27 September 2017, Prague, Czech Republic

EDQM discusses the place of its Certification procedure (CEPs) in the global regulatory environment

The EDQM held a 2-day conference in Prague to exchange with the worldwide pharmaceutical sector and to keep authorities and manufacturers alike informed of recent developments and of the future of its Certification of suitability to the monographs of the European Pharmacopoeia in the global regulatory environment. The event was attended by 175 representatives of medicines authorities and manufacturers from all continents. As the world of pharmaceuticals is becoming ever more globalised, the EDQM's certification procedure is becoming increasingly recognised and used beyond Europe.

Reflecting the developments of the European Pharmacopoeia (Ph. Eur.) and the Certification procedure in recent years, the first session at the conference covered the experience of European regulators and trade associations from Europe, with additions from China and India. Dedicated workshops focused on practical information on specific aspects of the Certification procedure such as the content of a CEP application, the change to electronic submissions, and information on GMP (Good Manufacturing Practices) inspections. The last part was dedicated to international initiatives for information and work sharing on medicinal products, as well as to the use of CEPs by those authorities which accept CEPs in spite of not being based in Europe. Ph. Eur. monographs and CEPs in fact support the development of generic drugs, which are crucial to ensure the sustainability of healthcare systems, and also facilitate the work of regulatory authorities in assessing the quality of medicinal products.

Susanne Keitel, Director at the EDQM, said on the fringe of the conference: "We are committed to providing fora for exchange with the users of CEPs, as our Certification procedure is shaping up as an ever more popular tool in the pharmaceutical sector for confirming the quality of medicines." Referring to the EDQM's commitment in supporting authorities and manufacturers using CEPs, Keitel continued: "Regular dialogue with our CEPs users is fundamental for ensuring that authorities and manufacturers can make good use of CEPs to protect the health of citizens and provides us with important feedback on our own performance".

The Certification procedure has become increasingly used by authorities worldwide: the current globalised context brings limited resources and similar challenges, prompting authorities to share not only information, but also working practices, such as those supported by the CEPs. The EDQM encourages these exchanges of good practices, but also actively seeks feedback from manufacturers and national authorities in order to help them to use the Certification procedure correctly and in a way which will support everyone, without delay, towards the common goal of protecting the health of medicines users in Europe and beyond.

Contact: Caroline Larsen Le Tarnec, Public Relations Division, EDQM, Council of Europe
Tel.: +33 (0) 3 88 41 28 15 - E-mail: caroline.letarnec@edqm.eu

Note for the Editor:

Based on a centralised assessment of applications describing the manufacture and quality control of substances for pharmaceutical use, the EDQM's procedure for the Certification of Suitability to the monographs of the European Pharmacopoeia:

- facilitates and simplifies exchanges between authorities and manufacturers to ensure the quality of substances used in the production of pharmaceutical products and their compliance with the European Pharmacopoeia quality standards;
- facilitates the management of marketing authorisation applications for medicinal products;
- acts as a complement to and a bridge between European Pharmacopoeia monographs and the need to submit a marketing authorisation dossier for a medicinal product;
- optimises the use of scarce resources available to public health authorities;
- optimises the use of scarce resources available for GMP inspections of drug substances through close collaboration with competent authorities.

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 Pharmacopeia 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 former Yugoslav Republic of Macedonia", Turkey, Ukraine, United Kingdom and the European Union.*

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.