ANNEX 6.3

PHARMACEUTICALS

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 pharmaceutical products 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 pharmaceutical product 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 pharmaceutical products 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, for the purposes of this Annex, a pharmaceutical product may include a human drug or biologic that is intended for use in the diagnosis, cure, mitigation, treatment, or prevention of a disease or condition in humans, or intended to affect the structure or any function of the body of a human.

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

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

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

8. When developing or implementing regulations for marketing authorisation of pharmaceutical products, each Party shall consider relevant scientific or technical guidance documents developed through international collaborative efforts. Each Party is encouraged to consider regionally-developed scientific or technical guidance documents that are aligned with international efforts.

[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.

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 pharmaceutical products and that do not fall within the definition of a technical regulation or conformity assessment procedure.

10. Each Party recognises that the applicant is responsible for providing sufficient information to a Party for it to make a regulatory determination on a pharmaceutical product.

11. Each Party shall make its determination whether to grant marketing authorisation for a specific pharmaceutical product on the basis of:

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

(b) information on the manufacturing quality of the product;

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

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

To this end, no Party shall require sale data or related financial data concerning the marketing of the product as part of the determination. Further, each Party shall endeavour to not require pricing data as part of the determination.

12. Each Party shall administer any marketing authorisation process that it maintains for pharmaceutical products 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 pharmaceutical product 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 product or regulatory implications that may arise.

(b) If a Party determines that a marketing authorisation application for a pharmaceutical product 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 a marketing authorisation for a pharmaceutical product, 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 pharmaceutical product that has previously received marketing authorisation from the Party, the Party shall allow the pharmaceutical product to remain on its market under the conditions of the previous marketing authorisation pending a decision on the periodic reauthorisation, unless the Party identifies a significant health or safety concern.[2]

13. When developing regulatory requirements for pharmaceutical products, 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 pharmaceutical products; or

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

14. No Party shall require that a pharmaceutical product receive marketing authorisation from a regulatory authority in the country of manufacture as a condition for the product to receive marketing authorisation from that Party.

15. For greater certainty, a Party may accept a prior marketing authorisation that is issued by another regulatory authority as evidence that a product 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 to be established and made public by that Party as a condition for the product's marketing authorisation from that Party.

16. For a marketing authorisation application for a pharmaceutical product, each Party shall review the safety, efficacy and manufacturing quality information submitted by the applicant requesting marketing authorisation in a format that is consistent with the principles found in the *International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use* Common Technical Document (CTD), as may be amended, recognising that the CTD may not address all aspects relevant to a Party's determination to approve marketing authorisation for a particular product.

[2] For greater certainty, the Parties recognise that an application for reauthorisation that is not filed in a timely manner; that contains insufficient information; or that is otherwise inconsistent with a Party's requirements, is deficient for the purposes of the reauthorisation decision.

17. The Parties shall seek to improve their collaboration on pharmaceutical inspection, and to this end, each Party shall, with respect to the inspection of a pharmaceutical product within the territory of another Party:

(a) notify the other Party prior to conducting an inspection, unless there are reasonable grounds to believe that doing so could prejudice the effectiveness of the inspection;

(b) if practicable, permit representatives of the other Party's competent authority to observe that inspection; and

(c) notify the other Party of its findings as soon as possible following the inspection and, if the findings will be publicly released, no later than a reasonable time before release. The inspecting Party is not required to notify the other Party of its findings if it considers that those findings are confidential and should not be disclosed.

18. The Parties shall seek to apply relevant scientific guidance documents that are developed through international collaborative efforts with respect to inspection of pharmaceuticals.