3. This Agreement shall apply to all Medicines which in Australia and/or Canada are subject to a GMP Compliance Program. These include:

(a) human pharmaceuticals such as prescription and non-prescription Medicines and medical gases;

(b) human biologicals including vaccines, immunologicals and biotherapeutics; and

(c) human radiopharmaceuticals.

4. This Agreement does not apply to the following products/processes:

(a) blood and blood components;

(b) tissues and organs of animal and human origin;

(c) official batch release of biologicals;

(d) stable Medicines derived from human blood or plasma; or

(e) veterinary pharmaceuticals, including sterile and non-sterile veterinary pharmaceuticals.

5. This Agreement shall not apply to Pre-Approval Inspections.

6. The Mandatory GMP Requirements covered by this Agreement are the Mandatory GMP Requirements of the Parties.

7. Agreements concluded by either Party with a third party shall not impose any obligation on the other Party to accept the results of a GMP Inspection undertaken by the third party, save where there is an express agreement between the Parties to do so.

ARTICLE III

Exchange of information

1. The Parties shall exchange information concerning their Mandatory GMP Requirements and GMP Compliance Programs, including any new technical guidance or inspection procedure.