

Post-Marketing Alert (PMA) System

for Defective or Unsafe Cosmetic Products
Status Update

6th ACC meeting, Cambodia, Siem Reap
15-16 June 2006

Status Update

- The 5th ACC meeting in Brunei
 - agreed in principle to formalize a single Alert System for all Healthcare products in ASEAN
 - requested that terminologies be revised to make it relevant for cosmetics
 - Contact list of focal point coordinators in ASEAN is attached with the report
- The 4th TMHS PWG Meeting in Jan 2006 in Bangkok
 - agreed to adopt the format
 - Requested Member States provide country-specific glossaries with each Alert Notification

Status Update

- The 11th PPWG Meeting in March 2006 in Hanoi adopted the revised format of the PMA Form and the country-specific glossary template with major revisions:
 - Previously two PMA forms now combined into one
 - Glossary of Terms Template (Annex A)
 - Country-specific
 - Reviewed annually, to send with ASEAN PMA Form for each Alert Notification
 - Agreed on a separate country-specific glossary for each product groups (for pharmaceuticals, cosmetics, traditional medicines and health supplements)

GLOSSARY OF TERMS

Name of Country: _____

Product Group: Pharmaceuticals/ Cosmetic Products/ Traditional Medicines and Health Supplements Products (note: please indicate the product group for this glossary and provide the appropriate inputs relevant to the indicated product group)

1.	Adverse Drug Reaction (ADR)* Adverse Reaction- ASEAN Harmonised Cosmetic Regulatory Scheme Definition For Cosmetic Product Any type of the harmful or unintended effects reasonably attributable to the normal or foreseeable use of a given cosmetic product.
2.	Adverse Event (AE)* (or a healthcare-related product)
3.	Complementary Medicine* Chinese Proprietary Medicine* Traditional Medicine* Health Supplement*
4.	Defect* (or a healthcare-related product)
5.	Level of Confidentiality (this explains the level of confidentiality matrix used in the PMA system Form A used in the reporting)
6.	Recall Classification* (e.g. Class 1 & 2 recalls of healthcare-related product)
7.	Recall Level* (e.g. consumer, retail, wholesale etc)
8.	Withdrawal*

Note:

This template is intended as a guide for each ASEAN Member Country to draft their respective country-specific glossary. The country-specific glossary will be helpful for the understanding of terminology and definitions by other Member countries when reading the PMA Form.

* To list the legal definitions, terms, terminologies, process or procedures that are commonly used in the Member Country. The Member Country can add or include new items to the glossary template if the country-specific items are not included in the template.

Country-Specific Glossary

- The country-specific glossary should be reviewed at least annually
- Countries to send the glossary together with PMA Form for each alert notification

THANK YOU