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OMCL Network support for the implementation of the CoE MEDICRIME Convention

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Please note that not all documents quoted in this paper are published on www.edqm.eu as some of them are for internal use only.

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

Introduction

This position paper presents a discussion on the role and contribution of the General OMCL Network (GEON) in combating the threat posed by counterfeit medicinal products and in enhancing the potential for 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).

In addition, several strategic recommendations in relation to the design of current surveillance programmes are outlined in this paper for discussion with key stakeholder groups.

Current Activities of the OMCL Network in relation to Counterfeit Medicinal Products:

The aim of an OMCL is to support the Competent Authorities in controlling the quality, safety and efficacy of medicinal products 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 EDQM.[1] The role of the Network is to co-ordinate the technical activities of OMCLs, 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 current activities that relate counterfeit medicinal products; these are summarised as follows:

- OMCLs are involved in performing confirmatory analysis on suspect samples. This has generally comprised of physico-chemical and microbiological/biological analyses, in performing detailed packaging/labelling examinations and in testing comparator samples. (The following OMCL Network document relates to this activity. "An 'Aide Memoire' for the confirmation of Counterfeit Medicines", PA/PH/OMCL (06) 81, in its current version). It has been recognised, however, among the Network that OMCL current surveillance testing is usually not specifically designed for detecting counterfeits in the absence of suspicions / indications of counterfeiting, or for confirming the authenticity of samples. The reasons for this are set out and discussed in the OMCL Network Position Paper titled "The Contribution of the GEON in Combating Counterfeit Medicinal Products", Document No. PA/PH/OMCL (08) 7.

- The OMCL Network has proven its ability to perform large survey-type surveillance activities of medicinal products, including products at risk of counterfeiting, such as Cialis film-coated tablets.

- Exchanging information between OMCLs on testing issues pertaining to possible counterfeit medicinal products 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. The following OMCL Network document describes this activity: "Information exchange in the GEON regarding counterfeit and suspected illegal Medicines", PA/PH/OMCL (04) 146, 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 three Annexes, Document PA/PH/OMCL (07) 89, PA/PH/OMCL (07) 90 and PA/PH/OMCL (09) 45. These documents are available on the OMCLnet.

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

In recent years, both patent-protected and generic medicinal products have been increasingly targeted by counterfeiters. At the same time, the illicit manufacture and illicit supply of medicinal products have also manifested itself as a serious problem.

The Council of Europe has long been involved in addressing the serious problems posed by the counterfeiting of medicinal products, 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 counterfeiting 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 can support 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 can support 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 counterfeit medicinal products between OMCLs and Competent Authorities.
  - The Competent Authorities may in turn make such information available to local law enforcement, customs and other governmental agencies, and this can lead to a more co-ordinated and collaborative approach between these key stakeholders in relation to dealing with counterfeit medicinal products.

- *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 can support the implementation of this Article at a practical and technical level, because the OMCL Network is primarily concerned with helping Competent Authorities assess and monitor the quality and safety of medicinal products, be it in 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 can also co-ordinate the testing of active substances, and this further supports the above goals.
  - In addition, the OMCL Network applies the quality requirements for medicinal products in various testing schemes that are governed by a harmonised quality management system that is 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 can support 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 15 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, the PIC/S, and the various working groups of the HMA, such as the HMA's Working Group of Enforcement Officers and the HMA's Product Testing Working Group.
- With respect to the exchange of information referred to in Article 22, as indicated above, the Network has functioning information-sharing tools already in place that facilitate the rapid dissemination of information and data on counterfeit medicinal products between OMCLs and Competent Authorities. This information can be 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 counterfeits.
- With respect to the provision of assistance referred to in Article 22, again, the OMCL Network can also play 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 counterfeit analysis work for governmental laboratories that may be both within and outside the OMCL Network. (This may 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 can support the implementation of this Article at a practical and technical level, because it can make the analytical capacity and expertise of the Network available to projects and activities that relate to achieving the goals of the Convention in relation to counterfeit medicinal products.
  - 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 recommendations to further strengthen the contribution of the OMCL Network in responding to the threat of counterfeiting and in supporting the MEDICRIME Convention

In relation to the current design of OMCL-related surveillance testing programmes, following detailed discussions within the OMCL Network, the strategic recommendations set out below are being made by the OMCL Network.

These recommendations are intended to provide a platform for discussions between the OMCL Network and its key stakeholders when developing enhanced and integrated programmes and strategies for responding to the threat of counterfeits. This is so that the best use can be made of

OMCL resources and of market surveillance programmes in general when working to combat the threat of counterfeit medicinal products.

1. OMCLs should devote a certain amount of routine surveillance work to checking for signs of counterfeiting in samples. The extent of routine surveillance work that might be devoted within an OMCL to this area should be defined in conjunction with its National Competent Authority. The OMCLs should document any indicators of non-authenticity in a sample that could then be used to trigger a more detailed examination of the product for its authenticity.

2. The current approach to surveillance programmes should be elaborated so as to increase the capabilities within OMCLs of identifying counterfeit samples. However, unless mandated to do so by its National Competent Authority, it should not be a normal responsibility of an OMCL to certify the presence of a counterfeit product during routine surveillance testing without being provided with any indication by the supplier of the sample (to the OMCL) that the sample may be a counterfeit product.

3. The amount of active substance testing being performed in the OMCL Network should be increased.

4. A formal listing of at-risk medicinal products (with respect to counterfeiting) should be compiled to serve as an input to the risk-based sampling and testing programme of the OMCL Network and national testing programmes.

5. Centres of expertise that may currently exist within the OMCL network in relation to counterfeit-related testing work should be identified. (This applies in particular to packaging and labelling examination work.)

6. Additional training on specific areas of counterfeit–related work, such as packaging and labelling examination work, should be provided to members of the OMCL Network.

It is considered by the OMCL Network that, if adopted, the measures set out above will further strengthen the contribution of the OMCL Network in responding to the threat of counterfeiting and in supporting the Convention.

Conclusion

This position paper is intended to provide a platform for discussions between the OMCL Network and its key stakeholders when developing integrated programmes and enhanced strategies for responding to the threat of counterfeits. This is so that the best use can be made of the resources of the OMCL Network, its expertise and infrastructure, in order to 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, national judicial systems, the OMCL Network can contribute 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 counterfeit medicinal products is not intended to protect the intellectual property rights of the trademark owner of the medicinal product.