The MEDICRIME Convention
La Convention MÉDICRIME

COUNCIL OF EUROPE
CONSEIL DE L'EUROPE

GENERAL OVERVIEW QUESTIONNAIRE ON THE IMPLEMENTATION OF THE MEDICRIME CONVENTION

As adopted by the Bureau of the MEDICRIME Committee on 7 July 2020

Replies should be addressed to the MEDICRIME Committee Secretariat by **23 September 2020** (**medicrime@coe.int**)

Document prepared by the MEDICRIME Committee Secretariat
Directorate General I – Human Rights and Rule of Law

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I. INTRODUCTION

1. The Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health [1] (hereinafter "the MEDICRIME Convention" or "the Convention"), which entered into force in January 2016, requires criminalisation of the manufacturing of counterfeit medical products, of the supplying, offering to supply and trafficking in counterfeit medical products, of the falsification of documents and of the unauthorised manufacturing or unauthorised supplying of medicinal products and of the placing on the market of medical devices which do not comply with conformity requirements. The Convention provides a framework for national and international co-operation across the different sectors of the public administration, measures for coordination at national level, preventive measures for use by public and private sectors and protection of victims and witnesses. Furthermore, it foresees the establishment of a monitoring body to oversee the implementation of the Convention by the States Parties.

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

> 1. *Following ratification and within six months from the entry into force of the MEDICRIME Convention in respect of the Party concerned, every Party to the Convention shall be required to reply to a questionnaire aimed at providing the MEDICRIME Committee with a general overview of its legislative practice, institutional framework and policies for the implementation of the Convention at the national, regional and local levels. Thereafter, the Parties should regularly inform the MEDICRIME Committee of any substantial changes to the situation described in their replies to the general overview questionnaire.*
>
> 2. *States which have signed the Convention shall be invited to reply to the questionnaire referred to in paragraph 1 of this rule.*
>
> 3. *The secretariat shall compile the replies received and make them public on the Committee's website[2].*

3. In accordance with Rule 26 of the Committee's Rules of Procedure:

> *" (…)*
> 2. *The secretariat shall address such questionnaires to the Parties through the member in the MEDICRIME Committee representing the Party to be monitored and who will act as "contact point".*
>
> 3. *Parties shall coordinate with their respective domestic authorities to collect replies, which shall be submitted to the secretariat in one of the official languages of the Council of Europe within the time limit set by the MEDICRIME Committee. The*

[1] Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health, CETS No. 211, Article 1, para. 2.
[2] MEDICRIME Committee's Rules of Procedure, Rule 24.

replies to the questionnaire shall be detailed, as comprehensive as possible, answer all questions and contain all relevant reference texts. The replies shall be made public, unless a Party makes a reasoned request to the MEDICRIME Committee to keep its reply confidential.

4. *The MEDICRIME Committee may also receive information on the implementation of the Convention from non-governmental organisations and civil society involved in preventing and combating the counterfeiting of medical products and similar crimes involving threats to public health, in one of the official languages of the Council of Europe and within the time-limit set by the MEDICRIME Committee. The secretariat transmits these comments to the Party or Parties concerned.*

5. *The secretariat may request additional information if it appears that the replies are not exhaustive or are unclear. Where warranted, with the consent of the Party or Parties concerned and within the limits of budgetary appropriations, the Bureau may decide to carry out an on-site visit to the Party or Parties concerned to clarify the situation. The bureau shall establish guidance as to the procedure governing the on-site visits."*

4. The purpose of this general questionnaire is to collect information to provide the MEDICRIME Committee with an overview of the situation, which will constitute the general framework within which it will assess replies by Parties to the thematic questionnaire for the first monitoring round (see Rule 24 of the MEDICRIME Committee's Rules of Procedure).

II. PRELIMINARY REMARKS

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

6. Parties will be invited to update their replies to this general questionnaire when they will receive the next thematic questionnaire. Responses to a thematic questionnaire should therefore be interrelated and combined with the responses provided in the context of this questionnaire.

7. Parties are kindly requested to:

- specify which state body/agency was responsible for collecting the replies to this questionnaire and which state bodies/agencies (and, at the discretion of the country, where relevant, civil society and external contributors) contributed to responding to this questionnaire;

- answer the questions with regard to central, regional and local levels to the extent possible. Federal states may, in respect of their sovereign entities, answer the questions in a summarised way;

- answer the questions from a non-discriminatory perspective (for example, related to gender)[3], i.e. specifying, where relevant, whether and how measures for victims and/or offenders take into account gender-specific requirements;

- bear in mind that when replying to questions related to "internal law" reference should also be made to the relevant case law;

- provide, whenever questions/answers refer to it, the relevant text (or a summary) of legislation or other regulations in English or French;

- if some of the questions below correspond to questions put to Parties by other bodies of the Council of Europe or other organisations (whether or not these are governmental bodies), Parties may refer to their initials answers (by providing a link to the relevant replies or by copying their answers) and update the information where necessary.

- in responding to questions, if you agree, please provide a reference to the legal provision. If you do not agree, please provide an explanation.

III. GENERAL FRAMEWORK

Question 1: Definitions

a. Does the understanding of "medical product" under your internal law correspond to that set out in **Article 4, letter (a)**, i.e. "medicinal products and medical devices"?

Answer: Specific definition on "medical product" is not defined in the legislation of the Republic of Armenia (hereinafter RA). However, the definition of the medicinal product and medical devices are defined in the legislation.

Comment: The "Law on Medicines" (ՀՕ-86-Ն, the text of the law is available with the link to Armenian juridical informational system: https://www.arlis.am/hy/acts/106446) is including the definition of the term "Medicinal Product" and the law on "Medical aid and service" (the text of the law is available with the link to Armenian juridical informational system https://www.arlis.am/hy/acts/208780/latest) is including definition of the term "Medical Device".

b. Does the understanding of "medicinal product" under your internal law correspond to that set out in **Article 4, letter (b)**, i.e. "medicines for human and veterinary use which may be:
   i. any substance or combination of substances presented as having properties for treating or preventing disease in humans or animals;
   ii. any substance or combination of substances which may be used in or administered to human beings or animals either with a view to restoring,

[3] As envisaged in Art. 2 of the MEDICRIME Convention.

correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis;

iii. an investigational medicinal product"?

Answer: All the three sub points are in compliance with the definition that is including in the "Law on Medicines" of the RA.

