



STRASBOURG, 02/11/09

Note for the attention of editors: further information is available on the Internet site: www.edqm.eu.

THE EDQM CONTINUES ITS INSPECTIONS AND REINFORCES ITS COMMUNICATION AND INFORMATION CAMPAIGNS IN CHINA

China, October 2009

The European Directorate for the Quality of Medicines & HealthCare (EDQM, Council of Europe) has recently carried out an inspection campaign of production sites for active substances for pharmaceutical use in China, with the assistance of official European inspectors.

This inspection campaign was part of its regular inspection programme for manufacturing sites covered by a certificate of suitability to the monographs of the European Pharmacopoeia (CEP) or an application for a certificate of suitability respectively.

This campaign brings the overall number of inspected sites to over 180, most of which are located in Asian countries.

A training session for Chinese manufacturers was also organised in a partnership with the Chamber of Commerce for Import and Export of Medicines and Health Products (CCCMHPIE, Beijing). China's pharmaceutical industry has undergone considerable transformation over the last few years and it should continue to grow, with China becoming one of the world's foremost markets. It is therefore very important for the EDQM to set up and maintain communications with the Chinese pharmaceutical industry and also to provide training sessions on a regular basis so that they can work together to ensure that production quality requirements are met in order to protect public health.

More than 120 professionals working in the areas of quality assurance, quality control and regulatory affairs participated in this training session. In addition to presentations on the key subjects of the Certification Procedure and the inspections associated with it, a large part of the programme was devoted to discussions and exchanges with the participants, which clarified a large number of technical details. Individual question-and-answer sessions were also included in the programme for those who had more specific questions on the Certification Procedure or on EDQM inspections.

This operation should be renewed in 2010.

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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