

## **ANNEX 5A**

### **Bilateral Cooperation on Pharmaceutical Products (Referred to in Chapter 5)**

#### **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 of finished pharmaceutical products (FPPs), and certain marketed biological products for human use, which are collectively referred to as "Pharmaceutical Products", as a means of continuing to improve the health of their populations.
2. Human blood, human plasma, human tissues, and organs are excluded from this Annex on Bilateral Cooperation on Pharmaceutical Products (BCPP).

##### **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 Practices (GMPs)"** means systems that assure proper design, monitoring, and control of manufacturing processes and facilities, the adherence to which assures the identity, strength, quality, and purity of pharmaceuticals. GMPs include strong quality management systems, obtaining appropriate quality raw materials (including starting materials) and packaging materials, establishing robust operating procedures, detecting and investigating product quality deviations, and maintaining reliable testing laboratories;

**"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;

**"PMDA"** means Japan's Pharmaceuticals and Medical Devices Agency; and

**"TGA"** means Australia's Therapeutic Goods Administration.

##### **ARTICLE 3 Scope**

1. This BCPP applies technical regulations, standards, conformity assessment procedures, marketing authorisations, notification procedures, and inspections

relating to GCPs and GMPs of manufacturers of Pharmaceutical Products carried out in the territories of the Parties that may affect trade in Pharmaceutical Products between the Parties. A Party's obligations under this BCPP apply to any product that the Party defines as a Pharmaceutical Product pursuant to paragraph 2.

2. Each Party shall define the scope of the products that qualify as Pharmaceutical Products for the purpose of this BCPP, which are subject to its laws and regulations, and make such information publicly available. 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 notified to the other Party.

## **Section B: Obligations**

### **ARTICLE 4**

#### **Recognition of Quality Standards**

In the event that there is no prescribed standard in the Pharmacopeia of a Party for a Pharmaceutical Product, the other Party shall accept all the standards relating to such Pharmaceutical Products that have been accepted by Pharmacopoeias of Australia, Canada, European Union, Japan, the United States of America, or the United Kingdom.

### **ARTICLE 5**

#### **GMP and GCP Inspections**

1. Each Party shall accept, without the need for prior inspection, the Pharmaceutical Products manufactured in the other Party's territory provided that these products are approved by the Regulatory Authorities of Australia, Canada, European Union, Japan, the United States of America, or the United Kingdom. However, each Party has a right to conduct its own inspection of the manufacturing facilities approved by the Regulatory Authorities of countries/institution mentioned in this paragraph. The Party's own inspection shall be an exception from the normal practice and shall be based on quality defects identified in post-market surveillance, or any specific evidence of serious concern in relation to the product quality or consumer safety.

2. The Parties shall exchange any information necessary for the mutual recognition of inspections.

### **ARTICLE 6**

#### **Fast Track Approval for Product Registration**

1. Each Party, subject to the norms of recognition of quality standards and inspections described in Articles 4 (Recognition of Quality Standards) and 5 (GMP and GCP Inspections) of this BCPP shall consider establishing "fast-track" procedures for Pharmaceutical Products having approvals from at least one of the Regulatory Authorities/ reference countries namely Australia, Canada, European Union, Japan, United States of America, or the United Kingdom. The products

considered for fast-track procedure under this clause shall be outside the purview of breakthrough or rare medicines in order to accelerate product registration.

2. Subject to paragraph 1 and pursuant to Articles 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 for the products already approved by reference countries included in Pharmaceutical Products under consideration for 'fast-track' procedure, except in case of specialised products.

## **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 an additional test, if necessary, in line with its domestic regulations.

## **ARTICLE 8**

### **Marketing Authorisation**

Each Party shall administer any marketing authorisation process it maintains for Pharmaceutical Products in a timely, reasonable, objective, transparent and impartial manner. In particular, the Parties shall adhere to the following timelines:

- (a) Marketing authorisation shall be provided within ninety (90) days without any inspections by each Party for Pharmaceutical Products of the other Party which have been approved by the relevant Regulatory Authorities of Australia, Canada, European Union, Japan, the United States of America, or United Kingdom.
- (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 two hundred and seventy (270) days of application for such marketing authorisation.

## **ARTICLE 9**

### **Alert System**

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 relevant reference country pharmacopoeias or validated test protocols as applicable to the manufacturer of such products.

**ARTICLE 10**  
**Suspension or Withdrawal of Marketing Authorisation**

1. The Parties shall ensure that any suspension or withdrawal (total or partial) of a marketing authorisation, as the case may be, shall be based on non-compliance with mandatory GMP/GCP requirements, the effect on the protection of public health or a quality defect in the product. The decision to suspend or withdraw manufacturing authorisation and/or marketing authorisation shall be communicated to the other Party with the appropriate degree of urgency and as per the applicable Pharmacovigilance procedures in each Party.

2. Each Party, in accordance with its laws and regulations, shall provide for adequate provisions for review and appeal against any decision of suspension or withdrawal of marketing authorisation and/or manufacturing authorisation.

**ARTICLE 11**  
**Review**

The Parties shall review the scope and the provisions of this Annex after two (2) years from the entry into force of the Agreement. Thereafter, the review shall take place every three (3) years or as mutually agreed by the Parties.

**Section C: Contact Points**

**ARTICLE 12**  
**Contact Points**

For the purpose of this BCPP, the contact points for any technical question, such as exchange of inspection reports, inspectors' training sessions and technical requirements, shall be:

(a) For the UAE:

Head of Drug Regulatory Authority of UAE  
Director of Drug Department  
Health Regulation sector  
Ministry of Health and Prevention

(b) For India:

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