Comment: The definition of the "Medicinal product" is included in the Article 3 of the Law on Medicines of the RA item number 1 sub item 1). The definition is following: "The medicinal product is a means having pharmacological and (or) immunological and (or) metabolic activities receivied from human, and (or) animal and (or) biotechnological source with with relevant dosage strength and dosage form, and packaging and labeling, which may be administered to human beings with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in human beings is likewise considered a medicinal product. Subt ítem 11) on defining what is the investigational medicina product it is mentioned that it is an an active ingredient in certain pharmaceutical form or placebo (a product with no active ingredient) being used as a test sample or reference in a clinical trial, including any registered medicinal product which route of administration or production is different from the registered medicinal product (in a pharmaceutical form or packaging material), or the given indication for use whereof is not registered or is investigated to obtain additional information on the registered pharmaceutical form.

c. Does the understanding of "active substance" under your internal law correspond to that set out in **Article 4, letter (c)**, i.e. "any substance or mixture of substances that is designated to be used in the manufacture of a medicinal product, and that, when used in the production of a medicinal product, becomes an active ingredient of the medicinal product"?

Answer: Yes. The definition of the "Medicinal product" is included in the Article 3 of the Law on Medicines of the RA item number 1 sub item 8).

Comment: The definition is following: a substance of human (human blood, blood preparation, other substances of human origin) and (or) animal (micro-organism, intact animal, parts of organs, animal secretions, toxins, extracts, blood products, other substances of animal origin) and (or) plant (micro-organisms, plants, parts of plants, plant secretions, extracts, other substances of plant origin) and (or) chemical origin (elements, naturally occurring chemical materials, chemical products obtained by chemical change or synthesis, other substances of chemical origin) having pharmacological or immunological or metabolic action used to prepare or produce medicinal products;

d. Does the understanding of "excipient" under your internal law correspond to that set out in **Article 4, letter (d)**, i.e. "any substance that is not an active substance or a finished medicinal product, but is part of the composition of a medicinal product for human or veterinary use and essential for the integrity of the finished product"?

Answer: Yes. The definition of the "Medicinal product" is included in the Article 3 of the Law on Medicines of the RA item number 1 sub item 10).

Comment: The definition is following: **excipient —** any component that is not an active ingredient of the medicinal product or a packaging material;

e. Does the understanding of “medical devices” under your internal law correspond to that set out in **Article 4, letter (e)**, i.e. “any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software, designated by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, designated by the manufacturer to be used for human beings for the purpose of:

i. diagnosis, prevention, monitoring, treatment or alleviation of disease;
ii. diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap;
iii. investigation, replacement or modification of the anatomy or of a physiological process;
iv. control of conception;

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means”?

Answer: Definition of the medical device is established by law “On Public Health and Services” of RA, Article 2, Item 1, sub item 50). According to definition the medical device is - any instrument, apparatus, device, equipment, materials and other products used for medical purposes separately or in combination, as well as the specified products, according to their intended use, with the accessories necessary for their intended use (including special software), which the manufacturer has intended for the prevention, diagnosis, treatment, medical rehabilitation and monitoring of the human body, conducting medical examinations, restoring, replacing, modifying the physiological functions or anatomical structure of the body, preventing or terminating pregnancy, and whose functional purpose is not achieved through pharmacological, immunological, genetic or metabolic effects on the human body, but may be accompanied by medicinal products or pharmaceutical substances;

Comment: the questions specified under items i, ii, iii and iv are covered by definition.

f. Does the understanding of “accessory” under your internal law correspond to that set out in **Article 4, letter (f)**, i.e. “an article which whilst not being a medical device is designated specifically by its manufacturer to be used together with a medical device to enable it to be used in accordance with the use of the medical device intended by the manufacturer of the medical device”?

Answer: Yes.

Comment: Armenia is a part of Eurasian Economic Union and as a union there several directives, decrees adopted by Council of Eurasian Economic Commission that are in force in Armenia without localization. One the decrees within this scope is the Decree of the Council of Eurasian Economic Commission is “ On Procedure for registration and expertise for safety, quality and efficacy of medical devices”. Accessory is defined as following: "accessory" - a product that is not a medical product intended by its

manufacturer for joint use with one or more medical products when used in accordance with their intended purpose;

g. Do the understanding of “parts” and “materials” under your internal law correspond to that set out in **Article 4, letter (g)**, i.e. “all parts and materials constructed and designated to be used for medical devices and that are essential for the integrity thereof”?
Answer: See, please, comments in other points.

h. Does the understanding of “document” under your internal law correspond to that set out in **Article 4, letter (h)**, i.e. “any document related to a medical product, an active substance, an excipient, a part, a material or an accessory, including the packaging, labelling, instructions for use, certificate of origin or any other certificate accompanying it, or otherwise directly associated with the manufacturing and/or distribution thereof”?

Answer: Specific definition that is included in the Medicrime Convention Article 4 that is “any document related to a medical product, an active substance, an excipient, a part, a material or an accessory, including the packaging, labelling, instruction for use, certificate of origin or any other certificate accompanying it, or otherwise directly associated with the manufacturing and/or distribution thereof” is not defined in any law governing medicinal products or medical devices.

Comment: However, in the Criminal Code of the RA, Article 3 Definitions used in the code, item 1, sub item 27) it is defined that the “document” is a material or holder of electronic information that has a legal matter. Moreover, Article 411 of the Criminal Code of the RA is defining that it is considered as an criminal offence the Illegal use of an authentic document certifying the identity or place of origin of a medicine, pharmaceutical substance, herbal raw materials, auxiliary substances, medical products, their parts or investigational pharmaceutical products, relating to the production, distribution or supply -

i. Does the understanding of “manufacturing” under your internal law correspond to that set out in **Article 4, letter (i)**, i.e.
   i. “as regards a medicinal product, any part of the process of producing the medicinal product, or an active substance or an excipient of such a product, or of bringing the medicinal product, active substance or excipient to its final state;

Answer: Yes, the definition of the manufacturing as regards to a medicinal product has the same aim.

Comment: The definition is: batch production activity which includes acquisition of starting materials or manufacturing and engineering processes or quality control or packaging or re-packaging or labelling or re-labelling or storage or batch release or related control;

   ii. as regards a medical device, any part of the process of producing the medical device, as well as parts or materials of such a device, including designing the

device, the parts or materials, or of bringing the medical device, the parts or materials to their final state;

Answer: See comments above

iii. as regards an accessory, any part of the process of producing the accessory, including designing the accessory, or of bringing the accessory to its final state"?
Answer: See comments avobe

j. Does the understanding of "counterfeit" under your internal law correspond to that set out in **Article 4, letter (j)**, i.e. "a false representation as regards identity and/or source"?

