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 on Mutual Recognition 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 on Mutual Recognition.

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

(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 of this Protocol, 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) With respect to medicinal products for which the equivalence of GMP requirements have not been confirmed, Articles 2, 4, 5, 7 and subparagraph 2(a) of Article 10 of this Protocol relating to this Sectoral Annex and the provisions of this Sectoral Annex other than paragraph 6, subparagraph 7(b) and this paragraph shall not be applied before the 30th day after the date of exchange of diplomatic notes confirming to each other that the preparatory work is completed.

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