



**REPORT OF THE THIRD MEETING OF THE  
ASEAN COSMETIC COMMITTEE (ACC) HEADS OF DELEGATIONS MEETING  
4-5 March 2008, Jakarta, Indonesia**

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**INTRODUCTION**

1. The 3<sup>rd</sup> ASEAN Cosmetic Committee (ACC) Heads of Delegations Meeting was held from 4-5 March 2008, in Jakarta, Indonesia.
2. The Meeting was attended by representatives from Brunei Darussalam, Cambodia, Indonesia, Lao PDR, Malaysia, Philippines, Singapore, and Thailand. Representatives from the ASEAN Secretariat, the ASEAN Cosmetic Association (ACA) and an expert from APRIS II were also in attendance. The list of participants appears as **ANNEX 1**.

**AGENDA ITEM 1: ADOPTION OF AGENDA**

3. The Meeting adopted the Agenda, which appears as **ANNEX 2**.

**AGENDA ITEM 2: REVIEW OF THE STATUS OF ACD IMPLEMENTATION**

**2.1 Update on Status of ACD Implementation at National Level**

**2.1.1 ACD Implementation - Industry's feedback**

4. The representative from the ASEAN Cosmetic Association (ACA) gave a presentation on their findings on the current status of the cosmetic industry in ASEAN with emphasis on the implementation on the ASEAN Cosmetic Directive (ACD) in Member States and the industry's concerns that need to be addressed. The presentation appears as **ANNEX 3**.
5. The ACA expressed its appreciation for the efforts by the Member States who have already implemented the ACD within the stipulated timeframe. The ACA also shared the concerns and difficulties of other Member States who were yet to implement the ACD.
6. The Meeting noted the concern of the ACA on the potential political, economic and social impacts of any delays in the implementation of the ACD. The Meeting noted the potential risk of trust by the business community worldwide with possible business interruption for the entire cosmetic industry. There could also be a possible relocation of investment of industry into Member States that have less administrative and regulatory burdens. This may also have an impact on other harmonisation activities in ASEAN.

7. The Meeting noted recommendations made by ACA as follows:

- a) develop a mechanism to address problem associated with the implementation of the ACD in a quick and effective manner;
- b) adhere to the decisions of ACC;
- c) any change or new requirement proposed by Member States and subsequently agreed by the ACC should be in line with the provision of the WTO TBT Agreement and the ASEAN Policy Guideline on Standards and Conformance to allow companies “reasonable time” to adjust their production or business plan; and
- d) maintain good partnership between regulatory authorities and industries to address and find solutions on problems that may arise with the implementation of the ACD.

8. ACA further highlighted that the implementation of ACD by all Member States is very important as the role model for other sectors as well towards the realisation of ASEAN Economic Community by 2015.

9. The Meeting agreed to address the industries’ concern under the respective country reports.

### **2.1.2 Report from Member States that have not yet implemented the ACD**

10. Brunei Darussalam, Cambodia, Indonesia, Lao PDR, and Thailand presented the progress made on the implementation of the ACD in their states. The Meeting also noted the report from Vietnam. The presentations appear as **ANNEXES 4, 5, 6, 7, 8 and 9** respectively.

#### **Brunei Darussalam**

11. The legislation for regulating cosmetic products i.e. Medicines (Cosmetic Products) Regulations 2007 has already been approved and gazetted in early 2008. The Ministry of Health is authorised to implement the ACD by 1 January 2008. Brunei Darussalam has targeted 1 April 2008 as the date for receiving notifications.

12. The Meeting noted questions raised by Brunei Darussalam and clarified as follows:

- a) For products which involve a change in product presentation, e.g. when a few shades of lipstick are later changed or packed into palettes, the company should submit an amendment to the previous notification.

- b) For combination of products in a single kit e.g. facial wash, facial toner, facial moisturizer, perfume, which does not carry a specific combined product name, there should be a separate notification for each product.
- c) For combination of products in a single kit e.g. facial wash, facial toner, facial moisturizer, perfume, which carries a specific combined product name, only one notification will be needed. Nevertheless, the industry can also choose to submit more than one notification as desired.
- d) For combination of products in a single kit that contains a few products which have been notified and a few that have not been notified e.g. lipstick (notified), blusher (notified), eye shadow (not yet notified) and mascara (not yet notified), there should be a new notification for the product.

13. Brunei Darussalam also sought guidance on the difficulty faced by the cosmetic importers to obtain the PIF when they import products from companies who are not the product Authorization Holders, the Meeting reiterated the earlier decision made by the ACC that the company that places the product in the market shall be responsible to ensure that the required information is available for PIF inspection.