Answer: Specific definition on "counterfeit" or "false" is not included in any law of the RA.

Comment: there are several provisions that are covering the definition "counterfeit" in the legislation of the RA, particularly:

i) Article 3 of the "Law on Medicines" or the Ra is setting up the definition of falsified medicinal product, falsified substance, which is a product with intentional and (or) fraudulent representation of incorrect information on the identity (including packaging, labelling, name, composition, quantity of separate ingredients) and (or) source (including manufacturer, manufacturing country, country of origin, holder of certificate of registration) and (or) data of distribution chain (including records, supporting documents);

ii) Article 457 of the Criminal Code of the RA On making counterfeit documents, stamps or using of the counterfeit documents, stamps or other formats. In the Article it is clearly listed the cases that are considered to counterfeit documents, particularly it is written that: forgery of a document certifying a fact of legal significance or reserving a right or exempting from an obligation or liability issued by a state or local government body or their organization, a commercial or other organization, an individual entrepreneur, a notary, an auditor or another person authorized to draw up, issue a document or verify its authenticity, for the purpose of using or selling it by the forger personally or by another person, or selling such a document or making or selling a false stamp, seal or form for the same purpose, as well as using a false document:

iii) Article 409 of the Criminal Code of the RA is defining that is criminlised following: Manufacturing, producing, storing, transporting, delivering, importing, exporting, supplying, offering to supply, placing on the market or selling counterfeit alcoholic beverages, baby food, biologically active additives, medicinal products, medicinal substances, herbal raw materials, excipients, medical products, their parts or investigational pharmaceutical products for the purpose of sale:

k. Does the understanding of "victim" under your internal law correspond to that set out in **Article 4, letter (k)**, i.e. "any natural person suffering adverse physical or psychological effects as a result of having used a counterfeit medical product or a medical product manufactured, supplied or placed on the market without

authorisation or without being in compliance with the conformity requirements as described in Article 8”?

Answer: Yes

Comment: Article 3 of the Criminal Law of the RA is defining under sub item 3) included in item 1 that: Victim of a crime - a person, organization, society or state whose rights, freedoms or legitimate interests have been harmed by the crime or could have been harmed if the crime had been completed, regardless of the fact of being recognized as a victim in a procedural manner.

Question 2: Non-discrimination

Is discrimination, on grounds such as the ones mentioned in the indicative list in **Article 2**, prohibited in the implementation of the Convention, in particular in the enjoyment of the rights guaranteed by it? If so, please specify. If not, please justify.

Answer: Specific provision to prevent the discrimination issues is not included in those provisions that are establishing criminal offences for counterfeiting medical products and similar crimes, such as in Criminal Cod of RA.

Comment: Principle of non-discrimination is established by a) Criminal Proceeding Code of RA (ՀՕ-306-Ն adopted on 21 July 2021). The Chapter 3 on Criminal Proceeding Principle, Article 16 on Equality of All Against Law item 1 is establishing that “All are equal before the law and are entitled without any discrimination to equal protection of the law”, and b) Constitution of RA Article 29 on Prohibition of Discrimination is establishing that Discrimination based on sex, race, skin color, ethnic or social origin, genetic features, language, religion, worldview, political or other opinions, membership of a national minority, property status, birth, disability, age or other circumstances of a personal or social nature is prohibited.

Question 3: Overview of the implementation

Please indicate (without entering into details):

a. the main legislative or other measures to combat counterfeiting of medical products and similar crimes involving threats to public health in accordance with the Convention;

Answer: Main legislative measures to combat against counterfeiting of medical products are

i. Criminal Code of RA, Articles 408 Illicit trafficking of medicinal products, herbal substances, excipients, medical devices or investigational pharmaceutical products, Article 409 Circulation or sale of counterfeit alcoholic beverages, baby food, biologically active supplements, medicinal products, active pharmaceutical ingredients, herbal substances, excipients, medical devices or investigational pharmaceutical products for the purpose of

sale, Article 410 Making or using false documents certifying the identity of counterfeit alcoholic beverages, baby food, biologically active additives, medicinal products, pharmaceutical substances, herbal raw materials, excipients, medical products or investigational pharmaceutical products (the article name should be changed, in accordance with the Medicrime Convention, it should be criminalized all the falsifications of the any document related to medical product, and the Article is telling that the falsifying of the documents related to counterfeit medical products), Article 411 Illegal use of documents certifying the identity of medicinal products, active pharmaceutical ingredients, herbal substances, excipients, medical devices or investigational pharmaceutical products.

ii. Criminal Proceeding Code of RA

iii. "Law on Medicines" of RA,

iv. "Law on Public Health and Services".

b. whether your country has adopted a national strategy and/or Action Plan to combat counterfeiting of medical products and similar crimes involving threats to public health. If so, please specify the main fields of action and the body/bodies responsible for its/their implementation;

Answer: Implementation of the Action Plan has started since 2019

Comment: it has been developed the draft of decree of the Government of the Republic of Armenia setting up the collaboration between different authorities, such as Customs, Police, National Security Services and medicines regulatory authority. The draft has not been adopted yet, due to non-stable situation that started since war in 2020. Draft is including all the provisions from the Medicrime Convention.

c. If there has not been any adoption of a national strategy and/or Action Plan to combat counterfeiting of medical products and similar crimes involving threats to public health, whether there is a strategy and /or Action Plan by a particular Ministry or State Agency that leads on this nationally.

Answer: On-going

Comment: it has been developed the draft of decree of the Government of the Republic of Armenia setting up the collaboration between different authorities, such as Customs, Police, National Security Services and medicines regulatory authority. According to the draft the Action Plan and co-ordination of the process toward to combat and prevent counterfeiting of medical products and similar crimes are led by medicines regulatory agency.

Question 4: National co-operation and information exchange

a. Please describe how co-operation and exchange of information is ensured between representatives of health authorities, law-enforcement (e.g. police and customs authorities) and other competent authorities in order to prevent and combat

effectively the counterfeiting of medical products and similar crimes involving threats to public health (**Article 17, para. 1**);

Answer: The legal is pending for adoption.

