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Committee of the Parties to the MEDICRIME Convention

Guidance Note 1

The term "counterfeit" under the MEDICRIME Convention

Adopted by the MEDICRIME Committee at its 7th Plenary meeting (28-29 November 2023)

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1. Introduction

The term ***counterfeit*** is provided by Article 4(j) of the Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health, known as the MEDICRIME Convention, in relation to the misrepresentation of the identity and/or source of medical products. While this term is different to the meaning of the same term applied to intellectual property crimes, its meaning is similar to the meaning relating to the falsification of medical products as used by the World Health Organization (hereinafter, WHO), and others. The terms counterfeit and falsification relating to medical products are often used interchangeably but are separated in official documents depending on the term favoured by the drafting organisation. Both terms, in this circumstance, have been used with the clear understanding that they exclude intellectual property rights. The MEDICRIME Committee has recognised that this has the potential to create ambiguities or misinterpretations regarding the meaning and use of the terms when addressing risks to public health and to the criminal justice sectors when faced with instances of medical product falsification. The MEDICRIME Committee[1] has decided to clarify the meaning of the term *counterfeit*, as it relates to medical product falsification, to avoid any confusion or misinterpretation and to assist the Parties, and others who may refer to the convention on this matter when applying this term, particularly when deciding whether a crime has been committed in relation to a medical product that has been counterfeited.

While this Guidance Note does not purport to interpret the meaning relating to falsified medical products provided in documents by other international and regional organisations, it intends to support a common understanding of the phenomenon of counterfeiting/falsification of medical products.

For the purpose of clarification, the meaning of Article 8 is included, below, in this Guidance relating to intentional behaviours impacting medical products not already covered under Articles 5-7.

2. Similarities in the terms and meaning of counterfeit and falsification

When the drafting of the MEDICRIME Convention took place (2007-2009) the term in common use relating to a false representation of medical products was the term *counterfeit*. The meaning then drafted, and as is provided in Article 4 (j) of the Convention, intended to clearly distinguish a false representation as regards identity and/or source of medical products from the meaning of counterfeit provided by intellectual property rights legislation to products generally relating to the economic rights of individuals. Hence, the MEDICRIME Convention, Article 4(j) provides that:

- "the term "*counterfeit*" shall mean a false representation as regards identity and/or source".

The MEDICRIME Convention refers to behaviours relating to intentional actions (false representation as regards identity and/or source) regarding medical products. When these

[1] Committee of the Parties - MEDICRIME Convention, *List of decisions*, 5th Plenary meeting (1-3 December 2021), 11 February 2022, §. 4.3.

behaviours are prohibited, as required by Article 5-7 of the convention, they become criminal behaviours.

2.1 False representation

Considering the meaning of a *false representation* in the term counterfeit, this is left to the ordinary meaning of this expression and not further explained in the convention's Explanatory Report. It is noted that the WHO, in its term *falsified medical products* refers to the deliberate misrepresentation of medical products and in a way which enables the specific exclusion of intellectual property rights[2]. As such, the false representation of the term *counterfeit* and the deliberate misrepresentation of the term *falsified* have the same meaning and intent.

2.2 Identity

Considering the term *identity* in the false representation in Article 4(j) of the convention, this is left to its ordinary meaning and not further expanded upon in the convention's Explanatory Report. It is noted that the WHO term *falsified medical product* also refers to the misrepresentation of the product's identity and expands on the meaning of identity to refer to the name, labelling or packaging or to documents that support the authenticity of an authorised medical product. It continues with an expansion of what the meaning of composition refers to as being any ingredient or component of the medical product in accordance with applicable specifications authorised/recognised by the national or regional regulatory authority (hereinafter, NRRA) for medical products. A similar approach is adopted by the European Union[3] and includes, regarding falsified medicinal products, the term identity to include its packaging and labelling, its name or its composition as regards any of the ingredients including excipients and the strength of those excipients. Regarding falsified medical devices[4], the EU refers to a false presentation of its identity and/or of its source and/or its CE marking certificates or documents relating to CE marking procedures. Both the WHO's term *falsified medical products* and the EU's terms *falsified medicinal products* and *falsified devices* provide an expansion of the meaning of identity and composition.