### **Cambodia**

14. The transposition of the ACD into the existing Sub-Decree on Cosmetic Management has been finalized and translated into National language (Khmer language) after consultation with legislators within the Ministry of Health. The draft was submitted to the Cabinet of the Government for consideration and discussion in Inter-Ministries meeting. At the end of first quarter of 2008 is the expected date of receiving approval from the Prime Minister and then will come into force and gazetted by the end of first quarter of 2008. Nevertheless, the products notification system has been put in place starting from 1 January 2008, whereas 450 application forms for products notification has been received until end of February 2008. The products notification will receive the approval at the Ministerial level after the new legislation is signed by the Prime Minister and enters into force.

15. The Meeting raised its concern on the requirements for the notification to be approved at the Ministerial level which may lead to a delay in the notification procedure. The Meeting noted the normal protocol of acknowledgement of notification by the Food and Drug Authority. In this regard, Cambodia agreed to bring this matter up to the Ministry for further consultation.

### **Indonesia**

16. Indonesia is yet to transpose the ACD into her national legislation due to some considerations of several internal issues by the relevant regulatory authorities. Internal assessment has concluded that the small and medium enterprises (SMEs) are not ready

to implement the ACD as they may not be able to fulfil the Good Manufacturing Practice (GMP) requirements of the ACD.

17. Indonesia also raised her concern with regard to consumer awareness in identifying products that meet the quality and safety requirements in the absence of notification numbers on these products. Indonesia proposed to print notification numbers for cosmetic products marketed in Indonesia during the grace period to assist in the post market surveillance of these products. The Meeting noted the industries' concern that this will burden the consumers as the printing notification numbers on labels will add to the cost of the products and the cost incurred will be added to the products.

18. Indonesia further requested the guidance of the Meeting to handle the flooding of imported cosmetic products into Indonesia which may have an effect on the SMEs with the implementation of the ACD. The ASEAN Secretariat informed the Meeting under the WTO TBT Agreement provisions, all Member States will have to adhere to the national treatment of products, however the Rules of Origin (ROO) could be used to support the local industry.

19. The Meeting raised concerns on the delay of the implementation of the ACD by Indonesia which may have an impact on the credibility of the ASEAN commitment to implement agreements and urged Indonesia to accelerate the ACD implementation process.

20. Indonesia informed the Meeting that further national consultations will be held before providing a firm commitment on the date of implementation of the ACD. The Meeting also noted that while the ACD is to be implemented, Indonesia will try her best to implement as much as possible the provisions of the ACD by all means, starting with the acceleration and simplification of the current registration procedures.

21. The ASEAN Secretariat informed the Meeting that the ASEAN Dialogue Partners as well as Donor Agencies would be willing to provide further assistance to Member States and Indonesia can make request for technical assistance especially on the GMP to assist the local industry to meet the ACD requirements.

### **Lao PDR**

22. Lao PDR update the Meeting that she was ready for the implementation of the ACD and notifications will begin on 1 April 2008 upon approval of the Cosmetic Legislation by the Ministry. Lao PDR has also made an inventory of all cosmetic products that have been placed in the market.

### **Thailand**

23. The new Cosmetic Act which is aligned with the ACD is still under the drafting stage. In the interim, the current Cosmetic Act will still be used for enforcement and the

adaptation of Ministerial Announcements related to the List of Cosmetic Ingredients and the amendment of the Ministerial Regulation on the cosmetic notification template will be used. The Thai FDA authorities have requested for the submission of application forms together with the Notification Template with effect from 1 March 2008.

24. The Meeting noted the update from ACA on Thailand's request for information on the function of some ingredients such as preservatives and ingredients used in sunscreen products at the point of notification and the different requirements for labelling. Thailand will take this matter back to the Thai Cosmetic Committee to convince them to ensure compliance with the ACD.

### **Vietnam**

25. Vietnam has completed the transposition of the ACD into the Vietnamese Cosmetic Regulation which was signed by the Vice Minister of the Ministry of Health on 30 December 2007. The regulation will come into effect on 10 March 2008.

26. The Meeting commended the commitment of Vietnam to meet the timeframe for the implementation of the ACD despite the above concerns and encouraged the other Member States who are yet to implement the ACD to do so too.