Comments: During 2017-2018 it has been made draft for Government Decree based on the provisions of the Medicrime Convention by the Scientific Center of Drug and Medical Technology Expertise of the Ministry of Health of the Republic of Armenia. In the draft it has been included following: translation and revision by special group of specialists into Armenian language the text of the Convention of Council of Europe on Counterfeiting of Medical Products and Similar Crimes (The Medicrime Convention), translation of the Medicrime Convention by special group of specialists into Armenian the explanatory text, elaboration of the amendment of the Law on Medicines to include all the necessary provisions based on Medicrime Convention and submission to staff of the Premier Minister of the Republic of Armenia, elaboration of the amendment of the Criminal Code of the Republic of Armenia to include the relevant provisions based on Medicrime Convention and to submit it to staff of the Premier Minister of the Republic of Armenia, elaborate amendment of law on administrative offences of the Republic of Armenia, and the last point was to set up a system for reaction and interchange of information between different authorities on counterfeiting of medical products and similar crimes threatening public health. Independently, necessary amendments have been included in the Law on Medicines, Criminal Code. The point related to system for exchange of information and reaction to counterfeiting issues still legally not established. However, formally, it is established that the expert and expertise is involved in certain cases. Particularly, Item 1 of the Article 85 of Criminal Code of the Republic of Armenia is mentioned that an expert is a person who is not interested in the criminal case and who is appointed by the head of the expert institution, by decision of the body conducting the criminal proceedings or in accordance with the decision to appoint an expert examination, to examine the case materials using his or her special knowledge in any field of science, technology, art or craft and to issue a conclusion based on it. An expert may be appointed from among the persons proposed by a participant in the proceedings. Normally, all the cases detected by law enforcement agencies are send to Health authorities to receive an expertise and conclusion related to medicinal products and medical devices, cases for counterfeit as well.

b. Is any form of cooperation between the competent authorities and the commercial and industrial sectors promoted as regards risk management of counterfeit medical products and similar crimes involving threats to public health? (**Article 17, para. 2**)

Answer: No formally

Comment: Legal procedure is not established, however information, normally is submitted by industry to Health authorities.

c. Which legislative or other structured measures have been taken to set up or strengthen mechanisms for:

- receiving and collecting information and data, including through contact points, at national or local levels and in collaboration with private sector and civil society, for the purpose of preventing and combating the counterfeiting of medical products and similar crimes involving threats to public health? (**Article 17, para. 3, letter (a)**);

- making available the information and data obtained by the health authorities, customs, police and other competent authorities for the co-operation between them? (**Article 17, para. 3, letter (b)**);

Answer: Legislative regulation is in stage of adoption.

Comment: As it has been mentioned the draft of actions to be adopted by the Government Decree is including provision on legislative means to make mandatory SPOCs in different authorities and collaboration among them.

d. Please indicate the persons, units or services in charge of this co-operation and information exchange in the field of the MEDICRIME Convention. Please indicate how they are trained for this purpose and how resources are secured for it/them (**Article 17, para. 4**);

Answer: it has been agreed internally and send information to the Secretariat through the Ministry of Foreign Affairs of the Republic of Armenia that the Health Authorities are in charge of co-operation and information exchange in the field of medicrime.

Comment: The legal act will be adopted to establish legal requirement for co-operation between relevant authorities.

Question 5: International cooperation

a. Please indicate the national contact point responsible for transmitting and receiving requests for information and/or co-operation in connection with the fight against counterfeiting of medical products and similar crimes involving threats to public health (**Article 22, para. 2**).

Answer: Center of Expertise of Drug and Medical Technology Expertise SNCO of the Ministry of Health of the Republic of Armenia

b. Has your country integrated prevention and the fight against counterfeiting of medical products and similar crimes involving threats to public health in assistance programmes for development provided for the benefit of third states (**Article 22, para. 3**)? Please give examples.

Answer: Not established yet

IV. PROSECUTION OF PERPETRATORS OF COUNTERFEIT OF MEDICAL PRODUCTS AND SIMILAR CRIMES INVOLVING THREATS TO PUBLIC

HEALTH

Question 6: Criminal Law offences

a. Please indicate whether the intentional conducts in the box below are considered criminal offences in internal law.

Article 5 - Manufacturing of Counterfeits:

Item 1 ***Each Party shall take the necessary legislative and other measures to establish as offences under its domestic law, the intentional manufacturing of counterfeit medical products, active substances, excipients, parts, materials and accessories.***

Answer: Yes

Comment: The Article 409 of the Criminal Code of the RA item 1 is defining that it is considered as an criminal offence the manufacturing, producing, storing, transporting, delivering, importing, exporting, supplying, offering to supply, placing on the market or selling counterfeit alcoholic beverages, baby food, biologically active additives, medicinal products, medicinal substances, herbal raw materials, excipients, medical products, their parts or investigational pharmaceutical products for the purpose of sale:

Item 2 ***As regards medicinal products and, as appropriate, medical devices, active substances and excipients, paragraph 1 shall also apply to any adulteration thereof.***

Answer: No

Comment: Definition of adulteration is not included in the legislation as it is described in the Explanatory Note of the Medicrime Convention.

Article 6 - ***Supplying, offering to supply, and trafficking in counterfeits***

Item 1 ***Each Party shall take the necessary legislative and other measures to establish as offences under its domestic law, when committed intentionally, the supplying or the offering to supply, including brokering, the trafficking, including keeping in stock, importing and exporting of counterfeit medical products, active substances, excipients, parts, materials and accessories.***

Answer: Yes

Comment: Brokering, is not included in the legal provisions due to absence in the legislation and, actually, the activity as well. Brokering, is an activity that is not regulated in the RA.

Article 7 – ***Falsification of documents***

Item 1 ***Each Party shall take the necessary legislative and other measures to establish as offences under its domestic law the making of false documents or the act of tampering with documents, when committed intentionally.***

Answer: Yes

Comment: It is considered as a criminal offence of preparing or using a false document certifying the identity or place of origin of a counterfeit alcoholic beverage, baby food, biologically active additive, medicinal product, pharmaceutical substance, herbal raw material, excipient, medical product, their parts or a pharmaceutical product under investigation, related to the production, distribution or supply:

Article 8 - *Similar crimes involving threats to public health*

Item 1 - *Each Party shall take the necessary legislative and other measures to establish as offences under its domestic law the making of false documents or the act of tampering with documents, when committed intentionally.*

a) the manufacturing, the keeping in stock for supply, importing, exporting, supplying, offering to supply or placing on the market of:

i. medicinal products without authorisation where such authorisation is required under the domestic law of the Party; or

ii. medical devices without being in compliance with the conformity requirements, where such conformity is required under the domestic law of the Party;

Answer: *Yes*

Comment: *The Article 410 of the Criminal Code of the RA is defining that Preparing or using a false document certifying the identity or place of origin of a counterfeit alcoholic beverage, baby food, biologically active additive, medicinal product, pharmaceutical substance, herbal raw material, excipient, medical devices, their parts or a pharmaceutical product under investigation, related to the production, distribution or supply:*

b) the commercial use of original documents outside their intended use within the legal medical product supply chain, as specified by the domestic law of the Party.