2.3 Adulterated medical products

Both the MEDICRIME Convention term *counterfeit medical products* (in Article 5 relating to the manufacture of counterfeits) and the WHO term *falsified medical products* include references to the adulteration of a medical product as being included in a false representation. The convention's Explanatory Report, in paragraph 40, explains that an adulterated medical product is a counterfeit one and hence did not introduce *adulterated medical product* as a specific defined term different from *counterfeit medical product.*

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[2] World Health Organization (WHO), *Report by the Director-General on the Member State mechanism on substandard/spurious/falsely-labelled/falsified/counterfeit medical products*, Report of the Director-General, document A70/23, annex, appendix 3.

[3] European Union (EU), Directive 2011/62/EU of the European Parliament and of the Council *amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products*, 8 June 2011.

[4] EU, Regulation 2017/745 of the European Parliament and of the Council of 5 April 2017 *on medical devices*, amending Directive 2001/83/EC, Regulation (EC) No. 178/2002 and Regulation (EC) No. 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.

2.4 Source

Considering a false representation as regards the term source in Article 4 (j), the convention's Explanatory Report, in paragraph 40, explains that the term source should be understood in a wide sense, "…*thus including also the supply and distribution history of the medical product, active substance, excipient, part, material or accessory in question*". WHO's meaning of the term *source* refers to the "…*identification, including name and address, of the marketing authorization holder, manufacturer, importer, exporter, distributor or retailer, as applicable*". The EU provides two terms, source and history for this type of misrepresentation. It explains that the false representation of the *source* includes the medicinal product's manufacturer, its country of manufacture, its country of origin or its marketing authorization holder, and the false representation of its history includes the records and documents relating to the distribution channels used. Regarding falsified medical devices, the EU adds CE marking certificates or documents relating to CE marking procedures separate from the falsification of the source.

3. Exclusions from the meaning of counterfeit or falsified medical products

3.1 Unintentional quality defects and unintentional non-compliances

The meaning of the MEDICRIME Convention regarding the term *counterfeit*, the WHO's *falsified medical product*, and the EU's *falsified medicinal product* and *falsified device*, all provide that the meaning does not include unintentional quality defects or unintentional non-compliance. The convention's Explanatory Report, in paragraph 40, makes clear this point relating to medical products that are otherwise legal that they "… *shall not be considered as counterfeits for the sole reason that they form part of a sub-standard batch or are suffering from quality defects or non-compliance with good manufacturing or good distribution practices, it being understood that such defects and non-compliance are not resulting from an intentional act or omission on the part of the manufacturer".*

WHO describes such unintentional quality defects as ***substandard medical products*** and provides a meaning separate from falsified medical products: "*Also called "out of specification", these are authorized medical products that fail to meet either their quality standards or their specifications, or both"*. It, however, cautions that a deliberate failure by the authorised manufacturer to meet the quality standards or specifications due to a misrepresentation of identity, composition, or source will result in a falsified medical product.

3.2 Legally marketed medical products

The convention's Explanatory Report, in paragraph 40, clarifies that a "*medical product shall not be considered counterfeit for the sole reason that it is not authorised and/or legally marketed in a particular state"*. This same approach is adopted by the WHO, in its definition of falsified medical products, which considers that a medical product should not be considered falsified "*solely on the grounds that they are unauthorized for marketing in any given country*".

4. Article 8 Similar crimes - Unauthorized/unlicensed

In separating the terms *Unregistered/unlicensed medical products* from the term *falsified medical products*, the WHO clarifies that such medical products are separate and distinct from falsified medical products unless there is a deliberate intention to misrepresent their identity, composition or source. The MEDICRIME Convention adopts a similar position in Article 8 of the convention by creating an offence that is not considered to be a counterfeit offence, but one referred to as a ***similar crime involving a threat to public health***. Article 8 requires that an offence be created for the "*intentional manufacturing, keeping in stock for supply, importing, exporting, supplying, offering to supply, or placing on the market of medicinal products 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"*

This is the position in so far as such activity is not already covered by Articles 5, 6 and 7, that is there is no false representation involved as regards the identity and/or source of the medical product. Any false representation would then render the medical product subject to Articles 5-7 and would not be considered as a similar crime under Article 8.

