



**Strasbourg, 11/01/2010**

*Note for the Editors:* Further information is available on the internet site: [www.edqm.eu](http://www.edqm.eu)

## **EDQM receives ISO 9001:2008 Certification**

The European Directorate for the Quality of Medicines & HealthCare (EDQM) is proud to announce it has been certified as an ISO<sup>1</sup> 9001:2008 compliant organisation on 17 December 2009. The certification was awarded by the official French standardisation body Association française de normalisation (Afnor) via Afnor Certification (AFAQ).

Becoming registered as ISO 9001:2008 compliant, the EDQM underwent a stringent evaluation process that included its quality management system, a full documentation review, a three-day initial audit, and staff training and competence management, all of which work to identify corrective actions that eliminate non-conformities to the quality management standard. The process culminated in a comprehensive three-day certification audit by Afnor.

The certification of compliance with ISO 9001:2008 recognises that the policies, practices and procedures of our organisation ensure consistent quality in the services and products we provide to our customers and stakeholders. With this certification, our customers and stakeholders can be confident that the EDQM is dedicated to maintaining the highest efficiency and responsiveness in achieving our goal of total customer and stakeholder satisfaction.

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

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

To maintain our certification, Afnor will perform annual audits to ensure compliance and to assess initiatives for continuous improvement.

We believe that our decision to become ISO 9001 Certified is a proactive one that not only anticipates the demands of our clients, but also demonstrates our commitment to providing quality services to all our customers and stakeholders. They can be confident that the EDQM will continue to provide the highest quality of services and products now and in the future.

The EDQM has already begun to prepare for an extension of the scope of the current certification.

### **Note for the Editors**

The European Pharmacopoeia<sup>2</sup> and the EDQM (a Directorate of the Council of Europe notably in charge of the secretariat of the European Pharmacopoeia) have a mission to protect and promote public and animal health, through the elaboration of quality standards of medicines for human and veterinary use.

Medicines need to be safe, efficacious and of good quality in order to produce the expected therapeutic benefit. The EDQM works closely with its international and European partners to strengthen measures in order to ensure that substandard or counterfeit medicines do not reach the marketplace.

The EDQM's networks collaborate on a daily basis with all the authorities involved in the standardisation, regulation and control of medicines for human and veterinary use. The EDQM has expanded progressively its responsibilities to include additional areas: blood transfusion, organ transplantation, the legal classification of medicines and the co-ordination, on a European scale, of the fight against the production, transportation and distribution of counterfeit medicines. Activities in the field of cosmetic products and food contact materials were transferred to the EDQM in 2009.



*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.*

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<sup>1</sup>International Organization for Standardization (<http://www.iso.org/iso/home.htm>)

<sup>2</sup>There 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.*