



International Trade Centre
UNCTAD/WTO



Cosmetic Post Marketing Surveillance Training Report to ACC Head of Delegations Meeting

Siem Reap, Cambodia

June 15-16, 2006

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Regional Training

Manila 8-11 May, 2006

- 31 participants:
 - 13 (11 regulators and 2 industry) from 7 other ASEAN Member Countries
 - 8 regulators from Host Country
 - 10 Industry representatives from Host Country
- Training provided by 3 ASEAN and 1 International Experts. The ASEAN Secretariat also served as resource person. Presence of ITC representative

Regional Training

Manila 8-11 May, 2006

- Objective:
 - Upgrade knowledge and understanding on ASEAN Cosmetic Directive and Post Marketing Surveillance for regulators and industry
 - Establish a good network of experts on PMS in Member Countries. The trained trainees at regional workshop are requested to cascade training at the national level with support from International and ASEAN Experts
 - Alignment between countries on requirements, expectations and follow-up actions

Regional Training

Manila 8-11 May, 2006

Mix of:

- Presentations
- Trade and Product audit
- Provided Product Information Files (PIF) audit
- Companies audit
- Quiz to evaluate the learnings from the training

Regional Training

Manila 8-11 May, 2006

- Feedback:
 - The training was appreciated and helpful
 - Q&A sessions were animated allowing for clarifications on how to perform a PIF audit
- Assessment:
 - Good opportunity for the Regulatory Authorities to understand actual market situation
 - Gap among the participants in understanding the ACD requirements
 - Some of the participants had not been involved in the previous PMS trainings: this limits the ability to cascade the training at the National level

National Follow-up

Calendar

- May 17 – 18: Malaysia (KL)
- May 22 – 23: Indonesia (Jakarta)
- May 25 – 26: Thailand (Bangkok)
- May 29 – 30: Philippines (Manila)
- June 1 -2: Lao PDR (Vientiane)
- June 5 – 6: Viet Nam (HCMC)
- June 8 – 9: Cambodia (Phnom Penh)

National Follow-up

- 200 participants have attended the trainings, 1/3 from Regulators; 2/3 from Industry
- 21 trained trainers conducted the trainings with International Expert and in 5 locations ASEAN Expert in attendance. The ASEAN Secretariat attended the training in Laos, Viet Nam and Cambodia
- Presentations and PIF from Regional Training were used

National Follow-up

- Market Samples audit on labelling compliance (existing and future)
- PIF audits
- Q&A sessions allowed to clarify some points around interpretation and implementation
- Quiz to evaluate the learnings from the training

National Follow-up: Feedback

- Showed the trainings were appreciated, good and helpful
- The sessions were a good exercise for the participants to better understand the ACD and its requirements in term of the PIF (how to build it, how to audit it)
- Participants are requesting further training

National Follow-up: Assessment

- Animated discussions,
- Build up good network between Regulators and Industry
- Good opportunity to understand the actual market situation and the need to put in place strong and effective PMS
- Good cascading by trainers under training of trainer scheme (in general). Some of the participants bgs did not have good training skills or good understanding of the ACD

Assessment & Observations

- While the training was positive, it only covered a very small fraction of the industry concerned: mainly MNCs while local manufacturers, distributors, spas, derm clinics, etc, are not always aware of the requirements. In some countries the industry was exposed to the requirements for the first time
- Not all the documents developed by ACC (e.g. GMP training modules, information booklet, etc) have been distributed to all concerned in several countries while this has started in other countries

Assessment & Observations

- In few countries, lack of human and financial resources from the Authorities to properly cascade training and disseminate the information to the industry
- In few countries absence of Industry Association and/or weak networking between the Industry and the Authorities
- In few countries consumers do not know where to go in case of adverse event i.e. no proper PMS
- In some countries, not strong legislations to support regulators to conduct PMS (strong enforcement power to penalize possibility to conduct unannounced audits, etc)

Assessment

- Some points require clarification in the ASEAN Directive:
 - Ingredient labelling language
 - Ingredient labelling order
 - Stability and expiry date

CONCLUSIONS

Strong need for a bird's eye picture of requirements:

For regulators

- Collaboration with Customs, Trade, Industry, Consumer, Police, etc. Ministries / Agencies
- Partnership with Industry Association (strong collaboration in some countries, not in others)
- Partnership with Consumers Associations
- PMS enforcement legislations/regulations
 - Counterfeiting legislations
 - Consumer protection legislations
 - **Product Liability legislations**

For Regulators

- Fully understand the market structure:
 - Visible distribution e.g. department stores, supermarkets, etc
 - Non visible distribution e.g. direct selling, Spas, Skin Clinics, in-shop manufacturing, hotel samples, etc
 - Smuggled products, parallel imports, adulterated cosmetics/cosmetics containing medicinal ingredients
- Consumer complaints have to be viewed in relation to the market share

For Industry

- Partnership among local and MNC's, manufacturers and distributors
- Partnership with Regulators
- Cascading the training among its members: help others comply
- Contribute to identify and eliminate dangerous producers
- Contribute to identify and eliminate counterfeiters
- Responsibility endorsement (PMS is based on Industry's responsibility)

For Industry

- Industry needs to present regulators with Market Structure i.e. market shares by:
 - Distribution segment
 - Companies
 - Brands

For Consumers

- Need for partnership between regulators, industry and consumers:
 - For education on safe and non safe products as well as safe use
 - For easy communication system to enable consumer to contact in case of complaints

Regional Regulatory Networking

- Member Countries:
 - Need for fast and easy communication in case of adulterated products
 - Need for mutual help in auditing companies located across borders
 - Need to strengthen the consultation and arbitration principles of Article 11 of the Directive

RECOMMENDATIONS

- Training needs to be further cascaded in all countries to cover all/most of those concerned. Based on an estimate of the number, this is a huge task to finish in 18 months. Maximize the trained trainers
- There is a need in all countries to have a full inventory of the companies concerned and make sure that they are exposed to the ACD requirements and all documents developed and approved by the ACC. This will also help the Regulators in PMS

RECOMMENDATIONS

- Infrastructure and competency to perform PMS:
 - Product audits including lab testing
 - PIF audits, including safety, GMP and efficacy assessment
 - Market and Companies premises audits
 - Complaints handling and actions
- Put in place the legislative requirements to perform announced or unannounced audits, take legal and other actions against non-compliant products/companies, make sure there are no other barriers (e.g. customs)

Forthcoming Activities

Semi Regional Follow-up PMS Workshops (ITC):

- Bangkok, 26-28 July 2006 for Cambodia / Laos / Thailand / Vietnam
- Jakarta, 8-10 August, 2006 for Indonesia / Malaysia / Philippines

Brunei and Singapore are invited to join (but not sponsored)

Forthcoming Activities

Semi Regional Follow-up PMS Workshops (PTB):

- Vientiane, 16-17 November 2006 for Cambodia / Laos /Myanmar/ Thailand / Vietnam; 1 participant from Brunei as ASEAN expert
- Jakarta, 20-21 November, 2006 for Indonesia / Malaysia / Philippines; 1 participant from Singapore as ASEAN expert

Forthcoming Activities

- Second Workshop on Product Evaluation Guidelines (PTB) prior to the ACSB-ACC meetings in November in the Philippines

Recommended criteria for participants selection

Objective: build up and strengthen network of qualified experts on PMS from regulatory authorities and industry

- Participants must have attended previous PMS trainings (regional or national)
- Equal number of participants between regulatory authorities (sponsored) and industry (non sponsored)
- Skilled trainers

Success

It' s in your hands !

