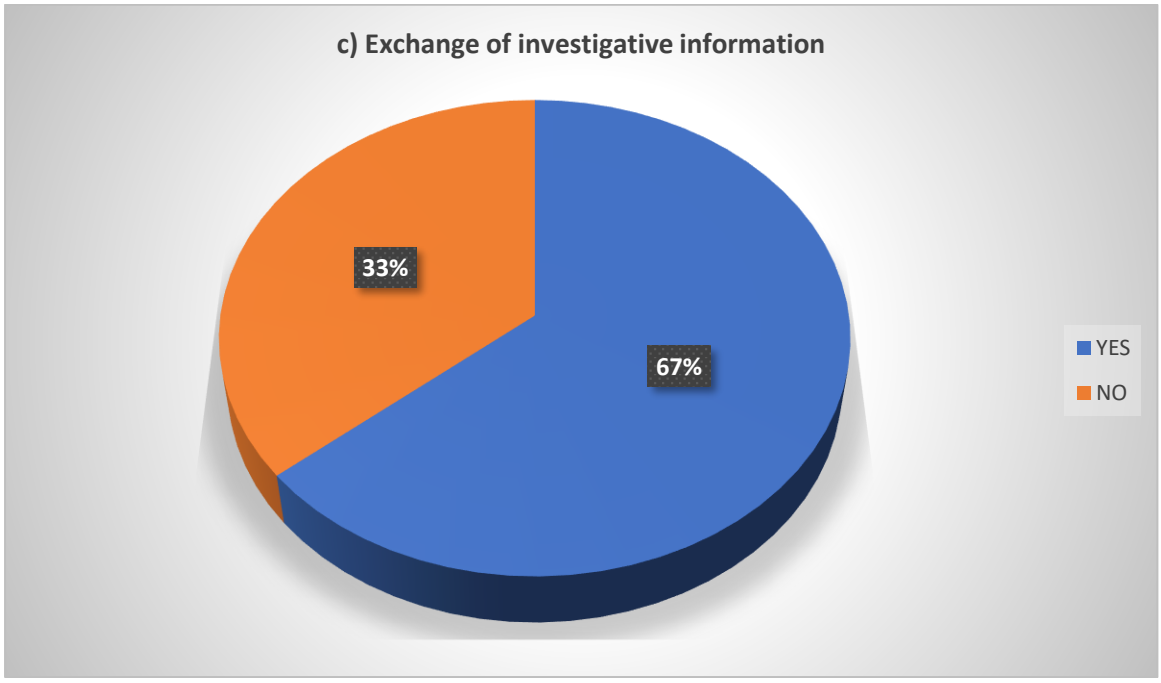
b. Preservation of evidence in another jurisdiction

- Seven (47%) countries (Belgium, Burkina Faso, Croatia, Ireland, Spain, Switzerland, and Ukraine) report that they make and receive requests for the exchange of information concerning category b) (*Preservation of evidence in another jurisdiction*). Eight countries (53%) (Armenia, Bosnia and Herzegovina, France, Hungary, Moldova, Morocco, Portugal, and Slovenia) report that they do not make or receive exchanges of such information.



c. Exchange of investigative information

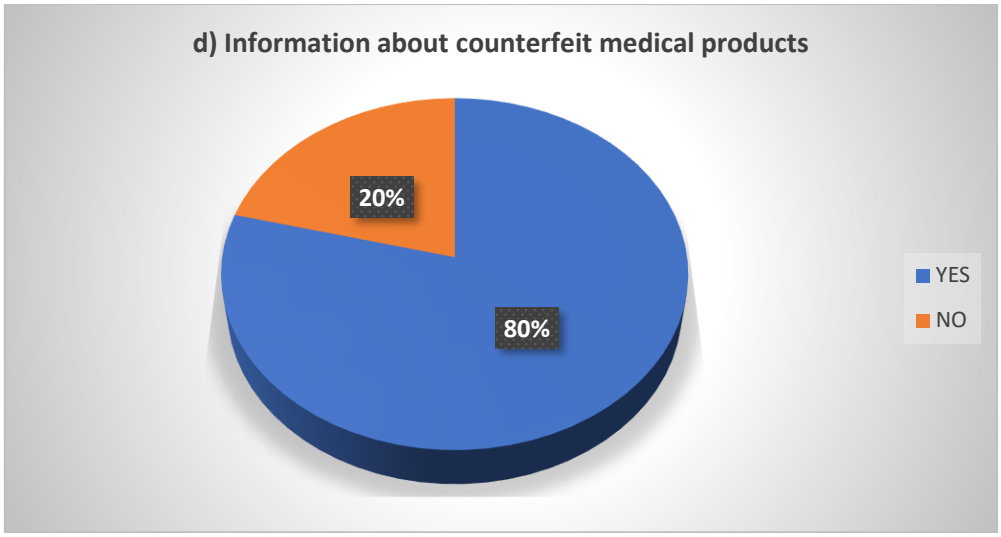
- 10 (67%) countries (Armenia, Belgium, Bosnia and Herzegovina, Burkina Faso, Croatia, France, Ireland, Morocco, Slovenia, and Spain) report that they make and receive requests for the exchange of information concerning category c) (*Exchange of investigative information*). Five (33%) countries (Hungary, Moldova, Portugal, Switzerland, and Ukraine) report that they do not make and receive requests for the exchange of such information.



d. Information about counterfeit medical products

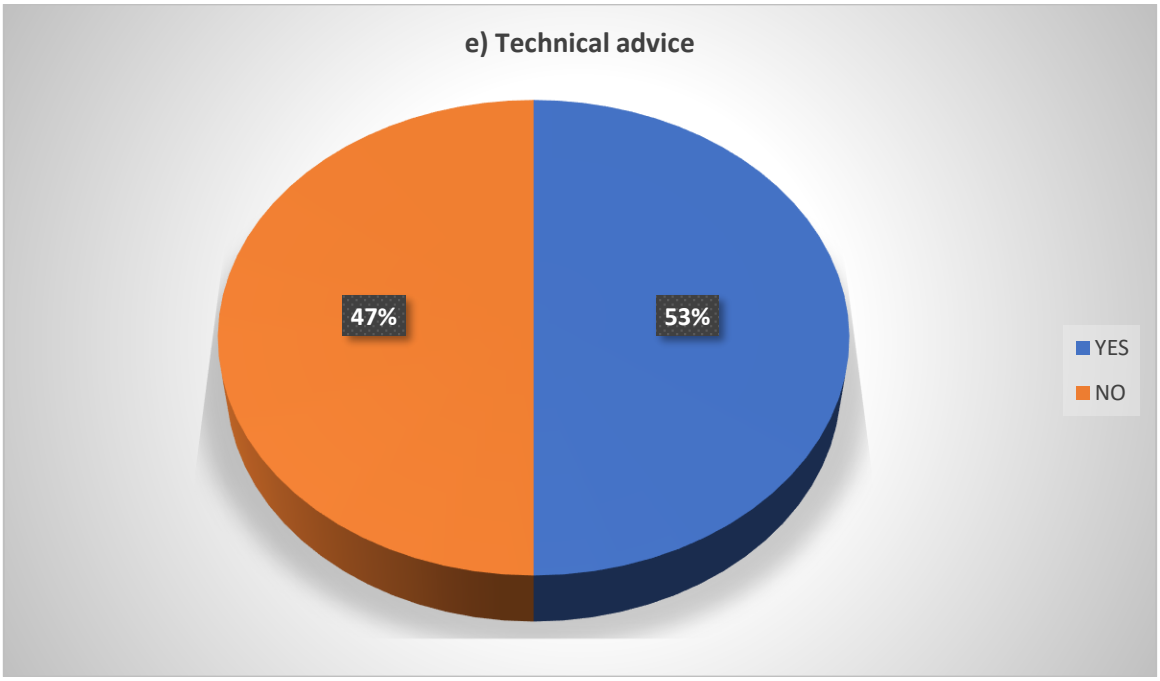
- 12 (80%) countries (Armenia, Bosnia and Herzegovina, Burkina Faso, Croatia, France, Ireland, Hungary, Moldova, Morocco, Slovenia, Spain, and Ukraine) report that they make and receive requests for the exchange of information concerning the

category d) (*information about counterfeit medical products*). Three (Belgium, Portugal, and Switzerland) report that they do not make and receive requests for the exchange of such information.



e. Technical advice

- Eight (53%) countries (Bosnia and Herzegovina, Burkina Faso, France, Hungary, Morocco, Ireland, Spain and Ukraine) report that they make and receive requests for the exchange information concerning category e) (*Technical advice*). Seven (47%) countries (Armenia, Belgium, Croatia, Moldova, Portugal, Slovenia and Switzerland) report that they do not make and receive requests for the exchange of such information.



Conclusions

All countries appear to engage in the making and receiving of requests for information based on the categories listed regarding counterfeit medical products and similar crimes.
The weakest categories for such activities appear to be the preservation of evidence in another jurisdiction (47%) and technical advice (47%).

Significantly, the greatest engagement is in the making and receiving of requests for information on counterfeit medical products (80%). This suggests that the health products regulatory authority may be the most active authority in the field of making and receiving requests for information on counterfeit medical products.

The making and receiving of requests for investigative information and for rapid access to evidence in criminal proceedings occur in two-thirds of countries (67%)

The information from Question 20 suggests that there is still a deficit in the making of requests for information, in particular relating to the preservation of evidence in another jurisdiction and for technical advice. It could be concluded from this that, there are still many authorities that do not consider this aspect as a priority.

There are continuing challenges to effective coordination mechanisms, and to the need for information sharing and data collection involving authorities in other countries.

A lack of awareness of the different stakeholders that may hold relevant information may hinder cooperation between them which can limit or prevent effective multi-stakeholder responses to combat against this risk to public health.

VIII. CONCLUSIONS AND RECOMMENDATIONS

8.1. Conclusions

a) National Cooperation

As to the adoption of a national strategy and/or a national action plan on cooperation and exchange of information between authorities/services in relation to the combating of counterfeiting of medical products and similar crimes

- A national strategy or action plan is not evident in over half (60%) of countries who report that they engage in cooperation and exchange of information between authorities/services in relation to the combating of counterfeiting of medical products and similar crimes.

- This may risk cooperation and information exchange faltering due to changes in the authorities, including change or absence from appointment in personnel involved in this function. This risks leading to a failure of cooperation and information exchange between authorities involved in combating counterfeit medical products and similar crimes.

- All but one country of those responding to the questionnaire report that there is some measure existing or planned to make specific provisions for cooperation and information exchange between the relevant State authorities involved in combating medical products and similar crimes.

As to structured bodies, committees, and systems in place for the collection and transmission of information and data specific to a) criminal behaviours associated with combating counterfeit medical products and similar crimes; b) counterfeit medical products, i.e. focusing on the actual product; c) general measures that include counterfeit medical products but not specifically established to focus on counterfeit medical products and similar crimes

- Over 90% of countries responding to the questionnaire have some measures, in place for the collection and transmission of information whether specific to the counterfeit medical product-related criminal behaviours and counterfeit medical products, or more generally that include both the criminal behaviours and the counterfeit medical product.

- - 11 countries responding to the questionnaire have legislative provisions, or other structured measures supporting the establishment and operation of bodies, committees, or systems for the collection and transmission of information and data specifically relating to the combating of counterfeit medical products and similar crimes (criminal behaviour), and/or the counterfeit medical product. All those 11 countries include law enforcement services, customs services, and the health product authority in their points of contact for these purposes.

- All but one country out of 14 countries (93%) responding to the questionnaire report that there are some measures making provisions, whether formal or informal, for the collection and transmission of information and data that are specific to or more generally including combating medical products and similar crimes involving criminal behaviour.

As to structured databases to collect information as regards a) Combating counterfeit medical products and similar crimes (i.e., concerning the crimes and criminal behaviours); b) Counterfeit medical products (I.e., concerning the product)

- Over half (57%) of those responding have structured databases to collect information regarding criminal behaviours and counterfeit medical products.

- Just over one-third (38%) of countries responding to this questionnaire did not have databases regarding counterfeit medical product-related crime and counterfeit medical products.

- Almost one-third (29%) do not have any structured databases to collect information on the combating of counterfeit medical product-related crime or counterfeit medical products.

- The indications from the results suggest that just below two-thirds (64%) of the responding countries have some arrangements for receiving and transmitting information and data, in collaboration with civil society and the private sector, and also sharing between the authorities the information collected by them, while just over half of the countries have arrangements for the recording on structured databases information and data (57%).

- It may be concluded that some of the information and data while being shared among the authorities, is not being recorded in a structured database such that it may be capable of analysis.

As to the existence of draft legislation, strategies, plans or other measures contemplated or in the process of development to provide for: a) Receiving and collecting information and data, including through contact points, at national or local levels and in collaboration with the private sector and civil society, for the purposes of preventing and combating counterfeit medical products and similar crimes involving threats to public health; b) Making available the information and data obtained by the health authorities, customs, police, and other competent authorities for the cooperation between them

- All but two out of 15 countries responding to the questionnaire report that there are some measures making provisions, whether formal or informal, for the collection and transmission of information and data that are specific to or more generally including combating medical products and similar crimes involving criminal behaviour.

b) <u>Training and resourcing</u>

As to the existence of specialised units, offices, groups, designated appointments, or similar, with the specific responsibility for: a) combating counterfeit medical products and similar crimes (i.e., concerning crimes and criminal behaviours); b) counterfeit medical products (i.e., concerning the product).

- It appears that just over three-quarters (78%) of the countries responding to the questionnaire have in place dedicated facilities to specifically focus on counterfeit medical product-related crimes (criminal behaviour focused), while a higher level (86%) has in place dedicated facilities to specifically focus on the counterfeit medical products (product focus).

- Only half (50%) of countries are assessed as having dedicated facilities in place to specifically focus on both criminal behaviours and counterfeit medical products, and the corresponding training for cooperation and information exchange. The other half have arrangements in place covering various elements of the issues raised by this question but not all. This other half includes four (29%) countries, although having dedicated facilities specifically relating to criminal behaviours and counterfeit medical products, do not have corresponding training arrangements for cooperation and information exchange.

- A minority (14%) of countries do not have in place arrangements for dedicated facilities to specifically focus on either the criminal behaviours or the counterfeit medical products and the same countries have no arrangements for training for cooperation and information exchange specifically relating to counterfeit medical products and similar crimes.

As to National measures, including legislation, strategy, action plan, or other measures providing for a 24/7 network for cooperation and information exchange as regards a) combating counterfeit medical products and similar crimes (i.e., concerning crimes and criminal behaviours); and b) counterfeit medical products (i.e., concerning the medical product)

- Nine (64%) of countries responding to this question report that they do not have a dedicated 24/7 network for cooperation and information exchange as regards both criminal behaviours and the counterfeit medical product. This questions whether existing measures enable rapid cooperation and information exchange requests can be made involving counterfeit medical products-related crime and counterfeit medical products.

As to the adequacy of resources provided for this area of work

- 30% of respondents do not believe that adequate resources are provided to ensure that those in charge of cooperation and information exchange, as regards counterfeit medical products and similar crimes, are trained for this purpose. While this is below the level of those agreeing that there are adequate resources provided for this purpose (47%), it still leaves a gap of 23% of respondents neither agreeing nor disagreeing with the adequacy of this provision.

c) <u>International Co-operation</u>

As to nominated national contact points responsible for transmitting and receiving requests for information and/or cooperation as regards a) Combating counterfeit medical products and similar crimes (i.e., concerning crimes and criminal behaviours); b) Counterfeit medical products (i.e., concerning the medical product)

- The majority of countries (79%) have in place a designated national contact point responsible for transmitting and receiving requests for information and/or cooperation with other countries as regards criminal behaviours and associated counterfeit medical products between countries. This indicates a high level of recognition of the need to coordinate communications and information exchange in an orderly manner with counterparts in other countries.

- Among those countries, half (50% of all countries) have the same designated point of contact for both counterfeit medical product-related crime and the counterfeit medical product. This means that almost one-third (29% of all countries) have a single point of contact for counterfeit medical product-related crime and a separate one for counterfeit medical products. The point of contact in each area is an agreed designated one for that purpose.

- The apparent differences in approach to the designated contact point by countries as to which authorities have competence in international cooperation and exchange of information result from internal legislative and other arrangements based on the remit of the authority (law enforcement, border control, or health product regulation) whether it is on the criminal behaviour associated with counterfeit medical products, or on the physical counterfeit medical product.

- The absence of an agreed national contact point for both criminal behaviours associated with, and counterfeit medical products may leave countries open to increased risks of cooperation and information exchange failures due to internal systems not being sufficiently robust to avoid gaps arising.

As to measures taken to provide training to the national contact point responsible for transmitting and receiving requests for information, and/or cooperation as regards a) Combating counterfeit medical products and similar crimes (i.e. concerning crimes and criminal behaviours); b) Counterfeit medical products (i.e. concerning the medical product).

- Nine countries (60%) indicated that they provide training for international contact points, either internally or externally though attendance at international events. The remaining six (40%) do not appear to provide any training.

- Cross-training and continuous training of designated contact points for international cooperation and exchange of information would facilitate a greater understanding by the contact points of both the counterfeit medical product crime-related matters and the counterfeit medical products. This could enable effective and efficient national contact points for international cooperation information exchange regarding counterfeit medical products and similar crimes.

As to other 24/7 networks that the national authority/service/office, or similar organization, participates in transmitting and receiving of requests for information and/or cooperation as regards a) Combating counterfeit medical products and similar crimes (i.e. concerning crimes and criminal behaviours); b) Counterfeit medical products (i.e. concerning the medical product).

- The majority (93%) of countries use a selection of domestic arrangements for selecting national contact points. These arrangements include consideration of the responsibilities and the operational role of the authorities of those contact points (law enforcement services, customs administrations, and health products regulatory authorities), and the subject matter of the exchange, whether crime-related or counterfeit medical product-related.

- Despite the existence of several international cooperation networks, the cooperation between all of the authorities involved in international cooperation and information exchange is sometimes based on complex, if not fragmented, and not fully coordinated systems. The cooperation networks used are primarily for operational use and do not make provision for prosecutor network involvement to specifically deal with matters concerning counterfeit medical products and similar crimes.

As to the number of requests for information or data exchange, including those emanating from the policing services, the customs service, the national health products regulatory authority, and others, as regards the combating of medical products and similar crimes.

- Almost one half of countries responding to the questionnaire have databases that are capable of producing retrievable statistical data specific to requests made or received relating to counterfeit medical products and similar crimes. However, this rises to over one-half (57%) of countries that record such statistical data, albeit 21% of the countries do not do so in a retrievable manner.

- A significant number of countries (35%) do not appear to record statistical data specific to requests made or received relating to counterfeit medical products and similar crimes.

As to the types of requests to be exchanged over a 24/7 network between countries

Types of request considered:

a. Rapid access to evidence in criminal proceedings
b. Preservation of evidence in another jurisdiction
c. Exchange of investigative information
d. Information about counterfeit medical products
e. Technical advice
f. Other

- All countries appear to engage in the making and receiving of requests for information based on the categories listed regarding counterfeit medical products and similar crimes.

- The weakest categories for such activities appear to be the preservation of evidence in another jurisdiction (50%) and technical advice (50%).

- Significantly, the greatest engagement is in the making and receiving of requests for information on counterfeit medical products (79%). This suggests that the health products regulatory authority may be the most active authority in the field of making and receiving requests for information on counterfeit medical products.

- The making and receiving of requests for investigative information and for rapid access to evidence in criminal proceedings occur in two-thirds of countries (64%)

- There appears to be a deficit in the making of requests for information, in particular relating to the preservation of evidence in another jurisdiction. It could be concluded from this that:

- There are still many authorities that do not consider this aspect as a priority.

- There are continuing challenges to effective coordination mechanisms, and to the need for information sharing and data collection involving authorities in other countries.

- A lack of awareness of the different stakeholders that potentially hold relevant information may hinder cooperation between them which can limit or prevent effective multi-stakeholder responses to combat against this risk to public health.

8.2. Recommendations

This report, following from its conclusions, recommends that:

The CoP should consider:

- Exploring solutions to support countries, in particular the Parties to the MEDICREIME Convention, to simplify current 24/7 network arrangements to reduce risks arising from often-complex systems operating between authorities when cooperating and exchanging information between them concerning counterfeit medical product-related criminal behaviour and counterfeit medical products. This is equally applicable to both national and international requests and exchanges;

- The need to have greater cohesiveness in information exchange systems to ensure that both the counterfeit medical products and the criminal behaviours associated with them are capable of being exchanged in a holistic system. The exchange of information should not have to rely on having to be delivered by separate systems and from different contact points in separate authorities;

- The need for a dedicated 24/7 network for the MEDICRIME Convention to overcome the challenges observed by this survey report should be further considered. Such consideration should view a dedicated 24/7 network in a holistic manner to be open to law enforcement, customs and health product regulators and to the judicial system and using the Convention as a legal instrument to achieve this (Arts. 10, 17, and 22)

CoE makes recommendations for countries concerning:

- The dedication of existing resources to specifically include counterfeit medical product-related crimes rather than including them as general crimes. This would avoid their misclassification as general criminal laws and economic crimes.

- Encouraging the Parties and signatory States to the Convention to actively participate in harmonising how medical product-related crime can be supported in a 24/7 network that recognises the specific crimes involved.

CoE decides:

- Whether it should provide guidance to States on the recording, retrieval, analysis and exchange of information and data concerning counterfeit medical products and their related crimes. This, among other objectives, would support cooperation and information exchange relating to this type of crime.

- Alternatively, it could facilitate cooperation and information exchange by States by developing a compatible database to coordinate these activities harmonized in accordance with the Convention.

- This would provide for authorised authorities and points of contact to directly interact with such a system in a manner that would automatically capture and analyse the data concerned as well as provide a secure mechanism for the exchanges.

CoE be open to considering:

- Establishing a MEDICRIME-specific 24/7 network separate from all other existing networks or running it in tandem with other similar networks utilising their capacities and experiences and leaving it to States to decide how to do this domestically according to their resources;

- Providing guidance to States that when developing structured mechanisms for cooperation and information exchange, including the designation of contact points, the connection be made with issues regarding the collection, analysis, and retrieval of information specific to counterfeit medical product-related crime.

IX. Annex I - State of play of replies to the Questionnaire

T-MEDICRIME (2023) SoP 24/7
Updated: 18/09/2023

THE QUESTIONNAIRE 24/7 NETWORK
Recipient countries and received replies

	COUNTRY	Questionnaire sent 27 April 2023	Questionnaire resent 15 May 2023	Questionnaire sent 26 May 2023	Answer received
1	ALBANIA	√	√		
2	ARMENIA	√	√		14 June 2023
3	AUSTRIA	√	√		
4	BELGIUM	√	√		8 June 2023
5	BENIN	√	√		
6	BOSNIA AND HERZEGOVINA	√	√		9 June 2023
7	BURKINA FASO	√	√		8 June 2023
8	COTE D'IVOIRE	√	√		
9	CROATIA	√	√		15 June 2023
10	CYPRUS	√	√		
11	DENMARK	√	√		
12	FINLAND	√	√		
13	FRANCE	√	√		5 September 2023
14	HUNGARY	√	√		6 July 2023
15	GERMANY	√	√		
16	ICELAND	√	√		
17	IRELAND			√	31 May 2023
18	ISRAEL	√	√		
19	ITALY	√	√		
20	LICHTENSTEIN	√	√		
21	LUXEMBURG	√	√		
22	KINGDOM OF MOROCCO	√	√		8 June 2023
23	NIGER	√	√		
24	PORTUGAL	√	√		2 May 2023
25	REPUBLIC OF MOLDOVA	√	√		10 May 2023
26	SERBIA	√	√		
27	SLOVENIA	√	√		17 July 2023
28	SPAIN	√	√		9 June 2023
29	SWITZERLAND	√	√		8 June 2023
30	TURKEY	√	√		
31	UKRAINE	√	√		9 June 2023

X. Annex II - QUESTIONNAIRE ON A 24/7 NETWORK

COUNCIL OF EUROPE

CONSEIL DE L'EUROPE

QUESTIONNAIRE ON A 24/7 NETWORK

19/04/2023

Replies should be addressed to the MEDICRIME Committee Secretariat

medicrime@coe.int

by (09/06/2023)

NAME OF COUNTRY	
Name of person making submission	
Position	
e-mail	
Mobile phone number	

1. Introduction

In the framework of the Project entitled "Countering falsified medical products - Global programme" (CRIMFAMED), the Council of Europe is conducting this **Survey** to assess the current state of 24/7 capabilities of national authorities involved in domestic criminal and other laws support the prohibition and enforcement against counterfeit/falsified medical products as criminal offences for the purpose of protecting public health.

This survey will bring light to the legislative procedures and national measures on collaboration between actors (such as justice, health, law enforcement and customs authorities). It will also assess training opportunities for those representatives involved in the MEDICRIME-related criminal proceedings in each state. Finally, participation in other international networks will also be considered.

Please note the object and purpose of the MEDICRIME Convention, as provided by its Article 1.1, while completing the Gap Analysis Survey

Article 1 – Object and purpose

1 The purpose of this Convention is to prevent and combat threats to public health by:

a. providing for the criminalisation of certain acts;
b. protecting the rights of victims of the offences established under this Convention;
c. promoting national and international co-operation

This project takes also into consideration articles 17 (national measures of co-operation and information exchange) and 22 (International co-operation on prevention and other administrative measures) of the MEDICRIME Convention.

Chapter I – Object and purpose, principle of non-discrimination, scope, definitions

Article 1 – Object and purpose

1. The purpose of this Convention is to prevent and combat threats to public health by:

   a. providing for the criminalisation of certain acts;
   b. protecting the rights of victims of the offences established under this Convention;
   c. promoting national and international co-operation.

2. In order to ensure effective implementation of its provisions by the Parties, this Convention sets up a specific follow-up mechanism.

Article 4 - Definitions

j. the term “counterfeit” shall mean a false representation as regards identity and/or source;

Chapter IV – Co-operation of authorities and information exchange

Article 17 – National measures of co-operation and information exchange

1. Each Party shall take the necessary legislative and other measures to ensure that representatives of health authorities, customs, police and other competent authorities exchange information and co-operate in accordance with domestic law in order to prevent and combat effectively the counterfeiting of medical products and similar crimes involving threats to public health.

2. Each Party shall endeavour to ensure co-operation between its competent authorities and the commercial and industrial sectors as regards risk management of counterfeit medical products and similar crimes involving threats to public health.

3. With due respect for the requirements of the protection of personal data, each Party shall take the necessary legislative and other measures to set up or strengthen mechanisms for:

   a. receiving and collecting information and data, including through contact points, at national or local levels and in collaboration with private sector and civil society, for the purpose of preventing and combating the counterfeiting of medical products and similar crimes involving threats to public health;

   b. making available the information and data obtained by the health authorities, customs, police and other competent authorities for the co-operation between them.

4. Each Party shall take the necessary measures to ensure that persons, units or services in charge of co-operation and information exchange are trained for this purpose. Such units or services shall have adequate resources.

Article 22 – International co-operation on prevention and other administrative measures

1. The Parties shall co-operate on protecting and providing assistance to victims.

2. The Parties shall, without prejudice to their internal reporting systems, designate a national contact point which shall be responsible for transmitting and receiving requests for information and/or co-operation in connection with the fight against counterfeiting of medical products and similar crimes involving threats to public health.

3. Each Party shall endeavour to integrate, where appropriate, prevention and combating of the counterfeiting of medical products and similar crimes involving threats to public health into assistance or development programmes provided for the benefit of third States.

2. Instruction for the completion of the questionnaire

- Strike out the incorrect response **Yes** or **No.**
- Please respond to each question. Do not leave any blanks.
- Please do not respond to any question with "*See above response in Q…*".
- If you do not know the answer, please state "*Answer is not known".*
- Each of the authorities/services should have the opportunity to assist in the drafting of the response as each may have different inputs. It is essential that all the relevant inputs are provided and not only those of one authority/service, etc. as this will avoid an inaccurate or misleading response on behalf of your country.
- Ideally, having regard to the purpose of Article 17, paragraph 1, each of the authorities/services representatives with responsibility for combating counterfeit medical products and similar crimes, should cooperate in the national drafting group to respond to this questionnaire. This way:
    a. each authority/service, etc., will have a better understanding of their contribution and that of the others to the overall response to the questionnaire;
    b. a single comprehensive and accurate response by the country will be available to the Council of Europe to make its assessment on the need for a 24/7 network as regards the MEDICRIME Convention.

RESPONDENT INFORMATION

- **Please list the name of the authorities participating in this questionnaire response.**

- **Please state if the response was completed as a team from these authorities or individually responded to and then consolidated by one authority for submission.**
- **Please advise if any authority that has a role in combating counterfeit medical products and similar crimes in your country is not involved in responding to this submission.**
- **Please provide the following information by whichever authority is making the submission on behalf of all of the authorities mentioned in the responses.**

National Cooperation

Article 17, paragraph 1

1. *Each Party shall take the necessary legislative and other measures to ensure that representatives of health authorities, customs, police and other competent authorities exchange information and co-operate in accordance with domestic law in order to prevent and combat effectively the counterfeiting of medical products and similar crimes involving threats to public health.*

Question 1

QUESTION	YES	NO
In relation to combating the counterfeiting of medical products and similar crimes, has your country adopted:		
c. A national strategy on cooperation and exchange of information between authorities/services?		
d. A national strategy or, a national action plan on cooperation and exchange of information between authorities/services?		

(if the response to both a. and b. above is “No”, please move to Question 3)

Question 2

Mark the corresponding box with an “X”

QUESTION
Has the national strategy and/or national action plan been put in place based on

d. A legislative requirement	
e. National policy	
f. Other	

If a) above:

Please provide the reference to the provision	
Please provide a web link:	
Please briefly state what this provides for:	

If b) above:

Please provide the reference this policy,	
Please provide a web link where this may be located:	
Please briefly state what this policy provides for:	

If c) above:

If so, please briefly state what this is based on	

Question 3

QUESTION	YES	NO
If there is no legislative provision, national policy, national strategy or action plan in place, is there:		
d) Any State authority (e.g. police, customs, health product regulatory authority, ministry) with a policy, strategy or action plan to ensure that there is provision for cooperation and information exchange between the various authorities who are engaged in combating counterfeit medical products and similar crimes?		

e) Please provide the details of the authority with such provision:	
f) If such a cooperation agreement exists, which authorities/services have signed it or have indicated an intention to sign	

QUESTION	YES	NO
g) Please specify the authorities/services/units included in the measure		
a. Police service (National, municipal/other)		
b. Customs service/border authority		
c. Health products regulatory authority		
d. Anti-doping authority		
e. Food safety authority/food consumer agency		
f. National INTERPOL NCB/Europol liaison office		
g. Other (specify only relevant authorities)		

Article 17.2

2. *Each Party shall endeavour to ensure co-operation between its competent authorities and the commercial and industrial sectors as regards risk management of counterfeit medical products and similar crimes involving threats to public health.*

Question 4

QUESTION	YES	NO
Does any of the above measures (legislative provision, national policy, strategy, action plan or other structured measures) (**Article 17, paragraph 2**)		
a. Provide for cooperation between the competent authorities (for the investigation of crime, border surveillance, health product regulation, other relevant authorities) and the industrial sector as regards risk management of counterfeit medical products and similar crimes involving threats to public health		

b. Specify, briefly, what the measure is	
c. Specify, briefly, how this cooperation works in practice	
d. Specify which authority/ies is/are responsible or have the lead or coordinating role for this	

Article 17, paragraph 3. a and b

With due respect for the requirements of the protection of personal data, each Party shall take the necessary legislative and other measures to set up or strengthen mechanisms for:

a. receiving and collecting information and data, including through contact points, at national or local levels and in collaboration with private sector and civil society, for the purpose of preventing and combating the counterfeiting of medical products and similar crimes involving threats to public health;

b. making available the information and data obtained by the health authorities, customs, police and other competent authorities for the co-operation between them

Question 5

QUESTION	YES	NO
Are there structured bodies/ committees/ systems in place for the collection and transmission of information and data that are specific to		
d. Combating counterfeit medical products and similar crimes (i.e. concerning crimes and criminal behaviours)		
e. Counterfeit medical products (i.e. concerning the product)		
f. Are not specific to counterfeit medical products but are general in nature and may include counterfeit medical products (i.e., a general criminal law)		

If the answer to 5. A. or b. is ‘No’, please move to Question 7

Question 6

QUESTION		
If the answer to 5. a or b is 'Yes', specify the legislative provision, or other policy measures supporting the establishment and operation of structured bodies/ committees/ systems for the collection and transmission of information and data as regards		
c. Combating counterfeit medical products and similar crimes (i.e. concerning crimes and criminal behaviours)		
d. Counterfeit medical products (i.e. concerning the product)		

In addition, please specify, briefly, how each of these structured bodies/ committees/ systems operate. This should include • The points of contact in the different authorities/services/units referred to	
• Which authorities/services are involved	

If Questions 5 and 6 have been answered, please move to Question 8, unless there is also relevant information that can be added by answering Question 7.
If Questions 5 and 6 have not been answered, please answer Question 7.

Question 7

QUESTION	YES	NO
Are there informal or ad hoc arrangements in place, instead of more structured arrangements, between the relevant authorities, for the collection, and transmission of information and data that are specific to		
c. Combating counterfeit medical products and similar crimes (i.e. concerning crimes and criminal behaviours)		
d. Counterfeit medical products (i.e. concerning the product)		

Please specify, briefly, how these informal or ad hoc arrangements work in practice This should include	
• The informal points of contact in the different authorities/services/units referred to	
• Which authorities/services are involved	

Question 8

QUESTION	YES	NO
Are there structured databases to collect information as regards		
c. Combating counterfeit medical products and similar crimes (i.e. concerning crimes and criminal behaviours)		
d. Counterfeit medical products (i.e. concerning the product)		

If the answer to a or b. is 'Yes', please specify who is responsible for the database(s)	

Question 9

QUESTION	YES	NO
Do you consider that there are no arrangements, i.e. neither formal nor informal, in place for the collection and transmission of information and data that are specific to		
c. Receiving and collecting information and data, including through contact points, at national or local levels and in collaboration with the private sector and civil society, for the purpose of preventing and combating the counterfeiting of medical products and similar crimes involving threats to public health		
d. Making available the information and data obtained by the health authorities, customs, police and other competent authorities for the co-operation between them		

Note for clarification: Answer 'Yes' if you consider that there are no arrangements in place.
Answer 'No' if you consider that there are arrangements in place

Question 10

QUESTION	YES	NO
If the answer to any part of question 9 is 'Yes' (that there are no formal or no informal arrangements in place), are there any draft legislation, strategies, plans or other measures contemplated or in the process of development to provide for such formal or informal arrangements		

If the answer is yes, please briefly specify what these are, when the process began, and when it is anticipated that the legislation, strategies, plans or other measures will be in place.	

Article 17, paragraph 4

Each Party shall take the necessary measures to ensure that persons, units or services in charge of co-operation and information exchange are trained for this purpose. Such units or services shall have adequate resources.

Question 11

QUESTION	YES	NO
Are there specialised units, offices, groups, designated appointments, or similar, with the specific responsibility		
A. To combat counterfeit medical products and similar crimes (i.e. concerning crimes and criminal behaviours)		

a. Please specify who or what these are (name of group/unit/office, etc.)	

b. What the primary competence of their organization is (select one only)		
i. Law enforcement		
ii. Border surveillance		
iii. Health product regulatory authority		
iv. Other (please specify the nature of the competence		

c. Are there members among them who are specifically trained for the purpose of cooperation and information exchange		

B. Counterfeit medical products (i.e. concerning the product)	
a. Please specify who or what these are	

b. What the primary competence of their organization is (select one only)		
i. Law enforcement		
ii. Border surveillance		
iii. Health product regulatory authority		
iv. Other (please specify the nature of the competence		
c. Are there members among them who are specifically trained for the purpose of cooperation and information exchange		

Please provide details, briefly, on the nature and frequency of the training provided for the purpose of being in charge of cooperation and information exchange.