Answer: *No*

Comment: *It is not clearly defined that the use of original documents outside of their intended use within the legal medical products supply chain, as specified is not defined in the legislation, criminal legislation as well.*

Article - 9 Aiding or abetting and attempt

1 Each Party shall take the necessary legislative and other measures to establish as offences when committed intentionally, aiding or abetting the commission of any of the offences established in accordance with this Convention

Answer: Yes

Comment:

Aiding: Criminal Code of RA, Article 46 on types of crimes item 5 is defining that an aiding person is considered a person who has contributed to the crime by providing advice, instructions, information or means, tools or removing obstacles, as well as a person who has previously promised to conceal from

the criminal the means or tools of the crime, traces of the crime or objects obtained through criminal means, as well as a person who has previously promised to acquire or sell such objects. Item 7 is defining, also, that an aiding person is, also, considered a person who: 1) incited another person to assist, 2) gave prior consent to participate in the crime as a co-perpetrator, but during the commission of the crime by the other co-perpetrator, without directly participating in the commission of the crime, strengthened the perpetrator's determination to commit the crime by his presence, 3) assisted in the crime through a person who is not subject to criminal liability by force of law or acted negligently, or 4) at the instigation of a special subject committed the objective side of a crime with a special subject, of which he is not considered a subject, or participated jointly with a special subject in the commission of the objective side of a crime with a special subject, if the conditions provided for in parts 4, 5 or 6 of Article 48 of this Code, by virtue of which a person is not considered an accessory to a crime with a special subject, are absent.

Abetting: Criminal Code of RA, Article 46 on types of crimes item 3 it is clearly defined that instigator is a person who has incited another person to commit a crime, whether through persuasion, financial inducement, threat, or other means. Item 4 is defining that an instigator is also considered a person who has incited another to commit an incitement or has incited another to commit a crime by using a person who is not subject to criminal liability by law or who has acted negligently.

Attempt: In the Criminal Code of RA, in Chapter 7 On Stages of Crime under Article 42 On Completed and not Completed Crime, in item it is specified that an intentional crime can go through three stages: preparation for a crime, an attempt, and a completed crime, and in item 2 it is specified that preparation for a crime and an attempt are considered unfinished crimes.

2 Each Party shall take the necessary legislative and other measures to establish as an offence the intentional attempt to commit any of the offences established in accordance with this Convention.

Answer: Yes

Comment: In the Criminal Code of RA, in Chapter 7 On Stages of Crime under Article 44 Attempt and the Types of Attempt, item 1 it is specified that 1. An attempted crime is considered to be an intentional act or omission that is directly aimed at committing a crime and contains the elements of a crime set forth in the Special Part of this Code, but the crime included in the person's intent is not committed due to circumstances independent of his will due to the absence of any element of the given crime.

3 Each State or the European Union may, at the time of signature or when depositing its instrument of ratification, acceptance or approval, by a declaration addressed to the Secretary General of the Council of Europe, declare that it reserves the right not to apply, or to apply only in specific cases or conditions, paragraph 2 to offences established in accordance with Articles 7 and 8.

Answer: Needs to be clarified

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

Answer: Chapter 5 in Criminal Proceeding Law of RA on Crime and its Features it is included specific Article 24 On Attempt and the Negligence.

Comment: According to the provision: 1. The subjective aspect of a crime may be manifested intentionally or through negligence, and 2. An act committed through negligence is a crime if this is provided for in the Special Part of this Code. Also, Article 25 On Committing the Crime Intentionally it is specified that: 1. A crime is considered to be committed intentionally if the person is aware of the factual circumstances of his act that are characteristic of the given crime; 2. Intention can be direct or indirect; 3. A crime is considered to be committed with direct intent if the person is aware of the factual circumstances of his act that are characteristic of the crime, and committing that act is his goal or a means to achieve that goal; 4. A crime is considered to be committed with indirect intent if the person is aware of the factual circumstances of his act that are characteristic of the crime, and although committing that act and committing the given crime is not his goal, he nevertheless does so; 5. If the law connects the completion of a crime with the occurrence of dangerous consequences, then the crime is considered to be committed with direct intent, if the occurrence of these consequences was the person's goal or a means to achieve the goal, or he foresaw the inevitability of their occurrence; 6. If the law connects the completion of a crime with the occurrence of dangerous consequences, then the crime is considered to be committed with indirect intent, if the occurrence of these consequences was not the person's goal, but he foresaw the real possibility of their occurrence, and it was indifferent to him whether they would occur or not; 7. If the person foresaw the possibility of the occurrence of any of more than one criminal consequences, and it was indifferent to him which consequence would occur, then the act is qualified according to the actually occurred consequence. If no consequence occurs, then the act is qualified as an attempt at the least serious crime possible in the given situation, included in the intent; 8. The aggravating circumstances of an intentional crime, as provided for by this Code, shall be imputed to a person only if he was aware of those circumstances.

9. If an aggravating circumstance of an intentional crime is the negligent causing of dangerous consequences, then this shall be imputed to a person if there is negligence in relation to them. In such a case, the crime shall be considered committed intentionally.

Answer: See, please, comment above.

c. Please highlight whether there are any other offences not included in the box below that involves counterfeit of medical products and similar crimes involving threats to public health in your country? Please provide their definitions and specify in which act these are included;

Answer: Adulteration is not included in the

Comment: This is specific understanding as it is clarified in the Explanatory Report to the Medicrime Convention Particularly, an adulterated medical product (i.e. a medical product – usually a powder or a liquid – made poorer in quality by intentionally adding or substituting another undeclared substance) simply as a counterfeit and hence not introduce "adulterated medical product" as a specific defined term, different from "counterfeit medical product". And this should be defined in the legislation regulating the medical products, afterwards to include in the criminal legislation.

