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

Third Subcommittee Meeting, 18 and 19 February 2004
Joint Common Statement

The third meeting of subcommittee set up under the Joint Committee of the Agreement on Mutual Recognition between the European Community and Japan took place in Brussels on 18 and 19 February 2004. Members of the subcommittee from both the EU and Japan participated in this meeting.

Both sides reviewed in this subcommittee meeting the progress of joint activities of the preparatory work to implement the Sectoral Annex on Good Manufacturing Practice (GMP) for Medicinal Products of the Agreement.

The subcommittee has confirmed that both Parties have re-confirmed the equivalence of the GMP requirements and their implementation pursuant to paragraph 9(b) of the Annex.

The subcommittee has also concluded the procedures required to be completed prior to the commencement of the operational phase.

The subcommittee prepared a report to the Joint Committee for decision on the completion of the preparatory work. This report details the scope, the alert procedure, certificate exchange, proposals for exchange of a list of confirmed manufacturing facilities and a definition of emergency and modalities of visits.

The Joint Committee is asked to accept this report and in so doing endorse the conclusions to exchange diplomatic notes on the completion of the preparatory phase.

The subcommittee will monitor the operation of this Annex and facilitate regulatory collaboration through information exchange and joint activities in the area of GMP.

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