European Medicines Agency
Inspections

London, 10 October 2007
Doc. Ref. EMEA/INS/MRA/470284/2007

EC-Canada Mutual Recognition Agreement

Sectoral Annex on Good Manufacturing Practices

Ninth Joint Sectoral Group Meeting

Update on the operation of the Sectoral Annex

The ninth meeting of the Joint Sectoral Group (JSG) responsible for managing the implementation and the operational aspects of the Sectoral Annex on Good Manufacturing Practices (GMP) for medicinal products of the European Community – Canada Mutual Recognition Agreement was held on 10 October 2007 by teleconference between representatives of the EC and Health Canada.

Key Actions - Decisions

1. The meeting reviewed the third year of the operational phase. Both Parties agreed that the agreement had been implemented successfully and the operational procedures were satisfactory.

2. Canada informed the EC of the new federal *Natural Health Products Regulations* governing Natural Health Products in Canada that came into effect 1 January 2004. As a result of these regulations certain products which were previously regulated as drugs (medicinal products) are now regulated as natural health products (e.g. vitamins, minerals, herbal remedies, homeopathic medicines and probiotics). Due to the new NHP regulations, establishment licenses held by natural health product companies expired and were not renewed as of January 2006. These products will no longer be covered under the scope of the MRA as of 1 January 2008. Health Canada and EC will investigate the impact on industry and regulators.

3. New EU Member States evaluation
   Canada provided an update on the assessment of the Regulatory Authorities in the new EU Member States. The Canadian assessments of Malta and Cyprus, human and veterinary authorities were successful and they are now included in the list of equivalent authorities. Canada will start to accept GMP certificates from Malta and Cyprus as of 1 November 2007.

   The assessments of Slovak Republic have been initiated and onsite visits to the authorities should start late in 2006. Assessments for Estonia, Poland, Lithuania, Slovenia and Latvia will not be scheduled before 2007. It was confirmed that observed inspections will be part of the visits. The Joint Sectoral Group will overview the assessments.

4. Scope

   GMP requirements for Active Pharmaceutical Ingredients (APIs) in both parties was discussed. EC has legislation in place since October 2005, while Canada is in the process of drafting regulations. It was agreed that for the moment APIs would not fall under the scope of the MRA.

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

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