Question 12

QUESTION	
If the answer to Question 11 is that there is no training provided as regards cooperation and information exchange, please state, briefly, what other arrangements are in place to ensure that	
c. This type of cooperation and information exchange takes place, and	
d. What training relating to the combating of counterfeit medical products and similar crimes is provided to them	

Question 13

QUESTION	YES	NO
Does the national legislation, strategy, action plan, or other measure provide for a 24 hours a day, 7 days a week network cooperation and information exchange as regards		
c. Combating counterfeit medical products and similar crimes (i.e. concerning crimes and criminal behaviours)		
d. Counterfeit medical products (i.e. concerning the medical product)		

If the answer to either or both a and b is 'Yes' please specify the measure providing for this and which authority is responsible for operating the network. This should include whether the 24/7 network is specific to combating counterfeit medical products and similar crimes or is more general in scope	

Question 14

QUESTION
Please answer this question placing an 'X' to the RIGHT on the option below that you consider is the closest to your view on whether adequate resources are provided to ensure that persons, units or services in charge of co-operation and information exchange are trained for this purpose relating to counterfeit medical products and related crimes.

a. I agree that adequate resources are provided	
b. I mostly agree that adequate resources are provided	
c. I neither agree nor disagree that adequate resources are provided	
d. I mostly agree that adequate resources are provided	
e. I disagree that adequate resources are provided	

International Cooperation

Article 22, paragraph 2

The Parties shall, without prejudice to their internal reporting systems, designate a national contact point which shall be responsible for transmitting and receiving requests for information and/or co-operation in connection with the fight against counterfeiting of medical products and similar crimes involving threats to public health.

Question 15

QUESTION	YES	NO
Is there a nominated national contact point responsible for transmitting and receiving requests for information and/or cooperation as regards		
d. Combating counterfeit medical products and similar crimes (i.e. concerning crimes and criminal behaviours)		
e. Counterfeit medical products (i.e. concerning the medical product)		
f. Is the contact point for a and b the same contact point		

• Please specify the designation of this contact point	
• Please specify the primary purpose of the responsible authority/service for the operation of this point of contact (i.e., law enforcement, border surveillance, health product regulation, etc.)	

Question 16

QUESTION	
If the response to Questions 15 a and b is that the contact points are different contact points according to their purpose, please specify, briefly,	
a. Why arrangements do not facilitate having one agreed national contact point that is responsible for all matters of transmitting and receiving requests for information and/or cooperation with other international contact points	
b. What arrangements are in place to coordinate this work to avoid duplication or gaps in transmitting and receiving requests for information and/or cooperation	

Question 17

QUESTION	YES	NO
Are there measures taken to provide training to the national contact point responsible for transmitting and receiving requests for information, and/or cooperation as regards		
c. Combating counterfeit medical products and similar crimes (i.e. concerning crimes and criminal behaviours)		
d. Counterfeit medical products (i.e. concerning the medical product)		

Please specify, briefly, what these measures include

Question 18

QUESTION
Please list below any other 24/7 networks that your authority/service/office, or similar organization, participates in transmitting and receiving of requests for information and/or cooperation as regards b. Combating counterfeit medical products and similar crimes (i.e. concerning crimes and criminal behaviours) b. Counterfeit medical products (i.e. concerning the medical product) Each listed 24/7 network, by authority/service/similar organisation, should specify the purpose as mentioned in a, or b, or both above (Please insert your response in place of the example below)

Example

Network	**Type of Network**	**Does it include counterfeit medical products and related crimes (both criminal behaviour and products)**
INTERPOL NCB 24/7 network	Law enforcement	Includes operational information exchange relating to the trafficking of counterfeit and other illicit medical products
HMA WGEO	Health Product Enforcement	Includes information exchange relating to the trafficking of counterfeit/falsified and other illicit medical products.

Question 19

Please state the number of requests for information or data exchange, including those emanating from the policing services, the customs service, the national health products regulatory authority, and others, as regards the combating of medical products and related crimes

Dates made/received	Made by your country to other countries	Received by other countries from other countries
01/01/2020 to 31/12/2022		
01/01/2017 to 31/12/2019		

QUESTION	YES	NO
If the data is unavailable for inclusion in the response to this questionnaire due to		
a. Not recorded in a retrievable manner relating to counterfeit medical products and similar crimes (relating to crimes and criminal behaviours)		
b. No recorded		

Question 20

QUESTION	YES	NO
Please identify what are the types of requests to be exchanged over a 24/7 network between countries:		
g. Rapid access to evidence in criminal proceedings		
h. Preservation of evidence in another jurisdiction		
i. Exchange of investigative information		
j. Information about counterfeit medical products		
k. Technical advice		
l. Other (please briefly describe)		

QUESTIONNAIRE SUR UN RÉSEAU 24/7

19/04/2023

Les réponses sont à envoyer au secrétariat du Comité MÉDICRIME

medicrime@coe.int

Avant le (09/06/2023)

NOM DU PAYS	
Nom de la personne qui répond au questionnaire	
Fonction	
Courriel	
Numéro de téléphone portable	

1. Introduction

Dans le cadre du projet baptisé « Lutte contre la falsification des produits médicaux – Programme mondial » (CRIMFAMED), le Conseil de l'Europe mène cette **étude** afin d'évaluer l'état actuel des capacités 24/7 des autorités nationales qui interviennent dans les processus liés à l'interdiction des produits médicaux contrefaits/falsifiés et à la répression des infractions pénales dans ce domaine, aux fins de la protection de la santé publique.

Cette enquête mettra en lumière les procédures législatives et les dispositions nationales concernant la collaboration entre les différents acteurs (autorités judiciaires, sanitaires, policières et douanières, notamment). Elle évaluera aussi les possibilités de formation dont bénéficient dans chaque État les personnes intervenant dans les procédures pénales liées à MEDICRIME. Enfin, la participation à d'autres réseaux internationaux sera également examinée.

Veuillez avoir à l'esprit l'objet et le but de la Convention MÉDICRIME tels qu'énoncés à l'article 1.1 lorsque vous répondez à cette enquête d'analyse des lacunes.

Article 1 – Objet et but
1 La présente Convention vise à prévenir et combattre les menaces qui pèsent sur la santé publique :

a. en incriminant certains actes ;
b. en protégeant les droits des victimes des infractions établies conformément à cette Convention ;
c. en promouvant la coopération nationale et internationale.

Ce projet prend aussi en considération les articles 17 (Mesures nationales de coopération et d'échange d'information) et 22 (Coopération internationale aux fins de la prévention et d'autres mesures administratives) de la Convention MÉDICRIME.

Chapitre I – Objet et but, principe de non-discrimination, champ d'application, définitions

Article 1 – Objet et but

1. La présente Convention vise à prévenir et combattre les menaces qui pèsent sur la santé publique :

   d. en incriminant certains actes ;
   e. en protégeant les droits des victimes des infractions établies conformément à cette Convention ;
   f. en promouvant la coopération nationale et internationale.

2. Afin d'assurer une mise en œuvre efficace de ses dispositions par les Parties, la présente Convention met en place un mécanisme de suivi spécifique.

Article 4 - Définitions

j. le terme « contrefaçon » désigne la présentation trompeuse de l'identité et/ou de la source ;

Chapitre IV – Coopération des autorités et échange d'information

Article 17 – Mesures nationales de coopération et d'échange d'information

1. Chaque Partie prend les mesures législatives et autres nécessaires pour assurer que les représentants des autorités sanitaires, des douanes, des forces de l'ordre, et autres autorités compétentes échangent des informations et coopèrent conformément à leur droit interne, afin de prévenir et de lutter efficacement contre la contrefaçon des produits médicaux et les infractions similaires menaçant la santé publique.

2. Chaque Partie s'efforce d'assurer la coopération entre ses autorités compétentes et les secteurs commercial et industriel afin de gérer les risques liés à la contrefaçon de produits médicaux et aux infractions similaires menaçant la santé publique.

3. En tenant dûment compte des exigences liées à la protection des données à caractère personnel, chaque Partie prend les mesures législatives et autres nécessaires pour mettre en place ou renforcer les mécanismes :
   a. de réception et de collecte d'informations et de données, y compris par le biais de points de contact, au niveau national ou local, en coopération avec le secteur privé et la société civile, aux fins de prévenir et de lutter contre la

contrefaçon des produits médicaux et les infractions similaires menaçant la santé publique ;

b. de mise à disposition des informations et données recueillies par les autorités sanitaires, les douanes, les forces de l'ordre et autres autorités compétentes, dans l'intérêt de la coopération de ces autorités entre elles.

4. Chaque Partie prend les mesures nécessaires pour que les personnes, les unités ou les services en charge de la coopération et des échanges d'information soient formés à cette fin. Ces unités ou services doivent être dotés de ressources adéquates.

Article 22 – Coopération internationale aux fins de la prévention et d'autres mesures administratives

1. Les Parties coopèrent aux fins de la protection et de l'assistance des victimes.

2. Les Parties, sans préjudice des systèmes de déclaration internes existants, désignent un point de contact national chargé de transmettre et de recevoir les demandes d'information et/ou de coopération se rapportant à la lutte contre la contrefaçon des produits médicaux et les infractions similaires menaçant la santé publique.

3. Chaque Partie s'efforce d'intégrer, le cas échéant, la prévention et la lutte contre la contrefaçon des produits médicaux et les infractions similaires menaçant la santé publique dans les programmes d'assistance au développement conduits au profit d'États tiers.

3. Instructions pour remplir le questionnaire

- Cochez la case **Oui** ou **Non** selon le cas.
- Veuillez répondre à toutes les questions. Ne laissez pas de cases vides.
- Merci de ne répondre à aucune question par la mention *« Voir plus haut la réponse à la question… »*.
- Si vous ne pouvez pas répondre à une question, veuillez indiquer *« NSP » (« Ne sait pas »).*
- Afin que la réponse fournie au nom de votre pays soit exacte et complète, il est souhaitable que le questionnaire soit rempli avec la participation de toutes les autorités et tous les services concernés car chacun peut apporter une contribution spécifique. Il est essentiel que toutes les contributions soient prises en compte et que ne figurent pas uniquement celles d'une seule autorité ou d'un seul service.
- Idéalement, eu égard à l'objectif de l'article 17, paragraphe 1, chaque représentant des autorités/services chargés de lutter contre la contrefaçon de produits médicaux et les infractions similaires devrait coopérer au groupe constitué au niveau national pour répondre à ce questionnaire. De cette façon :

a. chaque autorité/service, etc. aura une meilleure perception de sa contribution et de celle des autres à la réponse globale au questionnaire ;
b. le pays transmettra une réponse unique, complète et exacte au Conseil de l'Europe, qui pourra ainsi évaluer correctement la nécessité de mettre en place un réseau 24/7 dans le cadre de la Convention MÉDICRIME.

RENSEIGNEMENTS SUR LE RÉPONDANT

- **Veuillez donner le nom de toutes les autorités qui contribuent à la réponse au questionnaire.**
- **Veuillez préciser si la réponse a été rédigée collectivement dans le cadre d'un groupe constitué par ces autorités, ou si elle a été établie par une autorité à partir de diverses réponses faites individuellement.**
- **Veuillez nous signaler si une autorité jouant un rôle dans la lutte contre la contrefaçon des produits médicaux et les infractions similaires dans votre pays n'a pas participé à la réponse à ce questionnaire.**
- **Veuillez préciser quelle autorité soumet le questionnaire rempli au nom de toutes les autorités mentionnées dans les réponses.**

Coopération nationale

Article 17, paragraphe 1

1. *Chaque Partie prend les mesures législatives et autres nécessaires pour assurer que les représentants des autorités sanitaires, des douanes, des forces de l'ordre, et autres autorités compétentes échangent des informations et coopèrent conformément à leur droit interne, afin de prévenir et de lutter efficacement contre la contrefaçon des produits médicaux et les infractions similaires menaçant la santé publique.*

Question 1

QUESTION	OUI	NON
En ce qui concerne la lutte contre la contrefaçon des produits médicaux et les infractions similaires, votre pays a-t-il adopté :		
e. une stratégie nationale de coopération et d'échange d'informations entre les autorités/services ?		
f. un plan national d'action pour la coopération et l'échange d'informations entre les autorités/services ?		

(si vous avez répondu « Non » à la question 1.*a)* et à la question 1.*b)*, veuillez passer à la question 3)

Question 2

Veuillez cocher la case appropriée

QUESTION	
La stratégie nationale et/ou le plan national d'action ont-ils été mis en place en application :	
g. d'une disposition législative ?	
h. d'une politique nationale ?	
i. autre ?	

Si réponse *a)* :

Veuillez donner la référence de la disposition.	
Veuillez fournir un lien vers un site web.	
Veuillez indiquer brièvement ce que prévoit cette disposition.	

Si réponse *b)* :

Veuillez donner la référence de la politique.	

Veuillez fournir un lien vers un site web où on peut la trouver.	.
Veuillez indiquer brièvement ce que prévoit cette politique.	

Si réponse *c)* :

Veuillez expliquer brièvement dans quel cadre la coopération est mise en place.	

Question 3

QUESTION	OUI	NON
S'il n'existe pas de disposition législative, de politique nationale, de stratégie nationale ou de plan national d'action, y a-t-il :		
h) une autorité publique (police, douanes, autorité de réglementation des produits de santé, ministère, etc.) disposant d'une politique, d'une stratégie ou d'un plan d'action qui prévoit une coopération et un échange d'informations entre les diverses autorités chargées de la lutte contre la contrefaçon des produits médicaux et les autres infractions ?		

i) Veuillez préciser de quelle autorité il s'agit.	
j) S'il existe un accord de coopération, quels sont les services ou autorités l'ayant signé ou ayant fait part de leur intention de le signer ?	

QUESTION	OUI	NON
k) Veuillez mentionner les autorités/services/unités concernés par la mesure		
h. Police (nationale, municipale, autre)		
i. Service des douanes/autorité aux frontières		
j. Autorité de réglementation des produits de santé		
k. Autorité de lutte contre le dopage		
l. Autorité de sécurité des aliments/organisme pour l'alimentation et les consommateurs		
m. Bureau central national (BCN) d'INTERPOL/bureau de liaison d'Europol		
n. Autre (citez uniquement les autorités concernées)		

Article 17.2

2. *Chaque Partie s'efforce d'assurer la coopération entre ses autorités compétentes et les secteurs commercial et industriel afin de gérer les risques liés à la contrefaçon de produits médicaux et aux infractions similaires menaçant la santé publique.*

Question 4

QUESTION	OUI	NON
Les mesures citées plus haut (disposition législative, politique nationale, stratégie nationale, plan national d'action ou autre mesure structurée) (Article 17, paragraphe 2)		
a. prévoient-elles des dispositions pour assurer la coopération entre les autorités compétentes (à savoir les autorités chargées des enquêtes sur les infractions pénales, de la surveillance des frontières et de la réglementation des produits de santé, et les autres autorités compétentes) et le secteur industriel en ce qui concerne la gestion des risques liés à la contrefaçon de produits médicaux et aux infractions similaires menaçant la santé publique ?		

b. Précisez brièvement en quoi consiste la mesure	
c. Indiquez brièvement comment fonctionne concrètement la coopération.	
d. Précisez quelle(s) autorité(s) est/sont chargée(s) de/dirige(nt)/coordonne(nt) la coopération.	

Article 17, paragraphe 3 *a)* et *b)*

En tenant dûment compte des exigences liées à la protection des données à caractère personnel, chaque Partie prend les mesures législatives et autres nécessaires pour mettre en place ou renforcer les mécanismes :

c. de réception et de collecte d'informations et de données, y compris par le biais de points de contact, au niveau national ou local, en coopération avec le secteur privé et la société civile, aux fins de prévenir et de lutter contre la contrefaçon des produits médicaux et les infractions similaires menaçant la santé publique ;

d. *de mise à disposition des informations et données recueillies par les autorités sanitaires, les douanes, les forces de l'ordre et autres autorités compétentes, dans l'intérêt de la coopération de ces autorités entre elles.*

Question 5

QUESTION	OUI	NON

Existe-t-il des organes/comités/systèmes structurés de collecte et de transmission d'informations et de données :		
g. concernant spécifiquement la lutte contre la contrefaçon des produits médicaux et les infractions similaires (c'est-à-dire concernant les actes et comportements délictueux) ?		
h. concernant spécifiquement les produits médicaux contrefaits (c'est-à-dire concernant les produits eux-mêmes) ?		
i. ne concernant pas spécifiquement la contrefaçon des produits médicaux mais dont la portée générale peut inclure la contrefaçon des produits médicaux (loi pénale générale, par exemple) ?		

Si vous avez répondu « Non » à la question 5.*a)* ou 5.*b)*, veuillez passer à la question 7.

Question 6

QUESTION		
Si vous avez répondu « Oui » à la question 5.a) ou 5.b), veuillez indiquer quelles dispositions législatives ou autres mesures régissent la mise en place et le fonctionnement des organes/comités/systèmes structurés de collecte et de transmission d'informations et de données concernant :		
e. la lutte contre la contrefaçon des produits médicaux et les infractions similaires (c'est-à-dire concernant les actes et comportements délictueux).		
f. les produits médicaux contrefaits (c'est-à-dire concernant les produits eux-mêmes).		

Veuillez préciser brièvement comment fonctionnent ces organes/comités/systèmes structurés. Veuillez mentionner en particulier :	
• les points de contact dans les différents services/autorités/unités mentionnés	
• les autorités/services concernés	

Si vous avez répondu à la question 6, veuillez passer à la question 8, sauf si certaines informations intéressantes peuvent être ajoutées dans le cadre de la question 7.
Si vous n'avez pas répondu à la question 6, veuillez répondre à la question 7.

Question 7

QUESTION	OUI	NON
Existe-t-il des dispositifs informels ou ad hoc (par opposition à des dispositifs plus structurés) permettant la collecte et la transmission entre les autorités concernées d'informations et de données concernant spécifiquement :		
e. la lutte contre la contrefaçon des produits médicaux et les infractions similaires (c'est-à-dire concernant les actes et comportements délictueux) ?		
f. les produits médicaux contrefaits (c'est-à-dire concernant les produits eux-mêmes) ?		

Veuillez préciser brièvement comment fonctionnent concrètement ces dispositifs informels ou ad hoc. Veuillez mentionner en particulier :	
• les points de contact informels dans les différents services/autorités/unités mentionnés	
• les autorités/services concernés	

Question 8

QUESTION	OUI	NON
Existe-t-il des bases de données structurées pour la collecte d'informations concernant :		
e. la lutte contre la contrefaçon des produits médicaux et les infractions similaires (c'est-à-dire concernant les actes et comportements délictueux) ?		
f. les produits médicaux contrefaits (c'est-à-dire concernant les produits eux-mêmes) ?		

Si vous avez répondu « Oui » à la question 8.a) ou 8.b), veuillez préciser qui est chargé de la base/des bases de données.	

Question 9

QUESTION	OUI	NON
Considérez-vous qu'il n'existe pas de dispositif, structuré ou informel…		
e. de réception et de collecte d'informations et de données, y compris par le biais de points de contact, au niveau national ou local, en coopération avec le secteur privé et la société civile, pour prévenir et lutter contre la contrefaçon des produits médicaux et les infractions similaires menaçant la santé publique ?		
f. de mise à disposition des informations et données recueillies par les autorités sanitaires, les douanes, les forces de l'ordre et autres autorités compétentes, dans l'intérêt de la coopération de ces autorités entre elles ?		

Précision : répondez « Oui » si vous considérez qu'il n'existe pas de dispositif
répondez « Non » si vous considérez qu'un tel dispositif existe

Question 10

QUESTION	OUI	NON
Si vous avez répondu « Oui » à l'une ou l'autre partie de la question 9 (il n'existe pas de dispositif structuré ou informel) : une loi, une stratégie, un plan ou d'autres mesures prévoyant la mise en place d'un tel dispositif sont-ils envisagés, ou en préparation ?		

Si vous avez répondu « Oui », veuillez indiquer brièvement de quoi il s'agit exactement, quand le processus a commencé et quand il est prévu que la loi, la stratégie, le plan ou toute autre mesure soit en place.	

Article 17, paragraphe 4

Chaque Partie prend les mesures nécessaires pour que les personnes, les unités ou les services en charge de la coopération et des échanges d'information soient formés à cette fin. Ces unités ou ces services doivent être dotés de ressources adéquates.

Question 11

QUESTION	OUI	NON
Existe-t-il des unités, bureaux, groupes, personnes désignées ou autres structures chargés spécifiquement		
A. de la lutte contre la contrefaçon de produits médicaux et les infractions similaires (c'est-à-dire des actes et comportements délictueux) ?		

c. Veuillez préciser quelles sont ces structures ou personnes (nom du groupe, de l'unité, du bureau, etc.).	

d. Quelle est la compétence <u>première</u> de leur organisme de tutelle (un seul choix possible) ?		
j. Services répressifs		
ii. Surveillance des frontières		
iii. Autorité de réglementation des produits de santé		
iv. Autre (veuillez préciser la nature de la compétence)		

c. Y a-t-il dans la structure des personnes spécifiquement formées à la coopération et à l'échange d'informations ?		

B. des produits médicaux contrefaits (c'est-à-dire des produits eux-mêmes) ?	
a. Veuillez préciser quelles sont ces structures ou personnes.	

b. Quelle est la compétence <u>première</u> de leur organisme de tutelle (un seul choix possible) ?		
i. Services répressifs		
ii. Surveillance des frontières		
iii. Autorité de réglementation des produits de santé		
iv. Autre (veuillez préciser la nature de la compétence)		
c. Y a-t-il dans la structure des personnes spécifiquement formées à la coopération et à l'échange d'informations ?		

Veuillez indiquer brièvement quelle est la nature de la formation donnée aux personnes chargées de la coopération et de l'échange d'informations, et à quelle fréquence elle est dispensée.

Question 12

QUESTION	
Si vous avez répondu à la question 11 qu'aucune formation en matière de coopération et d'échange d'informations n'est dispensée, veuillez indiquer brièvement :	
e. quels sont les dispositifs en place permettant la coopération et l'échange d'information, et	
f. quelle formation en matière de lutte contre la contrefaçon de produits médicaux et les infractions similaires leur est dispensée.	

Question 13

QUESTION	OUI	NON
La législation nationale (ou la stratégie, le plan d'action ou toute autre mesure) prévoit-elle la mise en place d'un réseau, fonctionnant 24 heures sur 24 et 7 jours sur 7, pour la coopération et l'échange d'informations concernant		
e. la lutte contre la contrefaçon des produits médicaux et les infractions similaires (c'est-à-dire concernant les actes et comportements délictueux) ?		
f. les produits médicaux contrefaits (c'est-à-dire concernant les produits médicaux eux-mêmes) ?		

Si vous avez répondu « Oui », veuillez indiquer de quelle mesure il s'agit et quelle autorité est chargée de faire fonctionner ce réseau. Merci de préciser si le réseau 24/7 est spécifique à la lutte contre la contrefaçon des produits médicaux et les infractions similaires ou s'il est de portée plus générale.	

Question 14

QUESTION
Pensez-vous que des ressources adéquates sont dégagées pour que les personnes, unités ou services en charge de la coopération et des échanges d'informations soient formés à cette fin, dans le domaine de la lutte contre la contrefaçon des produits médicaux et les infractions similaires ? Veuillez cocher la case qui correspond le mieux à votre avis.

f. Oui, tout à fait	
g. Oui, dans l'ensemble	
h. Je ne me prononce pas	
i. Non, plutôt pas	
j. Non, pas du tout	

Coopération internationale

Article 22, paragraphe 2

Les Parties, sans préjudice des systèmes de déclaration internes existants, désignent un point de contact national chargé de transmettre et de recevoir les demandes d'information et/ou de coopération se rapportant à la lutte contre la contrefaçon des produits médicaux et les infractions similaires menaçant la santé publique.

Question 15

QUESTION	OUI	NON
Un point de contact national a-t-il été désigné pour transmettre et recevoir les demandes d'information et/ou de coopération concernant :		
2. la lutte contre la contrefaçon des produits médicaux et les infractions similaires (c'est-à-dire concernant les actes et comportements délictueux) ?		
3. les produits médicaux contrefaits (c'est-à-dire concernant les produits médicaux eux-mêmes) ?		
4. Le point de contact est-il le même pour a) et b) ?		

• Veuillez préciser le nom de ce point de contact.	
• Veuillez indiquer quelle est la compétence première de l'autorité/du service de tutelle du point de contact (services répressifs, surveillance aux frontières, réglementation des produits de santé, etc.).	

Question 16

QUESTION	
Si vous avez répondu à la question 15 que les points de contact ne sont pas les mêmes, veuillez indiquer brièvement :	
a. pourquoi les modalités en place ne permettent pas de disposer d'un point de contact national unique chargé de toutes les questions relatives à la transmission et à la réception des demandes d'informations et/ou de coopération avec les autres points de contact internationaux	
b. quelles sont les dispositions prises pour assurer la coordination de ces tâches afin d'éviter les doublons ou les failles dans la transmission et la réception des demandes d'informations et/ou de coopération.	

Question 17

QUESTION	OUI	NON
Des mesures sont-elles prises pour assurer la formation du point de contact national chargé de transmettre et de recevoir les demandes d'informations et/ou de coopération concernant :		
e. la lutte contre la contrefaçon des produits médicaux et les infractions similaires (c'est-à-dire concernant les actes et comportements délictueux) ?		
f. les produits médicaux contrefaits (c'est-à-dire concernant les produits médicaux eux-mêmes) ?		

Veuillez expliquer brièvement en quoi consistent ces mesures.

Question 18

QUESTION
Veuillez mentionner ci-dessous tout autre réseau 24/7 auquel votre autorité/service/bureau, ou organisation similaire, participe pour la transmission et la réception de demandes d'informations et/ou de coopération concernant : c. la lutte contre la contrefaçon des produits médicaux et les infractions similaires (c'est-à-dire concernant les actes et comportements délictueux). b. les produits médicaux contrefaits (c'est-à-dire concernant les produits médicaux eux-mêmes). Pour chaque réseau 24/7 mentionné, veuillez préciser l'autorité/le service/l'organisation similaire concerné ainsi que la finalité telle que mentionnée en a), ou b), ou aux deux rubriques (merci d'insérer votre réponse à la place de l'exemple ci-dessous).

Exemple

Réseau	Type de réseau	Concerne-t-il les produits médicaux contrefaits et les infractions dans ce domaine (les produits et le comportement délictueux) ?
INTERPOL NCB 24/7 network	Services répressifs	Concerne l'échange d'informations opérationnelles liées au trafic de produits médicaux contrefaits ou illicites
HMA WGEO	Réglementation des produits de santé	Concerne l'échange d'informations liées au trafic de produits médicaux contrefaits/falsifiés ou illicites.

Question 19

Veuillez indiquer le nombre de demandes d'informations ou d'échange de données, notamment celles émanant des forces de l'ordre, du service des douanes, de l'autorité nationale de réglementation des produits de santé et d'autres organismes, en ce qui concerne la lutte contre la contrefaçon des produits médicaux et les infractions qui y sont associées.

Dates faites/reçues	Envoyées par votre pays à d'autres pays	Émanant d'autres pays et reçues par votre pays
01/01/2020 au 31/12/2022		
01/01/2017 au 31/12/2019		

QUESTION	OUI	NON
Si vous ne disposez pas des données permettant de compléter le tableau ci-dessus, veuillez préciser le cas de figure :		
a. Données n'ayant pas été enregistrées de manière récupérable (pour les données concernant la contrefaçon des produits médicaux et les infractions similaires, c'est-à-dire les actes et comportements délictueux).		
b. Données non enregistrées.		

Question 20

QUESTION	OUI	NON
Veuillez indiquer quels sont les différents types de demandes qui peuvent être faites dans le cadre d'un réseau 24/7 entre pays :		
m. Accès rapide aux preuves dans les procédures pénales		
n. Conservation des preuves dans une autre juridiction		
o. Partage des éléments de l'enquête		
p. Informations sur des produits médicaux contrefaits		
q. Conseils techniques		
r. Autre (veuillez préciser)		

XI. Annex III - Tables on the situation by the Parties and other countries as regards the current state of 24/7 capabilities of national authorities

Tables on the situation by the Parties and other countries as regards the current state of 24/7 capabilities of national authorities involved in domestic criminal and other laws supporting the prohibition and enforcement against counterfeit /falsified medical products as criminal offences for the purpose of protecting public health.

Table 1. (Q.1) In relation to combating the counterfeiting of medical products and similar crimes, has your country adopted:
a. A national strategy on cooperation and exchange of information between authorities/services: Yes/No
b. A national strategy or, a national action plan on cooperation and exchange of information between authorities/services: Yes/No
(if the response in Table 1 is 'No', move to complete Table 3)

Armenia		**YES**	**NO**
	In relation to combating the counterfeiting of medical products and similar crimes, has your country adopted:		
	g. A national strategy on cooperation and exchange of information between authorities/services?	X	
	h. A national strategy or, a national action plan on cooperation and exchange of information between authorities/services?	X	
Belgium		**YES**	**NO**
	In relation to combating the counterfeiting of medical products and similar crimes, has your country adopted:		
	a. A national strategy on cooperation and exchange of information between authorities/services?		X
	b. A national strategy or, a national action plan on cooperation and exchange of information between authorities/service		X
Bosnia and Herzegovina		**OUI**	**NON**
	En ce qui concerne la lutte contre la contrefaçon des produits médicaux et les infractions similaires, votre pays a-t-il adopté:		
	a. a. une stratégie nationale de coopération et d'échange d'informations entre les autorités/services?		X
	b. b. un plan national d'action pour la coopération et l'échange d'informations entre les autorités/services		X
Burkina Faso		**OUI**	**NON**
	En ce qui concerne la lutte contre la contrefaçon des produits médicaux et les infractions similaires, votre pays a-t-il adopté:		
	a. a. une stratégie nationale de coopération et d'échange d'informations entre les autorités/services?	X	
	b. b. un plan national d'action pour la coopération et l'échange d'informations entre les autorités/services		X
Croatia		**YES**	**NO**
	In relation to combating the counterfeiting of medical products and similar crimes, has your country adopted:		
	a. A national strategy on cooperation and exchange of information between authorities/services?		X
	b. A national strategy or, a national action plan on cooperation and exchange of information between authorities/services?		X
France	**QUESTION**	**OUI/NON**	**NON**
	En ce qui concerne la lutte contre la contrefaçon des produits médicaux et les infractions similaires, votre pays a-t-il adopté :		
	a. une stratégie nationale de coopération et d'échange d'informations entre les autorités/services ?	Non	X
	b. un plan national d'action pour la coopération et l'échange d'informations entre les autorités/services ?	Non	X
Hungary		**YES**	**NO**
	In relation to combating the counterfeiting of medical products and similar crimes, has your country adopted:		
	a. A national strategy on cooperation and exchange of information between authorities/services?		×
	b. A national strategy or, a national action plan on cooperation and exchange of information between authorities/services?		x
Ireland		**YES**	**NO**
	In relation to combating the counterfeiting of medical products and similar crimes, has your country adopted:		

	a. A national strategy on cooperation and exchange of information between authorities/services?		No
	b. A national strategy or, a national action plan on cooperation and exchange of information between authorities/services?		No
Moldova		**YES**	**NO**
	In relation to combating the counterfeiting of medical products and similar crimes, has your country adopted:		
	a. A national strategy on cooperation and exchange of information between authorities/services?	-	No
	b. A national strategy or, a national action plan on cooperation and exchange of information between authorities/services?	-	No
Morocco		**OUI**	**NON**
	En ce qui concerne la lutte contre la contrefaçon des produits médicaux et les infractions similaires, votre pays a-t-il adopté:		
	a. a. une stratégie nationale de coopération et d'échange d'informations entre les autorités/services?	X	
	b. b. un plan national d'action pour la coopération et l'échange d'informations entre les autorités/services		X
Portugal		**YES**	**NO**
	In relation to combating the counterfeiting of medical products and similar crimes, has your country adopted:		
	a. A national strategy on cooperation and exchange of information between authorities/services?		No
	b. A national strategy or, a national action plan on cooperation and exchange of information between authorities/services?		No
Slovenia		**YES**	**NO**
	In relation to combating the counterfeiting of medical products and similar crimes, has your country adopted:		
	a. A national strategy on cooperation and exchange of information between authorities/services?	MP	JAZMP
	b. A national strategy or, a national action plan on cooperation and exchange of information between authorities/services?		JAZMP
Spain		**YES**	**NO**
	In relation to combating the counterfeiting of medical products and similar crimes, has your country adopted:		
	a. A national strategy on cooperation and exchange of information between authorities/services?	x	
	b. A national strategy or, a national action plan on cooperation and exchange of information between authorities/services?	x	
Switzerland		**YES**	**NO**
	In relation to combating the counterfeiting of medical products and similar crimes, has your country adopted:		
	a. A national strategy on cooperation and exchange of information between authorities/services?		X
	b. A national strategy or, a national action plan on cooperation and exchange of information between authorities/services?		X
Ukraine		**YES**	**NO**
	In relation to combating the counterfeiting of medical products and similar crimes, has your country adopted:		
	a. A national strategy on cooperation and exchange of information between authorities/services?	x	
	b. A national strategy or, a national action plan on cooperation and exchange of information between authorities/services?	x	

Table 2: (Q.2) Has the national strategy and/or national action plan been put in place based on
a. a legislative requirement (please provide the reference to the provision, a web link, and briefly state what this provides for)
b. national policy (please provide the reference for this policy, a web link where this may be located, and briefly state what this policy provides for)
c. Other, if so, please briefly state what this is based on

Armenia		
	Has the national strategy and/or national action plan been put in place based on	
	a. A legislative requirement	
	b. National policy	
	c. Other	
	If a) above:	
	Please provide the reference to the provision	It is internal collaboration set up be authorities, customs and law enfor authorities.
	Please provide a web link:	
	Please briefly state what this provides for:	
	If b) above:	
	Please provide the reference this policy,	

	Please provide a web link where this may be located:	
	Please briefly state what this policy provides for:	

If c) above:

If so, please briefly state what this is based on	The collaboration is including the training, inclusion of health authorities to investigations related to any criminal proceeding in medical products

Belgium	No response
Bosnia and Herzegovina	No response

Burkina Faso

La stratégie nationale et/ou le plan national d'action ont-ils été mis en place en application :

c.	d'une disposition législative ?	
d.	d'une politique nationale ?	X
e.	autre ?	X

Si réponse *a)* :

Veuillez donner la référence de la disposition.	
Veuillez fournir un lien vers un site web.	

