ANNEX 7A

MEDICAL DEVICES

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) **"Quality Management Systems" ("QMS")** means the management systems and risk management activities intended to ensure the design and manufacture of safe and effective medical devices.

Objectives

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

   (a) work together to reduce unnecessary regulatory barriers, as appropriate, in the approval of medical devices;

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

Conformity Assessments

3. To reduce unnecessary regulatory barriers in medical devices, each Party's National Regulatory Authority shall, where provided by the applicant, utilise, as appropriate, reports from regulatory authorities recognised by that Party's National Regulatory Authority as a comparable regulator[2] in relation to the pre-market evaluation of

[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.

[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.

medical devices manufactured in the territory of the other Party, subject to its laws, regulations and procedures, as amended from time to time.

4. Each Party shall accept, without prior inspection, the QMS or GCP certificates, or test results, issued by a conformity assessment body approved or recognised by that Party's comparable regulator, for the purpose of approval or registration of medical devices, in accordance with that Party's laws, regulations and procedures, as amended from time to time. However, each Party reserves the right to conduct its own inspection of manufacturing facilities or additional testing of the relevant medical device. The Party's own inspection or additional testing, as the case may be, shall be an exception from normal practice.

Review

5. 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

6. 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 Bureau of Indian Standards.

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

7. 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

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