



Strasbourg, 29/05/2009

EDQM ESTABLISHES CONFIDENTIALITY AGREEMENTS WITH US-FDA AND TGA

The EDQM has established bilateral confidentiality agreements with the United States Food and Drug Administration (US-FDA) and the Australian Therapeutic Goods Administration (TGA) respectively to share non-public information regarding inspections of active pharmaceutical ingredients (API) and excipients manufacturers.

These agreements will facilitate the participation of the three organisations in a pilot project involving European regulators, the US-FDA and TGA aimed at rationalising international good manufacturing practices (GMP) inspections. The scope of the agreements includes exchange of information relating to active pharmaceutical ingredients and excipients used in the manufacture of medicinal products.

Non-public information shared between the organisations is provided on a confidential basis and all parties have undertaken to protect any non-public information received.

Note for the Editors

The European Pharmacopoeia¹ 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 new 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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¹There 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.*