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COUNTERFEIT AND ILLEGAL MEDICINES: ACTIONS OF THE NETWORK OF OFFICIAL MEDICINES CONTROL LABORATORIES

Despite the numerous measures taken to prevent counterfeit medicines from entering the legal pharmaceutical supply chain in Europe, the use of products with non-declared pharmacological activity or "other illegal medicines", often from uncontrolled sources but also purchased from the legal market, is still a major problem within Europe, and the Official Medicines Control Laboratories (OMCLs) contribute greatly to combating this threat.

Undeclared active pharmaceutical ingredients (APIs) and other pharmacologically active substances can be found in "harmless" food supplements, cosmetics, herbal teas etc. offered for sale. In the OMCL Network these products are often called "medicines in disguise".

Data have shown that in 2013 from the pool of suspected samples tested in the OMCLs of the Network, only 12 cases of real counterfeits (copies of registered medicines sampled from the legal supply chain in the EU) were confirmed, while about 3900 other illegal medicines (non-registered medicines, undeclared medicines etc) were discovered during testing in the Network laboratories. These analyses were performed on behalf of authorities such as customs, police, enforcement / food inspectors, courts and forensic laboratories.

From 10-11 September 2014, the second symposium on combating counterfeits and other illegal medicines, specifically geared to OMCLs with the main focus on "medicines in disguise", took place at the European Directorate for the Quality of Medicines & HealthCare (EDQM). More than 80 participants were registered for the two-day event, which was split into a multidisciplinary open day and a closed session restricted to members of the OMCL Network.

For the open session representatives from forensic and customs laboratories, national medicines and food authorities, enforcement groups and the European Commission were invited to shed light on the problem of falsification of medicines from the viewpoint of European regulators, customs, police and medicines/food agencies, exchange experiences with the OMCLs in the fight against falsified and illegal medicines and discuss means of improving collaboration.

The restricted session gave the OMCL members an opportunity to present their work in the field of analysis of "illegal medicines" and to discuss technical issues encountered in the testing of unknown samples. In addition to lectures and scientific presentations, discussions and a workshop on photographic documentation, the OMCLs also had the opportunity to present their work using posters which were available during both days of the symposium and enabled the participants to contact the authors directly.

The added value of work-sharing and combining of resources within the Network as well as the need to collaborate with all contributors in the combat against illegal medicines was stressed. It was concluded that OMCLs, together with their partners, are ready to cope with the health threats coming from these potentially harmful products.

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Note for the Editor: Further information is available on the internet site www.edqm.eu

The EDQM is a leading organisation which protects public health by enabling development, supporting implementation and monitoring the application of quality standards for safe medicines and their safe use. Our standards are recognised as a scientific benchmark worldwide. The European Pharmacopoeia¹ is legally-



binding in European Member States. Similarly, the EDQM develops guidance and standards in the areas of blood transfusion, organ transplantation and consumer health issues.

The Official Medicines Control Laboratories (OMCL) Network was formed in 1994, under the aegis of the Council of Europe, to co-ordinate the administrative and technical activities of the OMCLs, to facilitate the exchange of knowledge among authorities in Europe and to influence future development through harmonised common standards, based on the legal requirement for testing medicinal products.

The OMCL Network's main goal is to share know-how, ensure access to state-of-the-art technology and to work-share and mutually recognise test results based on commonly agreed procedures and guidelines.

The Network's activities, which are co-funded by the European Commission (EU), are an essential contribution to ensuring the quality of medicines on the market while making best use of member States' resources. The increasing number of non-European countries requesting to join the OMCL Network demonstrates the interest and added value of this activity.

Since 2012, among numerous other activities in the field of falsified medicines testing, the OMCL Network has been developing joint market surveillance programmes on suspected counterfeit and illegal products (MSSIP) to cover a large part of the European market in a co-ordinated campaign targeting defined product groups (in 2012 a joint market surveillance study on suspected counterfeit and illegal products (MSSIP1) focused on [Slimming dietary supplements](#) for example).

¹There are now thirty-eight members of the [European Pharmacopoeia](#) Commission: *Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Montenegro, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, the former Yugoslav Republic of Macedonia, Turkey, Ukraine, the United Kingdom and the European Union*. There are twenty-seven observers: *Albania, Algeria, Argentina, Armenia, Australia, Azerbaijan, Brazil, Canada, China, Georgia, Israel, Madagascar, Malaysia, Moldova, Morocco, Republic of Belarus, Republic of Guinea, Republic of Kazakhstan, Republic of Singapore, the Russian Federation, Senegal, South Africa, Syria, Tunisia, United States of America, the Taiwan Food and Drug Administration (TFDA) and the World Health Organization (WHO)*.

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.