European Medicines Agency

London, 15 July 2004
Doc. Ref.: EMEA/MRA/CA/04/04

EC-Canada Mutual Recognition Agreement

Sectoral Annex on Good Manufacturing Practices

Seventh Joint Sectoral Group Meeting
First year of operation of the Sectoral Annex

The seventh meeting of the Joint Sectoral Group (JSG) responsible for managing the implementation of the Sectoral Annex on Good Manufacturing Practices (GMP) for medicinal products of the European Community - Canada Mutual Recognition Agreement was held on 13 July 2004 by teleconference between representatives of the EC and Health Canada.

Key Actions – Decisions

1. The meeting reviewed the first year of the operational phase. Both Parties stated that the agreement had been implemented successfully and the operational procedures were satisfactory. Initial problems with the issuance of GMP certificates had been overcome.

2. EU Enlargement and impact on the Sectoral Annex for GMP
   The Canadian assessment of the Regulatory Authorities in the new EU Member States was discussed. The Canadian assessments are expected to be initiated towards the end of the year, however visits to the authorities will not commence until 2005. It was confirmed that observed inspections will be part of the visits. The Joint Sectoral Group will overview the assessments.

3. The inclusion of Investigational Medicinal Products under the Scope of the MRA was confirmed. It is currently limited to sites in the EU and Canada already holding a manufacturing authorisation / establishment licence.

4. It was agreed to include GMP inspections in the pre-authorisation / pre-marketing framework under the Scope of the MRA as of 1 October 2004.

5. The contents of the batch certificates to be used in the operational phase by manufacturers were updated to include Investigational Medicinal Products. A revised explanatory note will be made available on the respective web sites.

6. The procedure for the Two-way Alert System was reviewed and amended in respect of reporting Class II batch recalls.

7. The Maintenance Programme was reviewed and it was agreed to update the document in respect of the activities to continuous monitoring of the GMP compliance programmes. This work is ongoing.

Further information on the MRA Sectoral Annex and details of the above mentioned documents can be found at:
http://www.emea.eu.int/inspections/mra.html and http://www.hc-sc.gc.ca/hpfb-dgpsa/inspectorate

Public

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 85 95
E-mail: mra@emea.eu.int http://www.emea.eu.int