

BEARING IN MIND their status as Contracting Parties to the Marrakesh Agreement Establishing the World Trade Organization, and conscious of their rights and obligations under the Agreement on Technical Barriers to Trade annexed thereto.

HAVE AGREED as follows:

ARTICLE I

Definitions

1. All general terms concerning standards and Conformity Assessment used in this Agreement shall have the meaning given in the definitions contained in ISO/IEC Guide 2:1996 "Standardization and related activities-General vocabulary" of the International Organization for Standardization and International Electrotechnical Commission unless the context requires otherwise. In addition, the following terms and definitions shall apply for the purpose of this Agreement:

- (a) *Confidence Building Exercise* means the exercise described in Article 14.
- (b) *Conformity Assessment* means any activity concerned with determining directly or indirectly that relevant Mandatory GMP Requirements are fulfilled.
- (c) *Good Manufacturing Practice* or *GMP* means that part of quality assurance which ensures that products are consistently produced and controlled during Manufacture to the quality standards appropriate to their intended use and as required by the Marketing Authorisation granted by the importing Party.
- (d) *GMP Compliance Certificate* means a certificate issued in accordance with Article 5.
- (e) *GMP Compliance Certification* means the issue of a GMP Compliance Certificate following confirmation by on site inspection that a manufacturer of Medicines is in compliance with Mandatory GMP Requirements.