

OMCL Network of the Council of Europe

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**OMCL Network support for the implementation of the CoE
MEDICRIME Convention**

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How the OMCL Network supports the implementation of the Council of Europe MEDICRIME Convention

Introduction

This position paper presents a discussion on the continuing contribution of the General European OMCL Network (GEON) in combating the threat posed by falsified (counterfeit) medicinal products and in supporting, at a co-ordinated practical and technical level, the implementation of the Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health (MEDICRIME Convention).

Activities of the OMCL Network in relation to Falsified Medicines

The aim of an OMCL is to support the Competent Authorities in controlling the quality, safety and efficacy of medicines on the market. With a view to creating a pool of resources with technical expertise, and based on the principles of information-sharing and work-sharing, a General European Network of OMCLs was formed under the aegis of the EDQM.¹ The role of the Network is to co-ordinate the technical activities of OMCLs and to foster the exchange of data and results, while promoting future development through harmonised common standards and guidelines.

Within the OMCL Network there are a number of activities that relate to falsified medicines; these are summarised as follows:

- OMCLs are involved in performing confirmatory analysis on suspect samples. This has generally comprised of physico-chemical and biological/microbiological analyses, performing detailed packaging/labelling examinations, and testing comparator samples. (The following publicly available OMCL Network document relates to this activity: “An ‘Aide-Memoire’ for the testing of suspected illegally traded and falsified medicines”, PA/PH/OMCL (06) 81, in its current version). The Network recognises, however, that current surveillance testing of OMCLs is usually not specifically designed to detect falsified medicines in the absence of suspicions/indications of falsification, or to confirm the authenticity of samples.
- The OMCL Network has proven, on different occasions, its ability to perform large survey-type surveillance activities of medicines, including products at risk of falsification such as Sildenafil generics, or “medicines in disguise” such as slimming dietary supplements including undeclared APIs.
- Exchanging information between OMCLs on testing issues pertaining to possible falsified medicines is a key activity of the Network. At a local level, such information is provided to the relevant Competent Authority and to other stakeholders, such as police and customs. Since 2014, a database with restricted access (Know-X) has been operational in this context. The following OMCL Network document describes this activity: “Information exchange in the General European OMCL Network (GEON) regarding suspect, falsified and other illegal medicines”, PA/PH/OMCL (15) 84, in its current version.

¹ See the following OMCL Network documents for detailed information on the structure and activities of the OMCL Network: GEON Terms of Reference, Document PA/PH/OMCL (07) 79 and its 8 Annexes, Document PA/PH/OMCL (07) 89, PA/PH/OMCL (07) 90, PA/PH/OMCL (09) 45, PA/PH/OMCL (08) 04, PA/PH/OMCL (10) 93, PA/PH/OMCL (09) 88, PA/PH/OMCL (16) 49 and PA/PH/OMCL (15) 99 in their current versions. These documents are available on Extranet in the GEON folder and on www.edqm.eu.

OMCL Network Support for the Implementation of the Council of Europe MEDICRIME Convention

Since the turn of the millennium, both patent-protected and generic medicinal products have been increasingly targeted by criminals. At the same time, the illicit manufacture and supply of medicines has become a serious problem.

The Council of Europe has long been involved in addressing the serious problems posed by the falsification of medicines, in particular through the work of the EDQM. By means of a decision of the Committee of Ministers, the Council of Europe set up a Group of Specialists on Counterfeit Pharmaceutical Products (PC-S-CP). In April 2008, the PC-S-CP reported on the feasibility of an international legal instrument in the field of falsification of medicinal products and similar crimes. The Group of Specialists (in which the OMCL Network was formally represented), along with a number of member states and the European Commission, as observers, prepared a draft Convention in February 2009. After a series of amendments the draft text was adopted for finalisation by the European Committee on Crime Problems in October 2009.

With regard to how the OMCL Network supports, on an ongoing basis, the Convention at a practical and technical level, reference is made to the following four Articles of the Convention:

- *As per Article 17 of the Convention, the implementation of the Convention calls for national measures of co-ordination, collaboration and information exchange.*
 - The OMCL Network supports the implementation of this Article at a practical and technical level, because it has functioning information-sharing tools already in place that facilitate the rapid dissemination of information and data on falsified medicines between OMCLs and Competent Authorities.
 - The Competent Authorities in turn make such information available to local law enforcement, customs and other governmental agencies, when necessary, and this leads to a more co-ordinated and collaborative approach between these key stakeholders in relation to dealing with falsified medicines.
- *Article 18 of the Convention refers to certain preventive measures in relation to "counterfeiting", and within these is the adoption of legislative or other measures, as may be necessary, to establish the quality and safety requirements of medicinal products. (Note that the prevention of the illegal supply of "counterfeit medicinal products", active substances and excipients is also covered in this article.)*
 - The OMCL Network supports the implementation of this Article at a practical and technical level, because the Network is primarily concerned with helping Competent Authorities assess and monitor the quality and safety of medicines, be it during surveillance testing of products already on the market, or prior to the granting of a marketing authorisation for a medicinal product. The OMCL Network also co-ordinates the testing of active substances, and this further supports the above goals.
 - In addition, the OMCL Network applies the quality requirements for medicines in various testing schemes that are governed by a harmonised quality management system implemented across the Network.
- *Article 22 of the Convention refers to how international co-operation on prevention and other administrative measures are also determining factors in the implementation of the Convention. Networking is indicated as a key element for effective co-operation at international level with the aim to exchange information and assistance.*
 - The OMCL Network supports the implementation of this Article at a practical and technical level, because networking and international co-operation are the very cornerstones of the

OMCL Network. Indeed, with the assistance of the EDQM, these activities have been developed and strengthened within the Network over the last 25 years. The Network facilitates networking and international co-operation at various levels, such as via the various international meetings and training activities that are organised by the EDQM for the OMCL Network, as well as via the meetings that representatives of the OMCL Network participate in with other key stakeholders, such as the EMA, PIC/S and the various working groups of the HMA, such as the Working Group of Enforcement Officers (WGEO).

