ANNEX 2-C

PHARMACEUTICAL PRODUCTS AND MEDICAL DEVICES

Article 1

General Provisions

The Parties confirm the following shared objectives and principles of:

(a) preventing and eliminating non-tariff barriers to bilateral trade;

(b) establishing competitive market conditions based on principles of openness, non-discrimination and transparency;

(c) promoting innovation of, and timely access to, safe and effective pharmaceutical products and medical devices through transparent and accountable procedures, without impeding a Party’s ability to apply high standards of safety, efficacy and quality; and

(d) enhancing cooperation between their respective health authorities, based on international standards, practices and guidelines within the framework of relevant international organisations such as the World Health Organization (hereinafter referred to as “WHO”), the Organisation for Economic Co-operation and Development (hereinafter referred to as “OECD”), the International Conference on Harmonisation (hereinafter referred to as “ICH”), the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (hereinafter referred to as “PIC/S”) for pharmaceutical products and the Global Harmonization Task Force (hereinafter referred to as “GHTF”) for medical devices.

Article 2

International Standards

The Parties shall use international standards, practices and guidelines for pharmaceutical products or medical devices, including those developed by the WHO, the OECD, the ICH, the PIC/S and the GHTF as a basis for their technical regulations, unless there are substantiated reasons based on scientific or technical information why such international standards, practices or guidelines would be ineffective or inappropriate for the fulfilment of legitimate objectives pursued.

Article 3

Transparency

1. With respect to measures of general application relating to pharmaceutical products and medical devices each Party shall ensure that:
such measures are readily available to interested persons and the other Party, in a non-discriminatory manner, via an officially designated medium and, where feasible and possible, electronic means, in such manner as to enable interested persons and the other Party to become acquainted with them;

(b) an explanation of the objective of and rationale for such measures is provided to the extent possible; and

(c) there is sufficient time between publication and entry into force of such measures, except where not possible on grounds of urgency.

2. In accordance with their respective domestic law, each Party shall, to the extent possible:

(a) publish in advance any proposal to adopt or amend any measure of general application relating to the regulation of pharmaceutical products and medical devices, including an explanation of the objective of and rationale for the proposal;

(b) provide reasonable opportunities for interested persons and the other Party to comment on such proposed measures, allowing, in particular, for sufficient time for such opportunities; and

(c) take into account the comments received from interested persons and the other Party with respect to such proposed measures.

3. To the extent that a Party’s health care authorities introduce or operate procedures for the listing, pricing and/or reimbursement of pharmaceutical products, the Party shall:

(a) ensure that the criteria, rules, procedures, and any guidelines, where relevant, that apply to the listing, pricing and/or reimbursement of pharmaceutical products, are objective, fair, reasonable and non-discriminatory, and are available upon request to interested persons;

(b) ensure that decisions on all applications for the pricing or approval of pharmaceutical products for reimbursement are adopted and communicated to the applicant within a reasonable and specified period from the date of the receipt of the application. If the information submitted by the applicant is deemed inadequate or insufficient and the procedure is suspended as a result, the Party’s competent authorities shall notify the applicant of what additional information is required and resume the original decision-making process upon receipt of this additional information;

(c) provide applicants with appropriate opportunities to provide comments at relevant points in the pricing and reimbursement decision-making processes without prejudice to the applicable domestic law on confidentiality;

(d) in case of a negative decision on listing, pricing and/or reimbursement, provide the applicant with a statement of reasons that is sufficiently detailed to understand the basis of the decision, including the criteria applied and, if appropriate, any expert opinions or recommendations on which the decision is
based. In addition, the applicant shall be informed of any remedies available under domestic law and of the time limits for applying for such remedies.

Article 4

Regulatory Cooperation

The Committee on Trade in Goods shall:

(a) monitor and support the implementation of this Annex;

(b) facilitate cooperation and exchange of information between the Parties with a view to furthering the objectives of this Annex;

(c) discuss ways to foster the compatibility of regulatory approval processes wherever possible; and

(d) discuss ways to facilitate bilateral trade in active pharmaceutical ingredients.

Article 5

Definitions

For the purposes of this Annex:

(a) “pharmaceutical products” means:

(i) any substance or combination of substances presented for treating or preventing diseases in human beings; or

(ii) any substance or combination of substances which may be administered to human beings with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in human beings.

Pharmaceutical products include, for example, chemical medicinal products, biological medicinal products (e.g. vaccines, (anti)toxins) including medicinal products derived from human blood or human plasma, advanced therapy medicinal products (e.g. gene therapy medicinal products, cell therapy medicinal products), herbal medicinal products, radiopharmaceuticals;

(b) “medical device” means any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of:

(i) diagnosis, prevention, monitoring, treatment or alleviation of disease;

For greater clarity, medical device does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but may be assisted in its function by such means.
(ii) diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury;

(iii) investigation, replacement, modification or support of the anatomy or of a physiological process;

(iv) control of conception;

(v) supporting or sustaining life;

(vi) disinfection of medical devices;

(vii) providing information for medical or diagnostic purposes by means of *in vitro* examination of specimens derived from the human body;

(c) “a Party’s health care authorities” means entities that are part of or have been established by a Party to operate or administer its health care programmes, unless otherwise specified; and

(d) “manufacturer” means the legal right holder of the product in the respective Party’s territory.