

- (f) *GMP Compliance Program* means the infrastructure and activities that support the issuance of a GMP Compliance Certificate as detailed in Appendix 4.
- (g) *GMP Inspection* means on site inspection or audit of a manufacturer of Medicines to confirm compliance with Mandatory GMP Requirements.
- (h) *Inspection Service* means a Regulatory Authority responsible for the inspection of manufacturers of Medicines and the granting of manufacturing licences and/or certificates for Medicines. The Inspection Service for a Party shall be as nominated by that Party in Appendix 2.
- (i) *Joint Sectoral Group* means the group of Party representatives established under, and for the purposes specified in, Article 7.
- (j) *Joint Sectoral Group's Maintenance Program* means a program developed and managed by the Joint Sectoral Group to provide continuous monitoring of the GMP Inspection procedures and GMP Compliance Programs of the Parties determined by the Joint Sectoral Group to be equivalent at the conclusion of the Confidence Building Exercise.
- (k) *Mandatory GMP Requirements* means in relation to a Party, the legislative, regulatory and administrative requirements that apply in relation to the Manufacture of Medicines covered by this Agreement in that Party's territory. The head legislative requirements are detailed in Appendix 3 and all other applicable requirements are specified in the Joint Sectoral Group's Maintenance Program.
- (l) *Manufacture* means to produce or engage in any part of the process of producing Medicines or of bringing Medicines to their final state, including engaging in the processing, packaging, labelling, sterilising, testing or releasing for supply of Medicines.
- (m) *Manufacturing Authorisation* means the authorisation or approval of a manufacturer to Manufacture Medicines.
- (n) *Marketing Authorisation* means the authorisation or approval of Medicines before they are available on the market.