- With respect to the exchange of information referred to in Article 22, as indicated above, the Network has functioning information-sharing tools in place that facilitate the rapid dissemination of information and data on falsified medicines between OMCLs and Competent Authorities. This information is utilised by Competent Authorities when taking measures to both reduce the risk to patients that may be presented by products already in the marketplace, and when developing preventative strategies in relation to falsifications.
- With respect to the provision of assistance referred to in Article 22, again, the OMCL Network plays a key role in this area. For example, the OMCL Network, in conjunction with the EDQM, has the expertise to co-ordinate and run specifically tailored training programmes in relation to falsified medicines analysis work for governmental laboratories both within and outside the OMCL Network. (This can be especially useful for governmental laboratories in developing countries).
- *Article 25 of the Convention requires the Committee of Parties to monitor the implementation of the Convention.*
 - The OMCL Network supports the implementation of this Article at a practical and technical level, because it makes the analytical capacity and expertise of the Network available for projects and activities that relate to achieving the goals of the Convention in relation to falsified medicines.
 - This is also facilitated by the fact that the EDQM, which co-ordinates the activities of the OMCL Network and which helps to implement the policies of the Network, is represented in the Committee of Parties. This means that, through the EDQM, there is a direct line of communication between the Committee of Parties and the OMCL Network.

Strategic elements of the work of the OMCL Network in responding to the threat of falsifications and in supporting the MEDICRIME Convention

Since around the time the MEDICRIME Convention was finalised, a number of strategic initiatives have been undertaken by the OMCL Network to support the Convention. These represented enhanced and integrated surveillance programmes designed to respond to the threat of falsified medicines, making the best use of OMCL resources and general surveillance work. The following are examples of such initiatives:

1. Some OMCLs began to devote a certain amount of their routine surveillance work to checking for signs of falsification in samples of medicinal products. The extent of routine surveillance work devoted to this area within an OMCL is usually defined in conjunction with the National Competent Authority. The OMCLs document any indicators of non-authenticity in samples and those findings can be used to trigger a more detailed examination of the product for its authenticity. However, unless mandated to do so by its National Competent Authority, it is not normally the responsibility of an OMCL to certify the authenticity of a product during routine surveillance testing. A conclusion about authenticity can only be made if authentic material from the MAH concerned is available.

While initiatives at national level on routine falsification testing have decreased, a programme focusing on authenticity checks of parallel distributed products was introduced into the CAP Sampling and Testing Programme in 2019.

2. Specific OMCL Network surveillance programmes (MSSIP – Market Surveillance Studies on Suspected Illegal Products) have been put in place focusing on product groups with a potential risk of falsification. The results of these testing campaigns are made publicly available on the EDQM website and in scientific journals.
3. Work was initiated to promote an increase in the amount of active substance testing being performed in the OMCL Network. To this end, a formal API Working Group was set up within the OMCL Network; while part of its work focuses on classical market surveillance testing activities of active substances, the group also runs specific fingerprint studies. API fingerprint studies are performed in order to identify potential substandard or falsified APIs. An API fingerprint is a specific analytical profile that includes information on the physico-chemical properties of the substance.
4. Certain OMCLs became centres of expertise for falsified medicines testing work by applying specialised techniques (NMR, X-ray diffraction, X-ray fluorescence spectrometry, etc.). Based on experience with the falsification of monoclonal antibodies (mAbs), a specialised OMCL working group has been established offering a scientific and technical discussion platform.
5. Training on specific areas of falsified medicines testing (some of which is tailored to small OMCLs with limited resources and equipment) has been provided to members of the OMCL Network, and such training courses will continue to be co-ordinated by the EDQM for the OMCL Network.
6. The OMCL Network has also started collaborating with other groups working in the same field of expertise (e.g. Committee of Experts on Minimising Public Health Risks Posed by Falsification of Medical Products and Similar Crimes - CMED, WGEO and the Customs Laboratories European Network – CLEN).

It is considered that the measures set out above represent a strong and practical contribution by the OMCL Network to respond to the threat of falsification and support the MEDICRIME Convention.

Conclusion

This paper outlines the significant contribution that the OMCL Network has made (and continues to make) to respond to the threat of falsified medicines and support the implementation of the MEDICRIME Convention.

It is recognised that the OMCL Network is only one of several partners within the general regulatory healthcare framework for medicines in Europe. In co-operation with other key stakeholders, such as Competent Authorities, the police, customs and national judicial systems, the OMCL Network contributes to a multi-sectorial, holistic and integrated approach to implementing the MEDICRIME Convention.

It is noted that, as the primary concern of the OMCL Network and the National Competent Authorities is the protection of public and animal health, OMCL work in the area of falsified medicines is not intended to protect the intellectual property rights of the trademark owner of the medicinal product.