ANNEX 7B

PHARMACEUTICALS

Definitions

1. For the purposes of this Annex:

   (a) **"Good Clinical Practice" ("GCP")** means a process that incorporates established ethical and scientific quality standards for the design, conduct, recording and reporting of clinical research involving human participants.

   (b) **"Good Manufacturing Practice" ("GMP")** means quality measures for both production and quality control and defines general measures to ensure that processes necessary for production and testing are clearly defined, validated, reviewed, and documented, and that the personnel, premises and materials are suitable for the production of human prescription medicines, including vaccines.

Objectives

2. The National Regulatory Authority[1] of each Party shall:

   (a) work together to reduce unnecessary regulatory barriers, where appropriate, in the approval of human prescription medicines;

   (b) seek to collaborate through, and actively participate in, relevant international initiatives, such as those aimed at harmonisation of international standards for pharmaceuticals, to improve the alignment of their respective laws, regulations and regulatory activities for pharmaceuticals; and

   (c) where not already a member, positively consider working towards membership of international organisations, such as those which are leading the development and harmonisation of international standards for pharmaceuticals.

3. To reduce unnecessary regulatory barriers in human prescription medicines, including prescription generic and biosimilar medicines, each Party's National Regulatory Authority shall utilise, where provided by the applicant, as appropriate, reports from regulatory authorities recognised by that Party's National Regulatory Authority as a

[1] For the purposes of this Annex, "National Regulatory Authority" means: for New Zealand, the Ministry of Health, or its successor; and for India, the Central Drugs Standard Control Organisation, or its successor.

comparable regulator[2] in relation to the pre-market evaluation of products manufactured in the territory of the other Party, subject to its laws, regulations, and procedures, as amended from time to time.

4. To reduce unnecessary regulatory barriers in human prescription medicines, including prescription generic and biosimilar medicines, each Party's National Regulatory Authority shall, utilise, as appropriate and where provided by the applicant, GMP inspection reports, or certificates from regulatory authorities recognised by that Party's National Regulatory Authority as a comparable regulator in relation to the quality assessment of manufacturing facilities in the territory of the other Party, subject to its laws, regulations and procedures, as amended from time to time. This may reduce the requirement for, or duration of, in-country inspections in the territory of the other Party.

Non-derogation

5. Nothing in this Annex shall derogate from each Party's rights and obligations under the data protection provisions in the TRIPS Agreement and other international agreements to which the Parties are party.

Recognition of Quality Standards

6. The Parties affirm that human prescription medicines approved in their respective territories shall meet the requirements as prescribed, from time to time, by their National Regulatory Authority. If the relevant quality standards are not included in those requirements, or any pharmacopeia recognised by that Party's National Regulatory Authority, that Party shall give positive consideration to the other Party's recognised or adopted pharmacopeia.

GMP and GCP Inspections

7. Each Party shall normally accept, without the need for prior inspection, the GMP certification of sites in the other Party's territory that manufacture human prescription medicines provided that this certification is issued by that Party's comparable regulator. However, each Party has a right to conduct its own inspection of the manufacturing facilities certified by that comparable regulator. The Party's own inspection shall be an exception from normal practice.

Market Authorisation

8. Market authorisation applications shall be assessed in accordance with the applicable laws, regulations, and procedures of a Party. Parties shall determine market authorisations in a timely, reasonable, objective, transparent, and impartial manner.

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[2] Each Party shall determine its comparable regulators and promptly advise this list to the other Party. Any changes are to be notified to the other Party in a timely manner.

9. Each Party, subject to the recognition of quality standards and inspections described in Paragraphs 6 (Recognition of Quality Standards) and 7 (GMP and GCP inspections) of this Annex shall consider establishing or maintaining “fast-track” procedures for human prescription medicines, having valid approvals from that Party’s comparable regulators. Any breakthrough or medicine for rare conditions shall be outside the purview of the products considered for fast-track procedure under this paragraph.

Review

10. The Parties shall review the scope and the provisions of this Annex five years after the date of entry into force of the Agreement. Thereafter, subsequent reviews shall take place as mutually agreed by the Parties.

Contact Points

11. For the purposes of this Annex, the contact point for any technical question, such as exchange of regulatory information, and technical requirements, shall be:

    (a) For India: Central Drugs Standard Control Organization (CDSCO), Ministry of Health & Family Welfare, Government of India; and

    (b) For New Zealand: Ministry of Health (Medsafe).

12. Each Party shall promptly notify the other Party of the relevant details of their contact point, including email addresses. Each Party shall promptly notify the other Party of any change to those contact details or the contact point.

Non-Application of Dispute Settlement

13. Neither Party shall have recourse to dispute settlement under Chapter 19 (Dispute Settlement) for any matter arising under this Annex.