CHAPTER 5
TECHNICAL BARRIERS TO TRADE

ARTICLE 5.1
Definitions

1. For the purposes of this Chapter, the terms and their definitions set out in Annex 1 of the TBT Agreement shall apply.

2. **"TBT Agreement"** means Agreement on Technical Barriers to Trade, set out in Annex 1A of the GATT 1994.

ARTICLE 5.2
Objectives

The objectives of this Chapter are to facilitate trade in goods among the Parties by:

(a) ensuring that standards, technical regulations, and conformity assessment procedures do not create unnecessary obstacles to trade;

(b) furthering cooperation pursuant to the TBT Agreement

(c) promoting mutual understanding of each Party's standards, technical regulations, and conformity assessment procedures and enhancing transparency;

(d) facilitating information exchange and cooperation among the Parties in the field of standards, technical regulations and conformity assessment procedures, including in the work of relevant international bodies; and

(e) addressing the issues that may arise under this Chapter.

ARTICLE 5.3
Scope

1. This Chapter shall apply to the standards, technical regulations and conformity assessment procedures that may affect trade in goods between the Parties. The Chapter shall not apply to:

(a) sanitary and phytosanitary measures which are covered in Chapter 4 (Sanitary and Phytosanitary Measures) of this Agreement; and

(b) purchasing specifications prepared by governmental bodies for production or consumption requirements of governmental bodies.

2. Without prejudice to paragraph 1, this Chapter shall apply to the preparation, adoption, and application of all technical regulations, standards, and conformity assessment procedures by: central government bodies; and, where explicitly provided for in this Agreement, government bodies at the level directly below that of the central level of government that may affect trade in goods between the Parties.

3. All references in this Chapter to technical regulations, standards, and conformity assessment procedures shall be construed to include any amendments[1] to them and any addition to the rules or the product coverage of those technical regulations, standards, and procedures, except amendments and additions of an insignificant nature.

4. Each Party shall take such reasonable measures that are within its authority to encourage observance by local government bodies, as the case may be, on the level directly below that of the central level of government within its territory which are responsible for the preparation, adoption and application of technical regulations, standards and conformity assessment procedures, of Articles 5.5 (Standards) and 5.7 (Conformity Assessment Procedures).

5. For greater certainty, nothing in this Chapter shall prevent a Party from preparing, adopting, applying, or maintaining technical regulations, standards, or conformity assessment procedures in accordance with its rights and obligations under this Agreement, the TBT Agreement, and any other relevant international agreement.

ARTICLE 5.4
Incorporation of the TBT Agreement

1. The Parties affirm their rights and obligations under the TBT Agreement, and the following provisions of the TBT Agreement are incorporated into and form part of this Agreement, *mutatis mutandis*:

(a) Article 2;

(b) Article 3;

(c) Article 4.1;

(d) Article 5;

(e) Article 6.1, 6.3; and

(f) Annex 3, except paragraph A.

2. In the event of any inconsistency between the provisions of the TBT Agreement incorporated under this Article and other provisions of this Chapter, the latter shall prevail.

3. This Chapter is subject to Chapter 15 (Dispute Settlement) at the entry into force of this Agreement.

4. No Party shall have recourse to dispute settlement under Chapter 15 (Dispute Settlement) for a dispute that exclusively alleges a violation of the provisions of the TBT Agreement incorporated under this paragraph.

[1] "Any amendment" includes the elimination of a technical regulation.

ARTICLE 5.5
Standards

1. The Parties recognise the important role that international standards, guides, and recommendations can play in harmonising technical regulations, conformity assessment procedures, and national standards, and in reducing unnecessary barriers to trade.

2. To determine whether there is an international standard, guide, or recommendation within the meaning of Articles 2 and 5 and Annex 3 of the TBT Agreement, each Party shall apply the Decision of the Committee on Principles for the Development of International Standards, Guides and Recommendations with relation to Articles 2, 5 and Annex 3 of the Agreement (G/TBT/9, 13 November 2000, Annex 4), and subsequent relevant decisions and recommendations in this regard, adopted by the WTO Committee on Technical Barriers to Trade (WTO TBT Committee) in order to recognise a standard as an international standard.

3. Each Party shall ensure that its standardising body or bodies, while formulating national standards, shall ensure that such standards are not prepared, adopted or applied with a view to, or with the effect of, creating unnecessary obstacles to international trade.

4. Where modifications to the contents or structure of the relevant international standards were necessary in developing a Party's national standards, that Party shall, on request of the other Party, encourage its standardising body or bodies to provide information about the differences in the contents and structure, and the reason for those differences. Any fees charged for this service shall, apart from the real cost of delivery, be the same for foreign and domestic persons.

5. The Parties shall cooperate with each other to ensure that international standards, guides, and recommendations that are likely to become a basis for technical regulations and conformity assessment procedures do not create unnecessary obstacles to international trade.

6. Each Party shall encourage the standardising body or bodies in its territory to cooperate with the standardising body or bodies of the other Party including:

(a) exchange of information on standards;

(b) exchange of information relating to standard setting procedures; and

(c) cooperation in the work of international standardising bodies in areas of mutual interest.

7. The Parties shall, where appropriate, strengthen coordination and communication with each other in the context of discussion on international standards and related issues in other international fora, such as the WTO TBT Committee.

ARTICLE 5.6
Technical Regulations

1. Each Party shall prepare, adopt and apply its technical regulations in accordance with Article 2 of the TBT Agreement and ensure adherence to Article 3 of the TBT Agreement.

2. Each Party shall use relevant international standards to the extent provided in paragraph 4 of Article 2 of the TBT Agreement, as a basis for its technical regulations. Where a Party does not use such international standards, or their relevant parts, as a basis for its technical regulations and these may have an effect on trade of the other Party, it shall, upon request of the other Party, explain the reasons therefor. The explanation shall make every effort to address why the standard has been judged inappropriate or ineffective for the objective pursued. Where the Party considers that the technical explanation provided is not satisfactory, both Parties shall enter into technical discussions that will take place as expeditiously as possible to arrive at a mutually satisfactory understanding.

3. In implementing Article 2.2 of the TBT Agreement, each Party shall consider available alternatives in order to ensure that any proposed technical regulations to be adopted are not more trade-restrictive than necessary to fulfil a legitimate objective, taking account of the risk non-fulfilment would create.

4. Each Party shall give positive consideration to accepting as equivalent, technical regulations of the other Party, even if these regulations differ from its own, provided it is satisfied that these regulations adequately fulfil the objectives of its own regulations.

5. In addition to Article 2.7 of the TBT Agreement, a Party shall, on request of the other Party,[2] provide the reasons why it has not accepted, or cannot accept, a technical regulation of that Party as equivalent to its own. The Party to which the request is made should provide its response within a reasonable period of time.

6. Each Party shall uniformly and consistently apply its technical regulations that are prepared and adopted by its central government bodies to its whole territory. For greater certainty, nothing in this paragraph shall be construed to prevent local government bodies from preparing, adopting and applying additional technical regulations in a manner consistent with the provisions of the TBT Agreement.

7. Except where urgent problems of safety, health, environmental protection or national security arise or threaten to arise, Parties shall allow a reasonable interval[3] between the publication of technical regulations and their entry into force in order to provide sufficient time for producers in exporting Parties to adapt their products or methods of production to the requirements of importing Parties.

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[2] The Party's request should identify with precision the respective technical regulations it considers to be equivalent and any data or evidence that supports its position.

[3] "**Reasonable interval"** means normally a period of not less than six (6) months, except when this would be ineffective in fulfilling the legitimate objectives pursued by the technical regulation or the conformity assessment procedure.

8. At the request of a Party that has an interest in developing a technical regulation similar to a technical regulation of the other Party, such other Party shall endeavour to provide, to the extent practicable, relevant information, including studies or documents, except for confidential information, on which it has relied in its development.

9. Consistent with the obligations of the TBT Agreement, incorporated by Article 5.4 (Incorporation of the TBT Agreement), each Party shall ensure that its technical regulations concerning labels:

(a) accord treatment no less favourable than that accorded to like goods of national origin; and

(b) do not create unnecessary obstacles to trade between the Parties.

ARTICLE 5.7
Conformity Assessment Procedures

1. In cases where a positive assurance is required that products conform with technical regulations or standards, and relevant international standards, guides or recommendations issued by international standardising bodies exist or their completion is imminent, Parties shall ensure that central government bodies use them, or the relevant parts of them, as a basis for their conformity assessment procedures, except where, as duly explained upon request, such international standards, guides, or recommendations or relevant parts are inappropriate for the Parties concerned, for, *inter alia*, such reasons as: national security requirements; the prevention of deceptive practices; protection of human health or safety, animal or plant life or health, or the environment; fundamental climatic or other geographical factors; fundamental technological or infrastructural problems.

2. Procedures for assessment of conformity by central government bodies of each Party shall be in accordance with Article 5 of the TBT Agreement.

3. Each Party shall ensure, whenever possible, that results of the conformity assessment procedures in the other Party are accepted, even when those procedures differ from its own, provided it is satisfied that those procedures offer an assurance of conformity with applicable technical regulations or standards equivalent to its own procedures.

4. A Party shall, upon request of the other Party, explain its reasons for not accepting the results of a conformity assessment procedure conducted in the other Party. Each Party recognises that, a broad range of mechanisms exists to facilitate the acceptance of the results of conformity assessment procedures conducted in the other Party. Such mechanisms may include:

(a) mutual recognition agreements for the results of conformity assessment procedures conducted by bodies in the Parties;

(b) cooperative (voluntary) arrangements between accreditation bodies or those between conformity assessment bodies in the Parties;

(c) use of accreditation to qualify conformity assessment bodies, including through relevant multilateral agreements or arrangements to recognise the accreditation granted by other Parties;

(d) designation of conformity assessment bodies in the other Party;

(e) unilateral recognition by a Party, of results of conformity assessment procedures conducted in the other Party; and

(f) manufacturer's or supplier's declaration of conformity.

5. Upon reasonable request, the Parties shall exchange information and/or share experiences on the mechanisms referred to in paragraph 4 above, with a view to facilitating the acceptance of the results of conformity assessment procedures.

6. Each Party shall, if it considers appropriate, permit participation of conformity assessment bodies in the other Party, in its conformity assessment procedures under conditions no less favourable than those accorded to conformity assessment bodies in the Party.

7. Where a Party permits participation of its conformity assessment bodies and does not permit participation of conformity assessment bodies in the other Party, in its conformity assessment procedures, it shall, upon written request of that Party, explain the reason for its refusal in writing.

8. The Parties recognise the important role that relevant regional or international organisations can play in cooperation in the area of conformity assessment. In this regard, each Party shall take into consideration the participation status or membership in such organisations of relevant bodies in the Parties in facilitating this cooperation.

9. The Parties agree to encourage cooperation between their relevant conformity assessment bodies in working closer with a view to facilitating the acceptance of conformity assessment results between Parties.

ARTICLE 5.8
Cooperation

1. The Parties shall encourage cooperation between their respective organisations responsible for standardisation, conformity assessment, accreditation, and metrology, with a view to facilitate trade.

2. Each Party shall, upon request of the other Party, give positive consideration to proposals for cooperation on matters of mutual interest on standards, technical regulations, and conformity assessment procedures.

3. Such cooperation, which shall be on terms and conditions the Parties mutually determine, may include:

(a) advice or technical assistance/capacity building relating to the development and application of standards, technical regulations and conformity assessment procedures;

(b) cooperation between conformity assessment bodies, both governmental and non-governmental, in the Parties on matters of mutual interest;

(c) cooperation in areas of mutual interest in the work of relevant regional and international bodies relating to the development and application of standards and conformity assessment procedures, such as enhancing participation in the frameworks for mutual recognition developed by relevant regional and international bodies;

(d) enhancing cooperation in the development and improvement of standards, technical regulations, and conformity assessment procedures;

(e) strengthening communication and coordination in the WTO TBT Committee and other relevant international or regional fora;

(f) greater alignment of national standards with relevant international standards, except where inappropriate or ineffective;

(g) facilitation of the greater use of relevant international standards, guides, and recommendations as the basis for technical regulations, and conformity assessment procedures; and

(h) promotion of the acceptance of technical regulations of the other Party as equivalent.

4. Each Party shall, upon request of the other Party, give due consideration for cooperation in areas of mutual interest under this Chapter.

ARTICLE 5.9
Information Exchange and Technical Discussions

1. A Party may request in writing that the other Party provide information on any matter arising under this Chapter. A Party receiving a request in writing, in the English language under this paragraph shall provide that information within a reasonable period of time, and if possible, by electronic means.

2. When a Party considers the need to resolve an issue related to trade and provisions under this Chapter, it may request in writing to hold technical discussions with the other Party. The requested Party shall respond as early as possible to such a request.

3. The Parties shall discuss the matter raised within sixty (60) days of the date of the request. If the requesting Party considers that the matter is urgent, it may request that any discussions take place within a shorter time frame. The Parties shall attempt to obtain satisfactory resolution of the matter as expeditiously as possible, recognising that the time required to resolve a matter will depend on a variety of factors, and that it may not be possible to resolve every matter through technical discussions.

4. Requests for information or technical discussions and communications shall be conveyed through the respective contact points designated pursuant to Article 5.11 (Contact Points).

5. For greater certainty, a Party may request technical discussions with the other Party regarding technical regulations or conformity assessment procedures on a level directly below that of the central government that may have a significant effect on trade.

6. Unless the Parties agree otherwise, the discussions and any information exchanged in the course of the discussions shall be confidential and without prejudice to the rights and obligations of the participating Parties under this Agreement, the WTO Agreement or any other agreement to which both Parties are party.

7. The Parties understand and agree that this Article is without prejudice to the rights and obligations of the Parties under Chapter 15 (Dispute Settlement).

ARTICLE 5.10
Transparency

1. The Parties recognise the importance of the provisions relating to transparency in the TBT Agreement. In this respect, the Parties shall take into account relevant Decisions and Recommendations adopted by the WTO TBT Committee since 01 January 1995 (G/TBT/1/Rev.13), and any revisions issued in the future by the WTO TBT Committee.

2. Upon request, a Party shall provide, if already available, the full text or summary of its notified technical regulations and conformity assessment procedures in the English language. If unavailable, the Party shall provide a summary stating the requirements of the notified technical regulations and conformity assessment procedures to the requesting Party in the English language, within a reasonable period of time agreed between the Parties and, if possible, within thirty (30) days after receiving the written request. In implementing the preceding sentence, the contents of the summary shall be determined by the responding Party.

3. Each Party shall, on request of the other Party, provide information regarding the objectives of, and rationale for, a technical regulation or conformity assessment procedure that Party has adopted or is proposing to adopt.

4. Each Party shall normally allow sixty (60) days from the date of notification to the WTO in accordance with Articles 2.9 and 5.6 of the TBT Agreement for the other Party to present comments in writing, except where urgent problems of safety, health, environmental protection or national security arise or threaten to arise.

5. Each Party shall take the comments of the other Party into account and shall endeavour to provide responses to these comments upon request.

6. Each Party shall allow persons of the other Party to participate in consultation procedures which are available to the general public for the development of technical regulations, national standards, and conformity assessment procedures by the Party, subject to laws and regulations of a Party, on terms no less favourable than those accorded to its own persons.

7. When a Party detains at the point of entry an imported consignment, due to non-compliance with a technical regulation or a conformity assessment procedure, it

shall notify the importer or its representative, as soon as possible, the reasons for the detention.

8. Unless this Chapter provides otherwise, any information or explanation requested by a Party pursuant to this Chapter shall be provided to the other Party, in print or electronic form, within a reasonable period of time as the Parties may agree, and, if possible, within sixty (60) days. Upon request, the requested Party shall provide such information or explanation in the language or languages as the Parties mutually agree, or whenever possible, in the English language.

ARTICLE 5.11
Contact Points

1. Within sixty (60) days of the date of entry into force of this Agreement, each Party shall designate a contact point or contact points responsible for coordinating the implementation of this Chapter.

2. Each Party shall provide the other Party with the name of the designated contact point or contact points and the contact details of the relevant official(s) in that organisation, including telephone, facsimile, email and any other relevant details.

3. Each Party shall notify the other Party promptly of any change in their contact points or any amendments to the details of the relevant official(s).

4. Each Party shall ensure that its contact point or contact points facilitate the exchange of information between the Parties on standards, technical regulations, and conformity assessment procedures, in response to all reasonable requests for such information from a Party.

ARTICLE 5.12
Subcommittee on Standards, Technical Regulations and Conformity Assessment Procedures

1. The Parties hereby establish a Subcommittee on Standards, Technical Regulations, and Conformity Assessment Procedures, under the CTG, consisting of representatives of the Parties.

2. The Subcommittee shall meet at such venues and time-period as the Parties mutually determine. Meetings may be conducted in person, or by any other means as the Parties mutually determine.

3. The functions of the Subcommittee may include:

(a) monitoring the implementation and operation of this Chapter;

(b) coordinating cooperation pursuant to Article 5.8 (Cooperation);

(c) facilitating technical discussions;

(d) reporting, where appropriate, its findings to the Committee on Trade in Goods; and

(e) carrying out other functions as may be delegated by the Committee on Trade in Goods.

ARTICLE 5.13
Annexes

1. The agreed text of Bilateral Cooperation on Pharmaceutical Products to Chapter 5 on Technical Barriers to Trade is placed at Annex 5A.

2. Within one (1) year of the entry into force of this Agreement, both Parties shall enter into discussions to negotiate and finalise an Annex on organic products which will form an integral part to this Chapter.

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