ANNEX 14

Report on the Status of Echo Seminar on GMP at National Level – Singapore

1. The Health Sciences Authority (HSA) of Singapore has jointly conducted a GMP workshop on ASEAN Guideline for Cosmetic GMP with the Cosmetic, Toiletry and Fragrance Association of Singapore (CTFAS) at Le Meridien Hotel, Singapore on 4th & 5th May 2006.

2. The workshop was organised with the objectives to familiarise the industry with the requirements stipulated in the ASEAN Guidelines for Cosmetic GMP and to consult the industry in particular the SMEs on the challenges which they may face with the implementation of GMP via Q&A sessions and a survey that was carried out during the workshop.

3. The workshop was opened and addressed by Mr Sia Chong Hock, the Deputy Director, Manufacturing and Quality Audit Division of Health Sciences Authority. Mr Sia provided an overview of the ASEAN Cosmetic Harmonised Regulatory Scheme as well as the forthcoming plans and changes. He also highlighted that factors such as product formulation, process design, process control and quality of starting materials are as important as GMP in assuring quality in the finished product.

4. Other than the regulatory officers from HSA, the trainers' panel also comprised of GMP experts from the academic institutions and industry. The workshop was attended by a total of 71 participants who came from various sectors. Among them, there are importers, manufactures, assemblers, academic lecturers as well as GMP consultants.

5. The workshop had covered all the 13 ASEAN Cosmetic GMP training modules as well as the key requirements of the ASEAN Cosmetic Directive. The detailed programme is attached at Annex 1.

6. Questions were raised during the workshop. Below are some of the major concerns expressed with regard to the GMP requirements:

(a) As it was mentioned in the ASEAN Guideline that chemical and microbiological properties of the water were required to be monitored, some participants opined that the limits with regard to those aspects should be standardised and clearly spelt out.

(b) Clarification was sought with regard to the appropriate storage conditions for products that were not labelled with the recommended storage conditions.

(c) Clarification was sought with regard to the conditions under which environmental monitoring should be considered necessary.

7, Questionnaires were distributed to the participants (see Annex 2) during the workshop with the intent to survey the readiness of the industry to implement GMP. From the survey results, the following findings were obtained:

(a) The workshop was well received by the participants. 93% expressed that the GMP workshop was either quite or very beneficial in providing them the understanding of GMP requirements. 98% of the participants indicated that they would recommend others to attend this workshop if it were to be held again in future.

(b) None of participants opined that GMP was not important for the manufacture of cosmetic products. 60% of the participants opined that GMP was very important and 38% opined that GMP was quite important whilst 2% opined that it was somewhat important.

(c) 39% of the manufacturers being surveyed opined that they have either met or exceeded the basic GMP requirements, whilst another 39% of them indicated that they complied with some of the basic requirements and 22% said that they were still far from meeting the basic requirements.

(d) Majority (i.e.73%) opined that they could either be ready by 2007 or 2008. However, the rest of them indicated that they could only be ready in 2009, 2011 or 2015.

(e) The challenges faced by industry with regard to the implementation of GMP included the following: lack of trained personnel, lack of time due to busy work schedule, lack of financial resources, extra work/cost involved to convert the labelling into English which was a product labelling requirement in Singapore, need to ensure that the overseas manufacturers comply with the ASEAN GMP guidelines, need to source from manufacturers which have GMP standards that are in line with the ASEAN Cosmetic GMP requirements.

(f) 70% of the manufacturers responded and expressed that they would embark on some forms of immediate action plan in order to comply with the GMP requirements. The action plans included outsourcing the work to manufacturers who are able to comply with ASEAN Cosmetic GMP, to source products from GMP complaints manufacturers, engaging the help from consultants and setting up a new GMP compliant plant.

8. In order to assist the industry in the implementation of GMP for the manufacture of cosmetic products, another round of echo seminar may be carried out at the suitable timing depending on the industry's need. In addition to this, we will look into the feasibility of conducting a round of visit to the local cosmetic manufacturers in 2007 &2008 to assess the progress made by the industry. We will also explore the feasibility of working with the academic institutions to provide in-depth training on specific topics.

ANNEX 14

ANNEX 1

WORKSHOP ON ASEAN GUIDELINES FOR COSMETICS GMP
Le Meridien Orchard Hotel
Latite Room & Latour Room (Level 3)
4-5 May 2006

4 May (Thursday)

8.30am -9.00am	Registration	
9.00am -9.15am	Opening Address	Sia Chong Hock
9.15am -9.30am	Introduction to ASEAN Cosmetics Directive	Suzie Quek
9.30am -10.15am	Quality Management	Hui Foong Mei
10.15am-10.45am	*Break*	
10.45am -11.15am	Personnel	Stephanie Chan
11.15am -12.00pm	Premises	Ronald Goon
12.00pm -12.30pm	Questions & Answers Session	
12.30pm -1.30pm	*Lunch*	
1.30pm -2.15pm	Equipment	Stephanie Chan
2.15pm -3.00pm	Sanitation and Hygiene	Stephanie Chan
3.00pm -3.30pm	*Break*	
3.30pm -5.00pm	Production	Ronald Goon
5.00pm -5.30pm	Questions & Answer Session	
5 May (Friday)		
9.00am - 9.30am	Documentation	Hui Foong Mei
9.30am -10.00am	Contract Manufacturing and Analysis	Hui Foong Mei
10.00am -10.30am	*Break*	
10.30am -12.00pm	Quality Control	Ronald Goon
12.00pm -12.30pm	Questions & Answers Session	
12.30pm -1.30pm	*Lunch*	
1.30pm -2.15pm	Internal Quality Audit	Lam Kok Seng
2.15pm -3.00pm	Good Storage Practice	Hui Foong Mei
3.00pm -3.30pm	*Break*	
3.30pm - 4.15pm	Product Complaint and Product Recall	Lam Kok Seng
4.15pm - 4.45pm	Questions & Answers Session	
4.45pm - 5.00pm	Wrap-up & Closing	Suzie Quek

Annex 2

SURVEY FORM

WORKSHOP ON ASEAN GUIDELINES FOR COSMETIC GOOD MANUFACTURING PRACTICE 4TH & 5TH MAY 2006

Dear Participants,
Please provide your valuable feedback to the questions below by ticking the appropriate boxes. Your inputs will be strictly confidential. Thank you!

