CMED Project proposal "Falsified medicines – What does it mean?"

1. ***Title*:**

Falsified medicines – What does it mean?

2. ***Project co-ordinator and participating experts:***

CMED: Anja Ebraert (BE), Sameer Kohli (DK), Bastiaan Venhuis (NL), Ruth Mosimann (CH), Rihards Burmistris (LV)
External member: Lotte van Nierop (RIVM, NL)

Rapporteur: RIVM (BV & LvN)

Secretariat: Ines du Plessis

3. ***Problem statement:***

After many years of discussion the WHO was able to come with a high-level definition for 'falsified medicines' similar to the definition used by the Falsified Medicines Directive and MEDICRIME. All three definitions provide a high-level statement trying to cover many possible scenarios of falsifications. However, due to this 'one-size fits all' approach guidance is needed for the different falsification scenarios that are (or should be) covered. Such guidance is key to bridge between legal definitions and ways to protect public health. It is of main importance to translate the proposed definitions into real world medicinal falsification situations and share this knowledge with regulators and legal professionals. From the public health perspective it is important that falsifications can be quickly identified to protect for irreparable health issues. Using a universal comprehensive document with evident examples will accelerate withdrawal from falsified medicines from the market.

Furthermore, nations from around the world often focus on the easy-to-understand cases of typical falsification like copying the legitimate product. However, these cases are just a fraction of the possible ways of medicinal falsifications in Europe. This raises the question whether new legislation offers patients the intended protection in the cases that are not clear-cut. An overview is needed to get insight in, and show the extent of how the different falsification cases are covered under "Falsified medical products and similar crimes".

4. ***Review of existing relevant activities of other organisations active in the field:***

WHO has published a Global Surveillance and monitoring system for substandard and falsified medicinal products[1]. Furthermore WHO Member States have agreed on a comprehensive global strategy focused on prevention, detection and response to move towards achieving increased access to quality, safe, effective and quality medical products[2]. The activities follow from regular member state meetings.

The European Commission has adopted the Falsified Medicines Directive (Directive 2011/62/EU) which introduces harmonised European measures to fight medicine falsifications and ensure that medicines

[1] Source: https://www.who.int/publications/i/item/978-92-4-151342-5
[2] Source: https://www.who.int/health-topics/substandard-and-falsified-medical-products#tab=tab_1

are safe and that the trade in medicines is rigorously controlled[3]. The Directive also contains a provision obliging EU countries to take the necessary measures to prevent that falsified medicinal products are introduced into the EU.
The Council of Europe drew up the first international treaty against *"counterfeit medical products and similar crimes involving threats to public health"*, the MEDICRIME Convention[4]. The MEDICRIME Convention is an international criminal law instrument allowing States Parties to criminalise certain acts, protect the rights of victims, and to promote national and international cooperation. The Committee of Experts (CMED) considers this legal tool as reference for its practical work programme to protect public health from the dangers of falsified medicines and related crimes. The committee carries out its work through risk management and prevention, and improved co-operation between member states and other stakeholders in Europe and beyond.

EMA coordinates the exchange of information on falsified medicine notifications related to centrally authorised medicines, providing information to the national competent authorities of the EU Member States who are responsible for investigating the supply chain and deciding on market action[5].

Pangea (coordinated by Interpol) is an annual international operation to disrupt the online sale of falsified and illicit health products[6].

The United Nations Office on Drugs and Crime (UNODC) has published in 2019 "Combating Falsified Medical Product-Related Crime: A Guide to Good Legislative Practices"[7] that takes existing legal frameworks, including the MEDICRIME convention, as basis to address this issue from a criminal law perspective. Furthermore, in the context of the UNODC's Conference of the Parties to the United Nations Convention against Transnational Organized Crime (UNTOC) a resolution has been adopted at its 10th session in October 2020 entitled *"Preventing and combatting the manufacturing of and trafficking in falsified medical products, as a transnational organized crime"*[8]. All UNODC's work in this field takes as reference the WHO definition as agreed upon in 2017.

