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EDQM CONFERENCE ADDRESSES KEY ISSUES AND WORK PRIORITIES FOR TOMORROW'S MEDICINES

The international conference "EDQM & European Pharmacopoeia: State-of-the-Art Science for Tomorrow's Medicines" took place on 19 to 20 June 2019 in Strasbourg to mark the publication of the 10th Edition of the European Pharmacopoeia (Ph. Eur.) and the 25th Anniversary of the European OMCL Network and of the Certification of Suitability Procedure. The plenary sessions and workshops at the conference were attended by more than 300 participants from 47 different countries in Europe and beyond, including, Brazil, Canada, China, India, Japan, Kazakhstan, Senegal, South Africa, the Taiwan Food and Drug Administration (TFDA) and the United States of America (USA).

The event, held under the patronage of the French Presidency of the Council of Europe, was opened by Ms Snežana Samardžić-Marković, Director General of Democracy at the Council of Europe, and Ambassador Jean-Baptiste Mattéi, Permanent Representative of France to the Council of Europe. Welcoming participants, Dr Susanne Keitel, Director of the EDQM, addressed the need to enhance cooperation at international level and explained that the feedback emerging during the conference would help shape future priorities for the work of the EDQM and the Ph. Eur. Commission.

In the opening session, Dr Andrzej Rys, European Commission, and Dr Dominique Martin, French National Agency for the Safety of Medicines and Health Products (ANSM), provided an update on current challenges faced by the European regulatory framework and underlined the important contribution by the EDQM in ensuring access to good quality medicines.

Interactive workshops were organised to facilitate exchanges on specific themes:

- In the field of biotherapeutic products, participants remarked the EDQM's efforts in regularly exchanging with users over the past 3 years, which bore significant progress in addressing their needs, notably explaining the flexible approaches introduced in respective Ph. Eur. monographs. Stakeholders (regulators (e.g. assessors and OMCLs), innovators and biosimilar companies) expressed differing views on the value of individual monographs, with some participants favouring a transversal approach based on the elaboration of general methods and class monographs, instead of product specific monographs. The Ph. Eur. portfolio of quality requirements for biotherapeutics will continue to rely on the experience gathered from product specific cases and use it as a basis for driving general, transversal matters.

- Participants commended the Ph. Eur. for providing a well-established and comprehensive framework for controlling impurities in its monographs on substances for pharmaceutical use. New challenges emerging from regulatory requirements (such as the European Medicines Agency (EMA) guideline on setting specifications for related impurities in antibiotics), increasing numbers of synthetic routes and changes in manufacturing settings and analytical fields were also highlighted. As a consequence, it was acknowledged that

developing complementary impurity control frameworks may be required for substances with complex, large and/or heterogenic impurity profiles, such as some antibiotics. Devising a smart reference standard strategy for impurities control was also seen of paramount importance, while in the context of elemental impurities, the EDQM encouraged the submission of risk management summaries in Certification of Suitability (CEP) dossiers.

- Innovators and generic manufacturers, as well as OMCLs, confirmed that Finished Product Monographs (FPMs) in the Ph. Eur. play an important role for the standardisation and harmonisation of the quality of medicines. Open points that still needed to be explored included: the status of dissolution test as provided in individual FPMs and the impact of these monographs on the assessment of Marketing Authorisation Applications (MAAs).

- Concerning General Methods in the Ph. Eur., participants noted that the work carried out by the related Group of experts brought a significant contribution to the Ph. Eur.'s modernisation process. New and revised general chapters as well as the General Notices demonstrate how the Ph. Eur. already allows for flexible approaches and fully supports the implementation of principles such as Quality by Design and Continuous Manufacturing. Participants also flagged many new challenges ahead, including the potential impact of ICH guidelines currently being developed or revised (such as ICH Q12, Q13, Q2/Q14), which will require close monitoring and assessment, or the so-called 'Big Data', data quality and end-to-end processes for continuous manufacturing.

- The pioneering role of the EDQM in the field of the 3Rs ('Replace, Reduce, Refine' animal tests in the quality control of medicines) was praised by participants. Even if some gaps still needed to be addressed, the role of Ph. Eur. chapter *Substitution of in vivo method(s) by in vitro method(s) for the quality control of vaccines* (5.2.14) was highlighted as an important driver for tackling remaining challenges.

- Concerning Advanced Therapy Medicinal Products (ATMPs), participants suggested developing guidance to address the specificities of these complex and innovative products; such guidance should also cover aspects such as calibration and performance verification of equipment as well as packaging materials. Participants recommended new and fast approaches in order to ensure the development of appropriate guidance on ATMPs.

- Discussions at the OMCL Network session addressed the benefits of Official Control Authorities Batch Release (OCABR) of vaccines, blood and plasma derivatives. The sampling and testing of APIs were reviewed, as well as risk-based sampling strategies for finished products and the contribution of the OMCLs in the fight against falsified and illegal medicines. Discussions also included proposals for further refinements of the existing market surveillance and testing programmes.

- The Certification of Suitability (CEP) session focused on current initiatives for facilitating the assessment of the quality documentation for active substances in the context of marketing authorisation applications, such as the EU ASMF Worksharing Programme, the

activities of the International Pharmaceutical Regulators Programme (IPRP) Quality Working Group for Generics and the CEP procedure. Industry representatives called for further harmonisation in assessment, irrespective of the procedure used. With an increasing number of participating regulatory agencies worldwide, ICH was seen as a good platform for harmonising technical requirements, such as those on mutagenic impurities or starting materials for active substances. Participants were also invited to give feedback on the future content of CEPs in order to best fit current stakeholder's needs. A survey will be conducted by the EDQM later this year.

- Special focus was given to the MEDICRIME Convention and the role played by the EDQM in the fight against falsified medical products. As a complement to the legal standards in the Convention, the activities organised and co-ordinated by the EDQM help to prevent, identify and remove falsified medical products in the supply chain.

For all the topics addressed during the conference, the EDQM and Ph. Eur. expressed their commitment to communicating and cooperating with all stakeholders concerned in the EDQM's activities. The importance of the participation of manufacturers and other stakeholders in the development and revision of texts of the Ph. Eur. from the beginning of the process was a key success factor for developing appropriate and suitable quality standards. Industry representatives also appealed for harmonisation between pharmacopoeias on topics of common interest, such as in the field of monographs for finished products or biotherapeutics.

The feedback and recommendations gathered at the event will be discussed at the upcoming November session of the Ph. Eur. Commission and will help to define the priorities for the next three years. Presentations in pdf format are now published on the EDQM website here.

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Note for the Editor: Further information is available on the internet site **https://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 worldwide. The European Pharmacopoeia is legally binding in member states[1]. Similarly, the EDQM develops guidance and standards in the areas of blood transfusion, organ transplantation and consumer health issues.

[1]There are thirty-nine 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, Republic of Moldova, Montenegro, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, The Republic of North Macedonia, Turkey, Ukraine, United Kingdom and the European Union.*