27. The Meeting noted the following issues from Vietnam's report with regard to the implementation of the ACD:

- a) To enhance the capability of the regulatory staff across the countries, especially those of provincial Departments of Health;
- b) The lack of official safety assessment centers for cosmetic products in Vietnam;
- c) The cosmetic industry in Vietnam is not ready to comply with GMP requirements of the ACD.

### **2.1.3 Experience sharing with Countries that have already implemented the ACD**

28. Malaysia, Philippines and Singapore presented the progress made on the implementation of the ACD in their states. The presentations appear as **ANNEXES 10, 11 and 12** respectively.

### **Malaysia**

29. The notification system has been put in place with effect from 1 January 2008. The National Pharmaceutical Control Board must be notified of new cosmetic products before placing the products in the market complying with ACD requirements. Existing cosmetic

products, i.e. products already registered with MAL No. will require notification upon the expiry of the existing registration validity period.

30. Malaysia further highlighted challenges that will be faced by the both the regulators and industry as follows:

- a) Free movement of cosmetic products in ASEAN during the post-ACD era which will lead to the following:
  - i. Potential flooding into the market of unauthorized import products due to easier notification process;
  - ii. Possibility of exposure of consumers to substandard products that make baseless claims;
  - iii. Potential of market competition with non notified products-no registration number to indicate whether or not a cosmetic product has been notified;
- b) Post Market Surveillance requirements:
  - i. The need for regulators to develop competency and capability for Post Marketing Surveillance (PMS)
  - ii. Lack of infrastructure and services in Malaysia for product testing and safety assessments.
  - iii. Lack of training infrastructure and services in Malaysia to develop competent internal personnel in product testing and assessments.
- c) Compliance to the requirements of Product Information File (PIF):
  - i. Difficulty in complying particularly to safety assessment and efficacy support requirements;
  - ii. Lack of understanding of some industry players with regards the dos and don'ts for cosmetic products claims.
- d) Difficulties in penetrating some ASEAN markets due to non-harmonisation of regulatory control of cosmetics despite ASEAN agreement for full implementation of ACD by 1 January 2008;

31. Malaysia further explained that the Certificate of Analysis (CoA) was needed for skin whitening products to be submitted to the NPCB within one month after the notification has been made. Malaysia took note of the concerns from the other Member States on this requirement and informed the Meeting this was part of the post market surveillance requirement.

32. Malaysia also informed the Meeting that "douche" (vaginal cleanser) is temporarily classified as a cosmetic due to insufficient data to classify it as a pharmaceutical product. The Meeting clarified that "douche" is not a cosmetic product as it does not satisfy the definition of a cosmetic product.

33. Malaysia also sought clarification on the use of alpha-arbutine in cosmetic products which might lead to the presence of hydroquinone when hydrolysed. The APRIS II expert informed the Meeting that this ingredient was widely used in cosmetic products at concentrations of the order of 3% and the appropriate method of analysis should be used to avoid the interference with hydroquinone.

34. The Meeting agreed that the above technical issues should be further discussed at the next ASEAN Cosmetic Scientific Body (ACSB).

### **Philippines**

35. The Philippines informed the Meeting the ACD is already implemented and efforts are being taken to reduce the lead time for acknowledgement of notification from seven to three days especially after March 2008 when all the existing products have been notified.

36. The Meeting also noted the requirement for License to Operate (LTO). Philippines clarified that the licensing and registration are two different categories which are handled by two different divisions. The cosmetic industry in the Philippines is not against the LTO but to streamline the requirements that may be contrary to the requirements of the ACD.

### **Singapore**

37. Singapore informed the Meeting that the ACD has been implemented beginning 1 January 2008. The Meeting further noted that several initiatives at the national level were carried out in 2007 in preparation for the implementation of the ACD such as media briefing, industry consultation and outreach.

38. The Meeting also noted the new updates on the implementation of the ACD as follows:

- a) There will be no change in product fees for one year but new notifications of higher risk products (previously Category I) will be charged \$15 and \$10 for re-notification, while there will be no charge for notification of lower risk products (previously Category II).
- b) The new fee structure for 2009 will be announced to the industry in 2008.
- c) Continued engagement with industry through dialogue sessions, briefings & workshops, leveraging from the support from the Cosmetic, Toiletry & Fragrance Association of Singapore (CTFAS) and other related associations to facilitate smooth implementation of the ACD.
- d) On-going consumer advisories on cosmetic safety issues, i.e. working with Consumer Association of Singapore to enhance safety in the use of hair dyes.

- e) Continued involvement and commitment in ASEAN cosmetic activities such as hosting of the 11th ACC Meeting from 17-21 November 2008.