5. Objective(s):

The main objective is that CMED as expert committee on falsified medical products provides guidance on which specific falsification practices should be considered as falling under the broad legal definition of 'falsification' as put in e.g. the MEDICRIME convention. By collecting exemplary cases of falsifications, the areas that need to be covered by the convention definition are highlighted, and the scope of the definition as such is interpreted. Highlighting real cases will give interpretation to what should be considered as crime, ideally focussing on those cases that are not straightforward.
In this way, the recently defined legal definition of falsification will lead to practical examples of interpretation from a health regulatory perspective. Regulators will get insight on how this legal definition of falsification is explained and elaborated into practice.

Furthermore, each member state has its own interpretation of the definition of falsification. Distinct interpretation of the definition will undeniable lead to deviating and risky threat levels for public health. A second objective is that this work can give insight in the differences in national legislation, interpretation or cultural aspects, which may influence practical considerations of defining falsified medicines between countries, but also provide a first step to a harmonised understanding of

[3] Source: https://ec.europa.eu/health/human-use/falsified_medicines_en
[4] Source: https://www.edqm.eu/en/Falsified-Medical-Products-Background-Mission
[5] Source: https://www.ema.europa.eu/en/human-regulatory/overview/public-health-threats/falsified-medicines-overview
[6] Source: https://www.interpol.int/News-and-Events/News/2019/Operation-Pangea-shining-a-light-on-pharmaceutical-crime
[7] Source: https://www.unodc.org/documents/treaties/publications/19-00741_Guide_Falsified_Medical_Products_ebook.pdf
[8] Source: https://www.unodc.org/documents/treaties/UNTOC/COP/SESSION_10/Resolutions/Resolution_10_5_-_English.pdf

falsification. Moreover, this work will also help to provide universal leads for verification, regulation and enforcement among countries. CMED, being mainly composed of representatives from health authorities, can advise regulators and legal representatives on cases of falsifications and similar crimes of medicines.

6. Scope:

The term "**Falsified**" shall mean a false representation as regards its source and/or identity.
Considering that the Medicrime Convention does not seek to address issues concerning intellectual property rights;

- **Medicines for human and veterinary use**
- Focus on **products**, not actors, nor documentation
- Keep pre-authorisation drugs (IMP)
- **Excluding** "borderline products" and medical devices. We may consider addressing these together with other issues of interest that could/should be covered by Medicrime in a dedicated chapter, as well as IPR issues.

7. Working methods:

- To obtain an exhaustive list of scenarios we will email CMED members to review a draft list of scenarios and complete with any further scenario they would suggest.
- This exhaustive list of cases will be discussed within the WG in order to select the broad range of representative scenarios covering the definition of falsification.
- The selected cases/scenarios will be elaborated into a useful and functional case description.
- Cases that under different legislations are open to contradicting interpretation are summarized.
- Make an inventory of potential use(s) and format(s) of the Guide among the target population
- Work in regular consultation with CMED delegates.
- Regular video calls for WG will take place

8. Results / Outputs (including expected impact):

Results will be published in a guidance document (in EDQM style). For each example a case is given and issues are discussed - for example, what is covered by the MEDICRIME definitions, what can be done or needs to be done to obtain legal ground for falsification classification in different countries, what are current challenges for MEDICRIME etc. The goal is to obtain a comprehensive and useful document for regulators, legal representatives and enforcement.

9. Target audience

- Focus on : Competent national authorities
- Inspirational for : Legal professionals, governments

10. Implementation strategy:

Online and printed document.

11. Monitoring and evaluation:

Not applicable at this stage.

12. Involvement of stakeholders:

To be considered if necessary.

13. Planning overview (start, end, milestones):

Preliminary proposal

Task	Description	Year 1												Year 2					
		1	2	3	4	5	6	7	8	9	10	11	12	1	2	3	4	5	6
1	Contact CMED partners and collect falsification cases																		
2	Select most illustrative falsification cases and discuss among CMED partners																		
3	Write down a chapter on each selected case																		
4	Relate cases to existing national legislation																		
5	Review chapters on cases, plus potential consultation of stakeholders																		
6	Finalise EDQM guidance booklet																		

14. Funding / Resources:

Depending on delegates input, a consultant may be considered for support in drafting.

15. Publication / Media strategy to publish results:

EDQM website. Through CDPPH committee network of authorities. Other.

16. Comments / Remarks:

17. References: