SECTORAL ANNEX
ON
GOOD MANUFACTURING PRACTICE (GMP)
FOR MEDICINAL PRODUCTS

PART A

1. This Sectoral Annex applies to:

   (a) the confirmation of the compliance with GMP requirements of manufacturing facilities for medicinal products to which the GMP requirements of both Parties are applied in accordance with the laws, regulations and administrative provisions of each Party specified in Section I of Part B of this Sectoral Annex; and

   (b) the acceptance of the data generated by confirmed manufacturing facilities (the certificate issued by confirmed manufacturing facilities in accordance with the provisions of Part A of this Sectoral Annex).

2. For the purpose of this Sectoral Annex:

   (a) The term "medicinal products" means drugs which are industrially manufactured for human use as defined in the laws, regulations and administrative provisions of Japan specified in Section I of Part B of this Sectoral Annex, and medicinal products and intermediate products which are industrially manufactured for human use as defined in the laws, regulations and administrative provisions of the European Community in Section I of Part B of this Sectoral Annex.

   The definition of medicinal products above may include medicinal products intended for clinical trials, active ingredients, chemical and biological pharmaceuticals, immunologicals, radiopharmaceuticals, stable medicinal products derived from human blood or human plasma and, where appropriate, vitamins, minerals and herbal medicines.

   (b) The term "criteria for confirmation" means the GMP requirements.

(c) The term "Good Manufacturing Practice (GMP)" means that part of quality assurance which ensures that products are consistently produced and controlled in accordance with the quality standards appropriate for their intended use and as required by the applicable marketing authorisation or product specifications.

(d) The term "inspection" means an on-site evaluation of a manufacturing facility to determine whether such manufacturing facility is operating in compliance with GMP requirements including the requirements of the applicable marketing authorisation or product specifications. Such inspection is conducted in accordance with the laws, regulations and administrative provisions specified in Section I of Part B of this Sectoral Annex carried out by a Competent Authority listed in Section II of Part B of this Sectoral Annex, and may include pre-marketing and post-marketing inspection.

(e) It is understood that the term "amendment" referred to in Part B of this Sectoral Annex includes the following cases:

(i) a Party entirely or partially changes its applicable laws, regulations and/or administrative provisions listed in Part B of this Sectoral Annex, whether or not those names are changed;

(ii) a Party repeals its applicable laws, regulations and/or administrative provisions listed in Part B of this Sectoral Annex and adopts new laws, regulations and/or administrative provisions substituting for the previous laws, regulations and/or administrative provisions, whether or not the previous names are changed; and

(iii) a Party incorporates the whole or a relevant part of its applicable laws, regulations and/or administrative provisions listed in Part B of this Sectoral Annex into other laws, regulations and/or administrative provisions.

3. This Agreement does not cover mutual recognition of batch release (Kentei) referred to in Article 43 of the Pharmaceutical Affairs Law (Law No. 145, 1960) of Japan and batch release referred to in Article 4 of Directive 89/342/EEC of 3 May 1989 and in Article 4 of Directive 89/381/EEC of 14 June 1989 of the European Community.

4. With respect to paragraph 2 of Article 2 of this Agreement, each Party shall, as a result of the acceptance of confirmation of manufacturing facilities carried out by the Competent Authorities of the other Party, accept, regarding the medicinal products for which its marketing authorisation has been issued or for which product specifications are applicable, the certificate issued by the confirmed manufacturing facilities of the conformity of each batch to the marketing authorisation or product specifications and exempt the importers from the testing of each batch, in accordance with the laws, regulations and administrative provisions of each Party specified in the Section I of Part B of this Sectoral Annex, taking into account the equivalence of GMP requirements of both Parties, provided that:

(a) such certificate is issued by the confirmed manufacturing facilities on the results of a full qualitative analysis, a quantitative analysis of all the active constituents and all the other tests or checks;

(b) the certificate contains a statement that the product has been manufactured in conformity with GMP requirements; and

(c) both Parties apply the equivalent GMP requirements to the products of which the certificate is issued.

5. In the certificate issued by the confirmed manufacturing facilities and related to each batch to be exported, as referred to in paragraph 4 above, it will be certified, through the testing which is required for the manufacturing of medicinal products in accordance with the laws, regulations and administrative provisions of each Party specified in Section I of Part B of this Sectoral Annex, that each batch of medicinal products is manufactured as required by the applicable marketing authorisation or product specifications of the importing Party.

6. A sub-committee of the Joint Committee will be established in particular to monitor the progress of the preparatory work set out in paragraph 9 of this Sectoral Annex and the operation of this Sectoral Annex. It will report to the Joint Committee.

7. (a) The Parties will exchange information on, in particular:

(i) GMP for specific products or classes of products;

(ii) new technical guidance or inspection procedures;

(iii) quality defects, batch recalls, counterfeiting and other problems concerning quality; and

(iv) any suspension or withdrawal of a manufacturing authorisation.

(b) The Parties will agree detailed alert procedures through the sub-committee of the Joint Committee to fulfil specific objectives of this Sectoral Annex.

(c) Equivalence of GMP for specific products or classes of products will be coordinated according to a procedure established by the sub-committee of the Joint Committee.

(d) Notwithstanding paragraph 6 of Article 8 of this Agreement, each Party shall provide the other Party and the Joint Committee with a list of the confirmed manufacturing facilities at the frequency to be decided by the Joint Committee.

(e) Each Party will, upon reasoned request by the other Party, provide a copy of the most recent inspection report on a confirmed facility within 30 days from the date of the request. If the requested Party conducts an additional inspection, that Party will provide a copy of the report of such additional inspection to the requesting Party within 60 days from the date of the request. If after the exchange of inspection reports there remains serious cause for concern on whether a manufacturing facility in the other Party complies with GMP requirements, each Party may request the other Party to conduct further inspections on that facility.

(f) The Competent Authority of a Party will, upon request by an exporter, importer or the Competent Authority of the other Party, confirm that a manufacturing facility in its territory:

(i) is appropriately authorised to manufacture medicinal products in accordance with its laws, regulations and administrative provisions specified in Section I of Part B of this Sectoral Annex;

(ii) is regularly inspected by the Competent Authorities; and

(iii) complies with its GMP requirements that are recognised by both Parties as equivalent.

8. With regard to paragraph 2 of Article 5, the exporting Party shall, in accordance with its applicable laws, regulations and administrative provisions, inspect periodically the manufacturing facilities in order to ensure that the facilities fulfil its GMP requirements set out in the laws, regulations and administrative provisions of that Party specified in Section I of Part B of this Sectoral Annex.

9. (a) Articles 2, 4, 5, 7 and subparagraph (a) of paragraph 2 of Article 10 relating to this Sectoral Annex and the provisions of this Sectoral Annex other than paragraph 6 and subparagraph (b) of paragraph 7 and this paragraph shall not be applied before the thirtieth day after the date of exchange of diplomatic notes confirming each other that the preparatory work is completed. Such exchange of diplomatic notes is expected to take place within 18 months after the entry into force of this Agreement.

(b) Through the preparatory work, the Parties shall reconfirm the equivalence of GMP requirements and their implementation through the Joint Committee. The Joint Committee will decide the detailed procedures for implementing this Sectoral Annex.