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*Note for the Editors:* Further information is available on the internet site: [www.edqm.eu](http://www.edqm.eu)

## **EDQM BEGINS DEVELOPMENT OF A DEMONSTRATOR OF ITS' FUTURE 'TRACK AND TRACE' SYSTEM**

As part of its anti-counterfeiting strategy, the EDQM has initiated an ambitious project for a "Track and Trace" system for medicines, open to any manufacturer marketing medicinal products in any of the 36 Member States of the European Pharmacopoeia. The project has now reached Phase 2 in which a demonstrator ("live demo") will be developed.

The "live demo" is to be shown as a proof of concept to authorities from the 36 Member States, to business stakeholders from the supply chain and to patient organisations during workshops taking place from the fourth quarter of 2011, mainly at the EDQM premises in Strasbourg. During these workshops, the features of the EDQM system will be demonstrated and discussed, and the concept and the 'live demo' will be fine-tuned so that the development of the future working system meets all expectations.

The EDQM has contracted for this purpose a very experienced world-wide integrator that will use robust, pre-existing middle-ware suitable for the project. The entire system will comply with non-proprietary standards, such as GS1 (*e.g.* also used for Electronic Product Code Information Systems ECPIS), thereby ensuring interoperability, especially with existing national traceability or anti-counterfeiting systems. The scope and governance of the project provides a platform for the development of a pan-European system that can implement the requirements of the future EU Directive on falsified medicines. Using a flexible framework of existing and inter-operating national systems and a directory of multiple repositories, the system will be co-ordinated under the governance of the EDQM, together with the Member States participating in the deployment.

The EDQM believes that the architecture and governance of the entire project will facilitate a successful, phased implementation during Phase 3. During the current Phase 2, between now and 2012, the EDQM will ensure that interaction with all stakeholders is maximised so that the future working system is properly designed and cost-effective. All the required scalability studies for this purpose will be carried out.

The pan-European deployment, under the governance of a public inter-governmental organisation such as the EDQM, will guarantee that all the goals of this long-term project are achieved and, in general, secure the future of European traceability systems.

Together with the recently adopted Council of Europe MEDICRIME Convention which is the first instrument to criminalise counterfeiting of medical products and similarly dangerous crimes, while providing a framework for proportionate sanctions, victim protection and international co-operation, and a number of other projects including a "fingerprint" database for active pharmaceutical ingredients and multisectorial training for government officials, the 'Track and Trace' project is part of a holistic strategy to combat counterfeited medical products in order to protect Public Health.

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*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.*



**Note for the editor:** The EDQM is a leading organisation that 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 world-wide. The European Pharmacopoeia <sup>1</sup>is legally-binding in European Member States. Similarly, the EDQM develops guidance and standards in the areas of blood transfusion, organ transplantations and consumer health issues.

<sup>1</sup>There are currently thirty-seven 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, United Kingdom and the European Union* and twenty-three observers: *The World Health Organisation (WHO); 6 member states of the Council of Europe: Albania, Armenia, Georgia, Moldova, Russian Federation and Ukraine; 16 other countries in the world: Algeria, Argentina, Australia, Brazil, Canada, China, Israel, Madagascar, Malaysia, Morocco, Republic of Belarus, Republic of Kazakhstan, Senegal, Syria, Tunisia, United States of America.*

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