European Medicines Agency
Inspections

27 October 2006
Doc. Ref. EMEA/INS/MRA/446188/2006

EC - Japan Mutual Recognition Agreement

Sectoral Annex on Good Manufacturing Practice for Medicinal Products

Fourth Subcommittee Meeting, 26 and 27 October 2006
Joint Common Statement

The fourth meeting of subcommittee set up under the Joint Committee of the Agreement on Mutual Recognition between the European Community (EC) and Japan took place in Tokyo on 26 and 27 October 2006. Members of the subcommittee from both the EC and Japan participated in this meeting.

This subcommittee meeting reviewed the operation of the Sectoral Annex on Good Manufacturing Practice (GMP) for Medicinal Products of the Agreement since the last meeting and exchanged information on GMP related legislation and requirements in both parties.

The implementation of the revised pharmaceutical affairs law in Japan and the changes to the EC legislation and GMP guidelines in Europe stipulate the re-confirmation of applicable GMP requirements for specific products or product categories.

Japan and EC have confirmed their willingness to reduce the limitations of the confirmed scope of the Sectoral Annex with a target of a review of activities after one year.

The subcommittee will prepare a summary record to the Joint Committee for information on the operation of the Annex and the continued work towards including specific products in the scope.

The subcommittee will continue to monitor the operation of this Annex and facilitate regulatory collaboration through information exchange and joint activities in the area of GMP for specific products, new technical guidance and inspection procedures.

Further information on the EC- Japan MRA, Sectoral Annex can be found at:
http://www.emea.europa.eu/ and http://www.mofa.go.jp

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