

2. Each Party shall inform the other Party of any significant changes to its Mandatory GMP Requirements and GMP Compliance Program including any new technical guidance or inspection procedure. Except where considerations of health, safety and environmental protection warrant more urgent action, each Party shall notify the other Party of the changes within at least 60 calendar days before the changes enter into force. Concerns about non-equivalency shall be addressed to the Joint Sectoral Group.

3. The Parties shall exchange any information necessary for the mutual recognition of GMP Inspections.

## ARTICLE IV

### Obligations

1. Australia shall accept GMP Compliance Certification by Canada's Inspection Service in accordance with Article 5, without re-control at import.

2. Canada shall accept GMP Compliance Certification by Australia's Inspection Service in accordance with Article 5, without re-control at import.

3. Where:

(a) Medicines are covered by the Mandatory GMP Requirements of the importing Party but not the exporting Party; or

(b) the Mandatory GMP Requirements of both Parties have not been determined to be equivalent in accordance with Article 14 of this Agreement,

then GMP Compliance Certification by the Inspection Service of the exporting Party, if that Inspection Service is willing, shall be in relation to the Mandatory GMP Requirements of the importing Party.

4. Where the Mandatory GMP Requirements of both Parties have been determined to be equivalent in accordance with Article 14 of this Agreement, GMP Compliance Certification by the Inspection Service of the exporting Party shall be in relation to the Mandatory GMP Requirements of the exporting Party.