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## THE EDQM PROGRESSES WITH eTACT, ITS PATIENT-ORIENTED TRACEABILITY SERVICE FOR MEDICINES

The European Directorate for the Quality of Medicines and HealthCare (EDQM) has received an invitation from the European Federation of Pharmaceutical Industries and Associations (EFPIA) to participate in a tender for the implementation of their planned mass serialisation system for medicines. This project is a follow-up to a limited pilot project by EFPIA, conducted in Swedish pharmacies in summer 2010. In this project, a consortium of business stakeholders from the medicines supply-chain<sup>1</sup> proposes to develop a test system for a European hub and a national system model in a limited hardware environment that could be proposed as a potential basis for a future mass serialisation system. According to EFPIA, the system to be delivered would be owned by this consortium of business stakeholders for the European hub and operated by them on behalf of respective national stakeholder organisations for the national system model.

The Council of Europe and its EDQM are a public inter-governmental organisation with a mission to protect public health. Hence, the organisation has specific obligations towards patients. Given today's environment and technical possibilities, the EDQM considers the approach taken by this industry consortium as insufficient, particularly as it does not include the possibility for patients to verify the authenticity of any pack of medicines they receive.

The EDQM is of the opinion that a system of mass serialisation for medicines, aimed at preventing counterfeit medicines from entering the legal supply-chain, has to strictly follow the interest of patients. Therefore, the development and operation of such a system cannot lie entirely in the hands of the industry and business stakeholders. The supply of medicines to patients relies on business stakeholders operating a suitably regulated supply-chain for medicines manufactured, distributed and dispensed in accordance with appropriate quality standards. The confidence of patients in this overall supply-chain needs to be maintained and strengthened.

A system of mass serialisation has to be transparently operated, ideally by an independent organisation, and has to be patient-oriented. This is why, in 2009, the EDQM had already started to develop a comprehensive mass serialisation system called eTACT, which could be implemented at a low cost and would cover the 36 member states of the Convention on the Elaboration of a European Pharmacopoeia and possibly beyond. By doing so, the EDQM promotes the emergence of a harmonised traceability system for Europe with full inter-operability between member states, public governance and access to patients. This is part of the holistic Council of Europe/EDQM anti-counterfeiting strategy developed to protect Public Health.

As an inter-governmental organisation with no commercial interests, the EDQM is therefore neither in a position nor is willing to enter into a tender process launched by strictly private organisations. However, the EDQM will follow the progress of this initiative and continue to liaise with the various stakeholders as they will be part of any system eventually put in place in Europe. The EDQM will continue to refine its eTACT system, taking into account the valuable comments and feedback already received and still to come from all categories of stakeholders participating in the project, including authorities from member states<sup>2</sup> and patient organisations.

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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.*

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<sup>1</sup> EFPIA, PGEU, GIRP, EAEPIC

<sup>2</sup> Signatory parties of the European Pharmacopoeia Convention: 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



**Note for the Editors:** Further information is available on the internet site: <http://www.edqm.eu/en/eTACT-1466.html>

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 Pharmacopeia 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.