

22 April 2013

FDA Circular
No. 2013-008

SUBJECT : Adoption of the Association of the Southeast Asian Nations (ASEAN) Post-Marketing Alert System (PMAS) for Defective or Unsafe Processed Food Products, Pharmaceutical Products, Traditional Medicines and Health Supplements, and Cosmetic and Household Hazardous Products and Devices

I. RATIONALE

The state has a duty to protect and promote the right to health of the people and instill health consciousness among them (Section 15, Article II, 1987 Constitution). Pursuant thereto, Republic Act No. 9711, an amendment of Republic Act No. 3720, also known as the "Food and Drug Administration (FDA) Act of 2009" was enacted, among other things, to establish an effective system in the registration, monitoring and regulation of drug products.

Meanwhile, Section 2, Article II of the 1987 Constitution provides that the Philippines adopts the generally accepted principles of international law as part of the law of the land and adheres to the policy of peace, equality, justice, freedom, cooperation and amity with all nations.

The Post-Marketing Alert System was drafted as part of the Post Market Surveillance of health products. It was created for the ASEAN member countries to share information relating to defective or unsafe cosmetics, health supplements, traditional medicines and pharmaceutical products. In cases of major safety concerns, the PMA System can be used as a tool for updating the other regulatory agencies of member countries in a timely manner.

The ASEAN 11th Meeting of the Pharmaceutical Product Working Group (PPWG) resulted to an agreement on the adoption of the Post-Marketing Alert System for Defective or Unsafe Pharmaceutical Products, Cosmetic Products, Traditional Medicines and Health Supplements. Pursuant to the mentioned agreement and to Bureau Circular No. 8 s. 2001 (Subject: Guidelines to be Observed on the Implementation of Product Recall), the Post-Marketing Alert System is hereby adopted as a national guideline to provide mechanism in informing member countries of any unsafe and defective health products and to protect the public from any risk associated with health products.



II. SCOPE

The PMAS shall 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- a. Products for which registration has been cancelled / suspended / withdrawn based on safety issues.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.

III. OBJECTIVE

The objectives of this Circular are:

1. To formally adopt and incorporate the ASEAN Post-Marketing Alert System for Defective or Unsafe Processed Food Products, Pharmaceutical Products, Cosmetic Products and Household Hazardous Substances, Traditional Medicines and Health Supplements and Devices
2. To establish an efficient and effective system of alert on post-marketing issues affecting the safety and quality of health products.
3. To enhance pharmacovigilance capabilities through mutual exchange of drug safety data among ASEAN member states.

IV. DETAILS/DIRECTIVES

The Post-Marketing Alert System shall be adopted as a national guideline for the surveillance of unsafe and defective processed food products, pharmaceutical products, traditional medicines and health supplements, cosmetics and devices.

A. Process and Communication

Each Center of the Food and Drug Administration shall assign a PMA System focal point or coordinator for each of the product sectors: processed food products, pharmaceuticals, traditional medicine and health supplements, cosmetic products and



household hazardous substance and devices. The International Affairs Office shall be the central coordinator to operationalize the system for all health product sectors for ease of communication across the Member States.

The FDA, through the IAO shall send (email or fax) an alert notification to other member states using the agreed standardized form of reporting, the PMA form. The validity of the content of the alert notification must be established prior to circulation. The timeline requirement for notification will be subject to individual Member State's professional judgement and discretion, to allow for reporting timeline flexibility.

Received alert notifications from other member states shall be screened and considered for its applicability on local setting.

B. Standardized Form of Reporting

ASEAN Post-Marketing Alert System Form A (Annex A) and Form B (Annex B) shall be adopted as the standard forms for reporting and information exchange.

Country-specific glossary shall be submitted together with the PMA form for each alert notification. See Annex B for the glossary.

V. REPEALING CLAUSE


All other issuances inconsistent with this Circular are hereby repealed.

VI. SEPARABILITY CLAUSE

In case any provision of this Circular is declared contrary to law or unconstitutional, other provisions which are not affected thereby remain in force and effect.

VII. EFFECTIVITY

This Circular shall take effect immediately.


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