Chapter 5

Technical Regulations, Standards and Conformity Assessment Procedures, and Sanitary and Phytosanitary Measures

Article 50 Scope

This Chapter shall apply to technical regulations, standards and conformity assessment procedures as defined in the Agreement on Technical Barriers to Trade in Annex 1A to the WTO Agreement (hereinafter referred to as "the TBT Agreement") and sanitary and phytosanitary (hereinafter referred to as "SPS") measures under the Agreement on the Application of Sanitary and Phytosanitary Measures in Annex 1A to the WTO Agreement (hereinafter referred to as "the SPS Agreement"), that may, directly or indirectly, affect trade in goods between the Parties.

Article 51 Reaffirmation of Rights and Obligations

The Parties reaffirm their rights and obligations relating to technical regulations, standards and conformity assessment procedures under the TBT Agreement, and their rights and obligations relating to SPS measures under the SPS Agreement.

Article 52 Enquiry Points

Each Party shall designate an enquiry point which is able to answer all reasonable enquiries from the other Party regarding technical regulations, standards and conformity assessment procedures, and SPS measures and, if appropriate, to provide their relevant information.

Article 53

Sub-Committee on Technical Regulations, Standards and Conformity Assessment Procedures, and SPS Measures

- 1. For the purposes of the effective implementation and operation of this Chapter, a Sub-Committee on Technical Regulations, Standards and Conformity Assessment Procedures, and SPS Measures (hereinafter referred to in this Chapter as "the Sub-Committee") shall be established on the date of entry into force of this Agreement.
- 2. The functions of the Sub-Committee shall be:
 - (a) exchanging information on technical regulations, standards and conformity assessment procedures, and SPS measures, and where necessary, coordinating the exchange of information on generic medicine provided for in Article 54;
 - (b) undertaking consultations on issues related to technical regulations, standards and conformity assessment procedures;
 - (c) undertaking science-based consultations to identify and address specific issues that may arise from the application of SPS measures;
 - (d) consulting cooperative efforts between the Parties in international fora in relation to technical regulations, standards and conformity assessment procedures, and SPS measures;
 - (e) holding discussions on the participation of each Party in the existing frameworks for mutual recognition in technical regulations, standards and conformity assessment procedures under international agreements;
 - (f) discussing Mutual Recognition Arrangements (hereinafter referred to in this Chapter as "MRAs") pursuant to Article 55 and other technical cooperation in relation to technical regulations, standards and conformity assessment procedures, and SPS measures;
 - (g) reviewing the implementation and operation of this Chapter;

- (h) reporting, where appropriate, its findings to the Joint Committee; and
- (i) carrying out other functions as may be delegated by the Joint Committee pursuant to Article 14.
- 3. The Sub-Committee shall meet at such venues and times as may be agreed upon by the Parties, unless otherwise provided for in this Chapter.
- 4. The Sub-Committee shall be composed of representatives of the Governments of the Parties.
- 5. The Parties shall determine in advance the agenda for the individual meeting of the Sub-Committee, with a view to ensuring appropriate participation of relevant experts.

Article 54 Cooperation on Generic Medicine

- 1. The Parties shall exchange information on their respective regulatory measures concerning generic medicine, with a view to promoting cooperation between the Parties in the field of pharmaceuticals and building mutual confidence in the regulatory measures of each Party.
- 2. For the purposes of this Article, the term "generic medicine" means drugs approved by the competent authority of a Party under the laws and regulations of the Party as equivalent, in terms of active ingredients, dosages, usages and indications, to the drugs approved preceding the former drugs.
- 3. Applications by a person of a Party for registration and other approvals required for release of a generic medicine in the market of the other Party shall be considered by the relevant authorities of the other Party. Such applications shall be accorded, in the relevant procedure, treatment no less favourable than that accorded to like applications by its own person, where they fulfil all the requirements under the laws and regulations of the other Party. Such procedure shall be completed within a reasonable period of time from the date of such application.

Article 55 Mutual Recognition

- 1. The Parties shall, through the Sub-Committee, discuss the feasibility of MRAs in such sectors as electrical products, telecommunications terminal equipment and radio equipment and other sectors as may be mutually agreed by the Parties. In elaborating MRAs, the Parties shall confirm the economic benefits of such arrangements and, where necessary, the equivalence of the technical regulations of both Parties.
- 2. The Sub-Committee shall meet within three months from the date of entry into force of this Agreement, in order to discuss the feasibility of MRAs in sectors referred to in paragraph 1, and shall endeavour to arrive at a conclusion about such feasibility within six months. The Parties shall endeavour to reach a conclusion of MRAs under paragraph 1 within a reasonable period of time, normally not exceeding three years, from the date of such conclusion about the feasibility.

Article 56 Non-Application of Chapter 14

The dispute settlement procedures provided for in Chapter 14 shall not apply to this Chapter, unless otherwise agreed by the Parties.