THE COORDINATING COMMITTEE ON THE IMPLEMENTATION OF THE ATIGA
SUBMISSION FORM FOR CASES OF THE 'MATRIX OF ACTUAL CASES'
ON TRADE BARRIERS

CASE REFERENCE ID *(For Secretariat's use)*	**REPORTING COUNTRY**	**INVOLVING COUNTRY**
	THAILAND	**VIETNAM**
DATE OF REPORT SUBMISSION	**HS CODE AND PRODUCT DESCRIPTION** *(where applicable)*	
10-Nov-20	**PHARMACEUTICAL PRODUCTS**	

DESCRIPTION OF TRADE BARRIER FACED
Please provide a description of the situation

Technical Barrier to Trade in Marketing authorization of Pharmaceutical Products:

- For foreign pharmaceutical products (import) in obtaining and maintaining marketing authorization in Vietnam, as part of the registration requirements, companies must submit Certificate of Pharmaceutical products (CPPs) which are issued by other health authorities of the manufacturing/ exporting country to the Vietnam Ministry of Health (MOH). (Circular of the Ministry of Public Health No: 32/2018/TT-BYT MARKETING AUTHORIZATION OF DRUGS AND MEDICINAL INGREDIENTS Article 23. 4. (e))

- Following "Guidelines on the implementation of the WHO certification scheme on the quality of pharmaceutical products moving in international commerce" of WHO (World Health Organization), WHO-CPP template was established to facilitate the use of competent authorities; importing and exporting, in product licensing, renewal, and variation, all countries are urged to adopt these formats to facilitate interpretation of certified information. Respectively, the WHO-CPP requirement according to this guideline is widely accepted by health authorities globally and considered sufficiently comprehensive to provide assurance on the quality of the medicinal product, its manufacture and control.

- According to the circular of the Ministry of Health No: 32/2018/TT-BYT, the MOH introduced Vietnam-specific requirements for all CPPs under Article 12 and Article 23. 4. (d) which created the technical barriers to trade and additional administrative burdens to the other health authorities as:
  1. **Under Article 12,** the **Vietnam Drug Administration will contact CPP-issuing authorities to verify the authenticity of CPPs** for all registration dossiers as additional procedure, which this would respectively **create unnecessary administrative burdens on health and other related authorities.**
  2. **Under Article 23, the requirements for Certificate of Pharmaceutical Product (CPP)** include the information of specification of the drug substance, drug product and name and address of drug substance manufacturing site which is **not conformed to WHO format that has been agreed by all ASEAN Member States and globally used by stringent regulatory authorities**, such additional

requested information also create redundancy since they are already included in the registration submission requirements. Request of this additional information deviated from the common practice of other CPP issuing authorities and **create technical barriers to trade and burdens** for Drug Regulatory Authority since other authorities cannot provide document to fulfil the requirements under the Article 23.

Drug manufacturers in Thailand have complained that the technical barriers to trade from these **additional requirements** for Certificate of Pharmaceutical Product, **as applied by Vietnam,** has severely disadvantaged in exporting drugs to Vietnam, as they found difficulties to enter Vietnam's market due to **such restrictive and unnecessary requirements.**

REFERENCE TO ATIGA PROVISION
Please provide a reference to the ATIGA provision to support your case, where applicable

(ATIGA)

- **ARTICLE 5: Most Favored Nation Treatment**

  With respect to import duties, after this Agreement enters into force, if a Member State enters into any agreement with a non-Member State where commitments are more favourable than that accorded under this Agreement, the other Member States have the right to request for negotiations with that Member State to request for the incorporation herein of treatment no less favourable than that provided under the aforesaid agreement. The decision to extend such tariff preference will be on a unilateral basis. The extension of such tariff preference shall be accorded to all Member States.

- **ARTICLE 41 : Quantitative Restriction**

  Each Member State undertakes **not to adopt or maintain any prohibition or quantitative restriction on the importation of any goods of the other Member States** or on the exportation of any goods destined for the territory of the other Member States, except in accordance with its WTO rights and obligations or other provisions in this Agreement. To this end, Article XI of GATT 1994, shall be incorporated into and form part of this Agreement, *mutatis mutandis.*

- **ARTICLE 40 : Application of Non-Tariff Measures**

  1. Each Member State shall not adopt or maintain any non-tariff measure on the importation of any good of any other Member State or on the exportation of any good destined for the territory of any other Member State, except in accordance with its WTO rights and obligations or in accordance with this Agreement.

- **ARTICLE 6: National Treatment on Internal Taxation and Regulation**

Each Member State shall accord national treatment to the goods of the other Member States in accordance with Article III of GATT 1994. To this end, Article III of GATT 1994 is incorporated into and shall form part of this Agreement, *mutatis mutandis*.

(GATT)

- **Article I: General Most-Favoured-Nation Treatment**

1. With respect to customs duties and charges of any kind imposed on or in connection with importation or exportation or imposed on the international transfer of payments for imports or exports, and with respect to the method of levying such duties and charges, and with respect to all rules and formalities in connection with importation and exportation, and with respect to all matters referred to in paragraphs 2 and 4 of Article III,* any advantage, favour, privilege or immunity granted by any contracting party to any product originating in or destined for any other country shall be accorded immediately and unconditionally to the like product originating in or destined for the territories of all other contracting parties.

- **Article III : National Treatment on Internal Taxation and Regulation**

4. The products of the territory of any contracting party imported into the territory of any other contracting party shall be accorded treatment no less favourable than that accorded to like products of national origin in respect of all laws, regulations and requirements affecting their internal sale, offering for sale, purchase, transportation, distribution or use. The provisions of this paragraph shall not prevent the application of differential internal transportation charges which are based exclusively on the economic operation of the means of transport and not on the nationality of the product

- **Article XI : General Elimination of Quantitative Restrictions**

1. No prohibitions or restrictions other than duties, taxes or other charges, whether made effective through quotas, import or export licences or other measures, shall be instituted or maintained by any contracting party on the importation of any product of the territory of any other contracting party or on the exportation or sale for export of any product destined for the territory of any other contracting party.

LIST OF SUPPORTING DOCUMENTS PROVIDED *(where applicable)*

- Circular No. 32/2018/TT-BYT on MARKETING AUTHORIZATION OF DRUGS AND MEDICINAL INGREDIENTS
- "Guidelines on the implementation of the WHO certification scheme on the quality of pharmaceutical products moving in international commerce", WHO (World Health Organization)

https://www.who.int/medicines/areas/quality_safety/regulation_legislation/certification/guidelines/en/