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EC - Japan Mutual Recognition Agreement

Sectoral Annex on Good Manufacturing Practice for Medicinal Products

The European Communities and Japan have today exchanged diplomatic notes confirming the completion of the preparatory work under the Sectoral Annex on Good Manufacturing Practice (GMP) for Medicinal Products of the EC-Japan Mutual Recognition Agreement (MRA). Following this exchange of diplomatic notes, the Sectoral Annex on GMP will become operational on 29 May 2004. Both Parties expect that the operation of the GMP Sectoral Annex will facilitate trade of medicinal products between them through the reduction of costs related to certification, as medicinal products imported into one party will circulate in the other without the need for additional testing, thus facilitating trade in the pharmaceutical sector.

Under the Sectoral Annex on GMP for Medicinal Products, certificates issued for confirmed manufacturing facilities in compliance with the GMP requirements of one of the Parties and in accordance with the provisions of the MRA will be accepted in the EC and Japan without additional testing. For the moment the Sectoral Annex will cover a limited number of products[1]. The Parties will review the scope for its possible expansion in the future.

For additional information on EC-Japan MRA:

- EC's websites:
http://trade-info.cec.eu.int/tbt/mra.cfm?id=44
http://www.emea.eu.int/Inspections/MRA.html
http://pharmacos.eudra.org

- Japan's websites:
http://www.mofa.go.jp
http://www.mhlw.go.jp

[1] The scope of medicinal products subject to the GMP Annex, based on the results of the preparatory work conducted jointly by the two Parties, is described below:
- Chemical pharmaceuticals are covered by the GMP Annex.
- Homeopathic medicinal products are covered by the GMP Annex as long as they are treated as drugs and subject to GMP requirements in Japan.
- Vitamins, minerals and herbal medicines are covered by the GMP Annex if they are considered as medicinal products in the both Parties.
- Medicinal gases, in-vitro diagnostics, blood, plasma and any unstable medicinal products derived from human blood or plasma are not covered as they are not treated as medicinal products or not subject to GMP requirements in the Parties.
- Biological pharmaceuticals, including immunologicals and stable medicinal products derived from human blood or plasma, and sterile medicinal products are currently not covered by the GMP Annex as the equivalence of their GMP requirements has not been reconfirmed, but may be covered in the future.
- Medicinal products for clinical trials and active pharmaceutical ingredients are currently not covered by the GMP Annex, but may be covered in the future.

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