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

China, October 2009

EDQM继续在中国进行检查, 并加强在中国的沟通

2009年10月, 中国

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.

欧洲药品质量与健康保健理事会（欧盟理事会EDQM）在欧洲官方检查员帮助下，最近在中国进行对活性医药物质进行了现场检查。

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.

根据欧洲药典适应性证书程序规定，该检查是生产现场常规检查计划的内容。

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

此次检查之后，总体的现场检查数量已达180家，大部分是在亚洲国家进行。

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.

在医药保健进出口商会（北京CCCMHPIE）的协助下，还对中国生产企业进行了培训。在过去几年中，中国医药企业经历了许多转变，并应继续成长，因为中国已经成为世界最重要的市场。因此，EDQM与中国医药企业建立并保持沟通就非常重要，举办定期培训可使双方共同努力，保证药品质量符合要求，进而保障公众健康。

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.

大约有来自质量保证、质量检验和法规事务方面的近120人参加了此次培训。培训中除了有关CEP证书程序和检查程序知识之外，还提供了大量时间与受训人员进行讨论和交流，澄清了很多技术细节。同时还举办了一对一的讨论，专门解答CEP证书或EDQM现场检查方面的具体问题。

This operation should be renewed in 2010.
2010年还将举办类似培训。

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.

欧盟理事会是1949年成立的政治机构，致力于发展全球民主与人权。同时在47个成员国内建立对社会、文化和法律等方面的挑战响应。

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