5. Article 8 Similar crimes – documents

Original documents (that support the authenticity of authorised/licensed/registered medical products)

It is noted above in the discussion on *identity* that the WHO includes references to documents that support the medical product's authenticity of an authorised medical product. The EU makes a similar reference as regards the term *source,* as regards medical devices, and the term *history*, as regards medicinal products and "*including records and documents relating to the distribution channels used*". The MEDICRIME Convention deals with this issue through Article 8(b), regarding the commercial use of original documents outside their intended use within the legal medical product supply chain, as specified by the domestic laws of the Parties. The convention's Explanatory Report expands on this in paragraph 60. It explains the provisions of Article 8(b), as regards original document, is intended to address the intentional abuse of original documents for criminal purposes related to conducts set out in Article 8(a), which refers to unauthorised/unlicensed/unregistered medical products where such is required by the Party for marketing in its jurisdiction.

6. Falsified documentation

In the MEDICRIME Convention, Article 7 requires the Parties to establish as offences, when committed intentionally, the making of false documents or the act of tampering with documents. The Explanatory Report, in paragraph 53, explains that this targets the deceptive actions against persons inspecting/reviewing documents into believing that the "*medical product, active substance, excipient, accessory, part, or material which the documents accompany, is legitimate, is not counterfeit or the subject of criminal conduct as described by*

Article 8, paragraph 1". It explains that the term *document* is considered in a wide manner to include certificates and similar trade and commercial documents, packaging and labelling associated with the medical product*, "… as well as texts provided on internet sites which are specifically designed to accompany the product in question*". This is wide-ranging.

WHO incorporates the concept of falsified documentation within its meaning of the identity of a falsified medical product where it refers to *"… documents that support the authenticity of an authorized medical product*".

The EU also includes references to false documents within its meaning of falsified medical products. Included in the false representation of identity to include packaging and labelling and other detail of the product name and composition, in the source regarding details of the source country or manufacturer or its marketing authorisation holder, or its history to include records and documents relating to the distribution channels used.

7. Other international and regional organizations

The United Nations Office on Drugs and Crime (hereinafter, UNODC) adopts the meaning of falsified medical products as adopted by the World Health Assembly and used by the WHO[5].

The African Union adopts the meaning of falsified medical products as used by the WHO[6].

8. Differences in mechanisms, commonality in purpose

It is important to understand that the terms **counterfeit** medical product, **falsified** medical product, and **falsified** medicinal product/falsified device, come from initiatives that have different mechanisms to achieve their purpose, but with the overall purpose to protect public health.

The MEDICRIME Convention's object and focus, as contained in Article 1, is to "…*prevent and combat threats to public health by providing for the criminalisation of certain acts, protecting the rights of victims of the offences established under the Convention, and promoting national and international cooperation*[7]*.* Hence, the focus of the term *counterfeit* is on intentional behaviours that result in a counterfeit medical product, a criminal law approach to protect public health.

The WHO's focus with substandard and falsified (hereinafter, SF) medical products aims to simplify the terminology in use by its surveillance and monitoring system and the WHO's Member State Mechanism on substandard and falsified medical products from the public

[5] UNODC, *Combating Falsified Medical Product-related Crime: A Guide to Good Legislative Practices*, Vienna, 2019, p. 1.
[6] African Union (AU), *Model Law on Medical Products Regulation*, Article 4. It is noted that Article 4 uses the term" substandard/spurious/falsified/falsely-labelled/counterfeit medical products" as used by the WHO prior to 2017 and since amended by WHO.
[7] *Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health*, Council of Europe, CETS No 211, Moscow, 28 October 2011.

health perspective. This supports the WHO to work with its member States *"…to improve the quality of reporting of substandard and falsified medical products, and, importantly, to ensure the data collected are analysed and used to influence policy, procedure and processes to protect public health, at the national, regional and the global level"*[8]. Hence, the focus of the term falsified medical products is on the medical product status that results from intentional behaviours, a public health protection approach.

The UNODC focus is to support States in enacting or strengthening domestic legislation to combat medical product-related crime and, in so doing, contributing to the protection of public health[9]. Hence, the focus is on intentional behaviour that results in a falsified medical product, a criminal law approach to protect public health.

The African Union's focus on falsified medical products is on the regulation of medical products. It is a model law for its member States, a public health protection approach[10].

