



03 July 2012, Strasbourg, France

THE EDQM IS EXPANDING ITS CONSULTATIONS ON eTACT TO BETTER SERVE PUBLIC HEALTH

On 21 June 2012 at its Brussels office, the Council of Europe hosted a Round-table Discussion on “Identifying falsified medicines: How best to protect European citizens?” The event was an opportunity to have a high-level discussion on what is at stake in the current discussions at European level on the future architecture of the mass serialisation systems to be used in the legal medicines supply-chain to protect it from counterfeit/falsified medicines.

As a result of the complexity of the topic and its far-reaching impact on maintaining the cost-effective distribution of medicines in Europe, several projects involving various bodies and stakeholders have been developed pro-actively. One of these projects is the eTACT service, which promotes public governance, traceability along the entire distribution chain and patient access. The Round-table Discussion was, therefore, a continuation of the communication and consultation process started in Q3/ 2011 through the various eTACT workshops and webinars organised for all kinds of stakeholders, including participants from most of the 36 European countries that are members of the European Pharmacopoeia Commission. The eTACT workshops focus on business stakeholders, regularly inviting them to the EDQM premises in Strasbourg to comment on the technicalities of the eTACT service, whereas webinars and events such as the Round-table Discussion on 21 June 2012 involve authorities and patients’ organisations in order to better address questions such as patient involvement and governance.

A wide range of questions were discussed during the event on 21 June, which will allow the EDQM to further fine-tune the concept of the eTACT service—not only to take into account the users and the business requirements of the various actors in the supply-chain, but also to strengthen and better prepare for patient involvement. Patients’ organisations have expressed the need to increase awareness of the risks of counterfeit/falsified products, while retaining the leading role of authorities, business stakeholders and healthcare providers in protecting patients. They have stressed that patient involvement should be viewed as long-term, transparent and unbiased. Patients are becoming increasingly involved in decision-making throughout the lifecycle of medicines, from product development right through to post-marketing pharmacovigilance activities. Therefore, there was agreement that there should be similar involvement by patients in issues related to the traceability of medicines. Patient verification should be further developed not as an add-on tool, but as a legitimate way to engage patients while leaving the ultimate responsibilities for system operation and product-decisions based on professional assessment to authorities and stakeholders. Authorities present at the Round-table Discussion supported the appeals for increased security and better transparency of the systems under development, and the added-value of the eTACT project in this context based on the widely acknowledged experience of the EDQM in secure regulatory processes was clearly demonstrated.

The open discussions organised by the EDQM, encompassing collaborations with parallel stakeholders’ projects, will continue with regular workshops, including a 2-day event (by invitation only) to be hosted in Sofia, Bulgaria on 14-15 November 2012.

Contact: Caroline Larsen Le Tarnec, Public Relations Division, EDQM

Tel.: +33 (0) 3 88 41 28 15 ; E-mail: caroline.letarnec@edqm.eu

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

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 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.

¹There 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-five observers: The World Health Organisation (WHO); 6 member states of the Council of Europe: Albania, Armenia, Georgia, Moldova, Russian Federation and Ukraine; 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.