Si réponse *b)* :

Veuillez donner la référence de la politique.	Plan stratégique pharmaceutique 2019-2023
Veuillez fournir un lien vers un site web où on peut la trouver.	Plan strategique pharmaceutique 2019-2023 adopté par le Ministère de la Santé et de l'Hygiene Publique (sante.bov.fr)
Veuillez indiquer brièvement ce que prévoit cette politique.	
Veuillez indiquer brièvement ce que prévoit cette disposition.	Au niveau de l'Axe 3. Régulation dans le sous-secteur pharmaceutique, il est prévu dans l'Objectif spécifique 3.3 Renforcer la lutte contre les faux médicaments de : -renforcer les capacités opérationnelles des acteurs intervenant dans la lutte contre les faux produits médicaux -appuyer la mise en œuvre du plan stratégique de lutte contre la drogue -organiser des campagnes de sensibilisation aux dangers des faux produits médicaux -renforcer la lutte contre les produits de santé falsifiés ou commercialisés sans autorisation (AMM et ASI) -renforcer la collaboration inter-pays dans le cadre de la lutte contre les faux produits médicaux -mettre en œuvre le plan de lutte contre la résistance aux antimicrobiens Les acteurs impliqués sont notamment: -le Ministère de la santé et d l'hygiène publique (Agence nationale de régulation pharmaceutique, Direction générale de l'approvisionnement pharmaceutique) -le ministère de la Justice -le ministère du commerce -le ministère de l'économie et des finances (douanes) -le ministère de l'administration territoriale (gouverneurs de régions) -le ministère de la sécurité (police) -le Comité national de lutte contre la drogue

Si réponse *c)* :

Veuillez expliquer brièvement dans quel cadre la coopération est mise en place.	Un réseau social sert de plateforme numérique et regroupe les différents

			acteurs (police-douanes-autorité de régulation pharmaceutique-ministère du commerce, comité national de lutte contre la drogue…) en vue d'échanger des informations en temps réels entre les autorités/services	
Croatia	No response			
France	No response			
Hungary	No response			
Ireland	No response			
Moldova	No response			
Morocco	La stratégie nationale et/ou le plan national d'action ont-ils été mis en place en application :			
	a. d'une disposition législative ?			
	b. d'une politique nationale ?			
	c. autre ?			
	Si réponse *a)* :			
	Veuillez donner la référence de la disposition.			
	Veuillez fournir un lien vers un site web.			
	Veuillez indiquer brièvement ce que prévoit cette disposition.			
	Si réponse *b)* :			
	Veuillez donner la référence de la politique.			
	Veuillez fournir un lien vers un site web où on peut la trouver.	.		
	Veuillez indiquer brièvement ce que prévoit cette politique.			
	Si réponse *c)* :			
	Veuillez expliquer brièvement dans quel cadre la coopération est mise en place.	Dans le cadre de la signature de la convention Medicrime, des réunions de concertation ont eu lieu avec les parties prenantes, des circulaires relatives au respect du circuit légal des médicaments et des produits de santé ont été établies et des formations des pharmaciens inspecteurs ont été réalisées.		
Portugal	No response			
Slovenia	**QUESTION**			
	Has the national strategy and/or national action plan been put in place based on			
	a. A legislative requirement MP			
	b. National policy			
	c. Other			
	If a) above:			
	Please provide the reference to the provision	MP: Criminal Procedure Act (Official Gazette of the RS, Nos. 176/21 – UPB16, 96/22 – odl. US in 2/23 – odl. US), Article 160.a, is the legal basis for the Decree on cooperation between the state prosecutor's office, the police and other competent national authorities and institutions in investigating and prosecuting criminal offenders and on the operation of specialised and joint investigation teams		
	Please provide a web link:	MP: Criminal Procedure Act: http://pisrs.si/Pis.web/pregledPredpisa?id=ZAKO362 Decree: http://pisrs.si/Pis.web/pregledPredpisa?id=URED8600		
	Please briefly state what this provides for:	MP: According to Criminal Procedure Act, Article 160.a: In exercising his or her powers, the state prosecutor may direct the work of the police and of the competent body within the ministry responsible for defence designated by an Act (Article 158), the work of a joint investigation team (Article 160b) and the work of other competent state		

			authorities and institutions in the field of taxes, customs, financial operations, securities, protection of competition, prevention of money laundering, prevention of corruption, illicit drugs and inspection supervision (also the Agency for Medicinal Products and Medical Devices of the Republic of Slovenia), by providing mandatory instructions, expert opinions and motions for the collection of information and the implementation of other measures within their competence for the purpose of uncovering the criminal offence and its perpetrator or collecting information necessary to decide on the criminal prosecution. In the cases involving complex criminal offences, especially in the field of economy, corruption and organised crime which are the subject of pre-trial proceedings, and which require a long-term targeted operation of a number of above-stated bodies and institutions, the head of the competent state prosecutor's office may, *ex officio* or upon a written motion of the police, establish a specialised investigation team together with the heads of particular bodies and institutions stated above. The "Decree on cooperation between the state prosecutor's office, the police and other competent national authorities and institutions in investigating and prosecuting criminal offenders and on the operation of specialised and joint investigation teams" (issued on the basis of Article 160.a, Paragraph 5 of the Criminal Procedure Act): regulates the procedure, the cases, time limits and the method of directing and informing in more detail. The cooperation includes mutual exchange of information, directing the work of police officers and representatives of other competent national authorities and institutions and directing the work of specialised investigation teams and of joint investigation team members.

If b) above:

Please provide the reference this policy,	
Please provide a web link where this may be located:	
Please briefly state what this policy provides for:	

If c) above:

If so, please briefly state what this is based on	

Spain	**QUESTION**	
	Has the national strategy and/or national action plan been put in place based on	
	a. A legislative requirement	X
	b. National policy	X
	c. Other	X

If a) above:

Please provide the reference to the provision	-Instrument of ratification of the Council of Europe Convention on the cour medical products and similar crimes involving threats to public health -BOE-A-2015-10389 Ley 36/2015, de 28 de septiembre, de Seguridad Na 11) , -BOE-A-1986-6859 Ley Orgánica 2/1986, de 13 de marzo, de Fuerzas y C Seguridad. -Directive 2011/62/EU, of 8 June 2011 (the "Directive"), amending Directiv the Community code relating to medicinal products for human use, as rega prevention of the entry into the legal supply chain of falsified medicinal pro subsequent changes to the national legislation
Please provide a web link:	https://www.boe.es/eli/es/ai/2011/10/28/(1 https://health.ec.europa.eu/system/files/2016-11/dir_2011_62_en_0.pdf
Please briefly state what this provides for:	"Within the framework of the National Security System, the Public Administrations with competences in areas of special interest of National Security, will be obliged to establish mechanisms for coordination and exchange of information, especially in relation to surveillance and alert systems for possible risks and threats".. Establishes coordination mechanisms between all security forces - The Directive 2011/62/EU introduces harmonised European

			measures to fight falsifications of medicinal products and ensure that medicines are safe and that the trade in medicines is rigorously controlled.

If b) above:

Please provide the reference this policy,	-Royal Decree 1275/2011 of 16 September, by which the State Agency "Agencia Española de Medicamentos y Productos Sanitarios" is created and its Statute approved. (article 7.26) -Amendments to Royal Legislative Decree 1/2015, of July 24, which approves the consolidated text of the Law on guarantees and rational use of medicines and medical devices, in response to Directive 2011/62/EU provided the basis for a number of legislative implementation measures carried out at a national level (e.g. - Royal Decree 870/2013, of November 8, regulating the distance sale at a distance to the public, through websites, of non-prescription medicinal products for human use.)
Please provide a web link where this may be located:	-Royal Decree 769/1987, de 19 de junio, sobre regulación de la Policía Judicial. (boe.es) -BOE-A-2015-8343 Real Decreto Legislativo 1/2015, de 24 de julio, por el que se aprueba el texto refundido de la Ley de garantías y uso racional de los medicamentos y productos sanitarios.
Please briefly state what this policy provides for:	"The members of the Organic Units of the Judicial Police must keep strict confidentiality on the evolution and result of the specific investigations that have been entrusted to them, as well as of all the information obtained through them. Violation of said duty will be corrected with disciplinary action, without prejudice to other responsibilities to which the itself could give rise. The obligation of reserve will not prevent, unless expressly prohibited by the competent Judge or Prosecutor, the exchange internal in the Organic Unit for better coordination and efficiency of services.." - Royal Decree 1/2015 incorporates the amendments introduced by Direct in particular degrading the internet sales, the requirements of medicines requiring safety features, dispositions concerning brokers and authenticity of active substances.

If c) above:

If so, please briefly state what this is based on	National strategy against counterfeit medicines 2016-2019 (is not updated). the principles contained therein continue to apply ESTRATEGIA FRENTE A MEDICAMENTOS FALSIFICADOS 2016–2019 (aemps.gob.es))

Switzerland

Has the national strategy and/or national action plan been put in place based on

a.	A legislative requirement	
b.	National policy	
c.	Other	X

If a) above:

Please provide the reference to the provision	
Please provide a web link:	
Please briefly state what this provides for:	

If b) above:

Please provide the reference this policy,	
Please provide a web link where this may be located:	
Please briefly state what this policy provides for:	

If c) above:

If so, please briefly state what this is based on	According to Art. 72a of the Therapeutic Products Act ("TPA") and guideline no. 17 of the Swiss Federal Council's Corporate Governance report, the Agency Council draws up strategic objectives and submits them to the Federal Council for approval. These strategic objectives are drawn up using recognised strategy development

			methods: sector and organisation analysis; defining vision, stakeholder value and positioning; SWOT analysis; deriving strategic priorities with key results; and finally formulating the individual strategic objectives. https://www.swissmedic.ch/swissmedic/en/home/about-us/swissmedic-swiss-agency-for-therapeutic-products/strategy.html	

Ukraine			
	Has the national strategy and/or national action plan been put in place based on		
	a. A legislative requirement		X
	b. National policy		
	c. Other		

If a) above:

Please provide the reference to the provision	Article 1 of the Law of Ukraine *on State Market Supervision and Control of Non-Food Products*
Please provide a web link:	https://zakon.rada.gov.ua/laws/show/2735-17#Text
Please briefly state what this provides for:	Market surveillance bodies interact and exchange information, as well as with customs authorities, central executive bodies that supervise and control products, law enforcement agencies, public consumer organizations (consumer associations) and associations of economic entities

If b) above:

Please provide the reference this policy,	
Please provide a web link where this may be located:	
Please briefly state what this policy provides for:	

If c) above:

If so, please briefly state what this is based on	

Table 3: (Q.3) If there is no legislative provision, national policy, national strategy or action plan in place, is there
a. Any State authority (e.g. police, customs, health product regulatory authority, ministry) with a policy, strategy or action plan to ensure that there is provision for cooperation and information exchange between the various authorities who are engaged in combating counterfeit medical products and similar crimes: Yes/No
b. Please provide the details of the authority with such provision and include a link or reference to the measure
c. If such a cooperation agreement exists, which authorities/services have signed it or have indicated an intention to sign]
d. Please specify the authorities/services/units included in the measure

- ***Police service (National, municipal/other) Yes/No***
- ***Customs service/border authority Yes/No***
- ***Health products regulatory authority Yes/No***
- ***Anti-doping authority Yes/No***
- ***Food safety authority/food consumer agency Yes/No***
- ***National INTERPOL NCB/Europol liaison office Yes/No***
- ***Other (specify only relevant authorities) Yes/No***

Armenia	**QUESTION**	**YES**	**NO**
	If there is no legislative provision, national policy, national strategy or action plan in place, is there:		
	l) Any State authority (e.g. police, customs, health product regulatory authority, ministry) with a policy, strategy or action plan to ensure that there is provision for cooperation and information exchange between the various authorities who are engaged in combating counterfeit medical products and similar crimes?	X	

	m) Please provide the details of the authority with such provision:	The Scientific Center of Drug and Medical Technology Expertise MoH RA
	n) If such a cooperation agreement exists, which authorities/services have signed it or have indicated an intention to sign	

	o) Please specify the authorities/services/units included in the measure		
	o. Police service (National, municipal/other)	X	
	p. Customs service/border authority	X	
	q. Health products regulatory authority	X	
	r. Anti-doping authority		
	s. Food safety authority/food consumer agency		
	t. National INTERPOL NCB/Europol liaison office		
	u. Other (specify only relevant authorities)	National security service	

Belgium		YES	NO
	If there is no legislative provision, national policy, national strategy or action plan in place, is there:		
	a) Any State authority (e.g. police, customs, health product regulatory authority, ministry) with a policy, strategy or action plan to ensure that there is provision for cooperation and information exchange between the various authorities who are engaged in combating counterfeit medical products and similar crimes?	X	

	b) Please provide the details of the authority with such provision:	Federal Agency for Medicines and Health Products
	c) If such a cooperation agreement exists, which authorities/services have signed it or have indicated an intention to sign	The cooperation is not formalised. It is based on our national legislation which allows information exchange between relevant authorities and services.

	d) Please specify the authorities/services/units included in the measure		
	a. Police service (National, municipal/other)	X	
	b. Customs service/border authority	X	
	c. Health products regulatory authority	X	
	d. Anti-doping authority	x	
	e. Food safety authority/food consumer agency	x	
	f. National INTERPOL NCB/Europol liaison office		
	g. Other (specify only relevant authorities)		

Bosnia and Herzegovina		OUI	NON
	S'il n'existe pas de disposition législative, de politique nationale, de stratégie nationale ou de plan national d'action, y a-t-il :		
	a) une autorité publique (police, douanes, autorité de réglementation des produits de santé, ministère, etc.) disposant d'une politique, d'une stratégie ou d'un plan d'action qui prévoit une coopération et un échange d'informations entre les diverses autorités chargées de la lutte contre la contrefaçon des produits médicaux et les autres infractions ?	OUI	

	b) Veuillez préciser de quelle autorité il s'agit.	Direction pour la Coordination des Corps de Police de la Bosnie-Herzegovine- Secteur de la Coopération Policière Opérationnelle Internat
	c) S'il existe un accord de coopération, quels sont les services ou autorités l'ayant signé ou ayant fait part de leur intention de le signer ?	L'accord définit les droits et obligations réciproques pour l'utilisation du système d'information et des bases de données d'INTERPOL, qui comprend un accès direct à INTERPOL via un réseau mondial sécurisé de comm policière I-24/7, EUROPOL via Siena et SELEC. Des accords de coopération ont été signés avec l'Agence pour les examens et expertises médico-légaux, les tribunaux, les parquets, les autorités re compris la Police de Frontiere de la Bosnie-Herzegovine (15 agences), l'Adminis impôts indirects de la Bosnie-Herzégovine dans laquelle se trouve la Douane, le Ministère de la Justice de Bosnie-Herzégovine. Une coopération a également été établie avec l'Agence des médicaments et des dispositifs médicaux, l'Agence de contrôle antidopage et l'Agence pour la sécurité de l'alimentation et des consommateurs. La Direction pour la Coordination des Corps de Police de la Bosnie-Herzegovine coopère avec toutes les autorités compétentes sur le plan national et international concernant tous les actes criminels à caractèr y compris la criminalité pharmaceutique.

	Il n'existe pas de réseau d'échange d'informations exclusivement dans ce domaine dans le cadre de la Convention Medicrime.	

d) Veuillez mentionner les autorités/services/unités concernés par la mesure	
a. Police (nationale, municipale, autre)	oui
b. Service des douanes/autorité aux frontières	oui
c. Autorité de réglementation des produits de santé	oui
d. Autorité de lutte contre le dopage	oui
e. Autorité de sécurité des aliments/organisme pour l'alimentation et les consommateurs	oui
f. Bureau central national (BCN) d'INTERPOL/bureau de liaison d'Europol	oui
g. Autre (citez uniquement les autorités concernées)	Les tribunaux, les parquets

Burkina Faso

No data content

Croatia

	YES	NO
If there is no legislative provision, national policy, national strategy or action plan in place, is there:		
a) Any State authority (e.g. police, customs, health product regulatory authority, ministry) with a policy, strategy or action plan to ensure that there is provision for cooperation and information exchange between the various authorities who are engaged in combating counterfeit medical products and similar crimes?	X	

b) Please provide the details of the authority with such provision:	Agreement on Cooperation (Memorandum of Understanding) between Agency for Medicinal Products and Medical Devices and Ministry of Interior
c) If such a cooperation agreement exists, which authorities/services have signed it or have indicated an intention to sign	Agency for Medicinal Products and Medical Devices and Ministry of Interior

	YES	NO
d) Please specify the authorities/services/units included in the measure		
a. Police service (National, municipal/other)	X	
b. Customs service/border authority	X	
c. Health products regulatory authority	X	
d. Anti-doping authority		
e. Food safety authority/food consumer agency		
f. National INTERPOL NCB/Europol liaison office		
g. Other (specify only relevant authorities)		

France

	OUI/NON	NON
S'il n'existe pas de disposition législative, de politique nationale, de stratégie nationale ou de plan national d'action, y a-t-il :		
a) une autorité publique (police, douanes, autorité de réglementation des produits de santé, ministère, etc.) disposant d'une politique, d'une stratégie ou d'un plan d'action qui prévoit une coopération et un échange d'informations entre les diverses autorités chargées de la lutte contre la contrefaçon des produits médicaux et les autres infractions ?	X OUI	

b) Veuillez préciser de quelle autorité il s'agit.	1) En matière de police judiciaire, il a été créé par le Décret n°2004-612 du 24 juin 2004 un Office centra les atteintes à l'environnement et à la santé publiqu Cet office est chargé : 1° D'animer et de coordonner, à l'échelon national et au plan opérationnel, les investigations de police judiciaire ; 2° D'observer et d'étudier les comportements les plus caractéristiques des auteurs et complices ; 3° De centraliser les informations relatives à cette forme de délinquance en favorisant leur meilleure circulation ;

	4° D'assister les unités de la gendarmerie nationale et les services de la police nationale, ainsi que ceux de tous les autres ministères intéressés. Cette assistance ne dessaisit pas les services investis des recherches ; 5° De participer à des actions de formation et d'information. https://www.legifrance.gouv.fr/loda/id/JORFTEXT000000801169 2) En matière douanière : la DGDDI a un plan national de lutte 3) contre la contrefaçon pour 2022-2023, qui comprend 4) la contrefaçon de médicaments. Ces autorités échangent avec leurs homologues (douanes, polices étrangères) ainsi qu'avec les partenaires institutionnels en matière de santé publique, notamment le ministère de la Justice pour ce qui est du suivi de l'action pénale (DACG)
c) S'il existe un accord de coopération, quels sont les services ou autorités l'ayant signé ou ayant fait part de leur intention de le signer ?	Voir Décret n°2004-612 du 24 juin 2004 un Office central de lutte contre les atteintes à l'environnement et à la santé publique. https://www.legifrance.gouv.fr/loda/id/JORFTEXT000000801169 Premier ministre ; Garde des sceaux, ministre de la justice ; Ministres d'Etats de l'économie, des finances et de l'industrie ; Ministres de : - La santé et de la protection sociale, - l'intérieur, de la sécurité intérieure et des libertés - locales, - la défense, - l'équipement, des transports, de - l'aménagement du territoire, - tourisme et de la mer, - l'agriculture, de l'alimentation, de la pêche et des - affaires rurales, - l'écologie et du développement durable, - l'outre-mer,

En droit français, la stricte contrefaçon d'un produit entre dans le champ de compétence des Douanes. Ces services sont chargés notamment du contrôle des flux en import et export.

Les services de Police et de Gendarmerie sont quant à eux en charge de la lutte contre le trafic de ces produits et donc contre les structures criminelles impliquées dans cette typologie criminelle.

Le Ministère de l'Intérieur, par le truchement d'un Office Central spécialisé (OCLAESP), a défini 2 axes :

1 – lutter plus efficacement contre les structures spécialisées dans les trafics de produits de santé en:
   a. conservant le niveau d'expertise et de technicité;
   b. formant les polices et magistrats des états aux problématiques en la matière;
   c. développant les capacités de lutte contre ces structures, notamment par l'utilisation de techniques spécifiques d'enquête;
   d. développant des capacités d'animation et de traitement du renseignement criminel et des capacités de détection de ces structures, notamment grâce à des partenariats entre les forces de police, les autorités sanitaires et le secteur privé;

2 – construire une ambition européenne de lutte contre ces trafics:
   a. par l'intermédiaire d'opérations de lutte globale sous l'égide d'EUROPOL (SHIELD: Opération contre les trafics de produits de santé en Europe) :
   b. par la prise de conscience au niveau européen de la nécessité de conception d'une priorité « crime pharmaceutique » dans le prochain cycle politique de l'UE (2022-2025).

La Direction des Affaires criminelles et des Grâces (DACG) du Ministère de la Justice a par ailleurs diffusé une fiche technique dite « fiche FOCUS » dès 2014 à l'attention de tous les magistrats relative aux médicaments falsifiés et contrefaits pour présenter les dispositions transposant en droit interne la directive européenne 2011/62/UE du 16 mai 2011, modifiant la directive 2001/83/CE « instituant un code communautaire relatif aux médicaments à usage humain, en ce qui concerne la prévention de l'introduction dans la chaîne d'approvisionnement légale de médicaments falsifiés » .

Dès décembre 2011, le Ministère de la Justice, associé à la Direction générale de la consommation, de la concurrence et de la répression des fraudes (DGCCRF), au Ministère de l'Intérieur (service de police et de gendarmerie), au Ministère de l'Economie et des Finances (douanes) et aux agences de santé, publiait le

MEDIGUIDE. Cet outil présentait notamment les services compétents et les infractions applicables afin de faciliter la lutte contre les trafics de produits de santé et de médicaments.

Le Ministère de la Justice a également diffusé une dépêche le 15 mars 2013 relative à l'entrée en vigueur de l'ordonnance n°2012-1427 du 19 décembre 2012 relative à au renforcement de la sécurité de la chaîne d'approvisionnement des médicaments, à l'encadrement de la vente de médicaments sur internet et à la lutte contre la falsification. Cette dépêche définit les orientations générales de politique pénale en la matière. De façon corrolaire, la DACG a publié une circulaire le 24 septembre 2013 sur les relations entre les parquets et les ordres des professions en lien avec la santé publique et une circulaire en date du 16 décembre 2014 présentant les dispositions de l'ordonnance n° 2013-1183 du 19 décembre 2013 relative à l'harmonisation des sanctions pénales et financières relatives aux produits de santé et à l'adaptation des prérogatives des autorités et des agents chargés de constater les manquements, et des textes pris pour son application.

Les dispositions de ces différents textes restent d'actualité, et les circulaires et dépêches de politique pénale en matière de santé publique s'y réfèrent régulièrement.

La DACG organise enfin régulièrement des séminaires réunissant les magistrats des « Pôles de santé publique et de l'environnement » sur différentes thématiques de santé publique ; un prochain séminaire est prévu en septembre 2023, le dernier ayant eu lieu le 12 octobre 2020 concernant les relations entre l'autorité judiciaire et les administrations dans les enquêtes de santé publique.

En matière de santé publique, toutes les autorités en charge de ces questions ont initié des échanges d'informations en collaborant directement (ANSM, ANSES (ANMV), Ordre National des Pharmaciens, Ordres des médecins, BNEVP, DIRRECTE, DGCCRF, AFLD, CNAMTS, etc).

Lorsqu'une autorité ayant pouvoir de contrôle en matière sanitaire constate ou détecte une suspicion d'atteinte à la santé publique, elle en informe l'autorité judiciaire par le biais d'un article 40. Cette information débouche alors sur la mise en mouvement de l'action publique par la réalisation d'investigations par les forces de police.

		OUI
d)	Veuillez mentionner les autorités/services/unités concernés par la mesure	
a.	Police (nationale, municipale, autre)	X
b.	Service des douanes/autorité aux frontières	X
c.	Autorité de réglementation des produits de santé	X
d.	Autorité de lutte contre le dopage	X
e.	Autorité de sécurité des aliments/organisme pour l'alimentation et les consommateurs	X
f.	Bureau central national (BCN) d'INTERPOL/bureau de liaison d'Europol	X
g.	Autre (citez uniquement les autorités concernées)	

Hungary

		YES	NO
If there is no legislative provision, national policy, national strategy or action plan in place, is there:			
a)	Any State authority (e.g. police, customs, health product regulatory authority, ministry) with a policy, strategy or action plan to ensure that there is provision for cooperation and information exchange between the various authorities who are engaged in combating counterfeit medical products and similar crimes?	×	

b)	Please provide the details of the authority with such provision:	NBAC has set up a Working Group on Counterfeiting of Medicines, whose members are the authorities involved in the counterfeiting of medicines, as well as representatives of pharmaceutical wholesalers and pharmaceutical companies who may be affected by the phenomenon. In 2015, a Cooperation Agreement was issued to record the details of the cooperation jointly with the relevant authorities, NBAC and healthcare providers.
c)	If such a cooperation agreement exists, which authorities/services have signed it or have indicated an intention to sign	Police, The Customs, Health authority, NBAC, National Food Chain Safety Office.

		YES	NO
d)	Please specify the authorities/services/units included in the measure		
a.	Police service (National, municipal/other)	×	
b.	Customs service/border authority	×	
c.	Health products regulatory authority	×	
d.	Anti-doping authority		**X**

			but there is a cooperation agreement between Police and Anti-doping agency
	e. Food safety authority/food consumer agency	x	
	f. National INTERPOL NCB/Europol liaison office		x
	g. Other		x

Ireland

	YES	NO
If there is no legislative provision, national policy, national strategy or action plan in place, is there:		
a) Any State authority (e.g. police, customs, health product regulatory authority, ministry) with a policy, strategy or action plan to ensure that there is provision for cooperation and information exchange between the various authorities who are engaged in combating counterfeit medical products and similar crimes?	Yes	

b) Please provide the details of the authority with such provisions:	There is no single provision. Provisions are agreed upon between different authorities on combating crime related to medical products 1. Health Products Regulatory Authority 2. Irish Customs Service (Revenue Customs Service) 3. Sport Ireland 4. Food Safety Authority of Ireland 5. Irish Police Service (Garda Síochána) is mandated by the Garda Síochána Act 2007, S.7, to cooperate with State authorities with responsibilities mandated by law in relation to policing objectives of the Garda Síochána (https://www.irishstatutebook.ie/eli/2005/act/20/section/7/enacted/en/html#sec7)
c) If such a cooperation agreement exists, which authorities/services have signed it or have indicated an intention to sign	Health Products Regulatory Authority has signed separate Memorandums of Understanding on cooperation and information exchange with the Irish Customs Service, Sport Ireland, and the Food Safety Authority of Ireland. The Health Products Regulatory Authority has also signed a Data Sharing Agreement with the Irish Customs Service. Health Products Regulatory Authority has an official structured liaison arrangement with the Irish Police Service regarding information and cooperation. This is not at this stage supported by either a Memorandum of Understanding, which has been drafted, or Data Sharing Agreement, but falls under cooperation provisions of S.7, Garda Síochána Act. Health Products Regulatory Authority may cooperate with other named State Authorities and others, including matters in this topic, in the enforcement of medical device regulations (https://www.irishstatutebook.ie/eli/2021/si/261/made/en/print). Similar provisions have been drafted as regards all medical products for inclusion in the Irish Medicines Board Act amendments.

	YES	NO
d) Please specify the authorities/services/units included in the measures		
Police service (National, municipal/other)	Yes	
a. Customs service/border authority	Yes	
b. Health products regulatory authority	Yes	
c. Anti-doping authority	Yes	
d. Food safety authority/food consumer agency	Yes	
e. National INTERPOL NCB/Europol liaison office	Yes	
f. Other (specify only relevant authorities)		

Moldova

	YES	NO
If there is no legislative provision, national policy, national strategy or action plan in place, is there:		
a) Any State authority (e.g. police, customs, health product regulatory authority, ministry) with a policy, strategy or action plan to ensure that there is provision for cooperation and information exchange between the various authorities who are engaged in combating counterfeit medical products and similar crimes?	-	No

b) Please provide the details of the authority with such provision:	Any of the cases identified by a competent authority is communicated to other relevant authority on a case by case basis.
c) If such a cooperation agreement exists, which authorities/services have signed it or have indicated an intention to sign	There are no formal agreements between competent authorities.

		YES	**NO**
	d) Please specify the authorities/services/units included in the measure		
	a. Police service (National, municipal/other)	Yes	-
	b. Customs service/border authority	Yes	-
	c. Health products regulatory authority	Yes	-
	d. Anti-doping authority	-	No
	e. Food safety authority/food consumer agency	Yes	-
	f. National INTERPOL NCB/Europol liaison office	Yes	-
	g. Other (specify only relevant authorities)	-	No

Morocco		**OUI**	**NON**
	S'il n'existe pas de disposition législative, de politique nationale, de stratégie nationale ou de plan national d'action, y a-t-il :		
	a) une autorité publique (police, douanes, autorité de réglementation des produits de santé, ministère, etc.) disposant d'une politique, d'une stratégie ou d'un plan d'action qui prévoit une coopération et un échange d'informations entre les diverses autorités chargées de la lutte contre la contrefaçon des produits médicaux et les autres infractions ?		

	b) Veuillez préciser de quelle autorité il s'agit.	
	c) S'il existe un accord de coopération, quels sont les services ou autorités l'ayant signé ou ayant fait part de leur intention de le signer ?	Il existe des compte rendus de réunions avec la Présidence du Ministère Public et avec les services de la Douane.

		OUI
	d) Veuillez mentionner les autorités/services/unités concernés par la mesure	
	a. Police (nationale, municipale, autre)	
	b. Service des douanes/autorité aux frontières	
	c. Autorité de réglementation des produits de santé	
	d. Autorité de lutte contre le dopage	
	e. Autorité de sécurité des aliments/organisme pour l'alimentation et les consommateurs	
	f. Bureau central national (BCN) d'INTERPOL/bureau de liaison d'Europol	
	g. Autre (citez uniquement les autorités concernées)	

Portugal		**YES**	**NO**
	If there is no legislative provision, national policy, national strategy or action plan in place, is there:		
	a) Any State authority (e.g. police, customs, health product regulatory authority, ministry) with a policy, strategy or action plan to ensure that there is provision for cooperation and information exchange between the various authorities who are engaged in combating counterfeit medical products and similar crimes?	yes	

	b) Please provide the details of the authority with such provision:	Autoridade do Medicamento - Infarmed, IP
	c) If such a cooperation agreement exists, which authorities/services have signed it or have indicated an intention to sign	AT (Tax and Customs Authority) Protocol signed by the Medicines Authority and Tax Administration, with a view to combating the entry of illegal and counterfeit medicines into the country. https://www.infarmed.pt/documents/15786/1269504/Plano+Estrat%C3%A9gico+2020-2022/1f490fe2-998a-4e64-bca9-939862f34217

		YES	**NO**
	d) Please specify the authorities/services/units included in the measure		
	a. Police service (National, municipal/other)		
	b. Customs service/border authority	yes	
	c. Health products regulatory authority	yes	
	d. Anti-doping authority	yes	
	e. Food safety authority/food consumer agency		
	f. National INTERPOL NCB/Europol liaison office		
	g. Other (specify only relevant authorities)		

Slovenia		**YES**	**NO**
	If there is no legislative provision, national policy, national strategy or action plan in place, is there:		
	a) Any State authority (e.g. police, customs, health product regulatory authority, ministry) with a policy, strategy or action plan to ensure that	MF: Government of Republic of Slovenia established Working group for the implementation of	

	there is provision for cooperation and information exchange between the various authorities who are engaged in combating counterfeit medical products and similar crimes?	the Council of Europe Convention on the counterfeiting of medical products and similar crimes that endanger public health. MKGP	

b)	Please provide the details of the authority with such provision:	JAZMP: On the basis of Article 4 of Act on Ratification of Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health, the Ministry of Health is responsible for the implementation of the Convention, in cooperation with the ministry responsible for justice, the ministry responsible for internal affairs, the ministry responsible for the customs system, the ministry responsible for veterinary medicine, the ministry responsible for foreign affairs, and the Supreme State Prosecutor's Office of the Republic of Slovenia. MF: The following authorities are taking part in the Working group: Ministry of Health, Ministry of Justice, Ministry of the Interior, Ministry of finance, Ministry of Agriculture, Forestry and Food, Supreme State Prosecutor's Office, Agency for Medicinal Products and Medical Devices. MKGP: Veterinary Compliance Criteria Act, Article 72., 3rd para and article 79
c)	If such a cooperation agreement exists, which authorities/services have signed it or have indicated an intention to sign	JAZMP: There is no signed agreement. For the purpose of implementation of the Convention, the Government of the Republic of Slovenia appointed a special working group consisting of members from different authorities (i.e. above mentioned ministries and Agency for Medicinal Products and Medical Devices) MF: Ministry of Health, Ministry of Justice, Ministry of the Interior, Ministry of finance, Ministry of Agriculture, Forestry and Food, Supreme State Prosecutor's Office; Agency for Medicinal Products and Medical Devices

		YES	**NO**
d)	Please specify the authorities/services/units included in the measure		
	a. Police service (National, municipal/other)	JAZMP MP	
	b. Customs service/border authority	JAZMP MF MP	
	c. Health products regulatory authority	JAZMP MP	
	d. Anti-doping authority		JAZMP
	e. Food safety authority/food consumer agency	JAZMP MP	
	f. National INTERPOL NCB/Europol liaison office	MP: YES (in cases of Joint Investigation Teams)	JAZMP
	g. Other (specify only relevant authorities)	JAZMP: Ministry of Justice, Ministry of Foreign Affairs, The State Prosecutors Office	

		MKGP: MKGP	

Spain

	YES	NO
If there is no legislative provision, national policy, national strategy or action plan in place, is there:		
a) Any State authority (e.g. police, customs, health product regulatory authority, ministry) with a policy, strategy or action plan to ensure that there is provision for cooperation and information exchange between the various authorities who are engaged in combating counterfeit medical products and similar crimes?	x	

b) Please provide the details of the authority with such provision:	(1) Framework Agreement between the Higher Sports Council, the Secretary of State for Security and Law Enforcement. (2) Collaboration Agreement between the Ministry of Health and Guardia Civil
c) If such a cooperation agreement exists, which authorities/services have signed it or have indicated an intention to sign	(1) Higher Sports Council, Secretary of State for Security, Guardia Civil, National Police. (2) Ministry of Health and Guardia Civil

	YES	NO
d) Please specify the authorities/services/units included in the measure		
a. Police service (National, municipal/other)	x	
b. Customs service/border authority	x	
c. Health products regulatory authority	x	
d. Anti-doping authority	x	
e. Food safety authority/food consumer agency		
f. National INTERPOL NCB/Europol liaison office	x	
g. Other (specify only relevant authorities)		

Switzerland

	YES	NO
If there is no legislative provision, national policy, national strategy or action plan in place, is there:		
a) Any State authority (e.g. police, customs, health product regulatory authority, ministry) with a policy, strategy or action plan to ensure that there is provision for cooperation and information exchange between the various authorities who are engaged in combating counterfeit medical products and similar crimes?		

