ANNEX 6.5

MEDICAL DEVICES

1. This Annex shall apply to the preparation, adoption and application of technical regulations, standards, conformity assessment procedures, marketing authorisation [1] and notification procedures of central government bodies that may affect trade in medical devices between the Parties. This Annex shall not apply to a technical specification prepared by a governmental entity for its production or consumption requirements or a sanitary or phytosanitary measure.

2. A Party's obligations under this Annex shall apply to any product that the Party defines as a medical device pursuant to paragraph 3. For the purposes of this Annex, preparation of a technical regulation, standard, conformity assessment procedure or marketing authorisation includes, as appropriate, the evaluation of the risks involved, the need to adopt a measure to address those risks, the review of relevant scientific or technical information, and the consideration of the characteristics or design of alternative approaches.

3. Each Party shall define the scope of the products subject to its laws and regulations for medical devices in its territory and make that information publicly available.

4. Recognising that each Party is required to define the scope of products covered by this Annex pursuant to paragraph 3, each Party should define the scope of products subject to its laws and regulations for medical devices in a manner that is consistent with the meaning assigned to the term "medical device" in the *Definition of the Terms 'Medical Device' and 'In Vitro Diagnostic (IVD) Medical Device'* endorsed by the Global Harmonization Task Force on May 16, 2012, as may be amended.

5. Each Party shall identify the agency or agencies that are authorised to regulate medical devices in its territory and make that information publicly available.

6. If more than one agency is authorised to regulate medical devices within the territory of a Party, that Party shall examine whether there is overlap or duplication in the scope of those authorities and to take reasonable measures to eliminate unnecessary duplication of any regulatory requirements resulting for medical devices.

7. The Parties shall seek to collaborate through relevant international initiatives, such as those aimed at harmonisation, as well as regional initiatives that support of those international initiatives, as appropriate, to improve the alignment of their respective regulations and regulatory activities for medical devices.

8. When developing or implementing regulations for marketing authorisation of medical devices, each Party shall consider relevant scientific or technical guidance documents developed through international collaborative efforts. Each Party is encouraged to consider

[1] The application of this Annex to marketing authorisations is without prejudice to whether a marketing authorisation meets the definition of a technical regulation, standard, or conformity assessment procedure.

regionally-developed scientific or technical guidance documents that are aligned with international efforts.

9. Each Party shall observe the obligations set out in Article 2.1 and Article 5.1.1 of the TBT Agreement with respect to a marketing authorisation, notification procedure or elements of either that the Party prepares, adopts or applies for medical devices and that do not fall within the definition of a technical regulation or conformity assessment procedure.

10. Recognising that different medical devices pose different levels of risk, each Party shall classify medical devices based on risk, taking into account scientifically relevant factors. Each Party shall ensure that, when it regulates a medical device, it regulates the device consistent with the classification the Party has assigned to that device.

11. Each Party recognises that the applicant is responsible for providing sufficient information to a Party for it to make a regulatory determination on a medical device.

12. Each Party shall make a determination whether to grant marketing authorisation for a specific medical device on the basis of:

(a) information, including, if appropriate, clinical data, on safety and efficacy;

(b) information on performance, design and manufacturing quality of the device;

(c) labelling information related to safety, efficacy and use of the device; and

(d) other matters that may directly affect the health or safety of the user of the device.

To this end, no Party shall require sale data, pricing or related financial data concerning the marketing of the medical device.

13. Each Party shall administer any marketing authorisation process that it maintains for medical devices in a timely, reasonable, objective, transparent and impartial manner, and identify and manage any conflicts of interest in order to mitigate any associated risks.

(a) Each Party shall provide an applicant that requests marketing authorisation for a medical device with its determination within a reasonable period of time. The Parties recognise that the reasonable period of time required to make a marketing authorisation determination may be affected by factors such as the novelty of a device or regulatory implications that may arise.

(b) If a Party determines that a marketing authorisation application for a medical device under review in its jurisdiction has deficiencies that have led or will lead to a decision not to authorise its marketing, that Party shall inform the applicant that requests marketing authorisation and provide reasons why the application is deficient.

(c) If a Party requires marketing authorisation for a medical device, the Party shall ensure that any marketing authorisation determination is subject to an appeal or review process that may be invoked at the request of the applicant. For greater certainty, the Party may maintain an appeal or review process that is either internal to the regulatory body responsible for the marketing authorisation determination, such as a dispute resolution or review process, or external to the regulatory body.

(d) If a Party requires periodic re-authorisation for a medical device that has previously received marketing authorisation from the Party, the Party shall allow the medical device to remain on its market under the conditions of the previous marketing authorisation pending a decision on the periodic re-authorisation, unless a Party identifies a significant health or safety concern.

14. When developing regulatory requirements for medical devices, a Party shall consider its available resources and technical capacity in order to minimise the implementation of requirements that could:

(a) inhibit the effectiveness of procedures for ensuring the safety, efficacy or manufacturing quality of medical devices; or

(b) lead to substantial delays in marketing authorisation regarding medical devices for sale on that Party's market.

15. No Party shall require that a medical device receive a marketing authorisation from a regulatory authority in the country of manufacture as a condition for the medical device to receive marketing authorisation from that Party.

16. For greater certainty, a Party may accept a prior marketing authorisation that is issued by another regulatory authority as evidence that a medical device may meet its own requirements. If there are regulatory resource limitations, a Party may require a marketing authorisation from one of a number of reference countries established and made public by that Party as a condition for the medical device's marketing authorisation from that Party.

17. If a Party requires a manufacturer or supplier of a medical device to indicate information on the product's label, the Party shall permit the manufacturer or supplier to indicate the required information by relabelling the product or by using supplementary labelling of the device in accordance with the Party's domestic requirements after importation but prior to offering the device for sale or supply in the Party's territory.