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**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
	INDONESIA	CAMBODIA
DATE OF REPORT SUBMISSION	HS CODE AND PRODUCT DESCRIPTION <i>(where applicable)</i>	
	Pharmaceutical Product	
DESCRIPTION OF TRADE BARRIER FACED <i>Please provide a description of the situation</i>		
<p>Tedious and Lengthy Procedure and Process for Pharmaceutical Products</p> <p>Efforts toward harmonization of ASEAN pharmaceutical regulations were initiated in 1992 through the ASEAN Consultative Committee for Standards and Quality (ACCSQ). The objective of the ACCSQ-PPWG is to develop harmonization schemes of pharmaceuticals' regulations of the ASEAN member countries to complement and facilitate the objective of ASEAN Free Trade Area (AFTA), particularly, the elimination of technical barriers to trade posed by these regulations, without compromising on drug quality, safety and efficacy.</p> <p>ACCSQ-PPWG has produced several important policies, such as the ASEAN Common Technical Requirements (ACTR), which contains the technical requirements in the context of drug registration and ASEAN Common Technical Dossier (ACTD), which contains the drug registration document format. Some technical guidelines have been completed and endorsed, are: Good Manufacturing Practices (GMP) inspection and Bioavailability and Bioequivalency (BA/BE) report. Other guidelines such as guideline for stability testings, guidelines analysis on validation method, guidelines on validation process and guidelines on Bioequivalence testings until now still under discussion to be finalised.</p> <p>In the field of pharmaceutical product, there is only an MRA for GMP inspection. There is no single regulatory scheme like in cosmetic. Some guidelines still under the discussion to fulfill the requirement on ACTD/ACTR. Every country in ASEAN requires registration before pharmaceutical products being marketed, and timeline for registration will be defined by each member country depends on their pre-market approval system, capacities and national regulation. Pre-market evaluation are needed before registration approval being issued. There is no consensus yet for time line registration, then this matter should be brought into the Pharmaceutical Product Working Group (PPWG) to be further discussed.</p> <p><u>Implications:</u> The products exported to Cambodia as well as other ASEAN countries get lengthy time for registration approval and cause delaying products going to the market.</p> <p>However, it should be understood that pharmaceutical product is different from other consumer goods because it is a very high risk and regulated product related to human health. Reducing technical barriers to trade among ASEAN Member States and contributing to the ASEAN Economic Integration initiatives should be without compromising to the safety, quality and efficacy of these products.</p>		

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REFERENCE TO ATIGA PROVISION

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

LIST OF SUPPORTING DOCUMENTS PROVIDED *(where applicable)*