* This question is misleading insofar as legislative provisions were not specifically asked about in Question 1 (only in Question 2 as basis for a national strategy and/or national action plan). Indeed, Swiss law provides for the exchange of information between authorities in relation to combating the counterfeiting of medical products and similar crimes (cf. Art. 63 TPA).

b) Please provide the details of the authority with such provision:	
c) If such a cooperation agreement exists, which authorities/services have signed it or have indicated an intention to sign	

	YES	NO
d) Please specify the authorities/services/units included in the measure		
a. Police service (National, municipal/other)		
b. Customs service/border authority		
c. Health products regulatory authority		
d. Anti-doping authority		
e. Food safety authority/food consumer agency		
f. National INTERPOL NCB/Europol liaison office		
g. Other (specify only relevant authorities)		

Ukraine

	YES	NO
If there is no legislative provision, national policy, national strategy or action plan in place, is there:		
a)Any State authority (e.g. police, customs, health product regulatory authority, ministry) with a policy, strategy or action plan to ensure that there is provision for cooperation and information exchange between the various authorities who are engaged in combating counterfeit medical products and similar crimes?	X	

a) Please provide the details of the authority with such provision:	The State Service of Ukraine on Medicines and Drugs Control is the central executive body that implements state policy in the field of quality and safety control of medicinal products

	b) If such a cooperation agreement exists, which authorities/services have signed it or have indicated an intention to sign	A permanent working group on monitoring the distribution channels of falsified drugs, substances imported into the territory of Ukraine, the movement of used and decommissioned technological equipment that can be used for the production of falsified drugs, as well as countermeasures in the field of illegal circulation of medical products, narcotic drugs, psychotropic substances and precursors, approved by the order of the State Service of Ukraine on Medicines and Drugs Control dated 16.06.2021 No. 662 *On Amendments to the Order of the State Medical Service dated 25.01.2019 No. 13;* - Memorandum on cooperation between the State Service of Ukraine on Medicines and Drugs Control and the Security Service of Ukraine; - Memorandum on cooperation between the State Service of Ukraine on Medicines and Drugs Control and the National Police of Ukraine; - Memorandum on partnership and cooperation between the State Service of Ukraine on Medicines and Drugs Control and the State Border Service of Ukraine; - Memorandum on partnership and cooperation between the State Service of Ukraine on Medicines and Drugs Control and the State Service of Ukraine on Food Safety and Consumer Protection; - Memorandum on cooperation in the control of medicines and narcotic drugs with the State Tax Service of Ukraine

		YES	NO
c)	Please specify the authorities/services/units included in the measure		
a.	Police service (National, municipal/other)	X	
b.	Customs service/border authority	X	
c.	Health products regulatory authority	X	
d.	Anti-doping authority		
e.	Food safety authority/food consumer agency	X	
f.	National INTERPOL NCB/Europol liaison office		
g.	Other (specify only relevant authorities)	X	

Table 4: (Q.4) Does any of the above measures (legislative provision, national policy, strategy, action plan or other structured measures) (Article 17, paragraph 2)
a. provide for cooperation between the competent authorities (for the investigation of crime, border surveillance, health product regulation, other relevant authorities) and the industrial sector as regards risk management of counterfeit medical products and similar crimes involving threats to public health: Yes/No
b. Specify what the measure is
c. Specify how this cooperation works in practice
d. Specify which authority/ies is/are responsible or have the lead or coordinating role for this

Armenia			YES	NO
	Does any of the above measures (legislative provision, national policy, strategy, action plan or other structured measures) (**Article 17, paragraph 2**)			
	a.	Provide for cooperation between the competent authorities (for the investigation of crime, border surveillance, health product regulation, other relevant authorities) and the industrial sector as regards risk management of counterfeit medical products and similar crimes involving threats to public health	X	
	b.	Specify, briefly, what the measure is	Training, collaboration among authorities in criminal cases	

	c. Specify, briefly, how this cooperation works in practice	With collaboration with any of specified authorities in criminal proceedings and training		
	d. Specify which authority/ies is/are responsible or have the lead or coordinating role for this	Health product authorities, police customs, national security services		
Belgium		**YES**	**NO**	
	Does any of the above measures (legislative provision, national policy, strategy, action plan or other structured measures) (**Article 17, paragraph 2**)			
	a. Provide for cooperation between the competent authorities (for the investigation of crime, border surveillance, health product regulation, other relevant authorities) and the industrial sector as regards risk management of counterfeit medical products and similar crimes involving threats to public health	X		
	b. Specify, briefly, what the measure is	Established operational cooperation between authorities and services		
	c. Specify, briefly, how this cooperation works in practice	Regular meetings to discuss cases and establish contact-point for exchange of information and cooperation		
	d. Specify which authority/ies is/are responsible or have the lead or coordinating role for this	FAMHP-police/justice-Customs		
Bosnia and Herzegovina		**OUI**		**NON**
	Les mesures citées plus haut (disposition législative, politique nationale, stratégie nationale, plan national d'action ou autre mesure structurée) (**Article 17, paragraphe 2**)			
	a. prévoient-elles des dispositions pour assurer la coopération entre les autorités compétentes (à savoir les autorités chargées des enquêtes sur les infractions pénales, de la surveillance des frontières et de la réglementation des produits de santé, et les autres autorités compétentes) et le secteur industriel en ce qui concerne la gestion des risques liés à la contrefaçon de produits médicaux et aux infractions similaires menaçant la santé publique ?			NON
	b. Précisez brièvement en quoi consiste la mesure			
	c. Indiquez brièvement comment fonctionne concrètement la coopération.			
	d. Précisez quelle(s) autorité(s) est/sont chargée(s) de/dirige(nt)/coordonne(nt) la coopération.			
Burkina Faso		**OUI**		**NON**
	Les mesures citées plus haut (disposition législative, politique nationale, stratégie nationale, plan national d'action ou autre mesure structurée) (**Article 17, paragraphe 2**)			
	a. prévoient-elles des dispositions pour assurer la coopération entre les autorités compétentes (à savoir les autorités chargées des enquêtes sur les infractions pénales, de la surveillance des frontières et de la réglementation des produits de santé, et les autres autorités compétentes) et le secteur industriel en ce qui concerne la gestion des risques liés à la contrefaçon de produits médicaux et aux infractions similaires menaçant la santé publique ?	Non		NON
	b. Précisez brièvement en quoi consiste la mesure	NSP		
	c. Indiquez brièvement comment fonctionne concrètement la coopération.	NSP		
	d. Précisez quelle(s) autorité(s) est/sont chargée(s) de/dirige(nt)/coordonne(nt) la coopération.	NSP		
Croatia	**QUESTION**	**YES**	**NO**	
	Does any of the above measures (legislative provision, national policy, strategy, action plan or other structured measures) (**Article 17, paragraph 2**)			
	a. Provide for cooperation between the competent authorities (for the investigation of crime, border surveillance, health product regulation, other relevant authorities) and the industrial sector as regards risk management of counterfeit medical products and similar crimes involving threats to public health	X		
	b. Specify, briefly, what the measure is	Cooperation and information exchange between public authorities is mandatory within the limits of their jurisdiction.		

		The legal provision in the Law on the system of the state administration ("Official Gazette", no 66/19), Article 8(1) .
	c. Specify, briefly, how this cooperation works in practice	If any administration needs information from another administration, it can request it. Also, if any administration gets an information that is in the scope of activity of another administration, it will share it with this administration. Marketing authorisation holder send information to Croatian health agency about cases of counterfeiting of their medicines, and the agency informs the authorization holder about cases of potential falsification of its products and asks for help regarding the authenticity of the batches found
	d. Specify which authority/ies is/are responsible or have the lead or coordinating role for this	It is left to these administrations to define the scope, range and model of the information exchange.

France				
		OUI		**NON**
	Les mesures citées plus haut (disposition législative, politique nationale, stratégie nationale, plan national d'action ou autre mesure structurée) (**Article 17, paragraphe 2**)			
	a. prévoient-elles des dispositions pour assurer la coopération entre les autorités compétentes (à savoir les autorités chargées des enquêtes sur les infractions pénales, de la surveillance des frontières et de la réglementation des produits de santé, et les autres autorités compétentes) et le secteur industriel en ce qui concerne la gestion des risques liés à la contrefaçon de produits médicaux et aux infractions similaires menaçant la santé publique ?	X		

	b. Précisez brièvement en quoi consiste la mesure	Le ministère de l'Intérieur, par le biais de ses ser particulier l'OCLAESP, et au travers de conventio partenariat, dirige des actions de sensibilisation a pouvoirs publics et des autorités de santé et entretient des relatio suivies avec l'industrie pharmaceutique, les gros répartiteurs et les officines en vue de sensibilise de la criminalité organisée et du crime pharmaceutique
	c. Indiquez brièvement comment fonctionne concrètement la coopération.	
	d. Précisez quelle(s) autorité(s) est/sont chargée(s) de/dirige(nt)/coordonne(nt) la coopération.	

Les services de la Police et de la Gendarmerie, aux côtés de la Douane et des ordres des pharmaciens et des médecins, participent aux réunions du comité du LEEM (les entreprises du médicament), aux travaux du G5 (groupe de huit laboratoires français dont SANOFI, SERVIER, IPSEN, PIERRE FABRE) et échange de façon régulière avec les groupes anti-contrefaçon et protection des marques des grands laboratoires pharmaceutiques.

Hungary				
		YES		**NO**
	Does any of the above measures (legislative provision, national policy, strategy, action plan or other structured measures) (**Article 17, paragraph 2**)			
	a. Provide for cooperation between the competent authorities (for the investigation of crime, border surveillance, health product regulation, other relevant authorities) and the industrial sector as regards risk management of counterfeit medical products and similar crimes involving threats to public health	x		

	b. Specify, briefly, what the measure is	Eight-party cooperation agreement.
	c. Specify, briefly, how this cooperation works in practice	Formal and informal cooperation exist among the Police, the Customs and OGYÉI as well. The informal cooperation between the Police and the Customs is maintained via phone and also face-to-face meetings. With the coordination and support of the Hungarian Intellectual Property Office (hereinafter: HIPO), an eight-party

		cooperation agreement is being prepared to combat counterfeiting, cross-border distribution and trade in falsified medicines, in particular to facilitate cooperation and exchange of information between the various authorities and stakeholders.
	d. Specify which authority/ies is/are responsible or have the lead or coordinating role for this	Coordinator: HIPO. The interested parties signing the agreement are: The National Tax and Customs Administration, The National Police Headquarters, The National Institute of Pharmacy and Nutrition (OGYÉI), and pharmaceutical industry associations whose member companies are marketing authorisation holders or pharmaceutical distributors or wholesalers in Hungary.

Ireland

	YES	**NO**
Does any of the above measures (legislative provision, national policy, strategy, action plan or other structured measures) (**Article 17, paragraph 2**)		
a. Provide for cooperation between the competent authorities (for the investigation of crime, border surveillance, health product regulation, other relevant authorities) and the industrial sector as regards risk management of counterfeit medical products and similar crimes involving threats to public health	Yes	

b. Specify, briefly, what the measure is	Licensing agreements with medical product authorisation holders
c. Specify, briefly, how this cooperation works in practice	When a counterfeit medical products is suspected or identified, the Health Products Regulatory Authority communicates with the relevant industry entity/ies as regards risk management issues
d. Specify which authority/ies is/are responsible or have the lead or coordinating role for this	Health Products Regulatory Authority

Moldova

	YES	**NO**
Does any of the above measures (legislative provision, national policy, strategy, action plan or other structured measures) (**Article 17, paragraph 2**)		
a. Provide for cooperation between the competent authorities (for the investigation of crime, border surveillance, health product regulation, other relevant authorities) and the industrial sector as regards risk management of counterfeit medical products and similar crimes involving threats to public health		

b. Specify, briefly, what the measure is	According to the provisions set out in Order of the Ministry of Health No. 1400 of 09.12.2014 on the approval of the Rules of Good Distribution Practice of Medicines (GDP) for human use, " Wholesale distributors must immediately inform the competent authority and the marketing authorisation holder of any medicinal products they identify as falsified or suspect to be falsified".
c. Specify, briefly, how this cooperation works in practice	No such cases have been reported.
d. Specify which authority/ies is/are responsible or have the lead or coordinating role for this	Currently, there Is no competent authority assigned to take the lead or coordinating role for this. Any of the cases identified being managed on a case by case basis.

Morocco

	OUI		**NON**
Les mesures citées plus haut (disposition législative, politique nationale, stratégie nationale, plan national d'action ou autre mesure structurée) (**Article 17, paragraphe 2**)			
a. prévoient-elles des dispositions pour assurer la coopération entre les autorités compétentes (à savoir les autorités chargées des enquêtes sur les infractions pénales, de la surveillance des frontières et de la réglementation des produits de santé, et les autres autorités compétentes) et le secteur industriel en ce qui concerne la gestion des risques liés à la contrefaçon de produits médicaux et aux infractions similaires menaçant la santé publique ?	x		

b. Précisez brièvement en quoi consiste la mesure	Il s'agit d'une collaboration de l'autorité de avec les services de la Douane, la Présid

		Ministère Public, la Direction Générale de la Sûreté Nationale	
	c. Indiquez brièvement comment fonctionne concrètement la coopération.		
	d. Précisez quelle(s) autorité(s) est/sont chargée(s) de/dirige(nt)/coordonne(nt) la coopération.		

Portugal		YES	NO
	Does any of the above measures (legislative provision, national policy, strategy, action plan or other structured measures) (**Article 17, paragraph 2**)		
	a. Provide for cooperation between the competent authorities (for the investigation of crime, border surveillance, health product regulation, other relevant authorities) and the industrial sector as regards risk management of counterfeit medical products and similar crimes involving threats to public health	yes	

	b. Specify, briefly, what the measure is	Control, border inspections and the obligation to remove counterfeit products or products that pose a threat to public health from the market.
	c. Specify, briefly, how this cooperation works in practice	Exchange of information between Entities.
	d. Specify which authority/ies is/are responsible or have the lead or coordinating role for this	Autoridade tributária, Infarmed e no doping a Autoridade Anti Doping (ADOP) e Polícia Judiciária (PJ) e ASAE (Autoridade para a Segurança Alimentar e Económica).

Slovenia		YES	NO
	Does any of the above measures (legislative provision, national policy, strategy, action plan or other structured measures) (**Article 17, paragraph 2**)		
	a. Provide for cooperation between the competent authorities (for the investigation of crime, border surveillance, health product regulation, other relevant authorities) and the industrial sector as regards risk management of counterfeit medical products and similar crimes involving threats to public health	JAZMP MKGP	MF MP

	b. Specify, briefly, what the measure is	JAZMP: Legislative provision: Article 4 of Act on Ratification of Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public. Based on this Article the Decision on Appointment of the working group was issued (with members appointed, certain work tasks and the method of operation and decision making) MKGP: Initiation of an inspection procedure for suspected use of unauthorised medicinal products (establishment of facts and circumstances and collection of material evidence from animal keepers)
	c. Specify, briefly, how this cooperation works in practice	JAZMP: The working group was nominated on 28. 4. 2022, but the working group has not yet been convened MKGP: Reporting a disputed consignment of veterinary medicinal products to the competent authority – Inspection of the Ministry of Agriculture, Forestry and Food
	d. Specify which authority/ies is/are responsible or have the lead or coordinating role for this	JAZMP: Ministry of Health MKGP: Depending on the authorities' competences. In the case of unauthorised use of a veterinary medicinal product, the competent authority is the Ministry of Agriculture, Forestry and Food.

Spain		YES	NO
	Does any of the above measures (legislative provision, national policy, strategy, action plan or other structured measures) (**Article 17, paragraph 2**)		

	a.	Provide for cooperation between the competent authorities (for the investigation of crime, border surveillance, health product regulation, other relevant authorities) and the industrial sector as regards risk management of counterfeit medical products and similar crimes involving threats to public health	x	

b.	Specify, briefly, what the measure is	1.Procedure for notification of thefts/diversion/losses of medicines (https://www.aemps.gob.es/industria-farmaceutica/industria_distribucion_medicamentos_instru_comunica_trafico_ilicito/) 2 .E-mail address to report to AEMPS any suspected and confirmed falsified medicine in the legal supply chain (medicamentos.falsificados@aemps.es).
c.	Specify, briefly, how this cooperation works in practice	-Development of police investigations detecting new modus operandi and establishing guidelines for action. - Procedure for notification of thefts/diversion/losses of medicines: 1. The communication of these events to the AEMPS is mandatory, in accordance to Royal Decree 782/2013, of 11 October, on distribution of medicinal products for human use. All the stakeholders involved (marketing authorisation holders, manufacturers, importers, wholesalers, logistic operators, pharmacies and hospital pharmacies) have to report these events. It is highly recommended that they also notify these cases to Police forces. 2. Marketing and manufacturing authorisation holders, wholesalers and health professionals should report to AEMPS if they detect any (suspected) falsification of a medicine that could pose a risk to public and animal health.
d.	Specify which authority/ies is/are responsible or have the lead or coordinating role for this	- Procedure for notification of thefts/diversion/losses of medicines: 1.The Pharmaceutical Inspection and Enforcement Department (AEMPS) is responsible of the database and the dissemination of information when needed. 2. The Pharmaceutical Inspection and Enforcement Department (AEMPS) is responsible of the information and the needed actions.

Switzerland

Does any of the above measures (legislative provision, national policy, strategy, action plan or other structured measures) (**Article 17, paragraph 2**)

	a.	Provide for cooperation between the competent authorities (for the investigation of crime, border surveillance, health product regulation, other relevant authorities) and the industrial sector as regards risk management of counterfeit medical products and similar crimes involving threats to public health		x

b.	Specify, briefly, what the measure is	Cooperation between the competent authorities and the other actors involved on a case-by-case basis, according to the pertinent provisions of the TPA
c.	Specify, briefly, how this cooperation works in practice	Exchange of information and/or data between the competent authorities and the other actors involved, in writing.
d.	Specify which authority/ies is/are responsible or have the lead or coordinating role for this	Swissmedic

Ukraine

			YES	**NO**
Does any of the above measures (legislative provision, national policy, strategy, action plan or other structured measures) (**Article 17, paragraph 2**)				
	a.	Provide for cooperation between the competent authorities (for the investigation of crime, border surveillance, health product regulation, other relevant authorities) and the industrial sector as regards risk management of counterfeit medical products and similar crimes involving threats to public health	X	

b.	Specify, briefly, what the measure is	In accordance with Article 15 of the *Law of Ukraine on Medicines*, officials of the central executive body, who implements state policy in the field of quality control and safety of medicinal products within the scope of

			competence defined by legislation, have the right to: -to transfer inspection materials containing signs of a criminal offense to pre-trial investigation bodies; -to make decisions in the established manner on withdrawal from circulation and prohibition (stopping) of production, sale and use of medicinal products that do not meet the requirements defined by normative legal acts and normative documents, as well as those imported into the territory of Ukraine or exported from the territory of Ukraine in violation of the procedure established by the Law. The Procedure for establishing a prohibition (temporary prohibition) and withdrawing medicinal products from circulation on the territory of Ukraine is established by the central executive body, that ensures the state policy making in the field of health care. According to the Procedure for establishing a prohibition (temporary prohibition) - As part of promoting the protection of intellectual property rights
		c. Specify, briefly, how this cooperation works in practice	- in accordance with Article 397 of the *Customs Code of Ukraine*, customs authorities take actions to promote the protection of intellectual property rights. - in accordance with Article 15 of the *Law of Ukraine on Medicines,* officials of the central executive body implementing state policy in the field of quality control and safety of medicinal products within the scope of competence defined by legislation have the right to: to transfer inspection materials containing signs of a criminal offense to pre-trial investigation bodies; to make decisions in the established manner on withdrawal from circulation and prohibition (stopping) of production, sale and use of medicinal products that do not meet the requirements defined by legal acts and normative documents, as well as those imported into the territory of Ukraine or exported from the territory of Ukraine in violation of the procedure established by law. The Procedure for establishing a prohibition (temporary prohibition) and withdrawing of medicinal products from circulation on the territory of Ukraine is established by the central executive body, which ensures the formation of state policy in the field of health care. According to the Procedure for establishing a prohibition (temporary prohibition) and resumption the circulation of medicinal products on the territory of Ukraine, approved by the order of the Ministry of Health of Ukraine of November 21, 2011 No. 809, in case of establishing the fact of the circulation of low-quality, falsified, unregistered medicinal products (except for the cases specified by the *Law of Ukraine on Medicines*) State Service of Ukraine on Medicines and Drugs Control: establishes a prohibition (temporary prohibition) on the circulation of the medicinal product; submits suggestion to the Ministry of Health of Ukraine regarding the adoption by the Ministry of Health of Ukraine of a decision to terminate the validity of the registration certificate of the corresponding medicinal product.

		In accordance with the Procedure for the termination of the validity of the registration certificate for a medicinal product, approved by the *Order of the Ministry of Health dated 05.08.2020 No. 1801 on the approval of the Procedure for the termination of the validity of the registration certificate for a medicinal product and the Regulation on the Commission of the Ministry of Health of Ukraine on the termination of the validity of the registration certificate for a medicinal product*, State Service of Ukraine on Medicines and Drug Control, Foreign Intelligence Service of Ukraine, State Enterprise "State Expert Center of the Ministry of Health of Ukraine" apply to the Ministry of Health with a substantiated proposal regarding a complete or temporary prohibition to use a medicinal product by terminating the validity of the registration certificate for the medicinal product or cancelling the state registration by terminating the validity of the Registration Certificate for medicinal product or temporary suspension of state registration by suspending the validity of the Registration Certificate for the medicinal product, taking into account the requirements of this Procedure, with reference to the discovered facts and violations.
	d. Specify which authority/ies is/are responsible or have the lead or coordinating role for this	-State Service of Ukraine on Medicines and Drugs Control -State Customs Service of Ukraine

Table 5: (Q.5) Structured bodies/ committees/ systems in place for the collection and transmission of information and data that are specific to:
a. combating counterfeit medical products and similar crimes (i.e. concerning crimes and criminal behaviours): Yes/No
b. counterfeit medical products (i.e. concerning the product): Yes/No
c. are not specific to counterfeit medical products but are general in nature and may include counterfeit medical products (i.e., a general criminal law): Yes/No
If Table 5. a or b is not completed, Table 7 is required to be completed

		YES	NO
Armenia	Are there structured bodies/ committees/ systems in place for the collection and transmission of information and data that are specific to		
	j. Combating counterfeit medical products and similar crimes (i.e. concerning crimes and criminal behaviours)	X	
	k. Counterfeit medical products (i.e. concerning the product)	X	
	l. Are not specific to counterfeit medical products but are general in nature and may include counterfeit medical products (i.e., a general criminal law)	X	
Belgium		**YES**	**NO**
	Are there structured bodies/ committees/ systems in place for the collection and transmission of information and data that are specific to		
	a. Combating counterfeit medical products and similar crimes (i.e. concerning crimes and criminal behaviours)	X	
	b. Counterfeit medical products (i.e. concerning the product)	X	
	c. Are not specific to counterfeit medical products but are general in nature and may include counterfeit medical products (i.e., a general criminal law)	X	

		OUI	NON
Bosnia and Herzegovina	Existe-t-il des organes/comités/systèmes structurés de collecte et de transmission d'informations et de données :		
	a. concernant spécifiquement la lutte contre la contrefaçon des produits médicaux et les infractions similaires (c'est-à-dire concernant les actes et comportements délictueux) ?	Oui, partiellement	
	b. concernant spécifiquement les produits médicaux contrefaits (c'est-à-dire concernant les produits eux-mêmes) ?	Oui, parciellement	

	c. ne concernant pas spécifiquement la contrefaçon des produits médicaux mais dont la portée générale peut inclure la contrefaçon des produits médicaux (loi pénale générale, par exemple) ?			

Burkina Faso		OUI/NON	NON
	Existe-t-il des organes/comités/systèmes structurés de collecte et de transmission d'informations et de données :		
	a. concernant spécifiquement la lutte contre la contrefaçon des produits médicaux et les infractions similaires (c'est-à-dire concernant les actes et comportements délictueux) ?	Non	
	b. concernant spécifiquement les produits médicaux contrefaits (c'est-à-dire concernant les produits eux-mêmes) ?	Non	
	c. ne concernant pas spécifiquement la contrefaçon des produits médicaux mais dont la portée générale peut inclure la contrefaçon des produits médicaux (loi pénale générale, par exemple) ?	Oui	

Croatia		YES	NO
	Are there structured bodies/ committees/ systems in place for the collection and transmission of information and data that are specific to		
	a. Combating counterfeit medical products and similar crimes (i.e. concerning crimes and criminal behaviours)		X
	b. Counterfeit medical products (i.e. concerning the product)	X	
	c. Are not specific to counterfeit medical products but are general in nature and may include counterfeit medical products (i.e., a general criminal law)		X

France		OUI/NON	NON
	Existe-t-il des organes/comités/systèmes structurés de collecte et de transmission d'informations et de données :		
	a. concernant spécifiquement la lutte contre la contrefaçon des produits médicaux et les infractions similaires (c'est-à-dire concernant les actes et comportements délictueux) ?	Non	X
	b. concernant spécifiquement les produits médicaux contrefaits (c'est-à-dire concernant les produits eux-mêmes) ?	Non	X
	c. ne concernant pas spécifiquement la contrefaçon des produits médicaux mais dont la portée générale peut inclure la contrefaçon des produits médicaux (loi pénale générale, par exemple) ?	Oui	

Si vous avez répondu « Non » à la question 5.*a)* ou 5.*b)*, veuillez passer à la question 7.

Sur le point c. : l'INPI propose un service de données en accès libre des entreprises concernant la propriété industrielle. La proposition de loi du 9 juillet 2021 propose d'institutionnaliser cela en confiant à l'INPI la mission de collecter les données relatives à la quantification de la contrefaçon (en général). De façon générale l'INPI et le CNAC (comité national anti contrefaçon) sont les deux organes en charge de la sensibilisation et de la communication institutionnelle sur la contrefaçon, avec l'aide d'associations de professionnels telles que l'UNIFAB.

Hungary		YES	NO
	Are there structured bodies/ committees/ systems in place for the collection and transmission of information and data that are specific to		
	a. Combating counterfeit medical products and similar crimes (i.e. concerning crimes and criminal behaviours)	x	
	b. Counterfeit medical products (i.e. concerning the product)	x	
	c. Are not specific to counterfeit medical products but are general in nature and may include counterfeit medical products (i.e., a general criminal law)	×	

Ireland		YES	NO
	Are there structured bodies/ committees/ systems in place for the collection and transmission of information and data that are specific to		
	a. Combating counterfeit medical products and similar crimes (i.e. concerning crimes and criminal behaviours)	Yes	
	b. Counterfeit medical products (i.e. concerning the product)	Yes	
	c. Are not specific to counterfeit medical products but are general in nature and may include counterfeit medical products (i.e., a general criminal law)		

Moldova		YES	NO
	Are there structured bodies/ committees/ systems in place for the collection and transmission of information and data that are specific to		
	a. Combating counterfeit medical products and similar crimes (i.e. concerning crimes and criminal behaviours)	-	No
	b. Counterfeit medical products (i.e. concerning the product)	-	No

	c. Are not specific to counterfeit medical products but are general in nature and may include counterfeit medical products (i.e., a general criminal law)	-	No	
Morocco		**OUI**		**NON**
	Existe-t-il des organes/comités/systèmes structurés de collecte et de transmission d'informations et de données :			
	a. concernant spécifiquement la lutte contre la contrefaçon des produits médicaux et les infractions similaires (c'est-à-dire concernant les actes et comportements délictueux) ?	X		
	b. concernant spécifiquement les produits médicaux contrefaits (c'est-à-dire concernant les produits eux-mêmes) ?	X		
	c. ne concernant pas spécifiquement la contrefaçon des produits médicaux mais dont la portée générale peut inclure la contrefaçon des produits médicaux (loi pénale générale, par exemple) ?			
Portugal		**YES**	**NO**	
	Are there structured bodies/ committees/ systems in place for the collection and transmission of information and data that are specific to			
	a. Combating counterfeit medical products and similar crimes (i.e. concerning crimes and criminal behaviours)	yes		
	b. Counterfeit medical products (i.e. concerning the product)	yes		
	c. Are not specific to counterfeit medical products but are general in nature and may include counterfeit medical products (i.e., a general criminal law)	Yes		
Slovenia		**YES**	**NO**	
	Are there structured bodies/ committees/ systems in place for the collection and transmission of information and data that are specific to			
	a. Combating counterfeit medical products and similar crimes (i.e. concerning crimes and criminal behaviours)	MP, MKGP: Answer is not known		
	b. Counterfeit medical products (i.e. concerning the product)	MP, MKGP: Answer is not known		
	c. Are not specific to counterfeit medical products but are general in nature and may include counterfeit medical products (i.e., a general criminal law)	MKGP: Answer is not known MP: Answer is not known		
Spain		**YES**	**NO**	
	Are there structured bodies/ committees/ systems in place for the collection and transmission of information and data that are specific to			
	a. Combating counterfeit medical products and similar crimes (i.e. concerning crimes and criminal behaviours)	x		
	b. Counterfeit medical products (i.e. concerning the product)	x		
	c. Are not specific to counterfeit medical products but are general in nature and may include counterfeit medical products (i.e., a general criminal law)			
Switzerland		**YES**	**NO**	
	Are there structured bodies/ committees/ systems in place for the collection and transmission of information and data that are specific to			
	a. Combating counterfeit medical products and similar crimes (i.e. concerning crimes and criminal behaviours)		X	
	b. Counterfeit medical products (i.e. concerning the product)		X	
	c. Are not specific to counterfeit medical products but are general in nature and may include counterfeit medical products (i.e., a general criminal law)	X		
Ukraine				

Table 6: (Q.6) If the response in the previous table (Table 5) to a or b is 'Yes', specify the legislative provision, or other policy measures supporting the establishment and operation of structured bodies/ committees/ systems for the collection and transmission of information and data as regards:
a. combating counterfeit medical products and similar crimes (i.e. concerning crimes and criminal behaviours);
b. counterfeit medical products (i.e. concerning the product)
In addition, please specify, briefly, how each of these structured bodies/ committees/ systems operate. This should include

• the points of contact in the different authorities/services/units referred to
• Which authorities/services are involved
If responses are completed in Tables 5 and 6, no response is required for Table 7, unless there is also relevant information that can be added to Table 7.
If Tables 5 and 6 have not been completed, Table 7 is required to be completed.

Armenia

QUESTION			
If the answer to 5. a or b is 'Yes', specify the legislative provision, or other policy measures supporting the establishment and operation of structured bodies/ committees/ systems for the collection and transmission of information and data as regards			
g.	Combating counterfeit medical products and similar crimes (i.e. concerning crimes and criminal behaviours)	Law on Medicines, Criminal code, Criminal proceeding law	
h.	Counterfeit medical products (i.e. concerning the product)	Law on Medicines, Criminal code, Criminal proceeding law	

In addition, please specify, briefly, how each of these structured bodies/ committees/ systems operate. This should include • The points of contact in the different authorities/services/units referred to	The point of contacts are set, transfer of information is done between authorities
• Which authorities/services are involved	Health authorities, Police, Customs and National security services

Belgium

If the answer to 5. a or b is 'Yes', specify the legislative provision, or other policy measures supporting the establishment and operation of structured bodies/ committees/ systems for the collection and transmission of information and data as regards			
a.	Combating counterfeit medical products and similar crimes (i.e. concerning crimes and criminal behaviours)	Special Investigations Unit of the FAMHP in collaboration with police/justice	
b.	Counterfeit medical products (i.e. concerning the product)	DG Inspection of the FAMHP, collaboration with Industry and police/justice	

In addition, please specify, briefly, how each of these structured bodies/ committees/ systems operate. This should include • The points of contact in the different authorities/services/units referred to	In each of the services a generic e-mail address is working.
• Which authorities/services are involved	FAMHP-police-customs

Bosnia and Herzegovina

Si vous avez répondu « Oui » à la question 5.*a)* ou 5.*b)*, veuillez indiquer quelles dispositions législatives ou autres mesures régissent la mise en place et le fonctionnement des organes/comités/systèmes structurés de collecte et de transmission d'informations et de données concernant :			
a.	la lutte contre la contrefaçon des produits médicaux et les infractions similaires (c'est-à-dire concernant les actes et comportements délictueux).	Conformément aux accords signés d'échange d'informations	
b.	les produits médicaux contrefaits (c'est-à-dire	Conformément aux accords	

		concernant les produits eux-mêmes).	signés d'échange d'informations	

Veuillez préciser brièvement comment fonctionnent ces organes/comités/systèmes structurés. Veuillez mentionner en particulier : • les points de contact dans les différents services/autorités/unités mentionnés	Le Secteur de la Coopération Policière Opérationn Internationale - BCN INTERPOL Sarajevo coopère toutes les autorités compétentes sur le plan nationa international concernant tous les actes criminels d nature internationale, y compris la criminalité pharmaceutique. **Il n'existe pas de réseau d'échange d'informatio exclusivement dans ce domaine dans le cadre Convention Medicrime.** Dans le cadre d'actions opérationnelles (PANGEA) initiées par le Secrétariat général d'INTERPOL Lyo qualité de coordinateur, le BCN INTERPOL collecte délivre des informations et des données concernan rubriques a) et b) auprès d'autres agences au niv national et international qui ont activement participe aux actions opérationnelles. Ou dans le cadre de l'operation Shield/EUROPOL A cette occasion, des points de contact sont détern d'échanger des informations le plus efficacement p n'est pas un système continu.
• les autorités/services concernés	

Burkina Faso	No data content

Croatia

If the answer to 5. a or b is 'Yes', specify the legislative provision, or other policy measures supporting the establishment and operation of structured bodies/ committees/ systems for the collection and transmission of information and data as regards

a. Combating counterfeit medical products and similar crimes (i.e. concerning crimes and criminal behaviours)		
b. Counterfeit medical products (i.e. concerning the product)	Formal SPOC network (WHO, EDQM, WGEO)	

In addition, please specify, briefly, how each of these structured bodies/ committees/ systems operate. This should include • The points of contact in the different authorities/services/units referred to	Information on counterfeit medicinal products is shared among points of contact at the national level; regular meetings once a year or more if needed. Agency for Medicinal Products and Medical Devices of Croatia: ljubica.hodak@halmed.hr (National point of contact) rajka.truban@halmed.hr teo.kolonic@halmed.hr Krivotvorine@halmed.hr Customs Administration, Sector for Customs Control: suzbijanje.krijumcarenja@carina.hr Service for Inspection and Controls Police: cyber.crime@mup.hr In addition, information on counterfeit medicinal products is shared via WGEO, WHO and EDQM network from national point of contacts, when applicable.
• Which authorities/services are involved	Agency for Medicinal Products and Medical Devices of Croatia Customs Administration, Sector for Customs Control, Service for Inspection and Controls Police

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<tr><td>France</td><td colspan="3">No data content</td></tr>
<tr><td>Hungary</td><td colspan="3"><table>
<tr><td colspan="3"></td></tr>
<tr><td colspan="3">If the answer to 5. a or b is ‘Yes’, specify the legislative provision, or other policy measures supporting the establishment and operation of structured bodies/ committees/ systems for the collection and transmission of information and data as regards</td></tr>
<tr><td>a. Combating counterfeit medical products and similar crimes (i.e. concerning crimes and criminal behaviours)</td><td>x</td><td></td></tr>
<tr><td>b. Counterfeit medical products (i.e. concerning the product)</td><td>x</td><td></td></tr>
</table>
<table>
<tr><td>In addition, please specify, briefly, how each of these structured bodies/ committees/ systems operate. This should include
• The points of contact in the different authorities/services/units referred to</td><td>The above-mentioned relevant authorities have designated contact persons among whom the information exchange is continuous and will take the necessary immediate action in a given situation.</td></tr>
<tr><td>• Which authorities/services are involved</td><td>The Police, The Customs, OGYÉI</td></tr>
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<tr><td>Ireland</td><td colspan="3"><table>
<tr><td colspan="3"></td></tr>
<tr><td colspan="3">If the answer to 5. a or b is ‘Yes’, specify the legislative provision, or other policy measures supporting the establishment and operation of structured bodies/ committees/ systems for the collection and transmission of information and data as regards</td></tr>
<tr><td>a. Combating counterfeit medical products and similar crimes (i.e. concerning crimes and criminal behaviours)</td><td>1. Health Products Regulatory Authority Memorandums of Understanding on cooperation and information exchange with the Irish Customs Service, Sport Ireland, and the Food Safety Authority of Ireland regarding combating counterfeit medical products provides for systems and meetings with specified contact points in each of the authorities.
2. Health Products Regulatory Authority has an official structured liaison arrangement with the Irish Police Service regarding information and cooperation. This is facilitated by S.7, Garda Síochána Act.
3. In addition, Health Products Regulatory Authority, Irish Police Service, and Irish Customs Service meet informally and are covered by the provisions mentioned above in 1 and 2.</td><td></td></tr>
<tr><td>b. Counterfeit medical products (i.e. concerning the product)</td><td>Alerts on a structured form are provided by the Health Products Regulatory Authority for counterfeit/falsified/other illicit medical products for law enforcement information</td><td></td></tr>
</table>
<table>
<tr><td>In addition, please specify, briefly, how each of these structured bodies/ committees/ systems operate. This should include
• The points of contact in the different authorities/services/units referred to</td><td>As regards the combating of counterfeit/falsified/other illicit medical products, the Memorandums of Understanding provided for periodic structured liaison meeting between specified contact points in the different authorities. While no Memorandum of Understanding or Data Sharing Agreement has been signed as yet between the Irish Police Service and the Health Products Regulatory Authority, there is an agreed system of cooperation and information exchange in operation.
Points of contact are:</td></tr>
</table></td></tr>
</table>

		1. Health Products Regulatory Authority – Intelligence Officer, Enforcement Section 2 Irish Police Service – Intelligence Officer, Drugs and Organised Crime Bureau 3 Interpol NCB – Liaison Officer, Garda Síochána Headquarters Irish Customs Service – 4 Sport Ireland – 5 Food Safety Authority of Ireland – 6 PSI, the pharmacy regulator -
	• Which authorities/services are involved	Health Products Regulatory Authority Irish Customs Service – Investigation, Prosecution and Frontier Management Division Irish Police Service (Garda Síochána) Sport Ireland Food Safety Authority of Ireland

Moldova			
	If the answer to 5. a or b is 'Yes', specify the legislative provision, or other policy measures supporting the establishment and operation of structured bodies/ committees/ systems for the collection and transmission of information and data as regards		
	a. Combating counterfeit medical products and similar crimes (i.e. concerning crimes and criminal behaviours)	-	-
	b. Counterfeit medical products (i.e. concerning the product)	-	-

In addition, please specify, briefly, how each of these structured bodies/ committees/ systems operate. This should include • The points of contact in the different authorities/services/units referred to	-
• Which authorities/services are involved	Pharmaceutical activity GMP, GDP and GPP authorization unit and Quality Control Laboratory are units of Medicines and Medical Devices Agency, directly involved in exchange of such information.

