ARTICLE V

GMP Compliance Certification

1. The Inspection Service of the exporting Party shall at the request of an exporter or importer of Medicines, or the Regulatory Authority of the importing Party, where appropriate, issue a GMP Compliance Certificate that certifies that a manufacturer of a Medicine located in the territory of the exporting Party:

(a) is appropriately authorised to Manufacture the relevant Medicines or to carry out the relevant specified manufacturing operation;

(b) is regularly inspected by the Regulatory Authority of the exporting Party; and

(c) (i) in cases to which Article 4, paragraph 3 applies, complies with the Mandatory GMP Requirements of the importing Party; or

(ii) in cases to which Article 4, paragraph 4 applies, complies with the Mandatory GMP Requirements of the exporting Party.

2. A GMP Compliance Certificate shall also include the following information:

(a) Name and address of the establishment to whom the certificate is issued;

(b) Site(s) of Manufacture;

(c) Certificate number;

(d) Category of Medicine (refer to Article 2, paragraph 3 for examples) and dosage form (eg tablets, small volume parenterals);

(e) Steps of Manufacture;

(f) Standards used to certify compliance with requirements;

(g) Date of last inspection;

(h) Period of validity of the certificate;