Article 5 – Manufacturing of counterfeits

1 *Each Party shall take the necessary legislative and other measures to establish as offences under its domestic law, the intentional manufacturing of counterfeit medical products, active substances, excipients, parts, materials and accessories.*

2 *As regards medicinal products and, as appropriate, medical devices, active substances and excipients, paragraph 1 shall also apply to any adulteration thereof.*

3 *Each State or the European Union may, at the time of signature or when depositing its instrument of ratification, acceptance or approval, by a declaration addressed to the Secretary General of the Council of Europe, declare that it reserves the right not to apply, or to apply only in specific cases or conditions, paragraph 1, as regards excipients, parts and materials, and paragraph 2, as regards excipients.*

Article 6 – Supplying, offering to supply, and trafficking in counterfeits

1 *Each Party shall take the necessary legislative and other measures to establish as offences under its domestic law, when committed intentionally, the supplying or the offering to supply, including brokering, the trafficking, including keeping in stock, importing and exporting of counterfeit medical products, active substances, excipients, parts, materials and accessories.*

2 *Each State or the European Union may, at the time of signature or when depositing its instrument of ratification, acceptance or approval, by a declaration addressed to the Secretary General of the Council of Europe, declare that it reserves the right not to apply, or to apply only in specific cases or conditions, paragraph 1, as regards excipients, parts and materials.*

Article 7 – Falsification of documents

1 *Each Party shall take the necessary legislative and other measures to establish as offences under its domestic law the making of false documents or the act of tampering with documents, when committed intentionally.*

2 *Each State or the European Union may, at the time of signature or when depositing its instrument of ratification, acceptance or approval, by a declaration addressed to the Secretary General of the Council of Europe, declare that it reserves the right not to apply, or to apply only in specific cases or conditions, paragraph 1, as regards documents related to excipients, parts and materials*

Article 8 – Similar crimes involving threats to public health

Each Party shall take the necessary legislative and other measures to establish as offences under its domestic law, when committed intentionally, in so far as such an activity is not covered by Articles 5, 6 and 7:

a the manufacturing, the keeping in stock for supply, importing, exporting,

supplying, offering to supply or placing on the market of:

i medicinal products without authorisation where such authorisation is required under the domestic law of the Party; or

ii medical devices without being in compliance with the conformity requirements, where such conformity is required under the domestic law of the Party;

b the commercial use of original documents outside their intended use within the legal medical product supply chain, as specified by the domestic law of the Party.

Article 9 – Aiding or abetting and attempt

1 Each Party shall take the necessary legislative and other measures to establish as offences when committed intentionally, aiding or abetting the commission of any of the offences established in accordance with this Convention.

2 Each Party shall take the necessary legislative and other measures to establish as an offence the intentional attempt to commit any of the offences established in accordance with this Convention.

3 Each State or the European Union may, at the time of signature or when depositing its instrument of ratification, acceptance or approval, by a declaration addressed to the Secretary General of the Council of Europe, declare that it reserves the right not to apply, or to apply only in specific cases or conditions, paragraph 2 to offences established in accordance with Articles 7 and 8.

Question 7: Jurisdiction

With regard to the offences referred to in question 6, please indicate which jurisdiction rules apply. Please specify under which conditions, if required (**Article 10, Explanatory Report, paras. 69-78**).

Answer: Please, see comments in other points.

Question 8: Corporate liability

Does your system provide that a legal person may be held liable for an offence established in accordance with **Article 11**? Please specify under which conditions.

Answer: Corporate liability is not explicitly available in criminal legislation of RA.

Comment: However, by Article 409 on Circulation or sale of counterfeit alcoholic beverages, baby food, biologically active supplements, medicinal products, active pharmaceutical ingredients, herbal substances, excipients, medical devices or investigational pharmaceutical products for the purpose of sale, it is established that it is criminalized, also the acts if the manufacturing, producing, storing, transporting, delivering, importing, exporting, supplying, offering to supply, placing on the market or selling counterfeit medicines, medicinal substances, herbal raw materials, excipients, medical devices, their parts or investigational pharmaceutical products for the purpose of sale is committed by abusing the trust formed in connection with the criminal`s performance of professional or official duties or acting as a manufacturer

or supplier. In “Law on Medicines” Article 17 it is mentioned that it is prohibited to manufacture counterfeit medicinal products and active pharmaceutical ingredients.

Question 9: Sanctions and measures

a. Please indicate which sanctions internal law provides for the criminal offences established in accordance with the Convention with regard to both natural and legal persons. Please specify whether the sanctions are criminal, civil and/or administrative sanctions (**Article 12, Explanatory Report, paras. 84-91**);

Answer: According Criminal Code of RA it is established that manufacturing of counterfeit medical products, active substances, excipients and medical devices are criminalized.

Comment: the points related to adulteration of medical products are not explicitly specified in the criminal legislation of RA due to absence of understanding what adulteration is. Particularly, however in the “Law on Medicines” Article 18 item 17 it is mentioned that it is prohibited manufacture of sub item 1) counterfeit medicinal products and active pharmaceutical ingredients, and in sub item 3) it is mentioned that it is prohibited manufacture medicinal products, active pharmaceutical substances, herbal materials and investigational medicinal products with violation of the requirements of this law.

- By Article 408 on Illicit trafficking of medicinal products, herbal substances, excipients, medical devices or investigational pharmaceutical products it is established that 1. Without the marketing authorization provided for by law or under the conditions of the registration being suspended, terminated or revoked in accordance with the procedure prescribed by law, without registration or a special permit (license), the preparation, production, storage, transportation, delivery, import, export, supply, offer to supply, placing on the market or sale of a medicine, pharmaceutical substance, herbal raw material, auxiliary substance, medical devices, their parts or investigational pharmaceutical product for the purpose of sale, is punishable by a fine in the amount of up to twenty times the minimum wage, or by community service for a term of eighty to one hundred and fifty hours, or by restriction of liberty for a term of up to two years, or by short-term imprisonment for a term of up to two months, or by imprisonment for a term of up to two years.
- By Article 409 on Circulation or sale of counterfeit alcoholic beverages, baby food, biologically active supplements, medicinal products, active pharmaceutical ingredients, herbal substances, excipients, medical devices or investigational pharmaceutical products for the purpose of sale, it is established that 1. Manufacturing, producing, storing, transporting, delivering, importing, exporting, supplying, offering to supply, placing on the market or selling counterfeit alcoholic beverages, baby food, biologically active additives, medicines, medicinal substances, herbal raw materials, excipients, medical devices, their parts or investigational pharmaceutical products for the purpose of sale shall be punishable by a fine in the amount of ten to thirty times the amount of the fine, or by community service for a term of one hundred to two hundred hours, or by restriction of liberty for a term of up

to two years, or by short-term imprisonment for a term of up to two months, or by imprisonment for a term of up to three years.

