



4 October 2016, Strasbourg, France

## European Pharmacopoeia prepares for the future through exchange with stakeholders

**International conference: "European Pharmacopoeia: Tackling future challenges of the Quality of Medicines together", 27-28 September 2016, Tallinn, Estonia**

To mark the publication of the 9th edition of the European Pharmacopoeia (Ph. Eur.), the EDQM organised a large international conference in Tallinn (Estonia), which brought together representatives of European and international regulatory authorities, the World Health Organization (WHO), pharmacopoeias from different continents as well as industry and associations from Europe and beyond. Participants came from 41 different countries, including Brazil, Canada, India, Japan, South Africa, Taiwan and USA.

Following welcoming addresses by Dr Susanne Keitel, EDQM Director, Ms Maris Jesse, Deputy Secretary General of the Ministry of Social Affairs of Estonia, and Dr Kristin Raudsepp, Director General of the Estonian State Agency of Medicines (Ravimiamet), the first plenary session addressed the EDQM's role in the context of the European regulatory environment. Speakers on this topic included Prof Guido Rasi, Executive Director of the European Medicines Agency (EMA), and Prof Klaus Cichutek, Chair of the Management Group of the European Union Heads of Medicines Agencies (HMA), who provided an update on current challenges faced by the European regulatory network and underlined the important contributions of the EDQM in ensuring access to good quality medicines for patients.

The next two sessions featured workshops dedicated to four key topics: setting pharmacopoeial standards for biotherapeutic products; the control of elemental impurities (i.e., the impact of the ICH Q3D Guideline on pharmacopoeial standards); new technologies; and excipients, other components and international harmonisation.

The feedback from each workshop was summarised during the final plenary session, which also included an update on progress on the replacement of animal tests in the Ph. Eur. and recent achievements and current hot topics. The outcome of the workshops and recommendations made during the conference will be discussed at the upcoming November session of the Ph. Eur. Commission and will help it shape its priorities for the next three years. More details will be made available in due course.

Participants were also reminded of the recent revision of the Ph. Eur. Commission's working procedures to open nominations for its Groups of Experts and Working Parties to experts from non-European Pharmacopoeia member states and non-observers. This will allow experts from all over the world to actively contribute to the elaboration of the 10th Edition of the Ph. Eur., ensuring that it remains of maximum relevance to its users as they "*tackle future challenges of the quality of medicines together*".

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**NOTES FOR EDITOR:** Further information is available on the website [www.edqm.eu](http://www.edqm.eu)

The final Conference programme can be found [here](#).



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 Member States<sup>1</sup>. Similarly, the EDQM develops guidance and standards in the areas of blood transfusion, organ transplantation and consumer health issues.

*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> There are thirty-eight members of the [European Pharmacopoeia](#) Commission: Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Montenegro, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, the Former Yugoslav Republic of Macedonia, Turkey, Ukraine, United Kingdom and the European Union.