(o) *Medicines* means those products which are defined as drugs under Section 2 of the *Food and Drugs Act* in Canada and those defined as medicines under the *Therapeutic Goods Act 1989* in Australia as those Acts are amended from time to time, excluding vitamins, minerals, herbal remedies and homeopathic medicines.

(p) *Pre-Approval Inspection* means a product or process orientated inspection conducted prior to the issue of a Marketing Authorisation.

(q) *Regulatory Authority* means an entity that has a legal right to control the import, export, re-analysis or supply of products within a Party's jurisdiction and that may take enforcement action to ensure that products marketed within its jurisdiction comply with that Party's Mandatory GMP Requirements.

(r) *Site Master File* means all documents compiled by a manufacturer of Medicines which verify to the Inspection Service that the factory, equipment, processes, products and personnel at the site of Manufacture are as documented by the manufacturer.

2. For the purposes of this Agreement the singular should be read to include the plural and vice-versa when appropriate.

ARTICLE II

Scope of this Agreement

1. This Agreement shall apply, on the one hand, to the territory of Australia and, on the other hand, to the territory of Canada.

2. This Agreement shall apply to GMP Inspections carried out in the territories of the Parties.