The EU's focus on falsified medicinal products is on the prevention of entry into the legal supply chain of falsified medical products[11], and on falsified devices, is focused on the regulation of medical devices to prevent falsified devices from reaching the market[12]. Hence, the focus on the medicinal product and the medical device product status that result from intentional behaviours, a public health protection approach.

While recognising such differences and similarities, **it is possible to equate the term *counterfeit medical products* and *falsified medical products***. In this way, it enables the possibility of interpreting certain terms, where not otherwise already defined in the MEDICRIME Convention or explained in the convention's Explanatory Report, to look to the other documents by other international and regional organisations, as mentioned in this Guidance Note.

9. Guidance in terms in addition to the Explanatory Report

9.1 Reference Explanatory Report paragraphs 38 and 39

In addition to the meaning in Article 4(j) of the term *counterfeit*, any reference to counterfeit medical products will be construed accordingly and equivalent to a meaning of falsified medical products as used by the WHO, UNODC or the EU.

It is clarified that the MEDICRIME Convention is a criminal-law convention with its object and purpose to protect public health from counterfeit medical products and similar crimes involving threats to public health. The term *counterfeit*, as in Article 4(j), is an intentional behaviour that

[8] *WHO Global Surveillance and Monitoring System for substandard and falsified medical products*, Geneva, World Health Organization, 2017.
[9] UNODC, *Combating Falsified Medical Product-related Crime: A Guide to Good Legislative Practices*, *op. cit.*
[10] AU, Model Law on Medical Products Regulation.
[11] EU, Directive 2011/62/EU of the European Parliament and of the Council amending Directive 2001/83/EC (…), *op. cit.,* 8 June 2011.
[12] EU, Regulation 2017/745 of the European Parliament and of the Council, (…), *op. cit*., 5 April 2017.

criminalises actions described in Articles 5-7. The term *counterfeit medical product,* being the result of the acts described in Articles 5-7 in relation to counterfeiting, is not given a specific meaning in the convention.

A false representation as regards identity and source has an equivalent meaning to a deliberate/fraudulent misrepresentation of identity, composition, or source.

9.2 Reference Explanatory Report paragraph 40

The term *identity* includes the medical product's name, its composition regarding any ingredient, including excipients, and their strengths, or components of the medical product in accordance with the applicable specifications authorised/recognised by the national or regional regulatory authority for medical products, or labelling and packaging accompanying the medical product or directly related to it that seeks to authenticate the medical product, whether authorised/licensed/registered or not by the national or regional regulatory authority for medical products.

Reference in paragraph 40 to substandard medical products and quality defects can be considered to be medical products that fail to meet their specifications or quality standards, or both. They may also be referred to as "out of specification".

9.3 Reference Explanatory Report paragraph 57

The term similar crimes are synonymous, for the purpose of this convention, with counterfeit medical product-related crimes.

10. Conclusions

10.1 Scope

This Guidance Note aims at clarifying the meaning of the term "counterfeit" provided by Article 4(j) of the MEDICRIME Convention.

The term "counterfeit" refers to medical product falsification and it applies when deciding whether intentional conducts – according to Articles 5-7 of the convention – become crimes involving threats to public health, as committed in relation to medical products that have been "counterfeited". Therefore, the "counterfeit medical product" is the object of those intentional criminal behaviours.

According to the convection, those typical forms of threat to public health (Articles 5-8) have to be "intentional". The definition of the required state of mind does not fall into the scope of this Guidance Note, therefore it may vary according to each domestic legal system and their categorical constraints on the scope of the criminal law. Nonetheless, this observation does not entail by itself that further efforts aimed at harmonising – not necessarily rigidly standardising – the meaning of the term "intentional" could not be made in the future. In any case, the term "intentional" shall be understood as excluding negligent behaviours resulting in substandard medical products (unintentional quality defects).

10.2 Content

Article 4(j) of the MEDICRIME Convention provides that “the term “counterfeit” shall mean a false representation as regards identity and/or source”.

This Guidance Note clarifies that the term “counterfeit” does not apply to intellectual property crimes. Rather, it recalls the meaning of “falsification” of medical products as used also by the WHO. Both the “false representation” as part of the notion of “counterfeit” according to Article 4(j), on the one hand, and the “misrepresentation” as part of the term “falsified” according to the WHO, on the other, refer to misrepresentations of the identity and/or source of medical products, including the “adulteration” of medical products.