### **AGENDA ITEM 3 CAPACITY BUILDING**

39. The APRIS II Expert presented to the Meeting the activities that have been conducted as well as future projects to be implemented in some Member States. The presentation appears as **ANNEX 13**.

40. The Meeting noted that under the APRIS II framework for technical assistance, there are provisions for technical assistance for Member States at both regional and national levels. The Meeting noted that under this phase of technical assistance at the national level, the APRIS II only covers the expense for the expert, while the Member States will have to bear the expenses for their respective participants.

41. In this regard, the Meeting requested ASEAN Secretariat to seek possible funding from other sources in order to support the implementation of ACD.

42. The Meeting noted the following requests from Member States for further training:

- a) Lao PDR requested training on increasing the awareness of the ACD for the Regulators, Customs and Economic Police Personnel.
- b) Indonesia requested training on the GMP for the SMEs.
- c) Philippines requested training on the conduct and evaluation of clinical studies to substantiate claims in relation with PIF.
- d) Vietnam requested more training for regulators especially in PIF, Safety assessment, support for the Drug Quality Control in establishing the safety assessment center and GMP audit and trainings for cosmetic companies

43. The APRIS II expert proposed a regional training in Singapore to include a module on e-notification by the Singapore authorities.

44. The Meeting also noted the proposal from Singapore to extend the relevant trainings to cosmetic products importers as well for the overall smooth implementation of the ACD.

### **AGENDA ITEM 4: ISSUES TO BE RAISED TO ACCSQ AND SEOM**

45. The Meeting sought the assistance of the ASEAN Secretariat in collaboration with the ACC to ensure that the non-implementation of the ACD among Member States be

made transparent in the spirit of ASEAN. This is also in line with Article 10.1 of the ACD where the ACC shall coordinate, review and monitor the implementation of the ACD.

46. The ASEAN Secretariat was requested to brief the SEOM on the progress made on the implementation of the ACD by Member States including the difficulties faced some Member States to implement the ACD.

47. The Meeting noted that the Chair will be unable to attend the 31<sup>st</sup> ACCSQ Meeting to be held from 18-20 March 2008 and as such the Co-Chair and the Secretary of the ACC were requested to attend the Meeting to update the ACCSQ on the progress of the activities of the ACC with special emphasis on the implementation of the ACD and the problems faced by Member States.

## **AGENDA ITEM 5: OTHER MATTERS**

### **5.1 Eye lash perming products**

48. Singapore raised the issue on classification of eyelash perming products. The Meeting noted that based on the ingredients, eyelash perming products could be categorized as cosmetic. In this regard, the Meeting agreed that this should be further discussed at the next ACSB.

### **5.2 Period after opening**

49. The Meeting noted that 7<sup>th</sup> Amendment of the EU Cosmetic Directive, there is a provision for “period after opening” (PAO) to identify the period for which cosmetic products can be used after opening. Since, the ASEAN Cosmetic Directive is modeled after the 6<sup>th</sup> Amendment of the EU Cosmetic Directive, the Meeting requested the ACSB to look into this matter and provide recommendations on the adoption of the amended requirements for the PAO to the ACC for their consideration.

50. Singapore was requested to circulate the relevant information on PAO to all the ACSB members.

### **5.3 Issues to be considered for effective implementation of the ACD**

51. Having reviewed the progress made by the Member States on the implementation of the ACD, the Meeting agreed on the importance of an effective Post Market Surveillance and Alert System to complement the implementation of the ACD.

52. Singapore reminded the Meeting to adhere as far as possible to Article 12.2 of the ACD which stipulates that Member States may, for a period of 36 months from the implementation of the ACD, authorise the marketing of the existing products within their territory.

### **5.4 Date and venue of future ACC Meetings**

53. The Meeting noted that the 10<sup>th</sup> ACC Meeting will be hosted by Indonesia and the 11<sup>th</sup> ACC Meeting will be hosted by Singapore from 17-20 November 2008. Indonesia will confirm the exact date and venue in due course.

54. Thailand indicated that she will be able to host the 13<sup>th</sup> ACC Meeting in December 2009.

#### **AGENDA ITEM 6: ADOPTION OF REPORT**

55. The Meeting considered and adopted the report of the ACC Heads of Delegation Meeting held from 4-5 March 2008 in Jakarta, Indonesia.

#### **ACKNOWLEDGEMENTS**

The Meeting expressed its sincere appreciation to the expert team of the APRIS II for their valuable technical support and to the ASEAN Secretariat for its facilitation and arrangements for the Meeting.

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