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QUALITY OF MEDICINES IN A GLOBALISED WORLD: DREAM AND REALITY 14-15 OCTOBER 2010, PRAGUE, CZECH REPUBLIC

Nearly 250 delegates and experts from 32 countries gathered in Prague on 14 -15 October 2010 to discuss the challenges and opportunities stemming from the globalisation in the trade in medicines. The two-day conference, organised by the European Directorate for the Quality of Medicines & HealthCare (EDQM), to mark the launch of the 7th Edition of the European Pharmacopoeia, was opened by Dr Leoš Heger, Minister for Health in the Czech Republic, who expressed his country's support to the invaluable work of the EDQM in protecting public health.

Regulators from around the world, including the European Commission, the EU Heads of Medicines Agencies, the European Medicines Agency, the US Food and Drug Administration and Japan's National Institute for Health Sciences, provided insights during the plenary session on the challenges and the opportunities for collaboration in a globalised market for medicines. The World Health Organization (WHO), pharmacopoeias (US, Japan, China, India and Brazil) and key industry associations were invited to present their views.

"Providing safe, effective and good quality medicines is a global concern. One of our major goals is to protect patients against illegal, falsified or substandard medicines," said Dr Susanne Keitel, Director of the EDQM. "It is important that we work together to promote the quality of medicine in a globalised world." In this context the leading role of the European Pharmacopoeia was unanimously acknowledged by the participants.

Interactive workshops were organised to stimulate discussion and debate around five specific themes:

- the characterisation of biological molecules: participants felt that the European Pharmacopoeia monographs are 'fit-for-purpose', but proposed that further consideration be given to the specificity of monographs, the standardisation of methods and the speed of revision process;
- the impact of new technologies on the European Pharmacopoeia: while experience of industry and regulators is currently still limited in this field, it is expected that the new ICH quality paradigm will soon have consequences for marketing authorisation applications. The work the European Pharmacopoeia Commission has initiated to support the implementation of these new concepts was highly welcomed by participants and further fields of activity were proposed;
- the control of impurities: new analytical technical developments, such as fast liquid chromatography (LC) and new stationary phases, liquid chromatography-mass spectrometry (LC-MS) techniques and nuclear magnetic resonance (NMR), will be applied by the European Pharmacopoeia to better characterise and control the quality of substances. Additionally, these techniques will be helpful in combating counterfeit medicines;
- the application of 3R principles: numerous initiatives and achievements were recognised, even if the global harmonisation of requirements for animal testing has yet to be realised due to differing regional ethical positions, with Europe being more advanced in this field than others. The need for the prioritisation of the work programme, as well as global collaboration and communication were highlighted.
- the need for changes in the European Pharmacopoeia: this workshop was designed to collect feed-back from participants on whether or not they consider that the European Pharmacopoeia is equipped to confront the challenges of the future. The conclusion was a resounding "yes", combined with the need for continuous adaptation to regulatory, technical and scientific developments.

"This conference will help us to assess the difficulties, to better understand the issues and to identify the direction we need to take," said Dr Keitel. The outcome of the discussions will be taken into account by the European Pharmacopoeia Commission in future decisions on policy and work programmes.

In her concluding remarks, the Chair of the European Pharmacopoeia Commission, Dr Marianne Ek, spoke of her own hopes and aspirations for the new mandate of the Commission and invited the audience to re-unite in 2013 to evaluate progress and whether new needs have emerged that would require further optimisation of the European Pharmacopoeia.

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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 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.

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.