Morocco			
	Si vous avez répondu « Oui » à la question 5.*a)* ou 5.*b)*, veuillez indiquer quelles dispositions législatives ou autres mesures régissent la mise en place et le fonctionnement des organes/comités/systèmes structurés de collecte et de transmission d'informations et de données concernant :		
	a. la lutte contre la contrefaçon des produits médicaux et les infractions similaires (c'est-à-dire concernant les actes et comportements délictueux).		
	b. les produits médicaux contrefaits (c'est-à-dire concernant les produits eux-mêmes).		

Veuillez préciser brièvement comment fonctionnent ces organes/comités/systèmes structurés. Veuillez mentionner en particulier : • les points de contact dans les différents services/autorités/unités mentionnés	Il existe un point contact de l'autorité de régle Ministère de la Santé et de la Protection Soc du Médicament et de la Pharmacie) avec l'O Présidence du Ministère Public, avec l'admin Douane et impôts indirects et avec INTERP A travers le point focal de l'autorité de réglem l'OMS, accès au portail électronique de l'OM Réception via RAPIDALERT des information d'alertes notifiées par les autorités compéten de l'OMS, de produits médicaux de qualité in falsifiés qui sont saisis par ces autorités de r
• les autorités/services concernés	

Portugal			
	If the answer to 5. a or b is 'Yes', specify the legislative provision, or other policy measures supporting the establishment and operation of structured bodies/ committees/ systems for the collection and transmission of information and data as regards		
	a. Combating counterfeit medical products and similar crimes (i.e. concerning crimes and criminal behaviours)	- Penal Code – art.º 282.º Corrupção de Substâncias alimentares ou medicinais (perigo para a vida).	

			- Lei n.º 81/2021, de 30 de Novembro Lei antidopagem no desporto - Dl n.º 110/2018, de 10 de dezembro - código da propriedade industrial – art.º 320.º (Contrafação, imitação e uso ilegal de marca).	
		b. Counterfeit medical products (i.e. concerning the product)	Decreto-Lei n.º 176/2006, de 30 de Agosto Estatuto do Medicamento Art.º 181.º - Infração e coima.	

In addition, please specify, briefly, how each of these structured bodies/ committees/ systems operate. This should include • The points of contact in the different authorities/services/units referred to	According to their statutes, where their competences are defined.
• Which authorities/services are involved	Autoridade tributária, Infarmed e no doping a Autoridade Anti Doping (ADOP) e Polícia Judiciária (PJ) e ASAE (Autoridade para a Segurança Alimentar e Económica) e Public Prossecuter.

Slovenia	No data content
Spain	

If the answer to 5. a or b is 'Yes', specify the legislative provision, or other policy measures supporting the establishment and operation of structured bodies/ committees/ systems for the collection and transmission of information and data as regards

a. Combating counterfeit medical products and similar crimes (i.e. concerning crimes and criminal behaviours)	BOE-A-1986-6859 Ley Orgánica 2/1986, de 13 de marzo, de Fuerzas y Cuerpos de Seguridad.	POLICIA NACIONAL
b. Counterfeit medical products (i.e. concerning the product)	BOE-A-1986-6859 Ley Orgánica 2/1986, de 13 de marzo, de Fuerzas y Cuerpos de Seguridad. Royal Decree 717/2019,of December 5, procedure for the authorization, registration and dispensing conditions of industrially manufactured medicinal products for human use. - Royal Decree 1275/2011 of 16 September by which the State Agency "Agencia	-POLICIA NACIONAL -Technical Inspection Committee (CTI) (harmonization/coordination forum for inspection services, central and regional) Coordination of Peripheral Pharmaceutical Services Committee. (harmonization/coordination forum for pharmaceutical border inspection services)

		Española de Medicamentos y Productos Sanitarios" is created and its Statute approved. (articles 27 and 28)	

In addition, please specify, briefly, how each of these structured bodies/ committees/ systems operate. This should include • The points of contact in the different authorities/services/units referred to	-The National Police has a specific central unit (UDEV Central) dedicated to the investigation of crimes related to sanitary products. That Unit do its own investigations and trains the rest of the police on the treatment of these crimes. It also has a specific unit dedicated to educate in schools and other relevant entities. -RD 71772019-(article 77) The Ministry of Health will publish on its website, as well as on the website of the Spanish Agency of Medicines and Health Products, updated information on the medicines marketed in Spain that must carry the safety devices required by European regulations: a unique identifier and an anti-tampering device
• Which authorities/services are involved	-UDEV Central -Ministry of Health and Spanish Agency of Medicines and Health Products(AEMPS), - Pharmaceutical Inspection services at borders/customs

Switzerland			
	If the answer to 5. a or b is 'Yes', specify the legislative provision, or other policy measures supporting the establishment and operation of structured bodies/ committees/ systems for the collection and transmission of information and data as regards		
	a. Combating counterfeit medical products and similar crimes (i.e. concerning crimes and criminal behaviours)	Art. 69 para. 4 TPA	
	b. Counterfeit medical products (i.e. concerning the product)	Art. 69 para. 4 TPA	

In addition, please specify, briefly, how each of these structured bodies/ committees/ systems operate. This should include • The points of contact in the different authorities/services/units referred to	Regular meetings and discussion of ongoing cases and "hot topics" related to pharmaceutical crime with the relevant stakeholders.
• Which authorities/services are involved	Federal Office for Customs and Border Security ("FOCBS"), Federal Office of Public Health ("FOPH"), Federal Office of Police ("fedpol"), the cantonal public prosecutor's offices, the cantonal health directorates, the cantonal police authorities, cantonal veterinarians, Swiss Sport Integrity Foundation.

Ukraine	**QUESTION**		
	If the answer to 5. a or b is 'Yes', specify the legislative provision, or other policy measures supporting the establishment and operation of structured bodies/ committees/ systems for the collection and transmission of information and data as regards		
	a. Combating counterfeit medical products and similar crimes (i.e. concerning crimes and criminal behaviours)		
	b. Counterfeit medical products (i.e. concerning the product)	X	

In addition, please specify, briefly, how each of these structured bodies/ committees/ systems operate. This should include • The points of contact in the different authorities/services/units referred to	
• Which authorities/services are involved	-Ministry of Health of Ukraine; -State Service of Ukraine on Medicines and Drugs Control;

			-National Policy of Ukraine; -Security Service of Ukraine; -State Border Guard Service of Ukraine; -State Customs Service of Ukraine

Table 7: (Q.7) Informal or ad hoc arrangements in place, instead of more structured arrangements, between the relevant authorities, for the collection, and transmission of information and data that are specific to:
a. combating counterfeit medical products and similar crimes (i.e. concerning crimes and criminal behaviours): Yes/No
b. counterfeit medical products (i.e. concerning the medical product): Yes/No
Specify, briefly, how these informal or ad hoc arrangements work in practice
This should include

- ***the informal points of contact in the different authorities/services/units referred to***
- ***Which authorities/services are involved***

Armenia

	YES	NO
Are there informal or ad hoc arrangements in place, instead of more structured arrangements, between the relevant authorities, for the collection, and transmission of information and data that are specific to		
g. Combating counterfeit medical products and similar crimes (i.e. concerning crimes and criminal behaviours)	X	
h. Counterfeit medical products (i.e. concerning the product)	X	

Please specify, briefly, how these informal or ad hoc arrangements work in practice This should include	
• The informal points of contact in the different authorities/services/units referred to	Personal contacts
• Which authorities/services are involved	Health authorities, Police, Customs and National security services

Belgium

No response

Bosnia and Herzegovina

No response

Burkina Faso

	OUI	NON
Existe-t-il des dispositifs informels ou ad hoc (par opposition à des dispositifs plus structurés) permettant la collecte et la transmission entre les autorités concernées d'informations et de données concernant spécifiquement :		
a. la lutte contre la contrefaçon des produits médicaux et les infractions similaires (c'est-à-dire concernant les actes et comportements délictueux) ?	Oui	
b. les produits médicaux contrefaits (c'est-à-dire concernant les produits eux-mêmes) ?	Oui	

Veuillez préciser brièvement comment fonctionnent concrètement ces dispositifs informels ou ad hoc. Veuillez mentionner en particulier :	Une plateforme WhatsApp est créée dans lequel, il y a des représentants des différents acteurs impliqués dans la lutte (police, gendarmerie, douane et Autorités sanitaires) servant de canal de partage d'informations et de données concernant ces infractions.
• les points de contact informels dans les différents services/autorités/unités mentionnés	NSP
• les autorités/services concernés	L'Agence Nationale de Régulation Pharmaceutique, la douane, la gendarmerie, la police.

Croatia

No response

France

	OUI	NON
Existe-t-il des dispositifs informels ou ad hoc (par opposition à des dispositifs plus structurés) permettant la collecte et la transmission entre les autorités concernées d'informations et de données concernant spécifiquement :		

a.	la lutte contre la contrefaçon des produits médicaux et les infractions similaires (c'est-à-dire concernant les actes et comportements délictueux) ?	X		
b.	les produits médicaux contrefaits (c'est-à-dire concernant les produits eux-mêmes) ?	X		

Veuillez préciser brièvement comment fonctionnent concrètement ces dispositifs informels ou ad hoc. Veuillez mentionner en particulier :	Dans l'optique d''optimiser la détection des trafics et d'améliorer les capacités de recoupement des renseignements, des initiatives sont menées avec le secteur privé. Ainsi, **une convention a été mise en place avec le G5** qui réunit 8 laboratoires français dont Ipsen, Sanofi, Servier et Pierre Fabre. Le secteur privé co problématiques de falsification de sa production a développé des dispositifs d'identification des sites vente sur internet qui constituent des ressources importantes d trafics. Il existe au **niveau interministériel un groupe opérationnel national anti-fraude (GONAF)** dédié à la contrefaçon, conduit sous l'égide de la DGDDI, auquel participe la DACG, et permettant d'échanger sur les grandes campagnes de contrôles et les priorités nationa matière, ainsi que d'échanger des données sur les procédures en cours. Au niveau départemental, cette structure est déclinée par les **c opérationnels départementaux anti-fraude**, menés sous l'ég procureurs, auxquels participent de nombreux partenaires parmi lesquels les douanes, la police et la gendarmerie, mais aussi les agences régionales de santé. Au sein de ces **CODAF**, au titre de l'article du code des douanes, les échanges d'informations entre les partenaires peuvent concerner la contrefaçon.
• les points de contact informels dans les différents services/autorités/unités mentionnés	**Convention G5** **groupe opérationnel national anti-fraude (GONAF)** **comités opérationnels départementaux anti-fraude (CODAF)**
• les autorités/services concernés	En matière de santé publique, toutes les autorités en charge de ces questions ont initié des échanges d'informations en collaborant directement (OCLESP, ANSM, ANSES (ANMV), Ordre National des Pharmaciens, Ordres des médecins, BNEVP, DIRRECTE, DGCCRF, AFLD, CNAMTS, etc).

Hungary

	YES	NO
Are there informal or ad hoc arrangements in place, instead of more structured arrangements, between the relevant authorities, for the collection, and transmission of information and data that are specific to		
a. Combating counterfeit medical products and similar crimes (i.e. concerning crimes and criminal behaviours)	x	
b. Counterfeit medical products (i.e. concerning the product)	x	

Please specify, briefly, how these informal or ad hoc arrangements work in practice This should include	
• The informal points of contact in the different authorities/services/units referred to	
• Which authorities/services are involved	The National Police Headquarters' working group on counterfeiting of medicines includes the National Tax and Customs Administration, the Prosecution Service, the pharmaceutical authority, the National Media and Info communications Authority.

Ireland

QUESTION	YES	NO
Are there informal or ad hoc arrangements in place, instead of more structured arrangements, between the relevant authorities, for the collection, and transmission of information and data that are specific to		

	a. Combating counterfeit medical products and similar crimes (i.e. concerning crimes and criminal behaviours)	Yes	
	b. Counterfeit medical products (i.e. concerning the product)	Yes	

Please specify, briefly, how these informal or ad hoc arrangements work in practice This should include	Arrangements are in place for informal or ad hoc cooperation and information exchange on specific issues, as appropriate, that operate in addition to structured pre-planned cooperation meetings.
• The informal points of contact in the different authorities/services/units referred to	1 Health Products Regulatory Authority- Intelligence Officer, Enforcement Section 2 Irish Customs Service – Investigation, Prosecution and Frontier Management Division 3 Irish Police Service (Garda Síochána) Garda National Drugs and Organised Crime Bureau 4 Sport Ireland – 5 Food Safety Authority of Ireland -
• Which authorities/services are involved	1 Health Products Regulatory Authority 2 Irish Customs Service 3 Irish Police Service (Garda Síochána) 4 Sport Ireland – 5 Food Safety Authority of Ireland

Moldova			
		YES	**NO**
	Are there informal or ad hoc arrangements in place, instead of more structured arrangements, between the relevant authorities, for the collection, and transmission of information and data that are specific to		
	a. Combating counterfeit medical products and similar crimes (i.e. concerning crimes and criminal behaviours)	-	No
	b. Counterfeit medical products (i.e. concerning the product)	-	No

Please specify, briefly, how these informal or ad hoc arrangements work in practice This should include	Any of the cases identified by a competent authority is communicated to other relevant authority and managed on a case by case basis.
• The informal points of contact in the different authorities/services/units referred to	Heads of Pharmaceutical activity GMP, GDP and GPP authorization unit and Quality Control Laboratory unit, as well as National Focal Point responsible for SF medical products to World Health Organization (WHO).
• Which authorities/services are involved	Medicines and Medical Devices Agency is responsible for the collection and transmission of information in respect of non compliant medicines (falsified, with quality defects).

Morocco	No response
Portugal	No response

Slovenia			
		YES	**NO**
	Are there informal or ad hoc arrangements in place, instead of more structured arrangements, between the relevant authorities, for the collection, and transmission of information and data that are specific to		
	a. Combating counterfeit medical products and similar crimes (i.e. concerning crimes and criminal behaviours)	MKGP: Answer is not known	
	b. Counterfeit medical products (i.e. concerning the product)	MKGP: Answer is not known	

Please specify, briefly, how these informal or ad hoc arrangements work in practice This should include	
• The informal points of contact in the different authorities/services/units referred to	
• Which authorities/services are involved	

Spain			
		YES	**NO**
	Are there informal or ad hoc arrangements in place, instead of more structured arrangements, between the relevant authorities, for the collection, and transmission of information and data that are specific to		
	a. Combating counterfeit medical products and similar crimes (i.e. concerning crimes and criminal behaviours)	x	
	b. Counterfeit medical products (i.e. concerning the product)	x	

Please specify, briefly, how these informal or ad hoc arrangements work in practice This should include	
• The informal points of contact in the different authorities/services/units referred to	-Different meetings and direct exchange of information (operative)- National Police -Exchange of information between the contact point of health authorities and law enforcements.-Guardia civil -Sharing information and expertise between the enforcements involved in the investigation- Heads of the investigation teams.
• Which authorities/services are involved	-Customs, National Police, Municipal and Local Police. - Spanish Agency of Medicines and Medical Devices Agency(AEMPS) -Spanish Food safety agency(AESAN) - Guardia civil.

Switzerland	Note Swissmedic: This question has not been answered in accordance with the reference made at the end of Question 6

Ukraine

	YES	NO
Are there informal or ad hoc arrangements in place, instead of more structured arrangements, between the relevant authorities, for the collection, and transmission of information and data that are specific to		
a. Combating counterfeit medical products and similar crimes (i.e. concerning crimes and criminal behaviours)	X	
b. Counterfeit medical products (i.e. concerning the product)	X	

Please specify, briefly, how these informal or ad hoc arrangements work in practice This should include	
• The informal points of contact in the different authorities/services/units referred to	
• Which authorities/services are involved	

Table 8: (Q.8) Structured databases to collect information as regards:
a. combating counterfeit medical products and similar crimes (i.e. concerning crimes and criminal behaviours): Yes/No
b. counterfeit medical products (i.e. concerning the medical product): Yes/No
If the response to a or b is 'Yes', please specify who is responsible for the database(s)

Armenia

	YES	NO
Are there structured databases to collect information as regards		
g. Combating counterfeit medical products and similar crimes (i.e. concerning crimes and criminal behaviours)	X	
h. Counterfeit medical products (i.e. concerning the product)	X	

If the answer to a or b. is 'Yes', please specify who is responsible for the database(s)	**Health authorities**

Belgium

	YES	NO
Are there structured databases to collect information as regards		
a. Combating counterfeit medical products and similar crimes (i.e. concerning crimes and criminal behaviours)		X
b. Counterfeit medical products (i.e. concerning the product)		X

If the answer to a or b. is 'Yes', please specify who is responsible for the database(s)	

Bosnia and Herzegovina

	OUI	NON
Existe-t-il des bases de données structurées pour la collecte d'informations concernant :		
a. la lutte contre la contrefaçon des produits médicaux et les infractions similaires (c'est-à-dire concernant les actes et comportements délictueux) ?	Oui, partiellement	

	b. les produits médicaux contrefaits (c'est-à-dire concernant les produits eux-mêmes) ?	Oui, partiellement		

Si vous avez répondu « Oui » à la question 8.*a)* ou 8.*b)*, veuillez préciser qui est chargé de la base/des bases de données.	**Le Secteur de la Coopération Policière Opération Internationale - BCN INTERPOL Sarajevo coopère toutes les autorités compétentes sur le plan natio et international concernant toutes les infractions pénales de nature internationale, y compris la criminalité pharmaceutique, mais ne dispose que d'informations de nature internationale, ainsi que d'informations (de nature nationale et internation reçues lors d'actions opérationnelles.** **Il n'existe pas de réseau d'échange d'information exclusivement dans ce domaine dans le cadre de Convention Medicrime.**

Burkina Faso		OUI/NON		NON
	Existe-t-il des bases de données structurées pour la collecte d'informations concernant :			
	a. la lutte contre la contrefaçon des produits médicaux et les infractions similaires (c'est-à-dire concernant les actes et comportements délictueux) ?	Non		
	b. les produits médicaux contrefaits (c'est-à-dire concernant les produits eux-mêmes) ?	Non		

Si vous avez répondu « Oui » à la question 8.*a)* ou 8.*b)*, veuillez préciser qui est chargé de la base/des bases de données.	

Croatia		YES	NO
	Are there structured databases to collect information as regards		
	a. Combating counterfeit medical products and similar crimes (i.e. concerning crimes and criminal behaviours)		X
	b. Counterfeit medical products (i.e. concerning the product)		X

If the answer to a or b. is 'Yes', please specify who is responsible for the database(s)	

France		OUI/NON		NON
	Existe-t-il des bases de données structurées pour la collecte d'informations concernant :			
	a. la lutte contre la contrefaçon des produits médicaux et les infractions similaires (c'est-à-dire concernant les actes et comportements délictueux) ?	Non		X
	b. les produits médicaux contrefaits (c'est-à-dire concernant les produits eux-mêmes) ?	Non		X

Si vous avez répondu « Oui » à la question 8.*a)* ou 8.*b)*, veuillez préciser qui est chargé de la base/des bases de données.	

Hungary		YES	NO
	Are there structured databases to collect information as regards		
	a. Combating counterfeit medical products and similar crimes (i.e. concerning crimes and criminal behaviours)	×	
	b. Counterfeit medical products (i.e. concerning the product)		×

If the answer to a or b. is 'Yes', please specify who is responsible for the database(s)	The database is collected in the United Database of the Investigative Authorities and the Prosecution Service, which is maintained by the Ministry of Interior and the Office of the Prosecutor General of Hungary.

Ireland		YES	NO
	Are there structured databases to collect information as regards		
	a. Combating counterfeit medical products and similar crimes (i.e. concerning crimes and criminal behaviours)	Yes	
	b. Counterfeit medical products (i.e. concerning the product)	Yes	

If the answer to a or b. is 'Yes', please specify who is responsible for the database(s)	Health Products Regulatory Authority Enforcement database

Moldova		YES	NO

	Are there structured databases to collect information as regards		
	a. Combating counterfeit medical products and similar crimes (i.e. concerning crimes and criminal behaviours)	-	No
	b. Counterfeit medical products (i.e. concerning the product)	-	No
	If the answer to a or b. is 'Yes', please specify who is responsible for the database(s)	-	
Morocco	No response		
Portugal		**YES**	**NO**
	Are there structured databases to collect information as regards		
	a. Combating counterfeit medical products and similar crimes (i.e. concerning crimes and criminal behaviours)	Yes	
	b. Counterfeit medical products (i.e. concerning the product)	Yes	
	If the answer to a or b. is 'Yes', please specify who is responsible for the database(s)	Autoridade do Medicamento, Infarmed, IP	
Slovenia		**YES**	**NO**
	Are there structured databases to collect information as regards		
	a. Combating counterfeit medical products and similar crimes (i.e. concerning crimes and criminal behaviours)	MP, MKGP: Answer is not known	
	b. Counterfeit medical products (i.e. concerning the product)	MP, MKGP: Answer is not known	
	If the answer to a or b. is 'Yes', please specify who is responsible for the database(s)		
Spain		**YES**	**NO**
	Are there structured databases to collect information as regards		
	a. Combating counterfeit medical products and similar crimes (i.e. concerning crimes and criminal behaviours)	x	
	b. Counterfeit medical products (i.e. concerning the product)	x	
	If the answer to a or b. is 'Yes', please specify who is responsible for the database(s)	-National Police has its own intelligence data base. - The information regarding the recall of illegal medicines from the market is disseminated to the interested parts.	
Switzerland		**YES**	**NO**
	Are there structured databases to collect information as regards		
	a. Combating counterfeit medical products and similar crimes (i.e. concerning crimes and criminal behaviours)	x	
	b. Counterfeit medical products (i.e. concerning the product)	x	
	If the answer to a or b. is 'Yes', please specify who is responsible for the database(s)		
Ukraine		**YES**	**NO**
	Are there structured databases to collect information as regards		
	a. Combating counterfeit medical products and similar crimes (i.e. concerning crimes and criminal behaviours)	X	
	b. Counterfeit medical products (i.e. concerning the product)	X	
	If the answer to a or b. is 'Yes', please specify who is responsible for the database(s)	Ministry of Health of Ukraine; State Service of Ukraine on Medicines and Drugs Control	

Table 9: (Q.9) Are there no arrangements, i.e. neither formal nor informal, in place for the collection and transmission of information and data that are specific to:
a.receiving and collecting information and data, including through contact points, at national or local levels and in collaboration with the private sector and civil society, for the purpose of preventing and combating the counterfeiting of medical products and similar crimes involving threats to public health: Yes/No
b.making available the information and data obtained by the health authorities, customs, police and other competent authorities for the co-operation between them: Yes/No
(Note for clarification: Answer 'Yes' if you consider that there are no arrangements in place. Answer 'No' if you consider that there are arrangements in place)

Armenia		**YES**	**NO**
	Do you consider that there are no arrangements, i.e. neither formal nor informal, in place for the collection and transmission of information and data that are specific to		
	g. Receiving and collecting information and data, including through contact points, at national or local levels and in collaboration with the private sector and civil society, for the purpose of preventing and combating the counterfeiting of medical products and similar crimes involving threats to public health		X
	h. Making available the information and data obtained by the health authorities, customs, police and other competent authorities for the co-operation between them		X
Belgium		**YES**	**NO**
	Do you consider that there are no arrangements, i.e. neither formal nor informal, in place for the collection and transmission of information and data that are specific to		
	a. Receiving and collecting information and data, including through contact points, at national or local levels and in collaboration with the private sector and civil society, for the purpose of preventing and combating the counterfeiting of medical products and similar crimes involving threats to public health		X
	b. Making available the information and data obtained by the health authorities, customs, police and other competent authorities for the co-operation between them		X
Bosnia and Herzegovina		**OUI**	**NON**
	Considérez-vous qu'il n'existe pas de dispositif, structuré ou informel…		
	a. de réception et de collecte d'informations et de données, y compris par le biais de points de contact, au niveau national ou local, en coopération avec le secteur privé et la société civile, pour prévenir et lutter contre la contrefaçon des produits médicaux et les infractions similaires menaçant la santé publique ?	oui	
	b. de mise à disposition des informations et données recueillies par les autorités sanitaires, les douanes, les forces de l'ordre et autres autorités compétentes, dans l'intérêt de la coopération de ces autorités entre elles ?	oui	
Burkina Faso		**OUI**	**NON**
	Considérez-vous qu'il n'existe pas de dispositif, structuré ou informel…		
	a. de réception et de collecte d'informations et de données, y compris par le biais de points de contact, au niveau national ou local, en coopération avec le secteur privé et la société civile, pour prévenir et lutter contre la contrefaçon des produits médicaux et les infractions similaires menaçant la santé publique ?	oui	
	b. de mise à disposition des informations et données recueillies par les autorités sanitaires, les douanes, les forces de l'ordre et autres autorités compétentes, dans l'intérêt de la coopération de ces autorités entre elles ?	oui	
Croatia		**YES**	**NO**
	Do you consider that there are no arrangements, i.e. neither formal nor informal, in place for the collection and transmission of information and data that are specific to		
	a. Receiving and collecting information and data, including through contact points, at national or local levels and in collaboration with the private sector and civil society, for the purpose of preventing and combating the counterfeiting of medical products and similar crimes involving threats to public health		X
	b. Making available the information and data obtained by the health authorities, customs, police and other competent authorities for the co-operation between them		X
France		**OUI**	**NON**
	Considérez-vous qu'il n'existe pas de dispositif, structuré ou informel…		
	a. de réception et de collecte d'informations et de données, y compris par le biais de points de contact, au niveau national ou local, en coopération avec le secteur privé et la société civile, pour prévenir et lutter contre la contrefaçon des produits médicaux et les infractions similaires menaçant la santé publique ?		X
	b. de mise à disposition des informations et données recueillies par les autorités sanitaires, les douanes, les forces de l'ordre et autres autorités compétentes, dans l'intérêt de la coopération de ces autorités entre elles ?		X

Hungary		**YES**	**NO**
	Do you consider that there are no arrangements, i.e. neither formal nor informal, in place for the collection and transmission of information and data that are specific to		
	a. Receiving and collecting information and data, including through contact points, at national or local levels and in collaboration with the private sector and civil society, for the purpose of preventing and combating the counterfeiting of medical products and similar crimes involving threats to public health		×
	b. Making available the information and data obtained by the health authorities, customs, police and other competent authorities for the co-operation between them		×
Ireland		**YES**	**NO**
	Do you consider that there are no arrangements, i.e. neither formal nor informal, in place for the collection and transmission of information and data that are specific to		
	a. Receiving and collecting information and data, including through contact points, at national or local levels and in collaboration with the private sector and civil society, for the purpose of preventing and combating the counterfeiting of medical products and similar crimes involving threats to public health		No
	b. Making available the information and data obtained by the health authorities, customs, police and other competent authorities for the co-operation between them		No
Moldova		**YES**	**NO**
	Do you consider that there are no arrangements, i.e. neither formal nor informal, in place for the collection and transmission of information and data that are specific to		
	a. Receiving and collecting information and data, including through contact points, at national or local levels and in collaboration with the private sector and civil society, for the purpose of preventing and combating the counterfeiting of medical products and similar crimes involving threats to public health	Yes	-
	b. Making available the information and data obtained by the health authorities, customs, police and other competent authorities for the co-operation between them	Yes	-
Morocco		**YES**	**NO**
	Do you consider that there are no arrangements, i.e. neither formal nor informal, in place for the collection and transmission of information and data that are specific to		
	a. Receiving and collecting information and data, including through contact points, at national or local levels and in collaboration with the private sector and civil society, for the purpose of preventing and combating the counterfeiting of medical products and similar crimes involving threats to public health	Yes	-
	b. Making available the information and data obtained by the health authorities, customs, police and other competent authorities for the co-operation between them	Yes	-
Portugal		**YES**	**NO**
	Do you consider that there are no arrangements, i.e. neither formal nor informal, in place for the collection and transmission of information and data that are specific to		
	a. Receiving and collecting information and data, including through contact points, at national or local levels and in collaboration with the private sector and civil society, for the purpose of preventing and combating the counterfeiting of medical products and similar crimes involving threats to public health		No
	b. Making available the information and data obtained by the health authorities, customs, police and other competent authorities for the co-operation between them		No
Slovenia		**YES**	**NO**
	Do you consider that there are no arrangements, i.e. neither formal nor informal, in place for the collection and transmission of information and data that are specific to		
	a. Receiving and collecting information and data, including through contact points, at national or local levels and in collaboration with the private sector and civil society, for the purpose of preventing and combating the counterfeiting of medical products and similar crimes involving threats to public health	MF: Yes MP: Answer is not known	
	b. Making available the information and data obtained by the health authorities, customs, police and other competent authorities for the co-operation between them	MF: Yes MP: Answer is not known	
Spain		**YES**	**NO**

	Do you consider that there are no arrangements, i.e. neither formal nor informal, in place for the collection and transmission of information and data that are specific to		
	a. Receiving and collecting information and data, including through contact points, at national or local levels and in collaboration with the private sector and civil society, for the purpose of preventing and combating the counterfeiting of medical products and similar crimes involving threats to public health		x
	b. Making available the information and data obtained by the health authorities, customs, police and other competent authorities for the co-operation between them		x
Switzerland		**YES**	**NO**
	Do you consider that there are no arrangements, i.e. neither formal nor informal, in place for the collection and transmission of information and data that are specific to		
	a. Receiving and collecting information and data, including through contact points, at national or local levels and in collaboration with the private sector and civil society, for the purpose of preventing and combating the counterfeiting of medical products and similar crimes involving threats to public health	X	
	b. Making available the information and data obtained by the health authorities, customs, police and other competent authorities for the co-operation between them	X	
Ukraine		**YES**	**NO**
	Do you consider that there are no arrangements, i.e. neither formal nor informal, in place for the collection and transmission of information and data that are specific to		
	a. Receiving and collecting information and data, including through contact points, at national or local levels and in collaboration with the private sector and civil society, for the purpose of preventing and combating the counterfeiting of medical products and similar crimes involving threats to public health		X
	b. Making available the information and data obtained by the health authorities, customs, police and other competent authorities for the co-operation between them		X

Table 10: (Q.10) If the response to any part of the previous table (Table 9) is 'Yes' (that there are no formal or no informal arrangements in place), are there any draft legislation, strategies, plans or other measures contemplated or in the process of development to provide for such formal or informal arrangements: Yes/No
If the answer is yes, please briefly specify what these are, when the process began, and when it is anticipated that the legislation, strategies, plans or other measures will be in place.

Armenia	No response		
Belgium		**YES**	**NO**
	If the answer to any part of question 9 is 'Yes' (that there are no formal or no informal arrangements in place), are there any draft legislation, strategies, plans or other measures contemplated or in the process of development to provide for such formal or informal arrangements		
	If the answer is yes, please briefly specify what these are, when the process began, and when it is anticipated that the legislation, strategies, plans or other measures will be in place.	Our national law stipulates that information regarding investigations can be shared with other relevant authorities. When the investigation is lead by the police information van only be shared after approval from the Prosecutor.	
Bosnia and Herzegovina	**QUESTION**	**OUI/NON**	**NON**
	Si vous avez répondu « Oui » à l'une ou l'autre partie de la question 9 (il n'existe pas de dispositif structuré ou informel) : une loi, une stratégie, un plan ou d'autres mesures prévoyant la mise en place d'un tel dispositif sont-ils envisagés, ou en préparation ?	Non	non
	Si vous avez répondu « Oui », veuillez indiquer brièvement de quoi il s'agit exactement, quand le processus a commencé et quand il est prévu que la loi, la stratégie, le plan ou toute autre mesure soit en place.		
Burkina Faso	**QUESTION**	**OUI/NON**	**NON**
	Si vous avez répondu « Oui » à l'une ou l'autre partie de la question 9 (il n'existe pas de dispositif structuré ou informel) : une loi, une stratégie, un plan ou d'autres mesures prévoyant	Oui	non

	la mise en place d'un tel dispositif sont-ils envisagés, ou en préparation ?		
	Si vous avez répondu « Oui », veuillez indiquer brièvement de quoi il s'agit exactement, quand le processus a commencé et quand il est prévu que la loi, la stratégie, le plan ou toute autre mesure soit en place.	Un projet de loi portant prévention et répress infractions en matière de trafic de faux médic autres produits médicaux au Burkina Faso es cours d'adoption. Ce projet de loi prévoit la création d'un Conseil national de lutte contre faux médicaments et autres produits médica en abrégé CONALFAM. Cette structure interministérielle et pluridisciplinaire est prév pour être un organe de coordination de la lut contre les faux médicaments et est chargée d'élaborer, de coordonner, de contrôler et d'évaluer les mesures nationales de préventi adoptées afin de prévenir toutes les formes c trafic de faux médicaments et autres produits médicaux et des infractions associées. Le processus a débuté depuis 2017 et se pours	

Croatia	No data content
France	No data content
Hungary	No data content
Ireland	No data content

Moldova

	YES	NO
If the answer to any part of question 9 is 'Yes' (that there are no formal or no informal arrangements in place), are there any draft legislation, strategies, plans or other measures contemplated or in the process of development to provide for such formal or informal arrangements	-	No

If the answer is yes, please briefly specify what these are, when the process began, and when it is anticipated that the legislation, strategies, plans or other measures will be in place.	-

Morocco	No data content
Portugal	No data content

Slovenia

	YES	NO
If the answer to any part of question 9 is 'Yes' (that there are no formal or no informal arrangements in place), are there any draft legislation, strategies, plans or other measures contemplated or in the process of development to provide for such formal or informal arrangements	MP, MKGP: Answer is not known	MF: No

If the answer is yes, please briefly specify what these are, when the process began, and when it is anticipated that the legislation, strategies, plans or other measures will be in place.	

Spain	No data content
Switzerland	**Note Swissmedic: This question has not been answered, as Question 9 has been answered with a "No"**
Ukraine	No data content

Table A-11: (Q.11) Are there specialised units, offices, groups, designated appointments, or similar, with the specific responsibility:
a) to combat counterfeit medical products and similar crimes (i.e. concerning crimes and criminal behaviours): Yes/No
Specify who or what these are (name of group/unit/office, etc.)
What the <u>primary</u> competence of their organization is (select one only)
i. law enforcement: Yes/No
ii. border surveillance: Yes/No
iii. health product regulatory authority: Yes/No
iv. Other (please specify the nature of the competence: Yes/No
Are there members among them who are specifically trained for the purpose of cooperation and information exchange: Yes/No
b. counterfeit medical products (i.e. concerning the product)

Please specify who or what these are
What the primary competence of their organization is (select one only)
i. law enforcement: Yes/No
ii. border surveillance: Yes/No
iii. health product regulatory authority: Yes/No
iv. Other (please specify the nature of the competence: Yes/No
Are there members among them who are specifically trained for the purpose of cooperation and information exchange: Yes/No
Please provide details, briefly, on the nature and frequency of the training provided for the purpose of being in charge of cooperation and information exchange.

Armenia

	YES	NO
Are there specialised units, offices, groups, designated appointments, or similar, with the specific responsibility		
A. To combat counterfeit medical products and similar crimes (i.e. concerning crimes and criminal behaviours)	X	

e. Please specify who or what these are (name of group/unit/office, etc.)	Persons Health authorities, Police, Customs and National security services

f. What the primary competence of their organization is (select one only)		
k. Law enforcement	X	
ii. Border surveillance	X	
iii. Health product regulatory authority	X	
iv.Other (please specify the nature of the competence		

c. Are there members among them who are specifically trained for the purpose of cooperation and information exchange	**X**	

B. Counterfeit medical products (i.e. concerning the product)	
a. Please specify who or what these are	

b. What the primary competence of their organization is (select one only)		
i. Law enforcement	X	
ii. Border surveillance	X	
iii.Health product regulatory authority	X	
iv.Other (please specify the nature of the competence		
c.Are there members among them who are specifically trained for the purpose of cooperation and information exchange	X	

Please provide details, briefly, on the nature and frequency of he training provided for the purpose of being in charge of cooperation and information exchange.