Both the terms “source” and “identity” shall be understood in a wide sense. The term “source” shall include the supply and distribution history of the medical product, e.g. records and documents relating to the distribution channels, including the identification of the medical product’s manufacturer, the marketing authorisation holder, its country of manufacture and of origin. The term “identity” shall be understood as referable to the name, labelling or packaging or to documents that support the authenticity of an authorised medical product, as well as to its “composition”, hence substances, excipients – and their strengths –, parts, materials and accessories. Therefore, the criminal behaviour may consist in – or derive from – a deliberate/fraudulent false representation of either or both the “source” and the “identity” of the resulting counterfeit medical product; in fact, the former may also be understood as part of the latter.

In no part of this Guidance Note have examples been discussed of counterfeit/falsified medical products that have been identified on the global, regional or national markets. Such examples may better be provided in relation to the intentional behaviours in any analysis of Articles 5-8, 9 and 11 of the MEDICRIME Convention.

10.3 Use of the term “Counterfeit”

The term counterfeit cannot be changed in the title of the MEDICRIME Convention, unless an amendment to the convention is made following its Chapter X.

In accordance with the analysis in this Guidance Note, **the term counterfeit** in the MEDICRIME Convention **is synonymous with the term falsified** as used by other international and regional organisations in relation to medical products.

Appendix 1 Examples of the practical application of terms

1. The Council of Europe

- *The Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health, (*known as the MEDICRIME Convention);

  - Article 4(j): the term "***counterfeit***" shall mean a false representation as regards identity and/or source.

2. World Health Organization

The WHO, since 2017, uses the term ***falsified medical products*** to distinguish medical products that deliberately/fraudulently misrepresent their identity, composition, or source from the meaning and use of the term *counterfeit* as provided by intellectual property rights legislation[13].

Such deliberate/fraudulent misrepresentation refers to any substitution, adulteration, reproduction of an authorized medical product or the manufacture of a medical product that is not an authorised product.

- **"Identity"** shall refer to the name, labelling or packaging or to documents that support the authenticity of an authorized medical product.

- **"Composition"** shall refer to any ingredient or component of the medical product in accordance with applicable specifications authorized/recognized by NRRA.

- "**Source**" shall refer to the identification, including name and address, of the marketing authorisation holder, manufacturer, importer, exporter, distributor or retailer, as applicable.

Medical products should not be considered as falsified solely on the grounds that they are unauthorised for marketing in any given country.

3. The European Union

3.1 EU Directive 2011/62/EU (Medicinal products)

Article 1. Any medicinal product with a false representation of:

(a) its **identity,** including its packaging and labelling, its name or its composition as regards any of the ingredients including excipients and the strength of those ingredients

(b) its **source**, including its manufacturer, its country of manufacturing, its country of origin or its marketing authorisation holder; or

[13] World Health Organization (WHO), Report by the Director-General on the Member State mechanism on substandard/spurious/falsely-labelled/falsified/counterfeit medical products, Report of the Director-General, document A70/23, Annex, Appendix 3.

(c) its **history**, including the records and documents relating to the distribution channels used.

This definition does not include unintentional quality defects and is without prejudice to infringements of intellectual property rights.

3.2 Regulation EU 2017/745 (Medical devices) (Article 2)

(9) 'falsified device' means any device with a false presentation of its identity and/or of its source and/or its

CE marking certificates or documents relating to CE marking procedures. This definition does not include unintentional non-compliance and is without prejudice to infringements of intellectual property rights.

4. United Nations Office on Drugs and Crime (UNODC)

- *Combating falsified medical product-related crime: a Guide to good legislative practices*, UNODC, Vienna, 2019, p. 8.

  - **Falsified medical product** means any medical product whose identity, composition or source is intentionally misrepresented.

The definition of "**falsified medical product**" follows the classification adopted at the World Health Assembly in 2017.

5. The African Union

- *African Union Model Law on Medical Products Regulation*:

  - Article 4: "**substandard/spurious/falsified/falsely-labelled/counterfeit medical product**" means the like-named products as defined by the World Health Organisation.