ANNEX XI

REFERRED TO IN ARTICLE 4.9

GOOD MANUFACTURING PRACTICE

ANNEX XI

REFERRED TO IN ARTICLE 4.9 (ANNEXES)

GOOD MANUFACTURING PRACTICE

ARTICLE 1

Scope

This Annex shall apply to all pharmaceutical products which are industrially manufactured in Switzerland or Malaysia, including active pharmaceutical ingredients or excipients used by manufacturers, and to which Good Manufacturing Practice (GMP) requirements apply.

ARTICLE 2

Definition

1. For the purposes of this Annex, "GMP standards" means most recent internationally recognised standards by the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S), related to quality assurance which ensures that pharmaceutical products are consistently produced and controlled.

2. For the purposes of this Annex, "GMP inspection report" means a report drawn up in accordance with GMP standards. It contains in particular the inspectors' observations, a brief summary of the findings, recommendations if applicable and conclusions regarding the GMP status of the inspected site where pharmaceutical products are manufactured.

ARTICLE 3

Affirmation

Switzerland and Malaysia acknowledge facing similar challenges when assessing and ensuring the high quality of production as well as the integrity in a globalised supply chain for pharmaceutical products. A key instrument in this regard is the establishment and enforcement of PIC/S GMP on manufacturing sites.

ARTICLE 4

GMP System

The GMP control system and GMP enforcement of a Party shall be assumed equivalent to the PIC/S standards for GMP inspectorates through membership in PIC/S.

ARTICLE 5

Reliance on GMP Inspections Reports and Authorisations

Following confirmed compliance of a Party's GMP system with GMP standards the other Party shall rely, in particular as part of the conformity assessment procedure:

(a) on that Party's GMP inspection reports, issued by the competent authorities; and

(b) on that Party's manufacturing authorisations, granted by the competent authorities.

ARTICLE 6

Exchange of GMP Data

Upon request and for use exclusively for the reliance on GMP inspection reports and authorisations, the competent authorities shall exchange GMP inspection reports, unless the concerned manufacturer disagrees.

ARTICLE 7

Certification of Manufacturers

1. At the request of a manufacturer or the competent authority of the other Party, the authority responsible for granting manufacturing authorisations and for supervising the manufacturer of pharmaceutical products shall certify that the manufacturer:

(a) is appropriately authorised to manufacture the relevant pharmaceutical product, or to carry out the relevant specified manufacturing operation;

(b) is regularly inspected by the authorities; and

(c) complies with GMP standards.

2. The certificates shall be issued within 30 days after conclusion of the corrective and preventive action. In exceptional circumstances, for instance if prior to issuing a certificate, a new inspection has to be undertaken, the time-limit of 30 days starts at the conclusion of the corrective and preventive action and may be extended to 60 days.

3. For requests by manufacturers, a reasonable fee may apply for the issuance of such certificates.

ARTICLE 8

Safeguard Clause for Inspections

In exceptional circumstances, the Parties reserve the right to conduct their own inspections in the territory of the other Party. Such inspections shall be duly justified, notified in advance to the inspected Party and may be observed by the inspected Party. The Parties may agree on joint inspections.

ARTICLE 9

Confidentiality

Each Party shall treat as confidential information submitted by another Party which that Party has designated as confidential.

ARTICLE 10

Contact Points

For the purposes of this Annex, the contact points established under Article 4.11 (Contact Points) of the Agreement shall keep an updated list of contact points within the respective competent authorities for any technical questions, such as exchange of inspection reports or technical requirements.