The training has been provided in 2014, 2016, 2017, 2018, 2019, not after COVID-19

Belgium

	YES	NO
Are there specialised units, offices, groups, designated appointments, or similar, with the specific responsibility		
A. To combat counterfeit medical products and similar crimes (i.e. concerning crimes and criminal behaviours)	X	

g. Please specify who or what these are (name of group/unit/office, etc.)	Persons Health authorities, Police, Customs and National security services

h. What the primary competence of their organization is (select one only)		
l. Law enforcement	X	
ii. Border surveillance		
iii.Health product regulatory authority		
iv.Other (please specify the nature of the competence		

c. Are there members among them who are specifically trained for the purpose of cooperation and information exchange		**X**

B. Counterfeit medical products (i.e. concerning the product)	
a. Please specify who or what these are	

b. What the primary competence of their organization is (select one only)		
i. Law enforcement		
ii. Border surveillance		
iii.Health product regulatory authority	X	
iv.Other (please specify the nature of the competence	X	

	c.Are there members among them who are specifically trained for the purpose of cooperation and information exchange		

Please provide details, briefly, on the nature and frequency of the training provided for the purpose of being in charge of cooperation and information exchange.

Inspectors who start working at the FAMHP do a one year training. For the Special Investigations Unit this includes getting to know the authorities and services with which we cooperate and the necessary actions to take to exchange information.

Bosnia and Herzegovina

	OUI	NON
Existe-t-il des unités, bureaux, groupes, personnes désignées ou autres structures chargés spécifiquement		
A. de la lutte contre la contrefaçon de produits médicaux et les infractions similaires (c'est-à-dire des actes et comportements délictueux) ?	oui	

i. Veuillez préciser quelles sont ces structures ou personnes (nom du groupe, de l'unité, du bureau, etc.).	**Conformément aux accords signés sur l'échange d'informations, une coopération a été établie entre les autorités compétentes, c'est-à-dire les autorités répressives, l'administration des impôts indirects de Bosnie-Herzégovine et d'autres. avec une note qu'il n'y a pas d'unités, de bureaux, de groupes ou d'autres structures spécialement désignées responsables dans ce domaine, c'est-à-dire qu'il n'y a pas d'unités spécialisées dans le cadre de la Convention Medicrime**

j. Quelle est la compétence <u>première</u> de leur organisme de tutelle (un seul choix possible) ?		
m. Services répressifs	oui	
ii. Surveillance des frontières		
iii. Autorité de réglementation des produits de santé		
iv. Autre (veuillez préciser la nature de la compétence)		

c. Y a-t-il dans la structure des personnes spécifiquement formées à la coopération et à l'échange d'informations ?	**oui**	

B. des produits médicaux contrefaits (c'est-à-dire des produits eux-mêmes) ?	
a. Veuillez préciser quelles sont ces structures ou personnes.	Agence des medicaments et des dispositifs medicaux au sein duquel se trouve le service de laboratoire

b. Quelle est la compétence <u>première</u> de leur organisme de tutelle (un seul choix possible) ?		
i. Services répressifs		
ii. Surveillance des frontières		
iii. Autorité de réglementation des produits de santé	oui	
iv. Autre (veuillez préciser la nature de la compétence)		
c. Y a-t-il dans la structure des personnes spécifiquement formées à la coopération et à l'échange d'informations ?	oui	

Veuillez indiquer brièvement quelle est la nature de la formation donnée aux personnes chargées de la coopération et de l'échange d'informations, et à quelle fréquence elle est dispensée.

Des formations sont organisées dans le cadre d'actions opérationnelles, telles que PANGEA, SHIELD, dans le cadre de la formation The Help - Le cours FIRST Help du Conseil de l'Europe a été lancé en 2021 - Il s'agit du cours Help en ligne du Conseil de l'Europe sur la criminalité pharmaceutique et la convention Médicrime visant à aider les professionnels du droit à répondre de manière appropriée à la criminalité pharmaceutique - organisée pour les procureurs et les juges. Plateforme en ligne HELP. **HELP online platformi.** Dans le cadre du CMED/EDQM. **Cependant, Il n'y a pas d'unités spécialisées pour lutter contre ce type de criminalité, une formation continue de l'ensemble du personnel est nécessaire afin de mettre en place les meilleures pratiques dans le cadre de la Convention Medicrime**

Burkina Faso

	OUI	NON
Existe-t-il des unités, bureaux, groupes, personnes désignées ou autres structures chargés spécifiquement		
A. de la lutte contre la contrefaçon de produits médicaux et les infractions similaires (c'est-à-dire des actes et comportements délictueux) ?	X	

a. Veuillez préciser quelles sont ces structures ou personnes (nom du groupe, de l'unité, du bureau, etc.).	**-Agence Nationale de Régulation Pharmaceutique;** **-Coordination nationale de la lutte contre la fraude ;**

	-Coordination nationale de la lutte contre la drogue	

b. Quelle est la compétence <u>première</u> de leur organisme de tutelle (un seul choix possible) ?		
n. Services répressifs		
ii. Surveillance des frontières		
iii. Autorité de réglementation des produits de santé		
iv. Autre (veuillez préciser la nature de la compétence)	Les trois entités ne relèvent pas d'un seul organisme de tutelle : - Agence Nationale de Régulation Pharmaceutique : autorité de réglementation des produits de santé - Coordination nationale de la lutte contre la fraude : Services répressifs -Coordination nationale de la lutte contre la drogue : Services répressifs	

c. Y a-t-il dans la structure des personnes spécifiquement formées à la coopération et à l'échange d'informations ?		**X**

B. des produits médicaux contrefaits (c'est-à-dire des produits eux-mêmes) ?	
a. Veuillez préciser quelles sont ces structures ou personnes.	Agence Nationale de Régulation Pharmaceutique

b. Quelle est la compétence <u>première</u> de leur organisme de tutelle (un seul choix possible) ?		
i. Services répressifs		X
ii. Surveillance des frontières		X
iii. Autorité de réglementation des produits de santé	X	
iv. Autre (veuillez préciser la nature de la compétence)		
c. Y a-t-il dans la structure des personnes spécifiquement formées à la coopération et à l'échange d'informations ?		X

Veuillez indiquer brièvement quelle est la nature de la formation donnée aux personnes chargées de la coopération et de l'échange d'informations, et à quelle fréquence elle est dispensée.

NSP

Croatia

	YES	**NO**
Are there specialised units, offices, groups, designated appointments, or similar, with the specific responsibility		
A. To combat counterfeit medical products and similar crimes (i.e. concerning crimes and criminal behaviours)	X	

a. Please specify who or what these are (name of group/unit/office, etc.)	Cyber Crime Unit

b. What the <u>primary</u> competence of their organization is (select one only)		
o. Law enforcement	X	
ii. Border surveillance		
iii. Health product regulatory authority		
iv. Other (please specify the nature of the competence		

c. Are there members among them who are specifically trained for the purpose of cooperation and information exchange		

B. Counterfeit medical products (i.e. concerning the product)		**X**
a. Please specify who or what these are	National point of contact and 2 replacements form a group in the Agency for Medicinal Products and Medical Devises with the responsibility for sharing information about counterfeit medical products Cyber Crime Unit	

b. What the <u>primary</u> competence of their organization is (select one only)	

	i. Law enforcement	X	
	ii. Border surveillance		
	iii. Health product regulatory authority	X	
	iv. Other (please specify the nature of the competence		
	c. Are there members among them who are specifically trained for the purpose of cooperation and information exchange	X	

Please provide details, briefly, on the nature and frequency of the training provided for the purpose of being in charge of cooperation and information exchange.

- WHO training for National Focal Points
- SPOC training in organisation of CMED and Council of Europe (Croatia was the host of the training)

France

	OUI		NON
Existe-t-il des unités, bureaux, groupes, personnes désignées ou autres structures chargés spécifiquement			
A. de la lutte contre la contrefaçon de produits médicaux et les infractions similaires (c'est-à-dire des actes et comportements délictueux) ?	X		

a. Veuillez préciser quelles sont ces structures ou personnes (nom du groupe, de l'unité, du bureau, etc.).	La Direction Générale de la Gendarmerie Natio a mis en place un **réseau d'enquêteurs spéci** formés en matière de lutte contre les atteintes publique dont la contrefaçon médicamenteuse piliers. A ce titre, elle a su assurer un maillage conséquent permettant d'identifier et de procéd premières investigations en la matière. Ce réseau de capteurs locaux peut s'appuyer s chaîne d'enquêteurs et d'unités spécialisés do angulaire est l'OCLAESP qui est plus particuliè charge de mener les enquêtes les plus comple En outre, la formation des personnels étant ca renforcer le contrôle des flux, orienter les inves lutter efficacement contre des délinquants de p professionnalisés, l'OCLAESP dirige diverses a formation auprès des militaires de la gendarme également au profit de certains de ses partena Au niveau de la DACG (Ministère de la justice) droit économique, financier et social, de la san de l'environnement est en charge du suivi de l' de l'autorité judiciaire en matière de contrefaço publique.

b. Quelle est la compétence <u>première</u> de leur organisme de tutelle (un seul choix possible) ?	
i. Services répressifs	X
ii. Surveillance des frontières	
iii. Autorité de réglementation des produits de santé	
iv. Autre (veuillez préciser la nature de la compétence)	

c. Y a-t-il dans la structure des personnes spécifiquement formées à la coopération et à l'échange d'informations ?	X

B. des produits médicaux contrefaits (c'est-à-dire des produits eux-mêmes) ?	
a. Veuillez préciser quelles sont ces structures ou personnes.	NON

b. Quelle est la compétence <u>première</u> de leur organisme de tutelle (un seul choix possible) ?	
i. Services répressifs	
ii. Surveillance des frontières	
iii. Autorité de réglementation des produits de santé	
iv. Autre (veuillez préciser la nature de la compétence)	
c. Y a-t-il dans la structure des personnes spécifiquement formées à la coopération et à l'échange d'informations ?	

Veuillez indiquer brièvement quelle est la nature de la formation donnée aux personnes chargées de la coopération et de l'échange d'informations, et à quelle fréquence elle est dispensée.

La formation des personnels est capitale pour renforcer le contrôle des flux, orienter les investigations et lutter contre les délinquants.
D'une part, pour les pharmaciens d'officine, de pharmacie à usage intérieur (UPI) et les grossistes, une formati réalisée dans le cadre du déploiement de la sérialisation par les éditeurs de logiciel. L'Ordre national des pharm pour sa part rédigé un cahier thématique « authentification des médicaments » en décembre 2019 destiné à la pharmaceutique. France MVO, l'organisme en charge de gérer le répertoire national de vérification des médica

	disposition différents outils pour lutter contre la contrefaçon. Enfin, les pharmaciens inspecteurs de santé publique ont des formations régulières sur ce thème lors de formations continues. D'autre part, l'Office en charge des trafics de produits de santé (OCLAESP) dirige diverses actions de formation auprès des forces de l'ordre mais également au profit de certains des autorités de santé et des actions de sensibilisation auprès de ses partenaires. Depuis 2019, une formation d'Enquêteur Atteinte à l'Environnement et à la Santé Publique (EAESP) est proposée. A compter de 2020, ces modules ont été proposés à la Police Nationale. L'OCLAESP intervient également dans plusieurs modules de formation des magistrats à l'Ecole Nationale de la Magistrature. L'OCLAESP dirige des actions de sensibilisation auprès des pouvoirs publics et des autorités de santé et entretient des relations suivies avec l'industrie pharmaceutique, les grossistes répartiteurs et les officines en vue de sensibiliser aux menaces de la criminalité organisée et du crime pharmaceutique. L'Office participe ainsi, aux côtés de la Douane et des ordres des pharmaciens et des médecins, aux réunions du comité du LEEM (les entreprises du médicament), aux travaux du G5 et échange de façon régulière avec les groupes anti-contrefaçon et protection des marques des grands laboratoires pharmaceutiques.

Hungary

	YES	NO
Are there specialised units, offices, groups, designated appointments, or similar, with the specific responsibility		
A. To combat counterfeit medical products and similar crimes (i.e. concerning crimes and criminal behaviours)		x

a. Please specify who or what these are (name of group/unit/office, etc.)	There is no dedicated department at the police in the fight against drug counterfeiting. Every county police criminal service is involved in this issue. There is a nominee at Directorate General for Criminal Investigation Criminal Investigation Department of National Police Headquarters (hereinafter: DGCI) who is responsible for the training of the other police forces and ensures the coordination between territorial police body and the designated unit of Europol.

b. What the primary competence of their organization is (select one only)		
i. Law enforcement	×	
ii. Border surveillance		
iii. Health product regulatory authority		
iv. Other (please specify the nature of the competence		

c. Are there members among them who are specifically trained for the purpose of cooperation and information exchange	x	

B. Counterfeit medical products (i.e. concerning the product)	
a. Please specify who or what these are	There is a nominee at the Directorate General for Criminal Investigation Department of National Police Headquarters (hereinafter: DGCI) who is responsible for the training of the other police forces and ensures the coordination between the territorial police the body and the designated unit of Europol.

b. What the primary competence of their organization is (select one only)		
i. Law enforcement	×	
ii. Border surveillance		
iii. Health product regulatory authority		
iv. Other (please specify the nature of the competence		
c. Are there members among them who are specifically trained for the purpose of cooperation and information exchange	x	

Please provide details, briefly, on the nature and frequency of the training provided for the purpose of being in charge of cooperation and information exchange.

Answer is not known.

Ireland

	YES	NO
Are there specialised units, offices, groups, designated appointments, or similar, with the specific responsibility		
A. To combat counterfeit medical products and similar crimes (i.e. concerning crimes and criminal behaviours)	Yes	

a. Please specify who or what these are (name of group/unit/office, etc.)	Enforcement Section, Health Products Regulatory Authority

b. What the primary competence of their organization is (select one only)		
i. Law enforcement		
ii. Border surveillance		
iii. Health product regulatory authority	Yes	

	iv. Other (please specify the nature of the competence		

c. Are there members among them who are specifically trained for the purpose of cooperation and information exchange	Yes	

B. Counterfeit medical products (i.e. concerning the product)	
a. Please specify who or what these are	Enforcement Section, Health Products Regulatory Authority

b. What the primary competence of their organization is (select one only)		
i. Law enforcement		
ii. Border surveillance		
iii. Health product regulatory authority	Yes	
iv. Other (please specify the nature of the competence		
c. Are there members among them who are specifically trained for the purpose of cooperation and information exchange	Yes	

Please provide details, briefly, on the nature and frequency of the training provided for the purpose of being in charge of cooperation and information exchange.

The Intelligence Group and Enforcement Group of the Enforcement Section, Health Products Regulatory Authority, receive ongoing training on cooperation and information sharing in the conduct of combating counterfeit/falsified/illicit medical products

Moldova

	YES	**NO**
Are there specialised units, offices, groups, designated appointments, or similar, with the specific responsibility		
A. To combat counterfeit medical products and similar crimes (i.e. concerning crimes and criminal behaviours)		

a. Please specify who or what these are (name of group/unit/office, etc.)	

b. What the primary competence of their organization is (select one only)		
p. Law enforcement		
ii. Border surveillance		
iii. Health product regulatory authority		
iv. Other (please specify the nature of the competence		

c. Are there members among them who are specifically trained for the purpose of cooperation and information exchange		

B. Counterfeit medical products (i.e. concerning the product)	
a. Please specify who or what these are	Pharmaceutical activity GMP, GDP and GPP authorization unit and Quality Control Laboratory are units of Medicines and Medical Devices Agency, directly involved in exchange of such information.

b. What the primary competence of their organization is (select one only)		
i. Law enforcement		
ii. Border surveillance		
iii. Health product regulatory authority	Yes	-
iv. Other (please specify the nature of the competence		
c. Are there members among them who are specifically trained for the purpose of cooperation and information exchange	Yes	-

Please provide details, briefly, on the nature and frequency of the training provided for the purpose of being in charge of cooperation and information exchange.

The MMDA employees receive training based on the annual training plan, which includes trainings, seminars and meetings organized by international bodies such as: World Health Organization (WHO), Pharmaceutical Inspectorate Co-operation Scheme (PIC/s), European Directorate for the Quality of Medicines & HealthCare (EDQM) where are addressed issues of preventing falsified medicinal products from entering the legal supply chain.

Morocco

	OUI	**NON**
Existe-t-il des unités, bureaux, groupes, personnes désignées ou autres structures chargés spécifiquement		
A. de la lutte contre la contrefaçon de produits médicaux et les infractions similaires (c'est-à-dire des actes et comportements délictueux) ?		

a. Veuillez préciser quelles sont ces structures ou personnes (nom du groupe, de l'unité, du bureau, etc.).	**Présidence du Ministère Public, Administration de la Douane et Impôts indirects , Ministère de la Santé et de la Protection Sociale, Direction Générale de la sûreté Nationale.**

b. Quelle est la compétence <u>première</u> de leur organisme de tutelle (un seul choix possible) ?			
q. Services répressifs			
ii. Surveillance des frontières			
iii. Autorité de réglementation des produits de santé			
iv. Autre (veuillez préciser la nature de la compétence)			

c. Y a-t-il dans la structure des personnes spécifiquement formées à la coopération et à l'échange d'informations ?		

B. des produits médicaux contrefaits (c'est-à-dire des produits eux-mêmes) ?	
a. Veuillez préciser quelles sont ces structures ou personnes.	**Présidence du Ministère Public, Administration de la Douane et Impôts indirects , Ministère de la Santé et de la Protection Sociale, Direction Générale de la sûreté Nationale.**

b. Quelle est la compétence <u>première</u> de leur organisme de tutelle (un seul choix possible) ?		
i. Services répressifs		
ii. Surveillance des frontières		
iii. Autorité de réglementation des produits de santé		
iv. Autre (veuillez préciser la nature de la compétence)		
c. Y a-t-il dans la structure des personnes spécifiquement formées à la coopération et à l'échange d'informations ?		

Veuillez indiquer brièvement quelle est la nature de la formation donnée aux personnes chargées de la coopération et de l'échange d'informations, et à quelle fréquence elle est dispensée.

Portugal

	YES	**NO**
Are there specialised units, offices, groups, designated appointments, or similar, with the specific responsibility		
A. To combat counterfeit medical products and similar crimes (i.e. concerning crimes and criminal behaviours)	yes	

k. Please specify who or what these are (name of group/unit/office, etc.)	**Polícia Judiciária - PJ (Unidade nacional de Combate à Corrupção) e Autoridade de Segurança Alimentar e Económica (ASAE), AT Administração Tributária e ADOP (Agency Anti Doping).**

l. What the <u>primary</u> competence of their organization is (select one only)		
r. Law enforcement	PJ	
ii. Border surveillance	AT	
iii. Health product regulatory authority	Infarmed/ASAE	
iv. Other (please specify the nature of the competence	ADOP	

c. Are there members among them who are specifically trained for the purpose of cooperation and information exchange		**NO**

B. Counterfeit medical products (i.e. concerning the product)	
a. Please specify who or what these are	INFARMED – Autoridade do Medicamento, IP e Autoridade de Segurança Alimentar (ASAE).

b. What the <u>primary</u> competence of their organization is (select one only)		
i. Law enforcement	ASAE	
ii. Border surveillance	AT	
iii. Health product regulatory authority	INFARMED	
iv. Other (please specify the nature of the competence	ADOP	
c. Are there members among them who are specifically trained for the purpose of cooperation and information exchange		No

Please provide details, briefly, on the nature and frequency of he training provided for the purpose of being in charge of cooperation and information exchange.

Slovenia

	YES	**NO**
Are there specialised units, offices, groups, designated appointments, or similar, with the specific responsibility		
A. To combat counterfeit medical products and similar crimes (i.e. concerning crimes and criminal behaviours)	MKGP: Answer is not known	MF: Financial Administration does not have any such

			specialised unit.

a. Please specify who or what these are (name of group/unit/office, etc.)	

b. What the primary competence of their organization is (select one only)		
s. Law enforcement		
ii. Border surveillance		
iii. Health product regulatory authority		
iv. Other (please specify the nature of the competence		

c. Are there members among them who are specifically trained for the purpose of cooperation and information exchange		

B. Counterfeit medical products (i.e. concerning the product)	
a. Please specify who or what these are	MF: Financial Administration does not have any such specially trained members.

b. What the primary competence of their organization is (select one only)		
i. Law enforcement		
ii. Border surveillance		
iii. Health product regulatory authority		
iv. Other (please specify the nature of the competence		
c. Are there members among them who are specifically trained for the purpose of cooperation and information exchange		

Please provide details, briefly, on the nature and frequency of the training provided for the purpose of being in charge of cooperation and information exchange.

MF: Representatives of Financial Administration did not yet participate at any such training.

Spain

	YES	**NO**
Are there specialised units, offices, groups, designated appointments, or similar, with the specific responsibility		
A. To combat counterfeit medical products and similar crimes (i.e. concerning crimes and criminal behaviours)	x	

a. Please specify who or what these are (name of group/unit/office, etc.)	-Criminal Intelligence Unit(UTP) -Policía Nacional: Specialized and violent Crime Unit (UDEV Central). Consumption and Antidoping Area -Operational units of DAVA(customs)

b. What the primary competence of their organization is (select one only)		
m. Law enforcement	x	
ii. Border surveillance		x
iii. Health product regulatory authority		x
iv. Other (please specify the nature of the competence		x

c. Are there members among them who are specifically trained for the purpose of cooperation and information exchange	X (Customs and National Police)	X (Guardia civil)

B. Counterfeit medical products (i.e. concerning the product)	
a. Please specify who or what these are	AEMPS Criminal Intelligence Unit(UTPJ) UDEV Central Regional regulatory authorities Pharmaceutical border inspection services

b. What the primary competence of their organization is (select one only)		
i. Law enforcement	x	
ii. Border surveillance		x
iii. Health product regulatory authority	x	
iv. Other (please specify the nature of the competence		x
c. Are there members among them who are specifically trained for the purpose of cooperation and information exchange	x	

Please provide details, briefly, on the nature and frequency of he training provided for the purpose of being in charge of cooperation and information exchange.

	it depends on each authority involved. In general terms: occasionally as required

Switzerland

	YES	NO
Are there specialised units, offices, groups, designated appointments, or similar, with the specific responsibility		
A. To combat counterfeit medical products and similar crimes (i.e. concerning crimes and criminal behaviours)		X

a. Please specify who or what these are (name of group/unit/office, etc.)	Swissmedic has its own Penal Division whose prosecutors are specialised in combatting counterfeit medical products and similar crimes. Specialised units/prosecutors can also be found within the FOCBS, fedpol and the cantonal prosecutor's offices.

b. What the primary competence of their organization is (select one only)		
n. Law enforcement		X (fedpol, cantonal prosecutor's offices)
ii. Border surveillance		x (FOCBS)
iii. Health product regulatory authority		(Swissmedic)
iv. Other (please specify the nature of the competence		x

*** Note Swissmedic: This question is understood in a way that a primary competence may be given for each of the competent authorities.**

c. Are there members among them who are specifically trained for the purpose of cooperation and information exchange		X

B. Counterfeit medical products (i.e. concerning the product)	
a. Please specify who or what these are	Swissmedic has its own Penal Division whose prosecutors are specialised in combatting counterfeit medical products and similar crimes. Specialised units/prosecutors can also be found within the FOCBS, fedpol and the cantonal prosecutor's offices.

b. What the primary competence of their organization is (select one only)		
i. Law enforcement		X (fedpol, cantonal prosecutor's offices)
ii. Border surveillance		X (FOCBS)
iii. Health product regulatory authority		X (Swissmedic)
iv. Other (please specify the nature of the competence		
c. Are there members among them who are specifically trained for the purpose of cooperation and information exchange		X

*** Note Swissmedic: This question is understood in a way that a primary competence may be given for each of the competent authorities.**

Please provide details, briefly, on the nature and frequency of he training provided for the purpose of being in charge of cooperation and information exchange.

The National Single Point of Contact ("SPOC") that lies with Swissmedic is regularly providing training to customs officers in about three training sessions/joint actions per year and in regular coordination meetings which are held every two months. Cooperation processes are laid down in formal documents issued by the FOCBS with input from the SPOC. Once a year a nationwide training for all stakeholders is provided by Swissmedic ("Medicrime Meeting Switzerland").

Ukraine

	YES	NO
Are there specialised units, offices, groups, designated appointments, or similar, with the specific responsibility		
A. To combat counterfeit medical products and similar crimes (i.e. concerning crimes and criminal behaviours)	X	

a. Please specify who or what these are (name of group/unit/office, etc.)	- Units of the Security Service of Ukraine in line of combating the smuggling of narcotic drugs, psychotropic substances, their analogues or precursors or falsified medicinal products; - Pharmaceutical Department of the Ministry of Health of Ukraine; - Division for Prevention of Circulation of Substandard, Low-Quality, Falsified and Unregistered Medicines and Blood of the Department of Medicines and Blood Quality Control

b. What the primary competence of their organization is (select one only)	

	i. Law enforcement	X	
	ii. Border surveillance		
	iii. Health product regulatory authority	X	
	iv. Other (please specify the nature of the competence		

c. Are there members among them who are specifically trained for the purpose of cooperation and information exchange	X	

B.	**Counterfeit medical products (i.e. concerning the product)**	
a.	Please specify who or what these are	- Pharmaceutical Department of the Ministry of Health of Ukraine; - Division for Prevention of Circulation of Substandard, Low-Quality, Falsified and Unregistered Medicines and Blood of the Department of Medicines and Blood Quality Control of the State Service of Ukraine on Medicines and Drugs Control

b. What the primary competence of their organization is (select one only)		
i. Law enforcement		
ii. Border surveillance		
iii. Health product regulatory authority	X	
iv. Other (please specify the nature of the competence		
c. Are there members among them who are specifically trained for the purpose of cooperation and information exchange		X

Please provide details, briefly, on the nature and frequency of he training provided for the purpose of being in charge of cooperation and information exchange.

Table 12: (Q.12) If the response in the previous table (Table 11) is that there is no training provided as regards cooperation and information exchange, what other arrangements are in place to ensure that
a. This type of cooperation and information exchange takes place, and
b. What training relating to the combating of counterfeit medical products and similar crimes is provided to them

Armenia	No data content	
Belgium	No data content	
Bosnia and Herzegovina	No data content	
Burkina Faso	**QUESTION**	
	Si vous avez répondu à la question 11 qu'aucune formation en matière de coopération et d'échange d'informations n'est dispensée, veuillez indiquer brièvement :	
	g. quels sont les dispositifs en place permettant la coopération et l'échange d'information, et	NSP
	h. quelle formation en matière de lutte contre la contrefaçon de produits médicaux et les infractions similaires leur est dispensée.	Détection des produits contrefaisants, techniques d'enquêtes
Croatia		
	If the answer to Question 11 is that there is no training provided as regards cooperation and information exchange, please state, briefly, what other arrangements are in place to ensure that	
	a. This type of cooperation and information exchange takes place, and	Even though Customs do not have nor specialised units neither specialised customs officers to combat counterfeit medicines (from the criminal behaviour and infringing products perspective), Customs Administration provides regular training for customs officers where we cover specific activities on the information exchange
	b. What training relating to the combating of counterfeit medical products and similar crimes is provided to them	Customs Administration organises training with rights holders (including from the pharma sector) where right holders provide information on combating of counterfeit medical products
France	No data content	

<table>
<tr><td>Hungary</td><td>No data content</td></tr>
<tr><td>Ireland</td><td>No data content</td></tr>
<tr><td>Moldova</td><td>
<table>
<tr><td colspan="2"></td></tr>
<tr><td colspan="2">If the answer to Question 11 is that there is no training provided as regards cooperation and information exchange, please state, briefly, what other arrangements are in place to ensure that</td></tr>
<tr><td>a. This type of cooperation and information exchange takes place, and</td><td>Based on collaboration with WHO and EDQM are received data through Rapid Alert System.</td></tr>
<tr><td>b. What training relating to the combating of counterfeit medical products and similar crimes is provided to them</td><td>An example of the latest training in this respect is “WHO e-Course on SF medical products, for national regulatory focal points of the Global Surveillance and Monitoring System” conducted in March 2023.</td></tr>
</table>
</td></tr>
<tr><td>Morocco</td><td>No response</td></tr>
<tr><td>Portugal</td><td>
<table>
<tr><td colspan="2"></td></tr>
<tr><td colspan="2">If the answer to Question 11 is that there is no training provided as regards cooperation and information exchange, please state, briefly, what other arrangements are in place to ensure that</td></tr>
<tr><td>a. This type of cooperation and information exchange takes place, and</td><td>According to the law, each entity has the duty of Communication in accordance with the competences defined therein.</td></tr>
<tr><td>b. What training relating to the combating of counterfeit medical products and similar crimes is provided to them</td><td>The existence of protocols between Entities.</td></tr>
</table>
</td></tr>
<tr><td>Slovenia</td><td>
<table>
<tr><td colspan="2"></td></tr>
<tr><td colspan="2">If the answer to Question 11 is that there is no training provided as regards cooperation and information exchange, please state, briefly, what other arrangements are in place to ensure that</td></tr>
<tr><td>a. This type of cooperation and information exchange takes place, and</td><td>MF:
The tasks of the Working group are:
– preparation for the implementation of the Council of Europe Convention on the Counterfeiting of Medical Products and similar crimes that endanger public health (hereinafter: convention);
– preparation and adoption of a plan for training, raising awareness and cooperation with the Committee Parties to the Council of Europe;
– determination of the national contact point in accordance with the second paragraph of Article 22 conventions,
– monitoring and coordinating the implementation of the convention.

VDT:
Regarding cooperation and information exchange in all criminal cases, not only in criminal cases involving threats to public health the State prosecutors are bound to the Decree on the cooperation of the State prosecutorial service, Police and other competent state bodies and institutions in detection and prosecution of perpetrators of criminal offences and operation of specialised and joint investigation teams. The purpose of cooperation according to this decree is directed, coordinated and efficient operation of the bodies, institutions and before mentioned groups to detect criminal acts and their perpetrators and to obtain the information necessary for the state prosecutor's decision in a specific case. The Decree provides the legal ground for the exchange of information and defines how directions and guidelines should be given.
Regarding information exchange in all criminal cases, the state prosecutor may demand necessary information from government agencies, enterprises, and other legal entities, and may for the same purpose summon the person who has submitted a crime report. Legal ground for described authority is based in Article 161, paragraph 3 of the Criminal Procedures Act.</td></tr>
<tr><td>b. What training relating to the combating of counterfeit</td><td>MF: There was no such training yet.</td></tr>
</table>
</td></tr>
</table>

	medical products and similar crimes is provided to them	VDT: Training relating to the combating of counterfeit medical products are mostly in the form of conference regarding counterfeit medical products, for example Conference about counterfeit medicines in theory and practice organized by University of Maribor.
Spain		
	If the answer to Question 11 is that there is no training provided as regards cooperation and information exchange, please state, briefly, what other arrangements are in place to ensure that	
	a. This type of cooperation and information exchange takes place, and	it depends on each authority involved, Customs Surveillance Service: which is necessary when it comes to a joint action team.
	b. What training relating to the combating of counterfeit medical products and similar crimes is provided to them	it depends on each authority involved
Switzerland	Note Swissmedic: This question has not been answered, as the answer to Question 11 is that there is training provided as regards cooperation and information exchange.	
Ukraine		
	If the answer to Question 11 is that there is no training provided as regards cooperation and information exchange, please state, briefly, what other arrangements are in place to ensure that	
	a. This type of cooperation and information exchange takes place, and	Not known
	b. What training relating to the combating of counterfeit medical products and similar crimes is provided to them	The State Customs Service of Ukraine (Department of Non-Tariff Regulation) holds a monthly webinar on the topic: "Main features of original goods of well-known European companies and goods suspected of violating intellectual property rights" with the participation of representatives of these companies and representatives of the EU Program for the Support of Public Finance Management in Ukraine (EU4PFM)

Table 13: (Q. 13) Does the national legislation, strategy, action plan, or other measure provide for a 24 hours a day, 7 days a week network cooperation and information exchange as regards a. combating counterfeit medical products and similar crimes (i.e. concerning crimes and criminal behaviours): Yes/No
b. counterfeit medical products (i.e. concerning the medical product): Yes/N
If the answer to either or both a and b is 'Yes' please specify the measure providing for this and which authority is responsible for operating the network. This should include whether the 24/7 network is specific to combating counterfeit medical products and similar crimes or is more general in scope

Armenia		**YES**	**NO**
	Does the national legislation, strategy, action plan, or other measure provide for a 24 hours a day, 7 days a week network cooperation and information exchange as regards		
	g. Combating counterfeit medical products and similar crimes (i.e. concerning crimes and criminal behaviours)	X	
	h. Counterfeit medical products (i.e. concerning the medical product)	X	
	If the answer to either or both a and b is 'Yes' please specify the measure providing for this and which authority is responsible for operating the network. This should include whether the 24/7 network is specific to combating counterfeit medical products and similar crimes or is more general in scope	**Health authority is collecting data on** 24/7 basis and, if applicable, transferring to other relevant authorities	
Belgium		**YES**	**NO**
	Does the national legislation, strategy, action plan, or other measure provide for a 24 hours a day, 7 days a week network cooperation and information exchange as regards		
	a. Combating counterfeit medical products and similar crimes (i.e. concerning crimes and criminal behaviours)		X
	b. Counterfeit medical products (i.e. concerning the medical product)	X	

	If the answer to either or both a and b is 'Yes' please specify the measure providing for this and which authority is responsible for operating the network. This should include whether the 24/7 network is specific to combating counterfeit medical products and similar crimes or is more general in scope	The existing 24/7 system is not a system which focusses on crime, but it focusses on public health. The system is in place to allow manufacturers and health authorities to send out alerts in cases of substandard medicines which can be a danger to public health and to be able to react immediately (p.e. recall of the affected batches)

Bosnia and Herzegovina		OUI	NON
	La législation nationale (ou la stratégie, le plan d'action ou toute autre mesure) prévoit-elle la mise en place d'un réseau, fonctionnant 24 heures sur 24 et 7 jours sur 7, pour la coopération et l'échange d'informations concernant		
	a. la lutte contre la contrefaçon des produits médicaux et les infractions similaires (c'est-à-dire concernant les actes et comportements délictueux) ?	oui	
	b. les produits médicaux contrefaits (c'est-à-dire concernant les produits médicaux eux-mêmes) ?	oui	

	Si vous avez répondu « Oui », veuillez indiquer de quelle mesure il s'agit et quelle autorité est chargée de faire fonctionner ce réseau. Merci de préciser si le réseau 24/7 est spécifique à la lutte contre la contrefaçon des produits médicaux et les infractions similaires ou s'il est de portée plus générale.	Le Secteur de la Coopération Policière Opérationnelle Internationale - BCN INTERPOL Sarajevo coopère avec toutes les autorités compétentes concernant toutes les infractions pénales de nature internationale, y compris la criminalité pharmaceutique, mais ne dispose que d'informations de nature internationale, ainsi que d'informations (de nature nationale et internationale) reçues lors d'actions opérationnelles. L'échange d'informations se rapporte aux rubriques a) et b) car le Secrétariat général d'INTERPOL Lyon dispose des notices vertes et violetes qui sont délivrés sous forme d'avertissement ou d'information sur le mode opératoire concernant les produits médicaux contrefaits, c'est-à-dire les produits eux-mêmes. En fonction de la nature des informations et de la demande, elles sont transmises aux agences en fonction de leurs compétences. Il existe également un réseau par l'intermédiaire de l'Agence des médicaments et des dispositifs médicaux - Alerte rapide/Rapid alert - échange d'informations concernant les produits médicaux contrefaits. L'échange d'informations se fait exclusivement entre les agences du médicament et des dispositifs médicaux. Il n'existe pas de réseau d'échange d'informations exclusivement dans ce domaine dans le cadre de la Convention Medicrime.

