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EC - Japan Mutual Recognition Agreement Sectoral Annex on Good Manufacturing Practice for Medicinal Products

Second Sub-Committee Meeting, 30 June 2003 Joint Common Statement

The second meeting of Sub-Committee set up under the Joint Committee of the Agreement on Mutual Recognition between the European Community and Japan took place by video conference on 30 June 2003. Members of the Sub-Committee from both the EU and Japan participated in this meeting via video or audio connection.

Both sides reviewed in this Sub-Committee the progress of joint activities and coordination between the two Parties during the preparatory phase to implement the Sectoral Annex on Good Manufacturing Practice (GMP) for Medicinal Products of the Agreement and discussed future work.

The first mutual visits to regulatory authorities were carried out in the EU in June 2002 and in Japan in July 2002 respectively and were followed by a second round of mutual visits in March 2003 including observed inspections. The observed inspections were conducted in accordance with a Standard Operating Procedure tentatively agreed at the last Sub-Committee.

Both sides shared the same view that some of the preparatory work for implementing this Annex has not yet been completed, recognising that reconfirming carefully the equivalence of GMP requirements between the two Parties is of crucial importance for ensuring quality of medicinal products traded between the two Parties and also the protection of health and safety of the people of the two Parties.

Both sides also recognised the necessity to accelerate the advancement of the preparatory work under this Annex in order to start the operational phase of this Annex at the earliest possible date.

Both sides expect that the Joint Committee set up by this Agreement will discuss this issue at its next meeting after receipt of a report from the second Sub-Committee meeting.

Japan and EU are to continue regular contacts to discuss progress.

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