

## Summary report of the 8<sup>th</sup> meeting of the ASEAN Cosmetic Committee (ACC)

The meeting was held on June 13-14, 2007 in Vientiane, Lao PDR.

### Highlights of ASEAN meetings

- At the 13<sup>th</sup> ASEAN Economic Ministers Retreat it was agreed for a single and coherent blueprint to be developed for advancing the AEC (ASEAN Economic Community) to meet the accelerated target in 2015. An ASEAN Charter is also to be developed to provide a broad direction for ASEAN economic integration beyond 2015. Both documents are expected to be signed at the 13<sup>th</sup> ASEAN Summit to be held in November 2007.
- At the 29<sup>th</sup> ACCSQ meeting, it was agreed to endorse the final draft mechanism to monitor the implementation of ASEAN Policy Guideline on Standards and Conformance. The ASEAN Cosmetic Committee (ACC) was also commended for the progress on the implementation of the ASEAN Harmonized Cosmetic Regulatory Scheme (AHCRS), especially on GMP and Post Marketing Surveillance.

### Outcome of the ACC Heads of Delegations Meeting

- The meeting was held in Jakarta, Indonesia on May 9-10, 2007 and attended by the representatives of all ASEAN countries, with the exception of Myanmar.
- Member countries that have not transposed the ASEAN Cosmetic Directive (ACD) were urged to make extra effort in ensuring that the transposition to local regulations be completed by January 2008.
- Member countries have also been asked to ensure that technical documents and documents that have been adopted by the ACC are not modified when they are transposed into local regulations. Countries are to notify and seek the approval of the ACC in the event that they would like to make changes to the documents.
- It was also agreed that with regards to Article 4.1, all amendments made to Annex II of the EU Directive be adopted with immediate effect after circulation by the ACSB Secretariat. Countries are to respond immediately upon receipt of the circulation if they would like to raise concerns.
- It was confirmed that cosmetics for hotels and spas, including products used within the spa facilities, are to come under the scope of the ACD. Products for use in dermatology clinics will however be further discussed, while products produced for research will be exempted from the scope of the ACD.
- As with regards to scope of products that will be allowed the 36-month grace period, it was agreed that the grace period would be applicable to products of the same brand and name as products that have been on the market before ACD implementation, as long as the product will continue to be classified as cosmetics under the ACD. Companies with products that are not compliant to the ACD are advised to consult with their local regulatory authority for discussion on a case-by-case basis.
- The need for the following was also identified
  - > Guidelines on the Product Information File (PIF)
  - > Common criteria and principles to be used by regulators for conducting post market surveillance
  - > Organization of on the job training for regulators
  - > Setting up of a network for testing laboratories
- With regards to labeling, it was agreed that

- > Countries should start to allow companies to modify their labels to meet the requirements of the ACD, even if they would be non compliant to current country regulations.
- > Companies can choose to label “expiry date” or “best before date” and that regulators should not demand stability date before products are placed on the market
- Singapore was tasked to come up with the updated notification for presentation at the upcoming ACC meeting.
- It was deemed necessary to put in place a mechanism to ensure confidentiality of information shared under the Post Marketing Alert System (PMAS)
- It was also clarified that all modifications to the ACD Annexes approved by June 14, 2007 will be implemented on January 1 2008, while modifications done after this date will be given a grace period based on ACSB recommendation and ACC approval.

#### Updated to the Cosmetic Notification Template

- Following changes were proposed
  1. 2 sections were added to include particulars of the importer and particulars of storage facilities (section on storage facilities to be a Singapore specific requirement)
  2. Clause added to state that service providers are required to provide a letter of authorization
  3. Declaration section amended to introduce separate declarations for “New Product and Existing Product (marketed before 1 Jan 2008) that comply with ACD” and for “Existing Product (marketed before 1 Jan 2008) that does not comply with ACD”. The latter will allow the companies to initiate case-by-case discussions with the local regulatory authorities on whether the 3-year grace period will be applicable to the specific product. (Singapore specific requirement)
  4. To add to the responsibility of the person notifying, a clause stating that the company will recall or cease to sell the product if directed by the Authority
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#### Clarification on Notification Timelines for Existing Products

- It was agreed that
  1. Products meeting the ACD requirements and are already registered with the authorities will only require notification upon the expiry of the existing registration
  2. Products meeting the ACD requirements and are already registered/notified without validity period will require notification by January 1, 2011
  3. Product meeting the ACD requirements but has not been notified or registered with the authorities can also remain in the market in the respective countries up to December 31, 2010. The timing for their notification will be decided by the individual regulatory authorities but will be no later than December 31, 2010
  4. Products no longer fitting the scope of cosmetics under ACD definition or Annexes requirements, regardless of whether they have been registered/notified will need to be notified no later than January 1 20011.

#### Country updates on the implementation of the ASEAN Harmonized Cosmetic Regulatory Scheme (AHCERS)

- Each country presented their status on the transposition of the ACD into the local regulations, the building of infrastructure in preparation for the implementation of the ACD,

as well as local activities that have been carried out over the last 6 months to train local industry and regulators on the ACD.

- Brunei has started the drafting of the Cosmetic Rules and Regulation
- Indonesia is currently awaiting the passing of the umbrella regulation, under which the ACD will be transposed. Deadlines for notification and labeling changes will be developed and announced to the industry before 2008
- Malaysia has completed the draft amendment to the existing legislation to allow for transposition of the ACD requirements into local law.
- Singapore will be implementing the AHCRS under the new Health Products Act on January 1, 2008. Post-implementation, notification for existing products will take place over 4 phases within the ACD grace period timeline.
- Thailand is preparing to issue an amendment to set temporary notification procedures for controlled cosmetics, before the amended Cosmetic Act is promulgated near January 1, 2008.

#### ASEAN Cosmetic Directive Guidelines for PIF

- The PIF workshop was conducted in Vientiane, Laos on June 10-11, 2007
- The guidelines are intended to provide to companies recommendations on how to compile and organize the PIF, while providing guidance on who is responsible to keep the PIF and for PIF audits
- Key points from the guidelines include
  1. The company or person keeping the PIF needs to have an address in the local market
  2. It is recommended that the PIF be kept for a minimum of 3 years after the product is last placed in the market
  3. Part I of the PIF should be made readily available while other parts of the PIF should be made available, upon regulatory authority approval, within 15-60 days depending on the urgency of the audit
- A PIF mock up and PIF training module will be developed as follow up to the workshop
- The PIF guidelines were adopted by the ACC

An ACC Heads of Delegates meeting is scheduled to be held in September 2007.

The next meeting will be held in December 2007, in Viet Nam. Venue and date will be communicated in due course.