Participant's Name (Optional): _____

Organisation (Optional):_____

Job Designation: _____

Type of business that your company is involved in (please tick):

☐ Manufacture ☐ Assembly ☐ Import ☐ Export

☐ Wholesale ☐ Retail ☐ Warehousing ☐ Education

☐ Consultancy ☐ Others (Please specify):_____

Type of cosmetic products that your company is manufacturing/handling (if applicable):

_____

_____

1. How beneficial is this workshop in providing you with the understanding of the GMP requirements for the manufacture of cosmetics?

   A. ☐ Very B. ☐ Quite C. ☐ Somewhat D. ☐ Not At All

2. Would you recommend others to attend this workshop?

   A. ☐ Yes B. ☐ No (Please specify reason:_____)

3 How do you rate the GMP compliance of your manufacturing plant now?

   A. ☐ Exceeds basic requirements (proceed to Q5)

   B. ☐ Meets basic requirements (proceed to Q5)

   C. ☐ Complies with some of the basic requirements only (proceed to Q4)

   D. ☐ Does not comply with most of the basic requirements (proceed to Q4)

   E. ☐ Not applicable (proceed to Q5)

4. If the answer for the above question is C or D, what would be the reasonable timeframe you require to comply fully with the basic requirement of the ASEAN Guidelines for Cosmetic Good Manufacturing Practice? By:

A. ☐ April 2007 B. ☐ January 2008
C. ☐ January 2011 D. ☐ Others (Please Specify:_____)

5. Do you think GMP is important for the manufacture of cosmetic?

A. ☐ Very B. ☐ Quite C. ☐ Somewhat
D. ☐ Not At All (Please provide reason:_____)

6. What is the best means do you think you could obtain the required knowledge for meeting the GMP requirements?

A. ☐ Engaging the service of consultant
B. ☐ Attending training /workshops
C. ☐ Employing the qualified and knowledgeable staff
D. ☐ Others (Please Specify:_____)

7. List 3 main challenges that your company would face in complying with the guideline ASEAN Cosmetic Good Manufacturing Practice (eg. lack of competent and trained staff, busy work schedule, etc)

_____

_____

_____

_____

_____

8. Does the company have any immediate plans to comply with the GMP guidelines? Please provide details:

_____

_____

_____

_____

_____

Appendix I – To complete this Form if your company is a local Manufacturer/Assembler/Contract Manufacturer

For the following questions, please respond with a tick (✓) in the "Yes" or "No" column. You may use "NA" (Not Applicable) if the question does not apply to your situation

Name of Company:

No	Question	Yes	No	Comments
1.	For assemblers, please tick the type of assembly activities involved: (a) Primary assembly only (b) Secondary assembly only (c) Both Primary and Secondary Assembly			
2.	Is your company ISO certified? If Yes, please specify the standard in the comments column			
3.	Do you currently manufacture: Category I cosmetic products? Category II cosmetic products?			
4.	Did any other regulatory authorities other than HSA audit your company? If Yes, please specify the authorities and date of last inspection.			
5.	Do you export your products to other countries? If Yes, please specify the countries			
6.	No of products (sku) manufactured/assembled			
7.	No of staff engaged for production, QC and warehousing? 1. < 10 2. <20 3. <30 4. <40 5. <50 6. Others. Please specify the number in the comment column			
8.	Do you have defined areas for the following? 1. Materials receiving 2. Material sampling 3. Weighing and Dispensing of starting material 4. Starting Materials Quarantine 5. Area for Processing 6. Area for Packaging			

	7. Quarantine area before final release of finished products 8. Laboratory			
9.	Do you monitor the store for: 1. Temperature 2. Relative Humidity			
10.	Do you have a system to clean and maintain your equipment			
11.	Do you calibrate your equipment			
12.	Do your production staff wear protective attire			
13.	Do you have a Pest Control program in place			
14.	What type of water do you use for production – please specify the grade (portable or purified water etc.)			
15.	Do you have a batch numbering system			
16.	Do you have a dust extraction system for handling of dry products			
17.	Do you practice line clearance prior to operation (i.e. all materials from previous operation are removed)			
18.	Do you test the following: (if yes, please state the tests done) 1. Starting material 2. In process material 3. Finished product			
19.	Do you have a system for handling Returned Products			
20.	Do you have a system for handling Recalled Products			
21.	Do you have a system for handling Complaints			
22.	Do you have Standard Operating Procedures (SOP) that bear step by step instructions			
23.	Do you have specifications for 1. Starting Materials 2. Finished Products			
24.	Do you have Batch Manufacturing Records			
25.	Do you have Quality Control Records			
26.	Do you have a Master Formula for each product			
27.	Do you conduct your own Internal Audits			
28.	Do you have written contracts establishing the duties and responsibilities of the contract giver and contract acceptor			
29.	Has anyone in your company gone for GMP related training in the past? If Yes, please provide their designations			

ANNEX 14