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EDQM LOOKS AT THE IMPLEMENTATION OF ITS PUBLICLY-GOVERNED eTACT TRACEABILITY SERVICE AT THE POINTS OF DISPENSING

The eTACT project, launched by the Council of Europe and its European Directorate for the Quality of Medicines & HealthCare (EDQM), has taken further steps towards achieving a secure, patient-friendly and cost-effective traceability service for medicines. The EDQM has been consulting business stakeholders in order to fine-tune the details of all business processes to be handled in the deployment of an effective anti-counterfeiting traceability service for medicines. This work follows the organisation over the last 18 months of workshops with more than 200 representatives of authorities and operators of the medicines supply chain from 30 countries, and paves the way for the establishment of a real-scale pan-European eTACT service that is fit-for-purpose.

The latest workshop, organised on 26 March 2013 on the EDQM premises in Strasbourg, brought together experts in pharmacy IT dispensing systems, who will be primarily responsible for interfacing those systems with the future traceability system(s) to be deployed in Europe. One such state-of-the-art system has already been integrated into the current eTACT live demo system, which has allowed the eTACT team to gain further practical experience in the implementation of such Point-of-Sale (PoS) systems. During this workshop, specificities of the different existing IT dispensing systems were discussed as well as differences in the national environments for business processes such as returns, pack splitting or stock management. The outcome of this workshop will give the EDQM the opportunity to design a system that balances business constraints with the requirements and opportunities offered by the deployment of traceability throughout the medicines supply-chain.

The workshop was also attended by experts involved in the point-of-dispensing verification system developed by business stakeholders, known as the European Stakeholder Model (ESM), who expressed their interest in the approach taken by the EDQM and in acquiring knowledge about the business processes it covers. As an inter-governmental organisation with the mission to protect public health, the EDQM is pleased to see that its efforts to develop a harmonised European architecture for mass serialisation are generating interest throughout the entire community of future users of such systems. This will make it easier for operators of the medicines supply chain (manufacturers, distributors, wholesalers, repackagers, parallel importers and pharmacies) to play their leading role in the development, deployment and running of the eTACT service proposed by the EDQM.

Further information is available on the webpage of the [project](#).

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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 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 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.

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, United Kingdom and the European Union. There are twenty-four observers: the World Health Organization (WHO); 5 member states of the Council of Europe - Albania, Armenia, Georgia, Moldova and the Russian Federation; and 18 other countries in the world - Algeria, Argentina, Australia, Brazil, Canada, China, Israel, Madagascar, Malaysia, Morocco, Republic of Belarus, Republic of Guinea, Republic of Kazakhstan, Republic of Singapore, Senegal, Syria, Tunisia, United States of America.

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