The EDQM’s Mission: Protecting public health

The mission of the EDQM is to contribute to the basic human right of access to good quality medicines and healthcare and to promote and protect human and animal health by:

- establishing and providing official standards which apply to the manufacture and quality control of medicines in all signatory States of the ‘Convention on the Elaboration of a European Pharmacopoeia’ and beyond;
- ensuring the application of these official standards to substances used in the production of medicines;
- co-ordinating a network of Official Medicines Control Laboratories (OMCL) to collaborate and share expertise among Member States and to use limited resources effectively;
- proposing ethical, safety and quality standards:
  - for the collection, preparation, storage, distribution and appropriate use of blood components in blood transfusion;
  - for the transplantation of organs, tissues and cells;
  - collaborating with national, European and international organisations in efforts to combat counterfeiting of medical products and similar crimes;
- providing policies and model approaches for the safe use of medicines in Europe, including guidelines on pharmaceutical care;
- and by:
  - establishing standards and coordinating controls for cosmetics and food packaging.

The European Pharmacopoeia (Ph. Eur.)

The ‘Convention on the Elaboration of a European Pharmacopoeia’ was adopted by the Council of Europe in 1964 and laid down the groundwork for the Ph. Eur. to ensure the quality of medicines in Europe.

The Ph. Eur. consists of monographs describing individual quality standards (set of control tests applicable to one substance or product) and general quality standards applicable to families of substances/products or to dosage forms, as well as general methods of analysis. In addition to being legally binding in its 37 member states, it defines the minimum acceptable standards for products to be authorised within the European Union because compliance with monographs is a mandatory requirement in the Convention and within Directives 2001/82/EC, 2001/83/EC, and 2003/63/EC, as amended.

The Ph. Eur. Convention has been signed by 38 signatory parties including the EU, 26 European and non-European countries, the World Health Organization (WHO) and the Taiwan Food and Drug Administration (TFDA) who have observer status.

Ph. Eur. Commission - An efficient collaboration

All the texts of the Ph. Eur. - elaborated or revised by the groups of experts and ad hoc working parties - are adopted by consensus by the Ph. Eur. Commission. Each national delegation has one vote. Member states’ representatives come from health authorities, national pharmacopoeia authorities, universities or industry and are appointed by the national authorities on the basis of their expertise. Once adopted, the texts of the Ph. Eur. become mandatory on the same date in all member states. They guarantee a single common quality standard for medicines throughout Europe.

The EDQM is responsible for the secretariat of the Ph. Eur. Commission and for preparing the general chapters and monographs of the Ph. Eur. with the groups of experts.

Certification of Suitability to the Ph. Eur. Monographs (CEP)

The Certification Procedure is based on the assessment of quality dossiers provided by manufacturers on the manufacturing processes and quality control tests of their active pharmaceutical ingredient or excipient. Certification indicates that the Ph. Eur. monograph(s) suitably control the quality of this substance. In addition, the EDQM carries out inspections of manufacturing and/or distribution sites of substances covered by Certificates of Suitability (CEPs), to ensure that Good Manufacturing Practices (GMPs) are enforced and the information supplied under the Certification Procedure is accurate.

What are the advantages of a CEP?

- Centralised and harmonised assessment by the EDQM.
- Recognised in all Ph. Eur. Convention member States and many non-European countries.
- Saves time and resources for all stakeholders, manufacturers and authorities.
- Facilitates management of applications for marketing authorisation applications (MAA) and variations for medicinal products.

A CEP simplifies marketing authorisation applications for regulatory authorities and the industry.

Key Fact & Figures

- The EDQM publishes a new edition of the Ph. Eur. every three years, both in English and French – the official languages of the Council of Europe.
- The current 8th Edition contains over 2200 monographs and 350 other texts - mostly covering excipients and active pharmaceutical ingredients.
- The Ph. Eur. Commission adopts on average 200 texts per year.
- More than 70 expert groups and 800 European experts, from all the member states, participate in the work of the Ph. Eur.
- Over 2600 reference standards of chemical, biological or herbal origin are available in the Ph. Eur. Catalogue.
- More than 3000 valid CEPs have been granted by the EDQM.
- In 2014, the EDQM carried out 34 site inspections - located mainly in Asia - with the participation of inspectors from national supervisory authorities.

References

5. Reference Standards Database: http://psp.edqm.eu/