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Note for the Editors: Further information is available on the internet site: www.edqm.eu

THE EDQM EXTENDS ITS ISO 9001 CERTIFICATE

The European Directorate for the Quality of Medicines & HealthCare (EDQM) is proud to announce that the scope of its ISO¹ 9001:2008 certificate has been extended to the market surveillance of finished medicinal products and issuance of guidelines for the release of human immunological and blood derivative medicinal products.

The certification of compliance with ISO 9001:2008 recognises that the policies, practices and procedures of the organisation ensure consistent quality in the services and products provided to customers and stakeholders.

With this new step in the development of its quality management system, the EDQM demonstrates its commitment to extending and maintaining the highest level of quality, efficiency and responsiveness in achieving our goal of total customer and stakeholders' satisfaction.

The EDQM is now certified as meeting the requirements of ISO 9001:2008 for the following activities:

“Evaluation of applications (initial, revisions and renewals) for certificates of suitability to the monographs of the European Pharmacopoeia, granting of certificates, and management of the inspection programme of manufacturing sites and associated brokers.

- *Planning, implementation and coordination of post-marketing surveillance studies for medicinal products authorised by the centralised (CAP) and national (MSS studies) procedures;*
- *Management of the database related to post-marketing surveillance studies of medicinal products authorised by the mutual recognition (MRP) and decentralised (DCP) procedures;*
- *Coordination of the elaboration and issuance of guidelines related to the OCABR procedure for the release of batches of human immunological medicinal products (blood and vaccine);*

according to the pharmaceutical legislation, notably directives 2001/82/EC and 2001/83/EC, as amended, and Regulation 726/2004 (EC) for the EU countries”.

The EDQM firmly believes that the decision to become ISO 9001 certified and progressively extend the scope of this certification supports the organisation's vision to be a leader notably in protecting public health by establishing high quality standards for human and veterinary medicinal products.

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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 Pharmacopoeia² is legally-binding in European Member States. 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.

¹International Organization for Standardization (www.iso.org)

²There are currently thirty-seven members of the European Pharmacopoeia Commission: *Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Montenegro, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, the former Yugoslav Republic of Macedonia, Turkey, United Kingdom and the European Union* and twenty-three observers: *The World Health Organisation (WHO); 6 member states of the Council of Europe: Albania, Armenia, Georgia, Moldova, Russian Federation and Ukraine; 16 other countries in the world: Algeria, Argentina, Australia, Brazil, Canada, China, Israel, Madagascar, Malaysia, Morocco, Republic of Belarus, Republic of Kazakhstan, Senegal, Syria, Tunisia, United States of America.*