(iv) "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 United Kingdom 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) 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 Protocol does not cover mutual recognition of batch release (Kentei) referred to in Article 43 of the Law on Securing Quality, Efficacy and Safety of Products including Pharmaceuticals and Medical Devices (Law No. 145 of 1960) of Japan and batch release referred to in regulation 60A of the Human Medicines Regulation 2012 of the United Kingdom.

4. With respect to paragraph 2 of Article 2 of this Protocol, 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, 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 on Mutual Recognition 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 on Mutual Recognition.