ANNEX 5A
BILATERAL COOPERATION ON PHARMACEUTICAL PRODUCTS

SECTION A
OBJECTIVES, DEFINITIONS AND SCOPE

Article 1
Objectives

1. The Parties, while recognising that there are differences between their health care systems, share a commitment to facilitate access to Pharmaceutical Products, as a means of continuing to improve the health of their populations.

2. The Parties shall encourage collaboration through the exchange of experiences, information on the laws and regulations pertinent to medical products, capacity building programmes and facilitate participation in those programmes.

Article 2
Definitions

For the purposes of this Annex:

"Good Clinical Practices (GCPs)" means a process that incorporates established ethical and scientific quality standards for the design, conduct, recording and reporting of clinical research involving the participation of human subjects;

"Good Manufacturing Practice (GMP)" defines quality measures for 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 pharmaceuticals and biologicals including vaccines;

"**Pharmaceutical Products"** mean a substance or combination of substances that is intended for human or animal/veterinary use to treat, prevent, or diagnose a disease, or to restore, correct or modify physiological functions by exerting a pharmacological, immunological or metabolic action;

"USFDA" means United States Food and Drug Administration;

"UK MHRA" means the United Kingdom's Medicines and Healthcare products Regulatory Agency;

"EMA" means European Medicines Agency; and

"TGA" means Australia's Therapeutic Goods Administration.

Article 3
Scope

1. This Annex applies to technical regulations, standards, conformity assessment procedures, marketing authorisations, notification procedures, and inspections relating to GCPs and GMPs of manufacturers of Pharmaceutical Products carried out by the Parties that may affect trade in Pharmaceutical Products between the Parties.

2. Laws and regulations of each Party on Pharmaceutical Products, both existing and new or any revisions or amendments thereof, including the details of the relevant regulatory authorities responsible for implementation of such laws and regulations shall be promptly shared with the other Party, on request.

3. Human blood, human plasma, human tissues, and organs are excluded from this Annex.

SECTION B
OBLIGATION

Article 4
Recognition of Quality Standards

1. The quality of a Pharmaceutical Product sold, distributed, or marketed in the territory of a Party shall meet the standards prescribed in the Pharmacopeia approved by the relevant regulatory authority of that Party.

2. In the event that there is no prescribed standard in the Pharmacopeia that is approved by the Party for a Pharmaceutical Product, the other Party shall accept all the standards relating to such Pharmaceutical Product that have been accepted by Pharmacopoeias of EMA, TGA, UK MHRA, or USFDA.

Article 5
GMP and GCP Inspections

Each Party shall accept, without prior inspection, the GMP or GCP Inspection documents approved by the EMA, TGA, UK MHRA, or USFDA provided that the GMP and GCP Certificate is valid for at least 6 months on the date of application. However, each Party has a right to conduct its own inspection of the manufacturing facilities in the territory of the other Party for the Pharmaceutical Products accepted by its regulatory authority.

Article 6
Marketing Authorisation

1. Marketing authorisation applications should be complete according to the approved guidelines of the Party. The marketing authorisations granted by the Parties should be in a timely, reasonable, objective, transparent, and impartial manner.

2. Each Party, subject to the norms or recognition of quality standards and inspections described in Articles 4 (Recognition of Quality Standards) and 5 (GMP and GCP inspections) of this Annex shall consider establishing "fast-track" procedures for Pharmaceutical Products having valid approvals from at least one of the regulatory authorities, namely EMA, TGA, UK MHRA, or USFDA. Breakthrough or rare medicines shall be outside the purview of the products considered for fast-track procedure under this paragraph.

3. Subject to Article 4 (Recognition of Quality Standards) and paragraph 1 of Article 5 (GMP and GCP inspections), each Party does not need to carry out a full assessment or inspect its manufacturing sites and clinical sites for the products already approved by reference countries, namely Australia, the European Union, United States of America, or the United Kingdom for which the applicant has provided a detailed assessment report, wherever available and approvals issued by regulatory authorities, namely USFDA, EMA, UK MHRA, TGA for Pharmaceutical Products included under fast-track procedure, except in case of specialised products.

4. The Parties shall adhere to the following timelines which represent the cumulative duration during which the application is under active review by the authorities, excluding the time spent by the applicant in responding to the authorities:

   (a) marketing authorisation under fast-track procedure shall be provided within 90 working days if they are without any prior

inspections by each Party for Pharmaceutical Products of the other Party which have been approved by the EMA, TGA, UK MHRA, or USFDA; and

(b) for all other Pharmaceutical Products where inspections are required, each Party shall, to the extent possible, and only as practicably feasible, grant marketing authorisation within 270 working days of application.

Article 7
Acceptance of Test Results from Accredited Laboratories

The regulatory authority of the importing Party shall accept tests conducted by the testing laboratories accredited by the exporting Party's national accreditation body and approved by the regulatory authority of the importing Party. The importing Party may conduct any test in line with its domestic regulations.

Article 8
Alert System, Suspension, and Withdrawal of Marketing Authorisation

1. Each Party shall maintain an alert system that permits authorities of the other Party, when relevant, to be made aware proactively and with the appropriate speed in case of quality defect, recalls, falsified products, or potential serious shortages and other problems concerning quality or non-compliance with GMPs, which could necessitate additional controls or suspension of the distribution of the affected products.

2. Each Party undertakes to ensure that any market surveillance related to imported Pharmaceutical Products of the other Party shall be conducted in accordance with protocols approved by the relevant regulatory authority of the Party.

3. In the event a party decided to suspend or withdraw or recall manufacturing authorisation or marketing authorization of any of its local manufacturers and products under this Annex such decision shall be communicated to the other Party with the appropriate degree of urgency and as per the applicable Pharmacovigilance procedures in each Party.

Article 9
Pricing of Pharmaceuticals Products

In the process of determining the prices for imported Pharmaceutical Products, each Party shall take into account various factors related to their market conditions. It is expressly understood that the negotiation process is designed to be flexible, and Parties agree not to strictly adhere to the domestic prices of the product in the Party of origin.

Article 10
Stability Study

1. Each Party agrees that applications for marketing authorizations should fulfil the stability requirements according to the guidelines approved by their regulatory authorities.

2. In the event that a marketing authorization application is to be considered for fast-track procedure, and which lacks stability data fulfilling the requirement stated in the approved stability guidelines, the Parties shall accept the application, accompanied by a study fulfilling the minimum requirements i.e. with real time and accelerated stability data for 6 months with a commitment to submit the complete long-term study when available.

Article 11
Review

The Parties shall review the scope and the provisions of this Annex after 5 years from the entry into force of the Agreement. Thereafter, the review shall take place every 5 years or as mutually agreed by the Parties.

SECTION C
RELEVANT REGULATORY AUTHORITY AND CONTACT POINTS

Article 12
Relevant Regulatory Authority and Contact Points

1. For the purpose of this Annex, the relevant regulatory authority and corresponding contact points for any technical question, such as exchange of inspection reports, inspectors' training sessions and technical requirements, shall be:

(a) For Oman:

(i) for human use medicines: Directorate General of Pharmaceutical Affairs and Drug Control, Ministry of Health, Sultanate of Oman; and

(ii) for animal use medicines: Directorate General of Animal Wealth, Ministry of Agriculture, Fisheries Wealth and Water Resources, Sultanate of Oman.

(b) For India:

Central Drugs Standard Control Organisation (CDSCO), Ministry of Health & Family Welfare, Government of the Republic of India.