Burkina Faso		**OUI**	**NON**
	La législation nationale (ou la stratégie, le plan d'action ou toute autre mesure) prévoit-elle la mise en place d'un réseau, fonctionnant 24 heures sur 24 et 7 jours sur 7, pour la coopération et l'échange d'informations concernant		
	a. la lutte contre la contrefaçon des produits médicaux et les infractions similaires (c'est-à-dire concernant les actes et comportements délictueux) ?		Non
	b. les produits médicaux contrefaits (c'est-à-dire concernant les produits médicaux eux-mêmes) ?		Non

	Si vous avez répondu « Oui », veuillez indiquer de quelle mesure il s'agit et quelle autorité est chargée de faire fonctionner ce réseau. Merci de préciser si le réseau 24/7 est spécifique à la lutte contre la contrefaçon des produits médicaux et les infractions similaires ou s'il est de portée plus générale.	

Croatia		**YES**	**NO**
	Does the national legislation, strategy, action plan, or other measure provide for a 24 hours a day, 7 days a week network cooperation and information exchange as regards		
	a. Combating counterfeit medical products and similar crimes (i.e. concerning crimes and criminal behaviours)		X

	b. Counterfeit medical products (i.e. concerning the medical product)		X

If the answer to either or both a and b is 'Yes' please specify the measure providing for this and which authority is responsible for operating the network. This should include whether the 24/7 network is specific to combating counterfeit medical products and similar crimes or is more general in scope	

France

	OUI/NON		NON
La législation nationale (ou la stratégie, le plan d'action ou toute autre mesure) prévoit-elle la mise en place d'un réseau, fonctionnant 24 heures sur 24 et 7 jours sur 7, pour la coopération et l'échange d'informations concernant			
a. la lutte contre la contrefaçon des produits médicaux et les infractions similaires (c'est-à-dire concernant les actes et comportements délictueux) ?	Non		X
b. les produits médicaux contrefaits (c'est-à-dire concernant les produits médicaux eux-mêmes) ?	Non		X

Si vous avez répondu « Oui », veuillez indiquer de quelle mesure il s'agit et quelle autorité est chargée de faire fonctionner ce réseau. Merci de préciser si le réseau 24/7 est spécifique à la lutte contre la contrefaçon des produits médicaux et les infractions similaires ou s'il est de portée plus générale.	

Hungary

	YES	NO
Does the national legislation, strategy, action plan, or other measure provide for a 24 hours a day, 7 days a week network cooperation and information exchange as regards		
a. Combating counterfeit medical products and similar crimes (i.e. concerning crimes and criminal behaviours)		×
b. Counterfeit medical products (i.e. concerning the medical product)		×

If the answer to either or both a and b is 'Yes' please specify the measure providing for this and which authority is responsible for operating the network. This should include whether the 24/7 network is specific to combating counterfeit medical products and similar crimes or is more general in scope	

Ireland

	YES	NO
Does the national legislation, strategy, action plan, or other measure provide for a 24 hours a day, 7 days a week network cooperation and information exchange as regards		
a. Combating counterfeit medical products and similar crimes (i.e. concerning crimes and criminal behaviours)	Yes	
b. Counterfeit medical products (i.e. concerning the medical product)	Yes	

If the answer to either or both a and b is 'Yes' please specify the measure providing for this and which authority is responsible for operating the network. This should include whether the 24/7 network is specific to combating counterfeit medical products and similar crimes or is more general in scope	The Health Products Regulatory Authority, Irish Customs Service, and the Irish Police Service operate cooperation and information exchange on a 24/7 basis. It is operated by the designated contact points for this type of liaison as regards counterfeit/falsified/illicit medical product-related crimes and as regards suspect or confirmed counterfeit/falsified/illicit medical products.

Moldova

	YES	NO
Does the national legislation, strategy, action plan, or other measure provide for a 24 hours a day, 7 days a week network cooperation and information exchange as regards		
a. Combating counterfeit medical products and similar crimes (i.e. concerning crimes and criminal behaviours)		
b. Counterfeit medical products (i.e. concerning the medical product)	-	No

If the answer to either or both a and b is 'Yes' please specify the measure providing for this and which authority is responsible for operating the network. This should include whether the 24/7 network is specific to combating counterfeit	-

	medical products and similar crimes or is more general in scope	

Morocco

	OUI	NON
La législation nationale (ou la stratégie, le plan d'action ou toute autre mesure) prévoit-elle la mise en place d'un réseau, fonctionnant 24 heures sur 24 et 7 jours sur 7, pour la coopération et l'échange d'informations concernant		
a. la lutte contre la contrefaçon des produits médicaux et les infractions similaires (c'est-à-dire concernant les actes et comportements délictueux) ?	Il existe un comité avec des points focaux (Présidence du Ministère Public , Ministère de la Santé et de la Protection Sociale, Administration de la Douane et impôts indirects)	
b. les produits médicaux contrefaits (c'est-à-dire concernant les produits médicaux eux-mêmes) ?	Il existe un comité avec des points focaux (Présidence du Ministère Public , Ministère de la Santé et de la Protection Sociale, Administration de la Douane et impôts indirects)	

Si vous avez répondu « Oui », veuillez indiquer de quelle mesure il s'agit et quelle autorité est chargée de faire fonctionner ce réseau. Merci de préciser si le réseau 24/7 est spécifique à la lutte contre la contrefaçon des produits médicaux et les infractions similaires ou s'il est de portée plus générale.	

Portugal

	YES	NO
Does the national legislation, strategy, action plan, or other measure provide for a 24 hours a day, 7 days a week network cooperation and information exchange as regards		
a. Combating counterfeit medical products and similar crimes (i.e. concerning crimes and criminal behaviours)		No
b. Counterfeit medical products (i.e. concerning the medical product)		No

If the answer to either or both a and b is 'Yes' please specify the measure providing for this and which authority is responsible for operating the network. This should include whether the 24/7 network is specific to combating counterfeit medical products and similar crimes or is more general in scope	

Slovenia

No response

Spain

	YES	NO
Does the national legislation, strategy, action plan, or other measure provide for a 24 hours a day, 7 days a week network cooperation and information exchange as regards		
a. Combating counterfeit medical products and similar crimes (i.e. concerning crimes and criminal behaviours)		x
b. Counterfeit medical products (i.e. concerning the medical product)		x

If the answer to either or both a and b is 'Yes' please specify the measure providing for this and which authority is responsible for operating the network. This should include whether the 24/7 network is specific to combating counterfeit medical products and similar crimes or is more general in scope	

Switzerland

	YES	NO
Does the national legislation, strategy, action plan, or other measure provide for a 24 hours a day, 7 days a week network cooperation and information exchange as regards		
a. Combating counterfeit medical products and similar crimes (i.e. concerning crimes and criminal behaviours)		x
b. Counterfeit medical products (i.e. concerning the medical product)		x

	If the answer to either or both a and b is 'Yes' please specify the measure providing for this and which authority is responsible for operating the network. This should include whether the 24/7 network is specific to combating counterfeit medical products and similar crimes or is more general in scope	In accordance with the MEDICRIME Convention and following the entry into force of the revised TPA on 1 January 2019, Swissmedic became the SPOC under Art. 69 para. 4 of the new legislation: National Point of Contact for Illegal Medicines medicrime@swissmedic.ch Hallerstrasse 7 3012 Bern The SPOC is the primary centre of information for law enforcement, healthcare professionals, private persons etc. Each seizure of medical products at the Swiss border is decided upon by the SPOC. Reports regarding suspected trafficking in medical products are submitted to the SPOC. From the moment criminal proceedings have been initiated, the Penal Division of Swissmedic is the competent authority and the exchange of information takes place by way of "mutual legal assistance in criminal matters".

Ukraine			
		YES	**NO**
	Does the national legislation, strategy, action plan, or other measure provide for a 24 hours a day, 7 days a week network cooperation and information exchange as regards		
	a. Combating counterfeit medical products and similar crimes (i.e. concerning crimes and criminal behaviours)	X	
	b. Counterfeit medical products (i.e. concerning the medical product)	X	

If the answer to either or both a and b is 'Yes' please specify the measure providing for this and which authority is responsible for operating the network. This should include whether the 24/7 network is specific to combating counterfeit medical products and similar crimes or is more general in scope	

Table 14: (Q14) Are adequate resources provided to ensure that persons, units or services in charge of co-operation and information exchange are trained for this purpose relating to counterfeit medical products and related crimes.
a. I agree that adequate resources are provided
b. I mostly agree that adequate resources are provided
c. I neither agree nor disagree that adequate resources are provided
d. I mostly disagree that adequate resources are provided
e. I disagree that adequate resources are provided

Armenia		
	Please answer this question placing an 'X' to the RIGHT on the option below that you consider is the closest to your view on whether adequate resources are provided to ensure that persons, units or services in charge of co-operation and information exchange are trained for this purpose relating to counterfeit medical products and related crimes.	
	k. I agree that adequate resources are provided	
	l. I mostly agree that adequate resources are provided	
	m. I neither agree nor disagree that adequate resources are provided	X
	n. I mostly disagree that adequate resources are provided	
	o. I disagree that adequate resources are provided	

Belgium		
	Please answer this question placing an 'X' to the RIGHT on the option below that you consider is the closest to your view on whether adequate resources are provided to ensure that persons, units or services in charge of co-operation and information exchange are trained for this purpose relating to counterfeit medical products and related crimes.	
	a. I agree that adequate resources are provided	
	b. I mostly agree that adequate resources are provided	
	c. I neither agree nor disagree that adequate resources are provided	X
	d. I mostly disagree that adequate resources are provided	
	e. I disagree that adequate resources are provided	

Bosnia and	

Herzegovina	Pensez-vous que des ressources adéquates sont dégagées pour que les personnes, unités ou services en charge de la coopération et des échanges d'informations soient formés à cette fin, dans le domaine de la lutte contre la contrefaçon des produits médicaux et les infractions similaires ? Veuillez cocher la case qui correspond le mieux à votre avis.	
	a. Oui, tout à fait	
	b. Oui, dans l'ensemble	oui
	c. Je ne me prononce pas	
	d. Non, plutôt pas	
	e. Non, pas du tout	
Burkina Faso		
	Pensez-vous que des ressources adéquates sont dégagées pour que les personnes, unités ou services en charge de la coopération et des échanges d'informations soient formés à cette fin, dans le domaine de la lutte contre la contrefaçon des produits médicaux et les infractions similaires ? Veuillez cocher la case qui correspond le mieux à votre avis.	
	a. Oui, tout à fait	
	b. Oui, dans l'ensemble	
	c. Je ne me prononce pas	
	d. Non, plutôt pas	
	e. Non, pas du tout	X
Croatia		
	Please answer this question placing an 'X' to the RIGHT on the option below that you consider is the closest to your view on whether adequate resources are provided to ensure that persons, units or services in charge of co-operation and information exchange are trained for this purpose relating to counterfeit medical products and related crimes.	
	a. I agree that adequate resources are provided	
	b. I mostly agree that adequate resources are provided	X
	c. I neither agree nor disagree that adequate resources are provided	
	d. I mostly disagree that adequate resources are provided	
	e. I disagree that adequate resources are provided	
France		
	Pensez-vous que des ressources adéquates sont dégagées pour que les personnes, unités ou services en charge de la coopération et des échanges d'informations soient formés à cette fin, dans le domaine de la lutte contre la contrefaçon des produits médicaux et les infractions similaires ? Veuillez cocher la case qui correspond le mieux à votre avis.	
	a. Oui, tout à fait	
	b. Oui, dans l'ensemble	
	c. Je ne me prononce pas X	
	d. Non, plutôt pas	
	e. Non, pas du tout	
Hungary		
	Please answer this question placing an 'X' to the RIGHT on the option below that you consider is the closest to your view on whether adequate resources are provided to ensure that persons, units or services in charge of co-operation and information exchange are trained for this purpose relating to counterfeit medical products and related crimes.	
	a. I agree that adequate resources are provided	
	b. I mostly agree that adequate resources are provided	
	c. I neither agree nor disagree that adequate resources are provided	
	d. I mostly disagree that adequate resources are provided	
	e. I disagree that adequate resources are provided	×
Ireland		
	Please answer this question by placing an 'X' to the RIGHT on the option below that you consider is the closest to your view on whether adequate resources are provided to ensure that persons, units or services in charge of co-operation and information exchange are trained for this purpose relating to counterfeit medical products and related crimes.	
	a. I agree that adequate resources are provided	
	b. I mostly agree that adequate resources are provided	X
	c. I neither agree nor disagree that adequate resources are provided	
	d. I mostly disagree that adequate resources are provided	
	e. I disagree that adequate resources are provided	
Moldova		
	Please answer this question placing an 'X' to the RIGHT on the option below that you consider is the closest to your view on whether adequate resources are provided to ensure that persons, units or services in charge of co-operation and information exchange are trained for this purpose relating to counterfeit medical products and related crimes.	

a. I agree that adequate resources are provided	
b. I mostly agree that adequate resources are provided	X
c. I neither agree nor disagree that adequate resources are provided	
d. I mostly disagree that adequate resources are provided	
e. I disagree that adequate resources are provided	

Morocco	No response
Portugal	Please answer this question placing an 'X' to the RIGHT on the option below that you consider is the closest to your view on whether adequate resources are provided to ensure that persons, units or services in charge of co-operation and information exchange are trained for this purpose relating to counterfeit medical products and related crimes.

a. I agree that adequate resources are provided	
b. I mostly agree that adequate resources are provided	
c. I neither agree nor disagree that adequate resources are provided	
d. I mostly disagree that adequate resources are provided	X
e. I disagree that adequate resources are provided	

Slovenia	Please answer this question placing an 'X' to the RIGHT on the option below that you consider is the closest to your view on whether adequate resources are provided to ensure that persons, units or services in charge of co-operation and information exchange are trained for this purpose relating to counterfeit medical products and related crimes.

a. I agree that adequate resources are provided	
b. I mostly agree that adequate resources are provided	
c. I neither agree nor disagree that adequate resources are provided	MP: x
d. I mostly disagree that adequate resources are provided	
e. I disagree that adequate resources are provided	

Spain	Please answer this question placing an 'X' to the RIGHT on the option below that you consider is the closest to your view on whether adequate resources are provided to ensure that persons, units or services in charge of co-operation and information exchange are trained for this purpose relating to counterfeit medical products and related crimes.

a. I agree that adequate resources are provided	
b. I mostly agree that adequate resources are provided	
c. I neither agree nor disagree that adequate resources are provided	
d. I mostly **disagree** that adequate resources are provided	x
e. I disagree that adequate resources are provided	

Switzerland	Please answer this question placing an 'X' to the RIGHT on the option below that you consider is the closest to your view on whether adequate resources are provided to ensure that persons, units or services in charge of co-operation and information exchange are trained for this purpose relating to counterfeit medical products and related crimes.

a. I agree that adequate resources are provided	X
b. I mostly agree that adequate resources are provided	
c. I neither agree nor disagree that adequate resources are provided	
d. I mostly **disagree** that adequate resources are provided	
e. I disagree that adequate resources are provided	

Ukraine	Please answer this question placing an 'X' to the RIGHT on the option below that you consider is the closest to your view on whether adequate resources are provided to ensure that persons, units or services in charge of co-operation and information exchange are trained for this purpose relating to counterfeit medical products and related crimes.

a. I agree that adequate resources are provided	
b. I mostly agree that adequate resources are provided	X
c. I neither agree nor disagree that adequate resources are provided	
d. I mostly agree that adequate resources are provided	
e. I disagree that adequate resources are provided	

Table 15: (Q15) Is there a nominated national contact point responsible for transmitting and receiving requests for information and/or cooperation as regards

a. combating counterfeit medical products and similar crimes (i.e. concerning crimes and criminal behaviours): Yes/No
b. counterfeit medical products (i.e. concerning the medical product): Yes/No
c. Is the contact point for a and b the same contact point: Yes/No
• Specify the designation of this contact point
• Specify the primary purpose of the responsible authority/service for the operation of this point of contact (i.e., law enforcement, border surveillance, health product regulation, etc.)

Armenia

	YES	NO
Is there a nominated national contact point responsible for transmitting and receiving requests for information and/or cooperation as regards		
5. Combating counterfeit medical products and similar crimes (i.e. concerning crimes and criminal behaviours)	X	
6. Counterfeit medical products (i.e. concerning the medical product)	X	
7. Is the contact point for a and b the same contact point	X	

• Please specify the designation of this contact point	**Combating against counterfeiting, transfer of information and training.**
• Please specify the primary purpose of the responsible authority/service for the operation of this point of contact (i.e., law enforcement, border surveillance, health product regulation, etc.)	**Combating against counterfeiting, transfer of information and training.**

Belgium

	YES	NO
Is there a nominated national contact point responsible for transmitting and receiving requests for information and/or cooperation as regards		
a. Combating counterfeit medical products and similar crimes (i.e. concerning crimes and criminal behaviours)	X	
b. Counterfeit medical products (i.e. concerning the medical product)	X	
c. Is the contact point for a and b the same contact point	X	

• Please specify the designation of this contact point	**Special Investigation Unit**
• Please specify the primary purpose of the responsible authority/service for the operation of this point of contact (i.e., law enforcement, border surveillance, health product regulation, etc.)	**Health product regulation**

Bosnia and Herzegovina

	OUI	NON
Un point de contact national a-t-il été désigné pour transmettre et recevoir les demandes d'information et/ou de coopération concernant :		
a. la lutte contre la contrefaçon des produits médicaux et les infractions similaires (c'est-à-dire concernant les actes et comportements délictueux) ?	OUI	
b. les produits médicaux contrefaits (c'est-à-dire concernant les produits médicaux eux-mêmes) ?	OUI	
c. Le point de contact est-il le même pour *a)* et *b)* ?		

• Veuillez préciser le nom de ce point de contact.	**Le Secteur de la coopération policière opérationnelle internationale – rubrique a et b.**
• Veuillez indiquer quelle est la compétence première de l'autorité/du service de tutelle du point de contact (services répressifs, surveillance aux frontières, réglementation des produits de santé, etc.).	**L'agence chargée de l'application de la loi - Direction de la Coordination des Corps de Police de Bosnie-Herzégovine - Coopération policière opérationnelle internationale échange d' informations conformément à ses compétences (a et b)** **Agence des medicaments et des dispositifs medicaux- rubrique b-rapid alert** **Il n'existe pas de réseau d'échange d'informations exclusivement dans ce domaine dans le cadre de la Convention Medicrime.**

Burkina Faso

	OUI	NON
Un point de contact national a-t-il été désigné pour transmettre et recevoir les demandes d'information et/ou de coopération concernant :		

	a. la lutte contre la contrefaçon des produits médicaux et les infractions similaires (c'est-à-dire concernant les actes et comportements délictueux) ?	X	
	b. les produits médicaux contrefaits (c'est-à-dire concernant les produits médicaux eux-mêmes) ?	X	
	c. Le point de contact est-il le même pour *a)* et *b)* ?	X	

• Veuillez préciser le nom de ce point de contact.	**SAWADOGO Boureima (bour_saw@yahoo.fr) Point Focal pour la Convention MEDICRIME Burkina Faso**
• Veuillez indiquer quelle est la compétence première de l'autorité/du service de tutelle du point de contact (services répressifs, surveillance aux frontières, réglementation des produits de santé, etc.).	**Services répressifs (Ministère de la justice)**

Croatia

	YES	NO
Is there a nominated national contact point responsible for transmitting and receiving requests for information and/or cooperation as regards		
a. Combating counterfeit medical products and similar crimes (i.e. concerning crimes and criminal behaviours)	X	
b. Counterfeit medical products (i.e. concerning the medical product)	X	
c. Is the contact point for a and b the same contact point	X	

• Please specify the designation of this contact point	WGEO SPOC EDQM SPOC WHO Focal Points Cyber Crime Unit
• Please specify the primary purpose of the responsible authority/service for the operation of this point of contact (i.e., law enforcement, border surveillance, health product regulation, etc.)	Health product regulation Law enforcement

France

	OUI		NON
Un point de contact national a-t-il été désigné pour transmettre et recevoir les demandes d'information et/ou de coopération concernant :			
a. la lutte contre la contrefaçon des produits médicaux et les infractions similaires (c'est-à-dire concernant les actes et comportements délictueux) ?	X		
b. les produits médicaux contrefaits (c'est-à-dire concernant les produits médicaux eux-mêmes) ?	X		
c. Le point de contact est-il le même pour *a)* et *b)* ?	X		

• Veuillez préciser le nom de ce point de contact.	**Bureau de l'entraide pénale internationale (DACG)**
• Veuillez indiquer quelle est la compétence première de l'autorité/du service de tutelle du point de contact (services répressifs, surveillance aux frontières, réglementation des produits de santé, etc.).	**Le bureau de l'entraide pénale internationale (BEPI Direction des affaires criminelles et des grâces est l'autorité centrale** désignée pour l'application des instruments relatifs à l'entraide pénale internationale. Il assure la mise en œuvre de l'entraide pénale internationale, notamment par l'examen, la transmissio ou le traitement et le suivi des demandes d'entraide au d'enquête, des procédures de mandat d'arrêt européer et de transfèrement de détenus, sauf lorsque des conv instruments prévoient que la transmission des demand directement entre autorités judiciaires. En outre, **le Ministère de l'Intérieur, par l'intermédia la direction centrale de la police judiciaire** s'est doté parallèlement avec la mise en place d'offices centraux **(OCLAESP pour les domaines des atteintes à la l'environnement et à la Santé Publique)**, d'une division des relations internationales (DRI) dont l des missions fondamentales est de coordonner la coopération policière opérationnelle. La division des relations internationales est l'élément moteur en charge de la coopération policière internatio à caractère opérationnel. Dans un **contexte aujourd'hui interministériel (Polic nationale, Gendarmerie nationale, Douane et Justic** DRI est au service de l'ensemble des services de sécu lorsqu'ils sont amenés à utiliser les canaux institutionne (demandes

		de coopération, exécution d'un mandat d'arrêt européen, observation transfrontalière...). La proximité avec l'autorité judiciaire du fait du détachement d'une mission justice, émanation du bureau d'entraide pénal international (BEPI) de la Chancellerie, est également un gage d'efficacité dans le traitement de certaines requêtes nécessitant l'aval d'un magistrat (demandes d'extradition, MAE, etc.). La DRI s'articule autour : - d'une section de coopération opérationnelle de - police (SCCOPOL) en charge de l'échange - d'informations H24 7/7 ; - d'un service en charge des actions de - coopération européenne et internationale - (SCACEI) chargé plus particulièrement du cadre - institutionnel lié au fonctionnement des trois - canaux que sont INTERPOL, EUROPOL et - SCHENGEN ; La mission de la DRI est plus globalement de faciliter l'utilisation, par les services répressifs, de tous les outils de coopération disponibles. »

Hungary		**YES**	**NO**
	Is there a nominated national contact point responsible for transmitting and receiving requests for information and/or cooperation as regards		
	a. Combating counterfeit medical products and similar crimes (i.e. concerning crimes and criminal behaviours)	×	
	b. Counterfeit medical products (i.e. concerning the medical product)	×	
	c. Is the contact point for a and b the same contact point	×	

• Please specify the designation of this contact point	National Focal Point or Single Point of Contact (SPOC).
• Please specify the primary purpose of the responsible authority/service for the operation of this point of contact (i.e., law enforcement, border surveillance, health product regulation, etc.)	One of designated national contacts point which shall be responsible for transmitting and receiving requests for information and/or co-operation in connection with the fight against counterfeiting of medical products and similar crimes involving threats to public health is the colleague of OGYÉI. The other designated national contact is **Ibolya Csako dr. lt. colonel** Hungarian National Police Headquarters Criminal Directorate, law enforcement/Police

Ireland		**YES**	**NO**
	Is there a nominated national contact point responsible for transmitting and receiving requests for information and/or cooperation as regards		
	a. Combating counterfeit medical products and similar crimes (i.e. concerning crimes and criminal behaviours)	Yes	
	b. Counterfeit medical products (i.e. concerning the medical product)	Yes	
	c. Is the contact point for a and b the same contact point	Yes	

• Please specify the designation of this contact point	Each of the authorities mentioned below are agreed points of contact for this purpose according to their relevant networks and then the information is transmitted to the others 1 Intelligence Officer, Enforcement Section, Health Products Regulatory Authority 2 Irish Customs Service with regards to Customs investigations 3 Irish Police Service, the INTERPOL NCB, and Europol NCBs in Ireland transmit and receive such requests for information and/or cooperation regarding investigations 4 Mutual Legal Assistance Section, Department of Justice, administer requests and transmissions relating to cooperation in criminal matters in accordance with the Mutual Legal Assistance Act
• Please specify the primary purpose of the responsible authority/service for the operation of this point of contact (i.e., law	1 Health product regulation 2 Customs and Border Surveillance 3 Law Enforcement 4 Ministry of State

	enforcement, border surveillance, health product regulation, etc.)		
Moldova		**YES**	**NO**
	Is there a nominated national contact point responsible for transmitting and receiving requests for information and/or cooperation as regards		
	a. Combating counterfeit medical products and similar crimes (i.e. concerning crimes and criminal behaviours)	-	-
	b. Counterfeit medical products (i.e. concerning the medical product)	-	-
	c. Is the contact point for a and b the same contact point	Yes	-
	• Please specify the designation of this contact point	Representative of the Republic of Moldova in the MEDICRIME Committee is nominated Ms. Lina Gudima, Deputy Director General, Medicines and Medical Devices Agency.	
	• Please specify the primary purpose of the responsible authority/service for the operation of this point of contact (i.e., law enforcement, border surveillance, health product regulation, etc.)	Medicines and Medical Devices Agency is the regulatory authority responsible for medicines and medical devices for human use.	
Morocco		**OUI**	**NON**
	Un point de contact national a-t-il été désigné pour transmettre et recevoir les demandes d'information et/ou de coopération concernant :		
	a. la lutte contre la contrefaçon des produits médicaux et les infractions similaires (c'est-à-dire concernant les actes et comportements délictueux) ?	X	
	b. les produits médicaux contrefaits (c'est-à-dire concernant les produits médicaux eux-mêmes) ?	X	
	c. Le point de contact est-il le même pour *a)* et *b)* ?	X	
	• Veuillez préciser le nom de ce point de contact.	**Aicha BAMMOU**	
	• Veuillez indiquer quelle est la compétence première de l'autorité/du service de tutelle du point de contact (services répressifs, surveillance aux frontières, réglementation des produits de santé, etc.).	**Réglementation et Contrôle des médicaments et des produits de santé**	
Portugal		**YES**	**NO**
	Is there a nominated national contact point responsible for transmitting and receiving requests for information and/or cooperation as regards		
	a. Combating counterfeit medical products and similar crimes (i.e. concerning crimes and criminal behaviours)		No
	b. Counterfeit medical products (i.e. concerning the medical product)		No
	c. Is the contact point for a and b the same contact point		No
	• Please specify the designation of this contact point		
	• Please specify the primary purpose of the responsible authority/service for the operation of this point of contact (i.e., law enforcement, border surveillance, health product regulation, etc.)	There is no point of contact, but when there are situations of counterfeiting of medicines, it is communicated to the Medicine Authority – Infarmed, IP	
Slovenia		**YES**	**NO**
	Is there a nominated national contact point responsible for transmitting and receiving requests for information and/or cooperation as regards		
	a. Combating counterfeit medical products and similar crimes (i.e. concerning crimes and criminal behaviours)		
	b. Counterfeit medical products (i.e. concerning the medical product)		JAZMP
	c. Is the contact point for a and b the same contact point		
	• Please specify the designation of this contact point		
	• Please specify the primary purpose of the responsible authority/service for the operation of this point of contact (i.e., law enforcement, border surveillance, health product regulation, etc.)	JAZMP: There is no official appointment of a national contact point, but in practice such an exchange of information already exists	
Spain		**YES**	**NO**
	Is there a nominated national contact point responsible for transmitting and receiving requests for information and/or cooperation as regards		
	a. Combating counterfeit medical products and similar crimes (i.e. concerning crimes and criminal behaviours)	x	

	b. Counterfeit medical products (i.e. concerning the medical product)	x	
	c. Is the contact point for a and b the same contact point	x	

• Please specify the designation of this contact point	-Criminal Intelligence Unit(UTPJ) -UCIF(International Cooperation Unit by its letters in Spain) -Ministry of Justice, National contact point - Illegal and Falsified Medicines Unit (AEMPS)
• Please specify the primary purpose of the responsible authority/service for the operation of this point of contact (i.e., law enforcement, border surveillance, health product regulation, etc.)	Law enforcement Health product regulatory authority(AEMPS)

Switzerland		YES	NO
	Is there a nominated national contact point responsible for transmitting and receiving requests for information and/or cooperation as regards		
	8. Combating counterfeit medical products and similar crimes (i.e. concerning crimes and criminal behaviours)		X
	9. Counterfeit medical products (i.e. concerning the medical product)		X
	10. Is the contact point for a and b the same contact point		X

• Please specify the designation of this contact point	National Point of Contact for Illegal Medicines During office hours reachable under +41 58 468 70 65 Outside office hours in urgent cases +41 58 462 07 27 medicrime@swissmedic.ch
• Please specify the primary purpose of the responsible authority/service for the operation of this point of contact (i.e., law enforcement, border surveillance, health product regulation, etc.)	Health product regulation.

Ukraine		YES	NO
	Is there a nominated national contact point responsible for transmitting and receiving requests for information and/or cooperation as regards		
	a. Combating counterfeit medical products and similar crimes (i.e. concerning crimes and criminal behaviours)	X	
	b. Counterfeit medical products (i.e. concerning the medical product)	X	
	c. Is the contact point for a and b the same contact point	X	

• Please specify the designation of this contact point	State Service of Ukraine on Medicines and Drugs Control
• Please specify the primary purpose of the responsible authority/service for the operation of this point of contact (i.e., law enforcement, border surveillance, health product regulation, etc.)	Control over the circulation of medicines and medical products

Table 16: (Q16) If the response in the previous table (Table 15) to a and b is that the contact points are different contact points according to their purpose, please specify, briefly,
a. why arrangements do not facilitate having one agreed national contact point that is responsible for all matters of transmitting and receiving requests for information and/or cooperation with other international contact points
b. What arrangements are in place to coordinate this work to avoid duplication or gaps in transmitting and receiving requests for information and/or cooperation

Armenia	No text content
Belgium	No text content
Bosnia and Herzegovina	Si vous avez répondu à la question 15 que les points de contact ne sont pas les mêmes, veuillez indiquer brièvement : a. pourquoi les modalités en place ne permettent pas de disposer d'un point de contact national unique chargé de toutes les questions relatives à la transmission et à la réception des demandes d'informations et/ou de coopération avec les autres points de contact internationaux : Les points de contact sont déterminés en fonction des compétences des institutions/agences. b. quelles sont les dispositions prises pour assurer la coordination de ces tâches afin d'éviter les doublons :

	ou les failles dans la transmission et la réception des demandes d'informations et/ou de coopération.	
Burkina Faso	No text content	
Croatia		
	If the response to Questions 15 a and b is that the contact points are different contact points according to their purpose, please specify, briefly,	
	a. Why arrangements do not facilitate having one agreed national contact point that is responsible for all matters of transmitting and receiving requests for information and/or cooperation with other international contact points	Contact points are appointed according to their responsibilities (e.g. law enforcement, health product regulation)
	b. What arrangements are in place to coordinate this work to avoid duplication or gaps in transmitting and receiving requests for information and/or cooperation	Information is shared between national contact points that are not on the list when necessary
France	No text content	
Hungary	No text content	
Ireland		
	If the response to Questions 15 a and b is that the contact points are different contact points according to their purpose, please specify, briefly,	
	a. Why arrangements do not facilitate having one agreed national contact point that is responsible for all matters of transmitting and receiving requests for information and/or cooperation with other international contact points	1 Each of the above investigation authorities in Question 15 makes informal requests within their competence with foreign law enforcement authorities and regulatory authorities on the basis of their enabling protocols. 2 The Health Products Regulatory Authority coordinates information relating to communications for counterfeit/falsified/illicit medical products in Question 15 a and b above, but not necessarily relating to making requests where the other authorities lead the investigation. 3 The Irish Customs Service and the Irish Police Service transmit and receive requests according to the investigations they are leading. 4 The Mutual Legal Assistance Section of the Department of Justice administers the formal requests made through the Court Service for the collection and handing over of evidence.
	b. What arrangements are in place to coordinate this work to avoid duplication or gaps in transmitting and receiving requests for information and/or cooperation	The contact points in the three investigation authorities mentioned in question 15 communicate with each other as matters arise, including matters of requests and communications as regards counterfeit/falsified/illicit medical products and in relation to requests made to the Mutual Legal Assistance Section of the Department of Justice.
Moldova	No text content	
Morocco	No text content	
Portugal	No text content	
Slovenia	No text content	
Spain	No text content	
Switzerland	Note Swissmedic: This question has not been answered, as the answer to Question 15 c is that the contact point for a and b is the same contact point.	
Ukraine	No text content	

Table 17: (Q.17) Measures taken to provide training to the national contact point responsible for transmitting and receiving requests for information, and/or cooperation as regards:
a. combating counterfeit medical products and similar crimes (i.e. concerning crimes and criminal behaviours): Yes/No
b. counterfeit medical products (i.e. concerning the medical product): Yes/No
Specify, briefly, what these measures include

Armenia		**YES**	**NO**
	Are there measures taken to provide training to the national contact point responsible for transmitting and receiving requests for information, and/or cooperation as regards		
	g. Combating counterfeit medical products and similar crimes (i.e. concerning crimes and criminal behaviours)	X	

	h. Counterfeit medical products (i.e. concerning the medical product)	X	

Please specify, briefly, what these measures include

The trainings was provided related to topics on general issues of counterfeiting of medical products and transfer of information

Belgium

	YES	**NO**
Are there measures taken to provide training to the national contact point responsible for transmitting and receiving requests for information, and/or cooperation as regards		
a. Combating counterfeit medical products and similar crimes (i.e. concerning crimes and criminal behaviours)	X	
b. Counterfeit medical products (i.e. concerning the medical product)	X	

Please specify, briefly, what these measures include

Inspectors who start working at the FAMHP do a one year training. For the Special Investigations Unit this includes getting to know the authorities and services with which we cooperate and the necessary actions to take to exchange information.

Bosnia and Herzegovina

	OUI	**NON**
Des mesures sont-elles prises pour assurer la formation du point de contact national chargé de transmettre et de recevoir les demandes d'informations et/ou de coopération concernant :		
a. la lutte contre la contrefaçon des produits médicaux et les infractions similaires (c'est-à-dire concernant les actes et comportements délictueux) ?	oui	
b. les produits médicaux contrefaits (c'est-à-dire concernant les produits médicaux eux-mêmes) ?	oui	

Veuillez expliquer brièvement en quoi consistent ces mesures.

Burkina Faso

	OUI	**NON**
Des mesures sont-elles prises pour assurer la formation du point de contact national chargé de transmettre et de recevoir les demandes d'informations et/ou de coopération concernant :		
a. la lutte contre la contrefaçon des produits médicaux et les infractions similaires (c'est-à-dire concernant les actes et comportements délictueux) ?		X
b. les produits médicaux contrefaits (c'est-à-dire concernant les produits médicaux eux-mêmes) ?		X

Veuillez expliquer brièvement en quoi consistent ces mesures.

Croatia

	YES	**NO**
Are there measures taken to provide training to the national contact point responsible for transmitting and receiving requests for information, and/or cooperation as regards		
a. Combating counterfeit medical products and similar crimes (i.e. concerning crimes and criminal behaviours)		X
b. Counterfeit medical products (i.e. concerning the medical product)	X	

Please specify, briefly, what these measures include

Health regulatory authority (HALMED) performs internal training on counterfeit medical products. In addition, SPOC participate in WGEO meetings and other workshops (e.g. the U.S. Food and Drug Administration (FDA) and the OECD Task Force on Countering Illicit Trade (TF-CIT) "Whole-of-Governments approach to protect consumers against illicit trade in health products" workshop held in September 2022).

France

	OUI/NON	**NON**
Des mesures sont-elles prises pour assurer la formation du point de contact national chargé de transmettre et de recevoir les demandes d'informations et/ou de coopération concernant :		
a. la lutte contre la contrefaçon des produits médicaux et les infractions similaires (c'est-à-dire concernant les actes et comportements délictueux) ?	Non	X
b. les produits médicaux contrefaits (c'est-à-dire concernant les produits médicaux eux-mêmes) ?	Non	X

Veuillez expliquer brièvement en quoi consistent ces mesures.