- Article 410 on Making or using false documents certifying the identity of counterfeit alcoholic beverages, baby food, biologically active additives, medicinal products, pharmaceutical substances, herbal raw materials, excipients, medical products or investigational pharmaceutical products it is established that: 1. Preparation or use of a false document certifying the identity or place of origin of counterfeit alcoholic beverages, baby food, biologically active additives, medicine, pharmaceutical substances, herbal raw materials, excipients, medical products, their parts or investigational pharmaceutical products, related to the production, distribution or supply shall be punishable by a fine in the amount of up to twenty times the minimum wage, or by community service for a term of eighty to one hundred and fifty hours, or by restriction of liberty for a term of up to two years, or by short-term imprisonment for a term of up to two months, or by imprisonment for a term of up to two years.
- By Article 411 on Illegal use of documents certifying the identity of medicinal products, active pharmaceutical ingredients, herbal substances, excipients, medical devices or investigational medicinal products it is established that: 1. Illegal use of an authentic document certifying the identity or place of origin of a medicine, pharmaceutical substance, herbal raw materials, excipients, medical products, their parts or investigational pharmaceutical products, relating to the production, distribution or supply shall be punishable by a fine in the amount of up to ten times the amount, or by community service for a term of up to one hundred hours, or by restriction of liberty for a term of up to one year, or by short-term imprisonment for a term of up to one month, or by imprisonment for a term of up to one year.

b. Which legislative or other measures have been taken to provide for the possibility of taking into account final sentences passed by another Party in relation to the offences established in accordance with the Convention? Please provide details and describe any good practice resulting from the taking of these measures (**Article 14, Explanatory Report, paras. 100-105**).

Question 10: Aggravating Circumstances

Please indicate which of the circumstances referred to in **Article 13**, in so far as they do not already form part of the constituent elements of the offence, may, in conformity with the relevant provisions of internal law, be taken into consideration in your legal system as aggravating circumstances in the determination of the sanctions in relation to the offences established in accordance with this Convention (**Explanatory Report, paras. 92-99**).

Answer: Item 2 of Article 409 of Criminal Code of RA is establishing that

Comment: Item 2 of Article 409 of Criminal Code of RA is establishing cases as an aggravating circumstances if:

- 1) it has caused moderate or minor harm to human health through negligence,

- 2) committed by abusing the trust formed in connection with the criminal's performance of professional or official duties or acting as a manufacturer or supplier, or

- 3) the offences of supplying and offering to supply were committed having resort to means of large scale distribution, (withuot specifing internet as it is mentioned in the Medicrime Convention),

Article 3 of the same article is defining, also specific aggravating circumstance for the acts provided for in Part 1 or 2 of this Article, which negligently causes the death of a person or serious harm to health or other serious consequences, is punishable by imprisonment for a term of three to six years.that

Question 11: Investigations and criminal measures

a. Which legislative or other measures have been taken to ensure that investigations or prosecutions of offences established in accordance with the Convention shall not be subordinate to a complaint and that the proceedings may continue even if the victim has withdrawn his or her statement? (**Article 15, Explanatory Report, para. 106**).

Answer: Criminal Code of RA is defining the cases when proceedings may continue even if the victim has withdrawn his or her statement.

b. Please indicate the persons, units or services or other formalised or agreed arrangements in charge of criminal investigations in the field of MEDICRIME Convention. Please indicate how specialisation in this field is achieved and how resources are secured for it/them (**Article 16, para. 1, Explanatory Report, paras. 107-110**).
Answer: Not specified by legislation

c. Please describe under which circumstances carrying out financial investigations, the use of covert operations, of controlled delivery and of other special investigative techniques by authorities is allowed in relation to the investigation of the offences established in accordance with the Convention (**Article 16, para. 2**).
Answer: Will be clarified.

Question 12: Measures of protection for the victim

a. Please describe the measures taken to (**Article 19**):
   - ensure that victims have access to information relevant to their case and which is necessary for the protection of their health;
   - assist victims in their physical, psychological and social recovery;
   - provide for the right of victims to compensation from the perpetrators.

b. Please describe the measures taken to inform victims of their rights, the services at their disposal, the follow-up given to their complaint, the charges, the general progress of the investigation or proceedings, and their role as well as the outcome of their cases (**Article 20, para. 1, letter (a) and para. 2**).

c. Please also indicate which measures have been taken to enable the victim to be heard, to supply evidence and to choose the means of having his/her views, needs and concerns presented, directly or through an intermediary, and considered (**Article 20, para. 1, letter (b)**);

d. What kind of support services are provided to victims so that their rights and interests are duly presented and taken into account? (**Article 20, para. 1, letter (c)**)

e. Please describe the measures taken to provide the safety of the victims, their families and witnesses from intimidation and retaliation (**Article 20, para. 1, letter (d)**);

f. Please specify under which conditions victims of the offences established according to the Convention have access to legal aid provided free of charge (**Article 20, para. 3**).

g. Which legislative or other measures have been taken to ensure that victims of an offence established in accordance with the Convention in the territory of a Party other than the one where they reside may make a complaint before the competent authorities of their state of residence? (**Article 20, para. 4, Explanatory Report, para. 128**).

h. Please describe how your internal law allows for groups, foundations, associations or governmental or non-governmental organisations assisting and/or supporting victims to participate in legal proceedings (for example, as third parties) (**Article 20, para. 5**). Please specify under which conditions, if so required;

Answer: Specific provisions as it is described in the Medicrime Convention it is not established in the legislation of the RA.

