



**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	Malaysia
DATE OF REPORT SUBMISSION	HS CODE AND PRODUCT DESCRIPTION(<i>where applicable</i>)	
	<ul style="list-style-type: none"> Prohibition of introducing founder on label of product as specified in appendix 5.2.7.4 of Drug Registration Guidance Document (DRGD) by National Pharmaceutical control Bureau (NPCB) 	
DESCRIPTION OF TRADE BARRIER FACED <i>Please provide a description of the situation</i>		
<p>The Regulation of BPFK / NPCB on Drug Registration Guidance Document Apendix 5.2.7.4 prohibits exposing the information / inclusion of the name of the owner / founder / manufacturer in the label/packaging of products sold in Malaysia .</p> <p>Under these regulation, each manufacturer must not include information about who the owner or the inventor of obat-obatan/jamu products. This rule applies since January 2013. Should the product packaging includes the name information about the founder / manufacturer that the product will not get the registration number from BPFK / NPCB and should not be circulated in Malaysia .</p> <p>The problem is , the herbal/jamu products of Mustika Ratu by BRA Mooryati Soedibyو has been distributed well in Malaysia since 1992 and quite famous amongst the consumers in Malaysia.</p> <p>Another fact is the brand of Mustika Ratu by BRA Mooryati Soedibyو has been registered in the Directorate General of intellectual property rights as an integral part of the discoverer/inventor BRA Mooryati Soedibyو together with the name Mustika Ratu.</p> <p>With this new regulation we are requested to remove the words" by BRA Mooryati Soedibyو " from the brand / from the label, otherwise the Malaysia Registered Number (MAL No) will not be released., meaning product can not be distributed in Malaysia again.</p> <p>We considered this as a potential to become technical barriers to trade , and the provision also does not exist in any other ATIGA members countries except Malaysia .</p>		

REFERENCE TO ATIGA PROVISION

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

Article 75

Technical Regulations

1. In adopting technical regulations, members states shall ensure that :
- (a). **These are not adopted with a view, to or with effect of, creating technical barriers to trade**
 - (b). These are based on international or national standards that harmonized to international standards, except where legitimate reasons for deviations exist

LIST OF SUPPORTING DOCUMENTS PROVIDED*(where applicable)*

2.7.4 Prohibited Visual Graphics/ Statement on Packaging Material (Label, Box , Package insert or Patient Information Leaflet)

General Requirement :

The graphics printed on outer and inner label has to be standardized to avoid the confusion to the customer

No	Subject Matter	Example(s)	Notes
10	Introduction of founder/ manufacturer		Prohibited on product label
12	Name/statement/logo/registered trade mark which does not satisfy the specification of the traditional unit	Example : “ Dr. ABC’s Formula” “nothing like it”	Prohibited on product label