5th ASEAN Cosmetic Committee Meeting
7-8 December 2005, Brunei Darussalam

PROGRESS REPORT
SINGAPORE

Implementation of ASEAN Harmonized Cosmetic Regulatory Scheme – ASEAN Cosmetic Directive

1. Anticipated Challenges

From on-going dialogue with our stakeholders and internal discussions, there are three main challenges in the implementation of the ASEAN Cosmetic Directive:

a. Product Notification System

As the volume of cosmetic products is anticipated to be large, product notification will be implemented in 4 phases to be spread over a 2 to 3-year timeframe. This would also allow sufficient time for the industry to prepare for the implementation.

The existing pre-market approval process will be replaced by a product notification system. As the intention of the Directive is to place the responsibility of ensuring product safety on the company that markets the product, self-regulation by the cosmetic industry to ensure compliance with the safety and quality criteria, becomes an important part of the regulatory regime.

Steps have to be taken to educate the industry that product notification is not merely an administration procedure to satisfy the regulatory authority. Thus an acknowledgment of receipt of product notification does not mean the regulatory authority approves or endorses the cosmetic product being notified. Product notification involves an upfront declaration of compliance with the requirements of the ASEAN Cosmetic Directive by the company responsible for placing the product in the market. As such cosmetic traders would have to be conversant with the requirements of the Directive, including the Annexes of banned and restricted ingredients as well as permitted ingredients, and ensure that due diligence has been carried out to ensure that the product does not cause harm to Singapore consumers and is made according to the ASEAN GMP guidelines for cosmetic products.

Through the local cosmetic industry association and frequent dialogue sessions with our industry stakeholders, the regulatory authority hopes to emphasise the important role of self-regulation by the industry and their responsibility to ensure product safety and quality.

b. Manufacturers lacking the capacity and resources to comply with the Cosmetic GMP requirements

There are an estimated forty SME manufacturers who require guidance and assistance on the requirements of the ASEAN Cosmetic GMP Guidelines. These industries will require time to improve their internal processes, procedures and setups.

c. Cosmetic importers and distributors have difficulty to obtain the information required for Product Information File

It is anticipated that many SMEs might face difficulty in obtaining the required information to draw up each Product Information File from their suppliers, especially in the case of imported products. Both raw material suppliers and importers need to have a full understanding of their responsibilities in complying with this requirement.

2. Dissemination of information and requirements to the Cosmetic Industry

A second briefing session for industry stakeholders was conducted in September 2005, during which they were informed of the implementation of the ASEAN Cosmetic Directive & its requirements. Cosmetic raw material suppliers, the spa industry, members of the Cosmetic, Toiletry & Fragrance Association of Singapore and other cosmetic traders were invited. More meetings are being planned for 2006, and would include sessions for local cosmetic manufacturers.

The regulatory authority has updated its website to inform the public and industry of the implementation of the ASEAN Cosmetic Directive. The ASEAN technical documents have been posted on the website to enable the industry to download and print for their information.

3. Capacity Building on Post-marketing Surveillance and Product Safety & Efficacy Evaluation

A 2-day workshop was conducted on Post-marketing Surveillance (Product Safety & Efficacy Assessment; Product Information File) in November 2005. The workshop was well-attended and included participants from the cosmetic industry, academia and the regulatory authority. The feedback from the industry was positive and depending on demand, 2 more similar workshops are in the pipeline for the first half of 2006. In addition, the GMP sub-committee which comprises trainees who have attended the recent GMP training in EU plus other nominated industry representatives, are planning a GMP workshop for cosmetic manufacturers in the first quarter of 2006.

4. Internal sessions with other regulatory divisions on the implementation of ASEAN Cosmetic Directive

On-going discussions are being held to address the disparity in the current regulations with the requirements of the ASEAN Cosmetic Directive. These include skin whitening products containing hydroquinone and tooth-whitening products containing more than 0.1 % hydrogen peroxide, both of which are currently controlled as cosmetic products.