

6TH ASEAN Cosmetic Committee Meeting
15-16 June 2006, Cambodia

Philippines Progress Report

1. Transposition of ASEAN Cosmetic Directive into National Legislation :

The Philippine Bureau of Food and Drugs (BFAD) has adopted and implemented the ASEAN Cosmetic Directive with the issuance of the following Administrative Orders (AOs) by the Department of Health (DOH) :

- DOH-AO No. 2005-0015 – Adoption of the ASEAN Harmonized Cosmetic Regulatory Scheme (AHCERS) and the ASEAN Common Technical Documents.

Objectives and Scope:

- i. Adopt and incorporate the AHCERS into the national requirements.
 - ii. Coordinate transitory period for the new regulatory scheme to be implemented.
- AO No 2005-0025 – Implementation of the AHCERS and the ASEAN Common Technical Documents.

Objectives and Scope:

- i. Provide the implementing details for the incorporation and alignment of the ASEAN Harmonized Cosmetic Regulatory Scheme
- ii. Allow the Bureau of Food and Drugs (BFAD) and the cosmetic industry a transitory period to shift from the registration policies to the notification scheme
- iii. Assist the Bureau of Food and Drugs in strengthening the conduct of its post marketing surveillance.

There is an existing National Law, the Republic Act 7394, also known as the Consumer Act of the Philippines, which is in conflict with the ASEAN Cosmetic Definition. The Philippine Legal experts are currently working to amend and align the said law with the ASEAN Cosmetic Directive before 01 January 2008.

2. Preparations or Progress in the Implementation of Good Manufacturing Practice, Post Marketing Surveillance/Safety Evaluation, Ingredient Listings and Labeling :

Good Manufacturing Practice

The ASEAN Cosmetic GMP Guideline has already been incorporated into the local requirements. This is currently being implemented and has served as guide to both the BFAD and cosmetic industry on plant inspections and issuance of License To Operate (LTO). Training/workshop on The ASEAN Cosmetic GMP 13 modules has been conducted.

Post Marketing Surveillance (PMS) / Safety Evaluation

Product Safety Workshops have been conducted among the local cosmetic industry to help them prepare for the forthcoming PMS/Safety Evaluation implementation. The industry has been continuously informed about the ASEAN Cosmetic Directive (ACD) via different venues e.g workshops, seminars, trainings, during LTO application/product registration etc. In these venues, it was importantly highlighted that PMS will be the focus of ACD (and no longer registration/pre-market approval) starting 01 January 2008.

In parallel, BFAD is assessing the existing PMS/SE system and identifying opportunity areas to strengthen it. The challenge is to improve the system to be fully functional for the ASEAN Cosmetic Directive (ACD) with minimum resources. Both BFAD and the industry have attended a series of EU-ASEAN PMS trainings from which learnings will be incorporated in the PMS system and implementation.

Product Notification / Ingredient Listings / Labeling

With the issuance of the Administrative Orders adopting the ASEAN Harmonized Cosmetic Regulatory Scheme, the Philippines has implemented in advance, starting January 2006, the Product Notification Scheme for most cosmetic products. The joint BFAD-Industry Group have worked together to assess industry readiness and identify cosmetic products which can already undergo Notification process. The proposed ASEAN Notification template has been used as a reference for the local document. In the process, the industry has been made aware of the Ingredient Listings and Labeling requirements as these are part of the Notification requirements. While A.O. No. 2005-0025 allows compliance with the Common ASEAN Labeling Requirements until 31 December 2007, the industry is encouraged to comply as soon as possible.

Meanwhile, the ASEAN Common Product Registration Requirements/Procedure Technical Document has also been implemented at the same time with the Notification process, for 'high risk' cosmetic products. The BFAD is adhering to the Technical Document and Certificate of Product Registration is released within 30-days from application.

The above is a very important step the Philippines took, as this has been identified to be critical to prepare the regulators and the industry for the ASEAN Cosmetic Directive by January 1, 2008. As a pre-requisite, the BFAD and the industry have undergone series of trainings and workshops on the AHCRS and 7 Technical Documents prior to the implementation. Compliance from both regulatory and industry is being monitored to identify implementation issues.

3. Programme /Activities to assist industry to comply with the Directive :

The Philippine GMP Task Force has completed as committed the national GMP Trainings on Cosmetics using the 13 Modules for the industry and the 14 Modules for the regulators in a series of two seminars held on 27-28 February 2006 and 2-3 May 2006. These seminars identified compliance difficulties on the following:

- Building/premises,
- Personnel job responsibilities
- documentation system, limited equipment used in the production
- limited instruments/apparatus used in the quality control
- Auditing - few have conducted self-auditing.

The above has been communicated to the industry and BFAD Licensing Divisions for appropriate action. The cosmetic industry has to take a lead role in addressing these compliance issues. It was evident that an in-depth training, particularly in developing a good documentation system, is needed among the industry.

Similar GMP seminars will be held and have been scheduled starting July 2006. The seminars will highlight the identified compliance issues.

For the PMS/Safety Evaluation, series of training/workshops have been conducted in the Philippines:

1. 08-11 May 2006 – Advanced Regional training on Cosmetics PMS
Conducted by EU and ASEAN PMS experts
Attendees: ASEAN regulators and industry
2. 29-30 May 2006 – National Workshop on Cosmetic Post Marketing
Conducted by Philippine PMS Committee
Attendees: BFAD regulators/inspectors and local cosmetic industry

The above PMS training/workshop will be conducted in Manila and regional/provincial areas to have a wider reach and coverage. Also, the same training/workshop will be incorporated by the cosmetic industry associations in their activities/programs.

Seminars on the Notification Scheme and the ASEAN Cosmetic Directive will be conducted by the BFAD by the 3rd and 4th quarters of 2006. The seminar will include discussion of the compliance issues resulting from the Notification and 30-day registration process implementation.

4. Concerns and difficulties and proposed solutions for consideration to ACC:

i. MRA with Malaysia

The Philippines has started implementing the ASEAN Common Product Registration Requirements. We have expressed to the ASEAN Secretariat and Malaysia that we are ready to accede MRA (Mutual Recognition Arrangement of Product Registration Approvals), but to date, we have not made significant progress. We are concerned with the MRA timing as ACD will be fully implemented in less than 18 months.

We wish to seek confirmation from Malaysia of their interest to accede MRA with the Philippines and get guidance from ACC whether the MRA needs to be pursued considering the timing.

ii. PMS/ Safety Evaluation /GMP

The Philippines is committed to conduct a complete program for information dissemination and training of both regulators and the cosmetic industry on ACD, Product Notification, PMS2/3, PMS 1 and GMP. We are focused to deliver our commitment to be ready for ACD implementation by 01 January 2008. However, we are constrained with our minimal resources to execute - the past programs have been conducted successfully with international support, as well as assistance from the industry.

We request the ACC and the ASEAN Secretariat to continue working with our international partners to provide assistance to ASEAN in terms of building infrastructure needs, to implement ASEAN Cosmetic Directive. This will enable ASEAN and the countries to pursue the critical regional and national programs.