

## EDQM suspends Certificates of Suitability for Chinese APIs

**Muenster (Germany), 22. April 2009.** On April 14th, 2009 the European Directorate for the Quality of Medicines & HealthCare (EDQM) has suspended the Certificates of Suitability of four active pharmaceutical ingredients (APIs) manufactured in China. Two Benzylpenicillin products (R0-CEP 2004-001-Rev 00, R0-CEP 2004-017-Rev 00) of the company *Hebei Huari Pharmaceuticals Ltd.* as well as Dihydrostreptomycin sulphate (R1-CEP 2000-069-Rev 00) and Neomycin sulphate (R0-CEP 2001-317-Rev 02) of *Sichuan Long March Pharmaceutical Co. Ltd* are affected. "The EDQM auditors have obviously detected that these APIs are not manufactured according to the submitted documentation or in line with the requirements of ICH Q7", explained Dr. Wolfgang Heisig from the blue inspection body GmbH ([www.blue-inspection.com](http://www.blue-inspection.com)) the proceedings of the EDQM. "Since the associated risk has changed, European pharmaceutical manufacturers should now also assess those APIs manufactured in the same premises, which have not been objected".

Already in mid of March the "Certificate of Suitability" for Clindamycin phosphate (R0-CEP 2003-060-Rev 00) of *Zhejiang Pharmaceutical Co. Ltd.* had been suspended by the EDQM. The Spanish Ministry of Health had thereupon demanded to recall 14 batches of medicinal products which contained the objected Clindamycin phosphate. In addition, GMP audit reports of Chinese suppliers were asked for from the pharmaceutical manufacturers.

"We currently do not know whether other health authorities will follow in that direction", comments Dr. Wolfgang Heisig. However, pharmaceutical companies using APIs from the affected companies should act now. He

**Contact:**

blue inspection body GmbH  
Hafenweg 18-20  
D-48155 Münster

Personal contact:  
Dr. Stefan Kettelhoit

phone: +49 (0)251 - 625620-40  
[stefan.kettelhoit@blue-inspection.com](mailto:stefan.kettelhoit@blue-inspection.com)  
[www.blue-inspection.com](http://www.blue-inspection.com)

**Agency contact:**

Advertising & Public relations  
co-operate Wegener & Rieke GmbH  
Zumsandstraße 32  
D-48145 Münster

Personal contact:  
Christian Rieke

phone: +49 (0)251 - 3222611  
[dialog@co-operate.net](mailto:dialog@co-operate.net)  
[www.co-operate.net](http://www.co-operate.net)

*blue inspection body press releases and photos in print quality are available for download: [www.blue-inspection.com](http://www.blue-inspection.com)*

illustrated: "A change of the supplier is not always mandatory. Additional measures such as GMP audits and more detailed quality analyses may also be appropriate actions which should in advance be confirmed with the relevant authority."

*(approx. 1.850 Characters)*

***Background information: blue inspection body GmbH***

The blue inspection body GmbH examines the Good Manufacturing Practice (GMP) of pharmaceutical companies around the globe. Third-party audits by blue efficiently relieve manufacturing authorisation holders, API suppliers and API manufacturers. The blue inspection body GmbH is the first independent and accredited service provider for GMP audits within the European Union.

---