Comment: Victims have rights and responsibilities as it is described in the Article 59 of the Criminal Code of RA and they are generally described for all the cases when the body performing investigation is recognizing a person or company as a victim. Particularly: Article 58 Victim 1. A victim is a person who has been directly caused moral, physical or property damage by an act not permitted by the Criminal Code. A victim is also a person who could have been directly caused moral, physical or property damage if the act not permitted by the Criminal Code had been completed. Article 59. Rights and obligations of the victim, 1. The victim, in accordance with the procedure established by this Code, has the right to: 1) familiarize himself with the accusation. 2) give testimony. 3) give explanations.4) submit materials for attachment to the criminal case and examination. 5) express objections. 6) initiate motions. 7) object to the actions of the bodies conducting the criminal proceedings and demand that his objections be included in the protocol of the investigative or other procedural action. 8) to familiarize himself with the records of investigative and other procedural actions in which he participated and to submit comments regarding the accuracy and completeness of the records in the records, to participate in investigative and other procedural actions, and to request that records be made in the records of the said actions or court sessions, in the event of his presence at the court session, about the circumstances that, in his opinion, should be noted, to familiarize himself with the

records of the court session and to submit his comments thereon. 9) to familiarize himself with all the materials of the case from the moment of completion of the preliminary investigation, to make copies of them and to write out any information of any volume from the case. 10) to participate in the sessions of the courts of first instance and appeals. 11) to receive, at his request, free of charge, copies of the decisions to dismiss the criminal case, to terminate the criminal prosecution, to involve the accused, a copy of the indictment or the final decision, as well as a copy of the verdict or other final decision of the court. 12) appeal against the actions and decisions of the investigative body, investigator, prosecutor, court, including the verdict and other final court decisions. 13) reconcile with the suspect and the accused in cases provided for by this Code. 14) submit objections to the complaints of other participants in the proceedings brought against the verdict or other final court decision. 15) receive compensation for damage caused by an act not permitted by the Criminal Code in accordance with the procedure established by law. 16) receive reimbursement of expenses incurred during the criminal proceedings. 17) receive back the property taken by the body conducting the criminal proceedings as material evidence or on other grounds, and the originals of official documents belonging to him. 18) have a representative and terminate the powers of the representative. 2. The victim is obliged to: 1) appear at the summons of the body conducting the criminal proceedings. 2) to give testimony at the request of the body conducting the criminal proceedings. 3) to present objects, documents, as well as samples in his possession for comparative examination at the request of the body conducting the criminal proceedings. 4) to undergo examination at the request of the body conducting the criminal proceedings in the criminal case on the crime allegedly committed against him. 5) to undergo an outpatient examination at the request of the body conducting the criminal proceedings in order to verify his ability to correctly perceive and reproduce the circumstances subject to disclosure in the criminal case, if there are grounds to doubt his presence of such ability. 6) to obey the lawful orders of the prosecutor, investigator, investigation body, and the person presiding over the court session. 7) to maintain order at the court session. 3. The victim also has other rights and obligations provided for by this Code. 4. The victim shall exercise the rights belonging to him and perform the duties imposed on him personally or through a representative, if this corresponds to the nature of the relevant rights and duties. The rights of a minor or incapacitated victim shall be exercised on his behalf by his legal representative in accordance with the procedure established by this Code. 5. The victim may be recognized as a legal entity to which moral or material damage has been caused by a crime. In this case, the rights and duties of the victim shall be exercised by the representative of the legal entity. 2. The decision to recognize a victim is made by the investigative body, investigator, prosecutor or court.

V. PREVENTION OF COUNTERFEITING OF MEDICAL PRODUCTS AND SIMILAR CRIMES INVOLVING THREATS TO PUBLIC HEALTH

Question 13: Ensure quality and safety requirements of medical products, awareness raising and training

a. Which legislative or other measures have been taken to establish the quality, efficacy and safety requirements of medical products? (**Article 18 para. 1, Explanatory Report, para. 113**)

Answer:

I. In the RA it is established that the medicinal products should be in compliance to three main policies for medicinal products and all the medicinal products that have marketing authorization in the RA should be guaranteed in terms of quality, safety and efficacy.

II. The Law on "Public Health and Services" is establishing that during the marketing authorization it is assessed the safety, quality and efficacy of the medical devices.

Comment:

I. "Law on Medicines" of the RA is establishing that the medicinal product in the RA should be manufactured in accordance with Good Manufacturing Practice. Article 18 Item 3 is establishing that The manufacturing of medicinal products, substances, investigational medicinal product must be carried out according to the rules of Good Manufacturing Practices approved by the Authorised Body. The rules of Good Manufacturing Practice adopted by the Authorised Body shall be posted on the official Internet website of the Authorised Body. Based on this Article Order of the Minister of Health of the RA 32-N from 14 June 2017 is establishing that the medicinal product marketed in RA must be manufactured in accordance to Good Manufacturing Practice of EU (based on Council of European Union 2003/94/EC) and (or) in accordance with Good Manufacturing Practice of Eurasian Economic Union (based on Decree 77 from 3 Nov 2016).

II. The Article 47.1 of the law on «Public Health and Services» Article 1 is establishing that there is necessary to receive specific marketing authorization to manufacture medical devices in the RA with exception of class 1 risk ranked products. It is written, also, that the manufacture of medical devices in the RA is carried out in accordance with ISO 13485 standard requirements.

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

Answer: Article 24 of the Law on Medicines item 1 is establishing that the wholesale distribution of the medicinal products in the RA is carried out in accordance with the Good Distribution Practice by licensed wholesale distributors.

Comment: Specific order of the Ministry of Health of RA is establishing that in the RA it is in force Good Distribution Practice of European Union and (or) the Good Distribution Practice of Eurasian Economic Union (which is equivalent document with the Good Distribution Practice of European Union).

c. Which measures have been taken to provide for (**Article 18 para. 3 letters a and c, Explanatory Report, para. 114**):

- training of healthcare professionals, providers, law-enforcement (including police and customs authorities), as well as other relevant authorities and civil society?
- the prevention of illegal supplying of counterfeit medical products, active substances, excipients, parts, materials and accessories?

Answer: Specific training requirements in the legislation is not established for healthcare professionals, providers, law-enforcement agencies (police and customs), as well as other relevant authorities and civil society.

Comment: However, Good Distribution Practice and Good Manufacturing Practice is establishing requirements on training in the topic of falsification of medicinal products.

d. Which policies or strategies have been implemented to promote or conduct awareness-raising campaigns targeted at the general public where the focus is directed especially towards the risks and realities of the counterfeiting of medical products and similar crimes involving threats to public health? Please describe the material used for the campaign/programme and its dissemination. If possible, please provide an assessment of the impact of the campaign/programme. If there are currently plans for launching a (new) campaign or programme, please provide details (**Article 18, para. 3 letter b**);

Answer: It is in progress.

Comment: N/A