Hungary

	YES	**NO**
Are there measures taken to provide training to the national contact point responsible for transmitting and receiving requests for information, and/or cooperation as regards		
a. Combating counterfeit medical products and similar crimes (i.e. concerning crimes and criminal behaviours)	×	
b. Counterfeit medical products (i.e. concerning the medical product)	×	

Please specify, briefly, what these measures include

The National Contact Point regularly participates in WHO and EDQM training on the SPOC network and activities.

Ireland

	YES	**NO**
Are there measures taken to provide training to the national contact point responsible for transmitting and receiving requests for information, and/or cooperation as regards		
a. Combating counterfeit medical products and similar crimes (i.e. concerning crimes and criminal behaviours)	Yes	

	b. Counterfeit medical products (i.e. concerning the medical product)	Yes	
	Please specify, briefly, what these measures include		
	Each of the three investigating authorities is trained internally on requesting information relating to a and b above and has received training on counterfeit medical products and related crimes. The Mutual Legal Assistance Section is competent in matters within its remit, but not specifically trained on counterfeit/falsified/illicit medical products.		
Moldova		**YES**	**NO**
	Are there measures taken to provide training to the national contact point responsible for transmitting and receiving requests for information, and/or cooperation as regards		
	a. Combating counterfeit medical products and similar crimes (i.e. concerning crimes and criminal behaviours)	-	No
	b. Counterfeit medical products (i.e. concerning the medical product)		
	Please specify, briefly, what these measures include		
Morocco	No text content		
Portugal		**YES**	**NO**
	Are there measures taken to provide training to the national contact point responsible for transmitting and receiving requests for information, and/or cooperation as regards		
	a. Combating counterfeit medical products and similar crimes (i.e. concerning crimes and criminal behaviours)		No
	b. Counterfeit medical products (i.e. concerning the medical product)		No
	Please specify, briefly, what these measures include		
Slovenia		**YES**	**NO**
	Are there measures taken to provide training to the national contact point responsible for transmitting and receiving requests for information, and/or cooperation as regards		
	a. Combating counterfeit medical products and similar crimes (i.e. concerning crimes and criminal behaviours)		JAZMP
	b. Counterfeit medical products (i.e. concerning the medical product)		JAZMP
	Please specify, briefly, what these measures include		
Spain		**YES**	**NO**
	Are there measures taken to provide training to the national contact point responsible for transmitting and receiving requests for information, and/or cooperation as regards		
	a. Combating counterfeit medical products and similar crimes (i.e. concerning crimes and criminal behaviours)		X(Guardia Civil)
	b. Counterfeit medical products (i.e. concerning the medical product)		X(Guardia civil)
	Please specify, briefly, what these measures include		
	Medicrime agreement course Kick off meeting operation Shield IV		
Switzerland		**YES**	**NO**
	Are there measures taken to provide training to the national contact point responsible for transmitting and receiving requests for information, and/or cooperation as regards		
	a. Combating counterfeit medical products and similar crimes (i.e. concerning crimes and criminal behaviours)		X
	b. Counterfeit medical products (i.e. concerning the medical product)		X
	Please specify, briefly, what these measures include		
Ukraine	The SPOC is “trained” by participating in the meetings of the following international committees and working groups: - Committee of Experts on Minimising Public Health Risks Posed by Falsification of Medical Products and Similar Crimes (CD-P-PH/CMED) - Working Group of Enforcement Officers (WGEO) - Permanent Forum on International Pharmaceutical Crime (PFIPC)		

Table 18: (Q. 18) Other 24/7 networks that your authority/service/office, or similar organization, participates in transmitting and receiving of requests for information and/or cooperation as regards
a. combating counterfeit medical products and similar crimes (i.e. concerning crimes and criminal behaviours)
b. counterfeit medical products (i.e. concerning the medical product)
Each listed 24/7 network, by authority/service/similar organisation, should specify the purpose as mentioned in a, or b, or both above

Armenia	
	Please list below any other 24/7 networks that your authority/service/office, or similar organization, participates in transmitting and receiving of requests for information and/or cooperation as regards a. Combating counterfeit medical products and similar crimes (i.e. concerning crimes and criminal behaviours)

b. Counterfeit medical products (i.e. concerning the medical product)

Each listed 24/7 network, by authority/service/similar organisation, should specify the purpose as mentioned in a, or b, or both above (Please insert your response in place of the example below)

Network	**Type of Network**	**Does it include counterfeit medical products and related crimes (both criminal behaviour and products)**
INTERPOL NCB 24/7 network	Law enforcement	Includes operational information exchange relating to the trafficking of counterfeit and other illicit medical products
HMA WGEO	Health Product Enforcement	Includes information exchange relating to the trafficking of counterfeit/falsified and other illicit medical products.

Belgium

Please list below any other 24/7 networks that your authority/service/office, or similar organization, participates in transmitting and receiving of requests for information and/or cooperation as regards

a. Combating counterfeit medical products and similar crimes (i.e. concerning crimes and criminal behaviours)
b. Counterfeit medical products (i.e. concerning the medical product)

Each listed 24/7 network, by authority/service/similar organisation, should specify the purpose as mentioned in a, or b, or both above (Please insert your response in place of the example below)

Network	**Type of Network**	**Does it include counterfeit medical products and related crimes (both criminal behaviour and products)**
INTERPOL NCB 24/7 network	Law enforcement	Includes operational information exchange relating to the trafficking of counterfeit and other illicit medical products
HMA WGEO	Health Product Enforcement	Includes information exchange relating to the trafficking of counterfeit/falsified and other illicit medical products.

Bosnia and Herzegovina

Veuillez mentionner ci-dessous tout autre réseau 24/7 auquel votre autorité/service/bureau, ou organisation similaire, participe pour la transmission et la réception de demandes d'informations et/ou de coopération concernant :

a. la lutte contre la contrefaçon des produits médicaux et les infractions similaires (c'est-à-dire concernant les actes et comportements délictueux).

b. les produits médicaux contrefaits (c'est-à-dire concernant les produits médicaux eux-mêmes).

Pour chaque réseau 24/7 mentionné, veuillez préciser l'autorité/le service/l'organisation similaire concerné ainsi que la finalité telle que mentionnée en *a)*, ou *b)*, ou aux deux rubriques (merci d'insérer votre réponse à la place de l'exemple ci-dessous).

Réseau	**Type de réseau**	**Concerne-t-il les produits médicaux contrefaits et les infractions dans ce domaine (les produits et le comportement délictueux) ?**
INTERPOL NCB 24/7 network	Services répressifs Le BCN INTERPOL échange des informations I 24 heures sur 24 et 7 jours sur 7 avec les autorités répressives y compris la Police de Frontiere de la Bosnie-Herzegovine (15 agences), les parquets, les tribunaux, l'Agence pour les examens et expertises médico-légaux, l'Administration des impôts indirects de Bosnie-Herzégovine, le ministère de la	Concerne l'échange d'informations opérationnelles liées au trafic de produits médicaux contrefaits ou illicites Concerne l'échange d'informations liées au trafic de produits médicaux contrefaits/falsifiés ou illicites

		Justice de Bosnie-Herzégovine, ainsi qu'avec l'Agence des médicaments et des dispositifs médicaux de la Bosnie-Herzégovine, l'Agence de contrôle antidopage et les inspections, et sur le plan international avec le Secretariat General INTERPOL Lyon et les Etats membres d'INTERPOL	L'échange d'informations s'effectue conformément aux compétences des agences. A savoir, s'il s'agit uniquement d'informations à des fins d'alerte, elles seront délivrées à toutes les agences, si les informations sont de nature opérationnelle, elles seront délivrées conformément aux compétences des agences.
	HMA WGEO	Réglementation des produits de santé	Concerne l'échange d'informations liées au trafic de produits médicaux contrefaits/falsifiés ou illicites mais ceci n'est pas un système d'echanges d'information continu et elles sont a seulement a „titre d'information"
	EUROPOL NCP 24/7 network-Siena	Echanges d'information avec les autorites repressives sur le plan national et sur le plan international (Pays de l'Europe)	
	Customs-network	Échange des informations avec BCN INTERPOL via I-24/7, avec EUROPOL, SELEC et les agences d'application de la loi au niveau de l'Etat (3 agences), et avec SCO via le réseau Cecom	
	Agence des medicaments et dispositifs medicaux	Echanges d'information –RAPID ALERT- avec les agences de reglementation des produits de sante	Concerne l'échange d'informations liées au trafic de produits médicaux contrefaits/falsifiés ou illicites.
	Cybercriminalité - réseau Point de contact désigné – BCN INTERPOL Sarajevo	Echanges d'information	

Burkina Faso

Veuillez mentionner ci-dessous tout autre réseau 24/7 auquel votre autorité/service/bureau, ou organisation similaire, participe pour la transmission et la réception de demandes d'informations et/ou de coopération concernant : a. la lutte contre la contrefaçon des produits médicaux et les infractions similaires (c'est-à-dire concernant les actes et comportements délictueux). b. les produits médicaux contrefaits (c'est-à-dire concernant les produits médicaux eux-mêmes). Pour chaque réseau 24/7 mentionné, veuillez préciser l'autorité/le service/l'organisation similaire concerné ainsi que la finalité telle que mentionnée en *a)*, ou *b)*, ou aux deux rubriques (merci d'insérer votre réponse à la place de l'exemple ci-dessous).

Réseau	**Type de réseau**	**Concerne-t-il les produits médicaux contrefaits et les infractions dans ce domaine (les produits et le comportement délictueux) ?**
INTERPOL NCB 24/7 network	Services répressifs	Concerne l'échange d'informations opérationnelles liées au trafic de produits médicaux contrefaits ou illicites
HMA WGEO	Réglementation des produits de santé	Concerne l'échange d'informations liées au trafic de produits médicaux contrefaits/falsifiés ou illicites

Croatia

Please list below any other 24/7 networks that your authority/service/office, or similar organization, participates in transmitting and receiving of requests for information and/or cooperation as regards

a. Combating counterfeit medical products and similar crimes (i.e. concerning crimes and criminal behaviours)
b. Counterfeit medical products (i.e. concerning the medical product)

Each listed 24/7 network, by authority/service/similar organisation, should specify the purpose as mentioned in a, or b, or both above (Please insert your response in place of the example below)

Network	**Type of Network**	**Does it include counterfeit medical products and related crimes (both criminal behaviour and products)**
INTERPOL NCB 24/7 network	Law enforcement	Includes operational information exchange relating to the trafficking of counterfeit and other illicit medical products
HMA WGEO	Health Product Enforcement	Includes information exchange relating to the trafficking of counterfeit/falsified and other illicit medical products.
Rapid Alert System	Health Product Enforcement	Includes information exchange relating to non-compliant (quality defects) and counterfeit medical products

France

Veuillez mentionner ci-dessous tout autre réseau 24/7 auquel votre autorité/service/bureau, ou organisation similaire, participe pour la transmission et la réception de demandes d'informations et/ou de coopération concernant :

a. la lutte contre la contrefaçon des produits médicaux et les infractions similaires (c'est-à-dire concernant les actes et comportements délictueux).

b. les produits médicaux contrefaits (c'est-à-dire concernant les produits médicaux eux-mêmes).

Pour chaque réseau 24/7 mentionné, veuillez préciser l'autorité/le service/l'organisation similaire concerné ainsi que la finalité telle que mentionnée en *a)*, ou *b)*, ou aux deux rubriques (merci d'insérer votre réponse à la place de l'exemple ci-dessous).

Réseau	**Type de réseau**	**Concerne-t-il les produits médicaux contref infractions dans ce domaine (les produits e comportement délictueux) ?**
INTERPOL NCB 24/7 network	Services répressifs	Concerne l'échange d'informations opérationne liées au trafic de produits médicaux contrefaits illicites
HMA WGEO	Réglementation des produits de santé	Concerne l'échange d'informations liées au tra médicaux contrefaits/falsifiés ou illicites.
EUROPOL SIENA	Services répressifs	Concerne l'échange d'informations opérationne liées au trafic de produits médicaux contrefaits illicites

Hungary

Please list below any other 24/7 networks that your authority/service/office, or similar organization, participates in transmitting and receiving of requests for information and/or cooperation as regards

a. Combating counterfeit medical products and similar crimes (i.e. concerning crimes and criminal behaviours)
b. Counterfeit medical products (i.e. concerning the medical product)

Each listed 24/7 network, by authority/service/similar organisation, should specify the purpose as mentioned in a, or b, or both above (Please insert your response in place of the example below)

Network	**Type of Network**	**Does it include counterfeit medical products and related crimes (both criminal behaviour and products)**
HMA WGEO	Health Product Enforcement	Includes information exchange relating to the trafficking of

			counterfeit/falsified and other illicit medical products.
	Europol	law enforcement	Includes operational information exchange relating to the trafficking of counterfeit and other illicit medical products

Ireland

Please list below any other 24/7 networks that your authority/service/office, or similar organization, participates in transmitting and receiving requests for information and/or cooperation as regards

a. Combating counterfeit medical products and similar crimes (i.e. concerning crimes and criminal behaviours)
b. Counterfeit medical products (i.e. concerning the medical product)

Each listed 24/7 network, by authority/service/similar organisation, should specify the purpose as mentioned in a, or b, or both above (Please insert your response in place of the example below)

Network	**Type of Network**	**Does it include counterfeit medical products and related crimes (both criminal behaviour and products)**
INTERPOL NCB 24/7 network	Law enforcement	Includes information exchange relating to the trafficking of counterfeit/falsified and other illicit medical products. This is a law enforcement network on all crime types
Heads of Medicines Agencies Working Group of Enforcement Officers (HMA WGEO)	Health Product Enforcement	Includes information exchange relating to the trafficking of counterfeit/falsified and other illicit medical products. The network is a specific network for counterfeit/falsified and other illicit medical products
Permanent Forum on International Pharmaceutical Crime (PFIPC)	Health Product Enforcement	Includes information exchange relating to the trafficking of counterfeit/falsified and other illicit medical products. The network is a specific network for counterfeit/falsified and other illicit medical products
CENcomm	Customs Enforcement Network	Includes information exchange relating to combating crime
Pharmaceutical Inspection Cooperation Scheme Rapid Alert network	Health Product Regulatory	Regulatory network among National health product regulatory authorities to exchange rapid alerts on medicinal product quality defects, including counterfeit medicinal products.

Moldova

Please list below any other 24/7 networks that your authority/service/office, or similar organization, participates in transmitting and receiving of requests for information and/or cooperation as regards

a. Combating counterfeit medical products and similar crimes (i.e. concerning crimes and criminal behaviours)
b. Counterfeit medical products (i.e. concerning the medical product)

Each listed 24/7 network, by authority/service/similar organisation, should specify the purpose as mentioned in a, or b, or both above (Please insert your response in place of the example below)

Network	**Type of Network**	**Does it include counterfeit medical products and related crimes (both criminal behaviour and products)**
WHO Global Surveillance and Monitoring System	Health Product Enforcement	Includes information exchange relating to prevention, detection and response to SF products

Morocco

Veuillez mentionner ci-dessous tout autre réseau 24/7 auquel votre autorité/service/bureau, ou organisation similaire, participe pour la transmission et la réception de demandes d'informations et/ou de coopération concernant :

a. la lutte contre la contrefaçon des produits médicaux et les infractions similaires (c'est-à-dire concernant les actes et comportements délictueux).

b. les produits médicaux contrefaits (c'est-à-dire concernant les produits médicaux eux-mêmes).

Pour chaque réseau 24/7 mentionné, veuillez préciser l'autorité/le service/l'organisation similaire concerné ainsi que la finalité telle que mentionnée en *a)*, ou *b)*, ou aux deux rubriques (merci d'insérer votre réponse à la place de l'exemple ci-dessous).

Réseau	**Type de réseau**	**Concerne-t-il les produits médicaux contrefaits et les infractions dans ce domaine (les produits et le comportement délictueux) ?**
OMS		**Réception des informations et des cas d'alertes notifiées par les autorités compétentes membres de l'OMS, de produits médicaux de qualité inférieure et falsifiés qui sont saisis par ces autorités de régulation.**
INTERPOL		**Echange d'informations opérationnelles liées au trafic de produits médicaux contrefaits ou illicites**

Portugal

QUESTION

Please list below any other 24/7 networks that your authority/service/office, or similar organization, participates in transmitting and receiving of requests for information and/or cooperation as regards

a. Combating counterfeit medical products and similar crimes (i.e. concerning crimes and criminal behaviours)
b. Counterfeit medical products (i.e. concerning the medical product)

Each listed 24/7 network, by authority/service/similar organisation, should specify the purpose as mentioned in a, or b, or both above (Please insert your response in place of the example below)

Network	**Type of Network**	**Does it include counterfeit medical products and related crimes (both criminal behaviour and products)**
INTERPOL NCB 24/7 network	Law enforcement	Includes operational information exchange relating to the trafficking of counterfeit and other illicit medical products
HMA WGEO	Health Product Enforcement	Includes information exchange relating to the trafficking of counterfeit/falsified and other illicit medical products.
Policia Judiciária 24/07	Law enforcement	The Judiciary Police has a 24/07 service for all types of crime, in which it can eventually, if it is a communication of crime, take care of the occurrence.
Autoridade do Medicamento, Infarmed, IP	Health Product Enforcement	Although there is no 24/07 system, there is a daily report from the Tax Authority (Customs) to the Medication Authority, Infarmed, IP about counterfeit and/or dangerous drugs.

Slovenia

Please list below any other 24/7 networks that your authority/service/office, or similar organization, participates in transmitting and receiving of requests for information and/or cooperation as regards

a. Combating counterfeit medical products and similar crimes (i.e. concerning crimes and criminal behaviours)
b. Counterfeit medical products (i.e. concerning the medical product)

Each listed 24/7 network, by authority/service/similar organisation, should specify the purpose as mentioned in a, or b, or both above (Please insert your response in place of the example below)

Network	Type of Network	Does it include counterfeit medical products and related crimes (both criminal behaviour and products)
INTERPOL NCB 24/7 network	Law enforcement	Includes operational information exchange relating to the trafficking of counterfeit and other illicit medical products
HMA WGEO	Health Product Enforcement	Includes information exchange relating to the trafficking of counterfeit/falsified and other illicit medical products.
JAZMP: Rapid Alert System	National Competent Authorities for Medicinal products	a system for the rapid exchange of information on quality defects (including counterfeit/falsified and other illicit medical products) or a recall of medicines between competent authorities for medicines
MF: There is no such unit in the Financial Administration of Republic of Slovenia.		
MNZ: EUROPOL SIENA network	Law enforcement	operational information exchange related to the trafficking of counterfeit and other illicit medical products

Spain

Please list below any other 24/7 networks that your authority/service/office, or similar organization, participates in transmitting and receiving of requests for information and/or cooperation as regards

a. Combating counterfeit medical products and similar crimes (i.e. concerning crimes and criminal behaviours)
b. Counterfeit medical products (i.e. concerning the medical product)

Each listed 24/7 network, by authority/service/similar organisation, should specify the purpose as mentioned in a, or b, or both above (Please insert your response in place of the example below)

Network	Type of Network	Does it include counterfeit medical products and related crimes (both criminal behaviour and products)
INTERPOL NCB 24/7 network	Law enforcement	Includes operational information exchange relating to the trafficking of counterfeit and other illicit medical products
HMA WGEO	Health Product Enforcement	Includes information exchange relating to the trafficking of counterfeit/falsified and other illicit medical products.
UCIF	Public prosecutors specialized on International Cooperation Network	Includes the management of all applicable international cooperation tools coming from abroad in order to pursue in front of the Criminal Courts trafficking of counterfeit/ falsified and another illicit medical products.
REJUE	Judges specialized on International Cooperation Network	The objective is to assist Spanish courts, upon request, in all requests for international judicial cooperation issued or received in the exercise of their jurisdictional activity and to assist other members of judicial cooperation networks.
EUROJUST	international judicial cooperation	The Spanish national member of Eurojust shall be empowered to receive, transmit, provide, follow up and provide complementary information in relation to the execution of requests and decisions on judicial cooperation, including instruments of mutual recognition, sent by the competent national authorities.
SIENA Europol channel	Law enforcement	Includes operational information exchange relating to the trafficking of

			counterfeit and other illicit medical products.
	POLICIA NACIONAL 24/7 CONTACT	Crime investigations	It includes an e-mail and a phone number where any police force (National Police or other) can contact in order to request a fast answer or any cooperation. This contact is situated in the Specialized Investigation Unit in charge of that kind of investigations.
	AEMPS	Health Product Enforcement	E-mail address to report to AEMPS any suspected and confirmed falsified medicine in the legal supply chain (medicamentos.falsificados@aemps.es).

Switzerland

Please list below any other 24/7 networks that your authority/service/office, or similar organization, participates in transmitting and receiving of requests for information and/or cooperation as regards

a. Combating counterfeit medical products and similar crimes (i.e. concerning crimes and criminal behaviours)
b. Counterfeit medical products (i.e. concerning the medical product)

Each listed 24/7 network, by authority/service/similar organisation, should specify the purpose as mentioned in a, or b, or both above (Please insert your response in place of the example below)

Network	**Type of Network**	**Does it include counterfeit medical products and related crimes (both criminal behaviour and products)**
INTERPOL NCB 24/7 network	Law enforcement	Includes operational information exchange relating to the trafficking of counterfeit and other illicit medical products
HMA WGEO	Health Product Enforcement	Includes information exchange relating to the trafficking of counterfeit/falsified and other illicit medical products.
24/7 network of the SPOC	Health Product and Law Enforcement	Includes information exchange relating to the trafficking of counterfeit/falsified and other illicit medical products.
Cantonal prosecutors' offices and cantonal police authorities	Law Enforcement	Includes information exchange relating to the trafficking of counterfeit/falsified and other illicit medical products.
FOCBS	Border Surveillance and Law Enforcement	Includes information exchange relating to the trafficking of counterfeit/falsified and other illicit medical products.

Ukraine

Please list below any other 24/7 networks that your authority/service/office, or similar organization, participates in transmitting and receiving of requests for information and/or cooperation as regards

a. Combating counterfeit medical products and similar crimes (i.e. concerning crimes and criminal behaviours)
b. Counterfeit medical products (i.e. concerning the medical product)

Each listed 24/7 network, by authority/service/similar organisation, should specify the purpose as mentioned in a, or b, or both above (Please insert your response in place of the example below)

Network	**Type of Network**	**Does it include counterfeit medical products and related crimes (both criminal behaviour and products)**
State Enterprise "Government Contact Center"	ensuring prompt response to appeals received on the government helpline mechanism	The mechanism of communication between the Government and citizens, which allows prompt response to problematic issues raised in citizens' appeals

Table 19: (Q.19) Number of requests for information or data exchange, including those emanating from the policing services, the customs service, the national health products regulatory authority, and others, as regards the combating of medical products and related crimes:
If the data is unavailable for inclusion in the response to this questionnaire is this due to the data:
a. Not recorded in a retrievable manner relating to counterfeit medical products and similar crimes (relating to crimes and criminal behaviours): Yes/No
b. No recorded: Yes/No

Armenia

Dates made/received	Made by your country to other countries	Received by other countries from other countries
01/01/2020 to 31/12/2022		
01/01/2017 to 31/12/2019		

	YES	NO
If the data is unavailable for inclusion in the response to this questionnaire due to		
a. Not recorded in a retrievable manner relating to counterfeit medical products and similar crimes (relating to crimes and criminal behaviours)		X
b. No recorded		X

Belgium

Dates made/received	Made by your country to other countries	Received by other countries from other countries
01/01/2020 to 31/12/2022		
01/01/2017 to 31/12/2019		

	YES	NO
If the data is unavailable for inclusion in the response to this questionnaire due to		
a. Not recorded in a retrievable manner relating to counterfeit medical products and similar crimes (relating to crimes and criminal behaviours)	X	
b. No recorded		X

Bosnia and Herzegovina

Dates faites/reçues	Envoyées par votre pays à d'autres pays	Émanant d'autres pays et reçues par votre pays
01/01/2020 au 31/12/2022	300 echanges d'information par le biais d'Interpol (18 cas ouverts)	700 echanges d'information par le biais d'Interpol (220 cas ouverts)
01/01/2017 au 31/12/2019		

Burkina Faso

Dates faites/reçues	Envoyées par votre pays à d'autres pays	Émanant d'autres pays et reçues par votre pays
01/01/2020 au 31/12/2022	NSP	NSP
01/01/2017 au 31/12/2019	NSP	NSP

	OUI	NON
Si vous ne disposez pas des données permettant de compléter le tableau ci-dessus, veuillez préciser le cas de figure :		
a. Données n'ayant pas été enregistrées de manière récupérable (pour les données concernant la contrefaçon des produits médicaux et les infractions similaires, c'est-à-dire les actes et comportements délictueux).		X
b. Données non enregistrées.		X

Croatia

Dates made/received	Made by your country to other countries	Received by other countries from other countries
01/01/2020 to 31/12/2022		Information and data exchange via rapid alert lists (SPOC lists)
01/01/2017 to 31/12/2019		Information and data exchange via rapid alert lists (SPOC lists)

	YES	NO
If the data is unavailable for inclusion in the response to this questionnaire due to		
a. Not recorded in a retrievable manner relating to counterfeit medical products and similar crimes (relating to crimes and criminal behaviours)	X	

	b. No recorded		

France

No data content

Hungary

Dates made/received	Made by your country to other countries via Europol	Received via Europol from other countries
01/01/2020 to 31/12/2022	55	155
01/01/2017 to 31/12/2019	64	198

	YES	NO
If the data is unavailable for inclusion in the response to this questionnaire due to		
a. Not recorded in a retrievable manner relating to counterfeit medical products and similar crimes (relating to crimes and criminal behaviours)	×	
b. No recorded		×

Ireland

Dates made/received	Made by your country to other countries	Received by other countries from other countries
01/01/2020 to 31/12/2022		
01/01/2017 to 31/12/2019		

	YES	NO
If the data is unavailable for inclusion in the response to this questionnaire due to		
a. Not recorded in a retrievable manner relating to counterfeit medical products and similar crimes (relating to crimes and criminal behaviours)	Yes	Yes
b. Not recorded	N/A	N/A

Moldova

Dates made/received	Made by your country to other countries	Received by other countries from other countries
01/01/2020 to 31/12/2022	0	30
01/01/2017 to 31/12/2019	0	12 (referred only for period between 01/01/2019 to 31.12.2019)

	YES	NO
If the data is unavailable for inclusion in the response to this questionnaire due to		
a. Not recorded in a retrievable manner relating to counterfeit medical products and similar crimes (relating to crimes and criminal behaviours)	Yes	-
b. No recorded	-	No

Morocco

No data content

Portugal

Dates made/received	Made by your country to other countries	Received by other countries from other countries
01/01/2020 to 31/12/2022		
01/01/2017 to 31/12/2019		

	YES	NO
If the data is unavailable for inclusion in the response to this questionnaire due to		
a. Not recorded in a retrievable manner relating to counterfeit medical products and similar crimes (relating to crimes and criminal behaviours)		NO
b. No recorded		NO

Slovenia

Dates made/received	Made by your country to other countries	Received by other countries from other countries
01/01/2020 to 31/12/2022		MF: Financial Administration did not receive any such information.
01/01/2017 to 31/12/2019		MF: Financial Administration did not receive any such information.

Spain

Dates made/received-**data from the Guardia civil**	Made by your country to other countries	Received by other countries from other countries
01/01/2020 to 31/12/2022	43	56
01/01/2017 to 31/12/2019	31	29

		YES	NO
	If the data is unavailable for inclusion in the response to this questionnaire due to		
	a. Not recorded in a retrievable manner relating to counterfeit medical products and similar crimes (relating to crimes and criminal behaviours)	x	
	b. No recorded		

Switzerland

Dates made/received	Made by your country to other countries	Received by other countries from other countries
01/01/2020 to 31/12/2022		
01/01/2017 to 31/12/2019		

	YES	NO
If the data is unavailable for inclusion in the response to this questionnaire due to		
a. Not recorded in a retrievable manner relating to counterfeit medical products and similar crimes (relating to crimes and criminal behaviours)	x	
b. No recorded		

Ukraine

Dates made/received	Made by your country to other countries	Received by other countries from other countries
01/01/2020 to 31/12/2022	78	648
01/01/2017 to 31/12/2019	180	Approximately 620

Table 20: (Q.20) Identify the types of requests to be exchanged over a 24/7 network between countries:
a. rapid access to evidence in criminal proceedings: Yes/No
b. preservation of evidence in another jurisdiction: Yes/No
c. exchange of investigative information: Yes/No
d. information about counterfeit medical products: Yes/No
e. technical advice: Yes/No
f. other (please briefly describe)

Armenia

	YES	NO
Please identify what are the types of requests to be exchanged over a 24/7 network between countries:		
s. Rapid access to evidence in criminal proceedings	X	
t. Preservation of evidence in another jurisdiction		
u. Exchange of investigative information	X	
v. Information about counterfeit medical products	X	
w. Technical advice		
x. Other (please briefly describe)		

Belgium

	YES	NO
Please identify what are the types of requests to be exchanged over a 24/7 network between countries:		
a. Rapid access to evidence in criminal proceedings	X	
b. Preservation of evidence in another jurisdiction	X	
c. Exchange of investigative information	X	
d. Information about counterfeit medical products		X
e. Technical advice		X
f. Other (please briefly describe)		

Bosnia and Herzegovina

	OUI	NON
Veuillez indiquer quels sont les différents types de demandes qui peuvent être faites dans le cadre d'un réseau 24/7 entre pays :		
a. Accès rapide aux preuves dans les procédures pénales		
b. Conservation des preuves dans une autre juridiction		
c. Partage des éléments de l'enquête	oui	
d. Informations sur des produits médicaux contrefaits	oui	
e. Conseils techniques	oui	
f. Autre (Extradition)	oui	

Burkina Faso

	OUI	NON
Veuillez indiquer quels sont les différents types de demandes qui peuvent être faites dans le cadre d'un réseau 24/7 entre pays :		
a. Accès rapide aux preuves dans les procédures pénales	X	
b. Conservation des preuves dans une autre juridiction	X	
c. Partage des éléments de l'enquête	X	
d. Informations sur des produits médicaux contrefaits	X	
e. Conseils techniques	X	

	f. Autre		
Croatia		**YES**	**NO**
	Please identify what are the types of requests to be exchanged over a 24/7 network between countries:		
	a. Rapid access to evidence in criminal proceedings	X	
	b. Preservation of evidence in another jurisdiction	X	
	c. Exchange of investigative information	X	
	d. Information about counterfeit medical products	X	
	e. Technical advice		
	f. Other (please briefly describe): information on quality defects	X	

France		**OUI**		**NON**
	Veuillez indiquer quels sont les différents types de demandes qui peuvent être faites dans le cadre d'un réseau 24/7 entre pays :			
	a. Accès rapide aux preuves dans les procédures pénales			
	b. Conservation des preuves dans une autre juridiction			
	c. Partage des éléments de l'enquête	X		
	d. Informations sur des produits médicaux contrefaits	X		
	e. Conseils techniques	X		
	f. Autre (veuillez préciser)			
	Les demandes d'entraide pénale internationale ne peuvent pas toutes passer par les points de contact 24/7 qui ne concernent que la coopération policière ou administrative, mais doivent passer par des demandes d'entraide pénale.			

Hungary	**QUESTION**	**YES**	**NO**
	Please identify what are the types of requests to be exchanged over a 24/7 network between countries:		
	a. Rapid access to evidence in criminal proceedings		
	b. Preservation of evidence in another jurisdiction		
	c. Exchange of investigative information		
	d. Information about counterfeit medical products	×	
	e. Technical advice	×	
	f. Other (please briefly describe)		
Ireland	**QUESTION**	**YES**	**NO**
	Please identify what are the types of requests to be exchanged over a 24/7 network between countries:		
	a. Rapid access to evidence in criminal proceedings	Yes	
	b. Preservation of evidence in another jurisdiction	Yes	
	c. Exchange of investigative information	Yes	
	d. Information about counterfeit medical products	Yes	
	e. Technical advice	Yes	
	f. Other (please briefly describe)		
Moldova		**YES**	**NO**
	Please identify what are the types of requests to be exchanged over a 24/7 network between countries:		
	a. Rapid access to evidence in criminal proceedings		
	b. Preservation of evidence in another jurisdiction		
	c. Exchange of investigative information		
	d. Information about counterfeit medical products	X	
	e. Technical advice		
	f. Other (please briefly describe)		
Morocco		**OUI**	**NON**
	Veuillez indiquer quels sont les différents types de demandes qui peuvent être faites dans le cadre d'un réseau 24/7 entre pays :		
	a. Accès rapide aux preuves dans les procédures pénales		
	b. Conservation des preuves dans une autre juridiction		
	c. Partage des éléments de l'enquête	X	
	d. Informations sur des produits médicaux contrefaits	X	
	e. Conseils techniques	X	
	f. Autre (veuillez préciser)		
Portugal		**YES**	**NO**
	Please identify what are the types of requests to be exchanged over a 24/7 network between countries:		
	a. Rapid access to evidence in criminal proceedings		No
	b. Preservation of evidence in another jurisdiction		No
	c. Exchange of investigative information		No
	d. Information about counterfeit medical products		No
	e. Technical advice		No
	f. Other (please briefly describe)		No
Slovenia		**YES**	**NO**

	Please identify what are the types of requests to be exchanged over a 24/7 network between countries:		
	a. Rapid access to evidence in criminal proceedings	MNZ	
	b. Preservation of evidence in another jurisdiction		
	c. Exchange of investigative information	MNZ	
	d. Information about counterfeit medical products	MNZ	
	e. Technical advice		
	f. Other (please briefly describe)		
Spain		**YES**	**NO**
	Please identify what are the types of requests to be exchanged over a 24/7 network between countries:		
	a. Rapid access to evidence in criminal proceedings	x	
	b. Preservation of evidence in another jurisdiction	x	
	c. Exchange of investigative information	x	
	d. Information about counterfeit medical products	x	
	e. Technical advice	x	
	f. Other (please briefly describe)		
Switzerland		**YES**	**NO**
	Please identify what are the types of requests to be exchanged over a 24/7 network between countries:		
	a. Rapid access to evidence in criminal proceedings	x	
	b. Preservation of evidence in another jurisdiction	x	
	c. Exchange of investigative information		X
	d. Information about counterfeit medical products		X
	e. Technical advice		X
	f. Other (please briefly describe)		
Ukraine		**YES**	**NO**
	Please identify what are the types of requests to be exchanged over a 24/7 network between countries:		
	a. Rapid access to evidence in criminal proceedings	X	
	b. Preservation of evidence in another jurisdiction	X	
	c. Exchange of investigative information		X
	d. Information about counterfeit medical products	X	
	e. Technical advice	X	
	f. Other (please briefly describe)		

Additional comments

Switzerland
"Before answering the Questionnaire on a 24/7 Network ("Questionnaire"), Swissmedic would like to emphasize its dissatisfaction with the process in which the Questionnaire was compiled. Swissmedic, which is a member of the Working Group MEDICRIME 24/7, was not invited to take part in developing the questions. Rather than taking an academic approach, it is of utmost importance, that the practitioners' point of view is taken into account. The question that has to be asked is: Why does a 24/7 network need to be established by the member states of the MEDICRIME Convention? In order to be able to answer this question, cases have to be identified in which 24/7 accessibility is necessary for criminal prosecution. Regardless of this, the questions are also poorly crafted as they overlap partially (cf. Question 1 lit. a: "national strategy" vs. lit. b: "national strategy or, a national action plan") or encompass sections which are not questions in the proper meaning of the word, but rather requests for (further) substantiation (e.g. "Questions" 3 b] or d]). Last but not least, the instruction for the completion of the Questionnaire, pursuant to which incorrect responses have to be striked out (see page 3, item 2), is ***very confusing and totally uncommon****. Usually, in questionnaires of any kind a correct box has to be ticked. It is foreseeable that many of the respondents to this questionnaire won't give their answers as intended".*

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