

# **Update on the ASEAN Post-Marketing Alert System For Defective or Unsafe Medicinal Products, Cosmetic Products, Traditional Medicines And Health Supplements**

## Introduction

1. The 8th ACCSQ PPWG Meeting assigned Singapore and Malaysia as the lead countries to look into a Post-Marketing Alert (PMA) System related to roadmap measure item 49 "Formalise a post-marketing alert system for defective and unsafe pharmaceutical / medicinal products" by 31 December 2005 under the ASEAN Healthcare Sector Integration Initiatives. A Malaysia-Singapore PMA System pilot scheme was launched early April 2005. This was presented and adopted in-principle by the 10<sup>th</sup> PPWG Meeting in August 2005 in Singapore.
2. Flexibility was considered during the early design phase of the ASEAN PMA system to cater for use in other product groups and hence the ASEAN PMA system was also presented at subsequent meetings of the ACC and TMHS Working Groups respectively.

## Objectives

3. The objectives of the Post-Marketing Alert (PMA) System are:
  - a. To establish an efficient and effective system of alert on post-marketing issues affecting the safety and quality of healthcare products
  - b. To enhance the pharmacovigilance capabilities among Member Countries through mutual exchange of drug safety data.

## Scope

4. The scope of the PMA System would include exchange of information and regulatory actions or measures on:
  - a. Products for which registration has been cancelled / suspended / withdrawn based on safety issues.
  - b. Products recalled from the market due to quality defects with serious public health implications and also known to be exported to Member Countries.
  - c. Products found to be adulterated and associated with serious public health implications.

- d. Significant label changes involving safety that are initiated by the regulators especially for traditional medicines.
- e. New restrictions to usage
- f. Exchange of the following which are produced and issued by the local regulatory authorities; (if available in English)
  - i. Dear Healthcare Professional Letter
  - ii. Media releases issues related to drug safety
  - iii. Adverse Drug Reaction bulletin publication
- g. Adverse Event reporting of cosmetic products, specifically fatal or life threatening serious adverse reactions or non-serious adverse reactions that occur at high incidence.

#### Process and Communication

5. Each country should nominate a country PMA System focal point or coordinator for each of the 3 product sectors of pharmaceuticals, TMHS and Cosmetics products. It is recommended that this should be the Director or Head of the respective ASEAN Drug Regulatory Authorities (DRAs). A local DRA central coordinator may be appointed to operationalise the system. If possible, it is recommended that the same DRA central coordinator could be appointed for all 3 product sectors for ease of communications across the Member Countries.

6. Based on the scope of the PMA System, an ASEAN Member Country will send (email or fax) an alert notification to other Member Countries using the agreed standardised form for reporting ASEAN Post-marketing Alert (PMA) Form. The Member Country sending the alert notification must establish the validity of the information prior to circulation. The timeline requirement for notification will be subject to individual Member Country's professional judgement and discretion, to allow for reporting timeline flexibility.

7. Upon receiving an alert notification a Member Country may then wish, if it is deemed appropriate, to follow-up with the reporting Member Country for further information, clarification or necessary regulatory action on an individual basis. The ASEAN PMA System is a voluntary sharing of information. It is not meant for sharing of information as a form of ADR reporting, recall reporting or any other type of formal reporting system.

#### Standardised Format for Reporting

8. There is a need to standardise the format, as per attached ASEAN Post-marketing Alert Form, for reporting and information exchange. The form should be completed in English.

9. There is also a need to list the definitions and terminologies used e.g. definitions of defective products, recalls and withdrawals. Due to different countries having different terminologies and definitions, it would be clearer if each Member Countries reflect their terminologies and definitions used into their own country-specific glossary document. The country-specific glossary template is attached as Annex A. It should be reviewed at least annually and sent to all Member Countries if there are any updates. For ease of reference, each Member Country should send the country-specific glossary together with ASEAN PMA Form for each alert notification.

### Status Update

10. The 5<sup>th</sup> ACC meeting in Brunei Darussalam, agreed in principle to the formalisation of a single Alert System for all healthcare Products in ASEAN but requested for the terminologies to be revised to make it more relevant for the cosmetics sector. Singapore was tasked to collate the contact list of focal point co-ordinators in ASEAN Member States, which is attached with this report.

11. The 4<sup>th</sup> TMHS PWG Meeting in January 2006 in Bangkok agreed to adopt the format presented and requested that Member countries provide country-specific glossaries when sending Alert to other Member Countries. The 11<sup>th</sup> PPWG Meeting in March 2006 in Hanoi agreed to adopt the revised format of the PMA Form and the country-specific glossary template with the following revisions:

- a. To ease the reporting process, the two previously recommended forms have been merged into a single called ASEAN Post-Marketing Alert Form.
- b. Due to possible different product classifications, the glossary would be country-specific and sent with the ASEAN Post-Marketing Alert Form for each alert notification, for ease of reference. Each Member Country should attempt to update the glossary annually and circulate the updated glossary to the other Member Countries.

12. The PPWG has embarked on a trial implementation of the PMAS which will be reviewed after one year by Singapore and Malaysia, the lead countries assigned to develop the ASEAN PMAS.

### **References:**

- a. Pharmaceutical Inspection Co-operation Scheme (PIC/S) SOP on "Procedure for Handling Rapid Alerts and Recalls Arising from Quality Defects", reference PI 010-1 dated 24 Jun 02
- b. The European Agency for the Evaluation of Medicinal Products (EMA) Committee for Proprietary Medicinal Products (CPMP) "Revised Note for Guidance on the Rapid Alert System (RAS) and Non-Urgent Information System (NUIS) in Human

Pharmacovigilance” Reference CPMP/PhVWP/005/96, Rev.1 London, dated 29 Jul 99

- c. A Guide Manual for the Industry: Adverse Event Reporting of Cosmetic Products (June 05)
- d. Paper on Post-Marketing Surveillance/Safety Evaluation of Cosmetic Products (Dec 03)