



**29 March 2017, Nicosia, Republic of Cyprus**

## **Falsified medicines in Europe: enhanced analytical capacity for national laboratories through the OMCL Network**

The European network of Official Medicines Control Laboratories has highlighted how new analytical techniques will support national authorities, such as health government agencies, customs, police and courts, in the fight against falsified medicines in Europe and globally. Discussions took place at the "Combating Counterfeit and Other Illegal Medicines" Symposium co-organised by the network of Official Medicines Control Laboratories (OMCLs) with the State General Laboratory of Cyprus under the Chairmanship by Cyprus of the Council of Europe.

More than 95 participants, including competent authorities, customs and police from 27 countries, gathered in Nicosia on 28-29 March 2017. The Symposium was part of the regular activities of the Network of OMCLs, which is composed of 71 public laboratories across Europe and is coordinated by the EDQM to foster efficient co-operation and facilitate information exchanges and sharing of best practices.

Discussions focused on how the OMCLs can develop their technical competence in the physicochemical and biological analysis of falsified medicinal products. In particular, OMCLs can play an important role in testing the authenticity of medicines and detecting falsifications through the use of advanced techniques, such as chemometric evaluation of testing results.

The threat to public health from falsified medical products has reached global proportions, and the measures to address this issue have to move beyond sharing of scientific knowledge, towards the use of enhanced analytical capacity in day-to-day work programmes. Falsification of medical products is a multi-billion euros' business that poses a major threat to patients. According to statistics from customs authorities in the European Union (EU), the number of falsified medicinal products seized at the borders of the EU accounted for 8% of all seized materials in 2014.

At the Symposium, Dr Popi Kanari, the Director of the State General Laboratory of the Republic of Cyprus, highlighted the value of the legal framework provided by the Council of Europe's activities aimed at combating falsified medicinal products. Dr Kanari explained that, "The work done within the OMCL network is of the utmost importance for the protection of patients across the continent, as it enables the detection of sub-standard or falsified medicinal products." She gave a reminder that "The Council of Europe's Medicrime Convention is left intentionally open for signature to non-member states of the Council of Europe, as a way of combating the problem through a global approach," and stressed the need to have more countries joining it.

Dr Michael Wierer, Head of the Biological Standardisation and OMCL Network Division at the EDQM, was also speaking at the Symposium in Cyprus and explained that there had been a significant shift in the day-to-day work carried out by OMCLs in recent years. "We have been moving from solely performing planned market surveillance testing of authorised medicines towards becoming more involved in the daily analysis of suspected falsified and illegal medicines on behalf of various authorities," Dr Wierer stated, and he noted how,



“This mission requires a wide variety of analytical techniques for screening unknown products”.

A global strategy has been developed, by the Council of Europe’s EDQM, against falsification of medical products and similar crimes. This works through risk management and prevention initiatives, as well as encouraging member states and other stakeholders to work closely together, in Europe and beyond.

The current priorities of the EDQM in relation to the Medicrime Convention were broadly supported by the Symposium in Cyprus too. They cover:

- encouraging countries to make the best use of the global framework provided by the Medicrime Convention for harmonising national criminal law and legal instruments for the prosecution of pharmaceutical crimes on a global scale;
- the transfer of know-how and best practices among national health and law enforcement agencies (police and customs) through tailored training programmes; and
- the coordination of existing resources and expertise across European member states for the physicochemical and biological analysis of falsified medical products, through the Network of Official Medicines Control Laboratories (OMCLs).

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### **Note for the Editor**

The OMCL Network also supports the implementation of the Medicrime Convention at a practical and technical level through:

- information-sharing tools that facilitate the rapid dissemination of information and data;
- its role in assessing and monitoring the quality and safety of medicinal products, applying quality requirements for medicinal products in various harmonised testing schemes; and
- the training programmes it runs to enhance the analytical capacity and expertise of OMCLs.

Ongoing projects focus on:

- developing a Single Point of Contacts’ (SPOCs) Network within the different competent authorities at a national level as a way to encourage co-operation amongst member states;
- feeding the "Know-X" database with information on closed falsified-medicine cases, so as to provide governments with detailed data from health authorities, police and testing laboratories as a support to decision-making on risk prevention and management; and
- supporting inspection authorities in their conformity assessment of mass serialisation systems for medicines, to prevent falsified medical products from entering the legal supply chain.



Further information is available on the web site [www.edqm.eu](http://www.edqm.eu)

More information on the activities organised during the **Chairmanship of Cyprus** can be found here: <https://www.coe.int/en/web/chairmanship>

More information on the **Medicrime Convention** can be found here: <https://www.edqm.eu/en/medicrime-convention>

More information on how the **laboratories of the European Network of Official Medicines Control (OMCLs)** contribute to ensuring the quality of medicines in Europe can be found here: <https://www.edqm.eu/en/general-european-omcl-network-geon>

*A political organisation set up in 1949, the Council of Europe works to promote democracy and human rights continent-wide. It also develops common responses to social, cultural and legal challenges in its 47 member states.*