



**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 <i>(For Secretariat's use)</i>	REPORTING COUNTRY	INVOLVING COUNTRY
C XXXX	Indonesia	Vietnam
DATE OF REPORT SUBMISSION	HS CODE AND PRODUCT DESCRIPTION <i>(where applicable)</i>	
12 December 2017	30049099	
DESCRIPTION OF TRADE BARRIER FACED <i>Please provide a description of the situation</i>		
<p>In 2014 Phapros have submitted registration documents for Pantoprazole Powder for Injections 40 mg to Drug Administration of Vietnam (DAV), in 2015 we received notification from DAV that our application was rejected due to some reasons. The first reason is because our product is stored under 25°C. DAV said that "Storage condition of product under 25°C is not according to regulation of ASEAN for Zone 4B. Now it is mandatory to provide stability study at Zone 4B at least 6 months by attach commitment will continue study until shelf life".</p> <p>ASEAN Stability Guideline that is established under Pharmaceutical Product Working Group (PPWG) in ASEAN, requires Stability zone 4B, BUT it is mentioned that if the product is not stable in temperature 30°C (there is significant changes during study), it is compulsory to do the alternative study in temperature 25°C. This is also common practice in Indonesia NADFC. We have to show the stability study in temperature 30°C and if it's Not Meet Specification, we will refer to stability study in temperature 25°C, and if it is stable, then it will agreed by Indonesia NADFC.</p> <p>Pantoprazole itself is a Heat Sensitive molecules.</p>		
REFERENCE TO ATIGA PROVISION <i>Please provide a reference to the ATIGA provision to support your case, where applicable</i>		
<p align="center">Article 75 Technical Regulations</p> <p>1. In adopting technical regulations, Member States shall ensure that:</p> <p>(a) these are not adopted with a view, to or with the effect of, creating technical barriers to trade;</p> <p>(b) these are based on international or national standards that are harmonised to international standards, except where legitimate reasons for deviations exist;</p> <p>(c) alternative means that are least trade restrictive to achieve the desired objectives are considered before a decision is taken on the adoption of technical regulations;</p> <p>(d) the adoption of prescriptive standards is avoided to ensure that unnecessary obstacles to trade are not introduced, to enhance fair competition in the market or that it does not lead to a reduction of business flexibility; and</p> <p>(e) treatment accorded to products imported from Member States is no less favourable than that accorded to like products of national origin and to like products originating from any other Member State.</p>		

2. Member States shall ensure that only those parts of a standard that represent minimum requirements to fulfil the desired objectives are referred to in the technical regulations.
3. Member States shall also ensure that, wherever applicable, the preparation, adoption and application of technical regulations are to facilitate the implementation of the respective ASEAN Sectoral Mutual Recognition Arrangements.
4. Whenever the need for technical regulations is urgent for overcoming problems that arise or threaten to arise within the territory of a Member State and the available time does not allow such Member State to harmonise the relevant national standards, that Member State shall consider using the appropriate international standards or the relevant parts of them as the first alternative.
5. Member States shall comply with the notification procedures as stipulated in Article 11. However, in the case of technical regulations under this Article, other Member States shall present their comments, if any, within sixty (60) days of the notification. Member States shall, upon request, provide to other Member States the draft of the technical regulation and other information regarding the deviations from the relevant international standards and the applicable pre-market conformity assessment procedure.
6. Except in urgent circumstances, Member States shall allow at least six (6) months between the publication of technical regulations and their entry into force in order to provide sufficient time for producers in exporting Member States to adapt their products or methods of production to the requirements of importing Member States.

LIST OF SUPPORTING DOCUMENTS PROVIDED *(where applicable)*

ASEAN Stability Guideline (attached)

Guidelines for the Matrix of Actual Cases on NTMs/Trade Barriers

1. The cases lodged in the Matrix of actual cases will be classified into 3 categories:

Category	Description
Category A: Resolved Cases	<ul style="list-style-type: none"> • Category A contains issues which have been resolved bilaterally/mutually by ASEAN Member States (AMSs). • Cases in other categories (on-going or new cases) which have been resolved bilaterally/mutually will be classified as Category A. • Cases justified/verified/agreed as NTB-free will be removed from the Matrix for simplifying and making the Matrix user-friendly
Category B: On-going Cases	<ul style="list-style-type: none"> • Category B contains any previously raised cases that ASEAN Member States would like to discuss at CCA meetings.
Category C: New Cases	<ul style="list-style-type: none"> • Category C contains the newly lodged cases that ASEAN Member States wish to discuss at CCA meetings.

2. Submission of Category C: New cases:

2.1 At CCA Meeting when ASEAN Member States raise new issues/case for discussions, such cases will be lodged into Category C: New cases.

2.2 Reporting country should inform the ASEAN Secretariat of these new issues by submission of the submission form and all relevant documents at least 4 weeks before each CCA Meeting in order to allow the responding country sufficient time to consult domestically. Should reporting country fail to raise a case within the time frame, such case will automatically be raised at the next CCA Meeting.

2.3 The responding country should provide the initial response at the CCA Meeting and should provide a written response to the reporting country, copied to other ASEAN Member States and the ASEAN Secretariat within 4 weeks after the CCA Meeting.

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2.4 After the new case is lodged into the Matrix under Category C: New cases, such case will be re-categorised into Category B: On-going cases at the next CCA meeting.

3. Addressing Category B: On-going cases:

3.1 Reporting and responding country may raise any on-going case for discussion at CCA Meetings.

3.2 On-going cases will be re-categorised into re-solved cases once mutually agreed upon by the reporting and responding country.

4. In case that the barrier element/NTBs effect is found in any case lodged, the CCA shall provide recommendations on how to address the issue to be submitted to the AFTA Council, through SEOM for endorsement. Should any case is justified/verified/agreed as NTB-free, it will be removed from the Matrix.

5. Recalling the decision of the 26th AFTA Council Meeting, to exercise the transparency and enhance the confidence of the private sectors on ASEAN process, the Matrix of actual cases will be uploaded onto the website of the ASEAN Secretariat within 1 month after each CCA Meeting. The information to be reflected in the Matrix of actual cases should be agreed upon by concerned parties (reporting and responding Member States). The specific information on the Matrix of actual cases should not contain specific details on which companies are involved in the cases to protect business confidentiality.

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