2nd Workshop on Good Regulatory Practice on Cosmetic Sector

13-15 March 2006, Jakarta, Indonesia

REPORT

Le Chau Giang
ASEAN Secretariat

Workshop Objectives

1. To complement and build on the objective of the 1st Cosmetic GRP Workshop held in June 2005 in Bangkok by:

   - ✓ Providing means to enhance capacity of ASEAN regulators to use standards and conformity assessment procedures in cosmetic sector, and
   - ✓ Soliciting inputs to the GRP Toolkit for the Cosmetic Sector

Workshop Objectives

2. To provide in depth information on principles of GRP and Risk Management in the context of the WTO TBT Agreement.

3. To facilitate the development of recommendation related to the implementation of the ACD

Participation in the Workshop

- All ASEAN Member Countries attended, except Myanmar
- Representatives from National Cosmetic Associations and ASEAN Cosmetic Association
- Representatives from Industry in some Member Countries also attended as observers.

Issues considered and discussed

- GRP and Risk Management:
  - ✓ *Generic Principles and Benefits of the GRP- WTO TBT*
  - ✓ *Generic Principles of Risk Management*
- Cosmetics Regulations- Lesson from others:
  - ✓ *EC, Australia, New Zealand, United States, Japan*
  - ✓ *Comparison between EC and other Regulatory Systems- GMP and Handling Borderline Products*
  - ✓ *Current legislation of ASEAN Member Countries on Borderline Products and their classification*

Issues considered and discussed

- Development of Recommendations to be considered by the ACC:

  - *WTO TBT Compliance*
  - *GMP Implementation in the context of the ACD*
  - *Borderline products between cosmetics and pharmaceuticals*

GPR Principles and Benefits
WTO TBT Agreement and ASEAN Policy on Standards and Conformance

Objectives:

* *…ensure that technical regulations and standards as well as conformity assessment procedures (e.g. GMP) do not create unnecessary obstacles to trade*

* *No country should be prevented from taking measures to ensures the protection of human, animal or plant life or health, or environment, or prevention of deceptive practices, at levels it consider appropriate, subject …not applied arbitrary or unjustified discrimination… disguised restriction on international trade…..*

GPR Principles and Benefits- WTO TBT and ASEAN Policy on S& C

In considering the development of technical regulations, the principles set out in the WTO TBT Agreement and the ASEAN Policy on Standards and Conformance can be used as guidance. While the TBT Agreement is mostly focused on trade issues it also recognizes the legitimate rights of countries to develop technical regulations to protect their citizens in regard to health, the environment, prevention of deceptive practices and essential security. These are all the elements of "consumer protection".

The issue of consumer protection in case of emergency is well reflected in Article 11 of the ACD.

GPR Principles and Benefits- WTO TBT and ASEAN Policy on S& C

Steps approach to development of technical regulations using the GPR Principles (11):

1. Identifying the problem
2. Assessing the risk
3. Considering the options whether the imposition of technical regulations is the best or only option?
4. Cost/ benefit analysis
5. Assessing trade impact
6. Performance based and equivalence rather then design or descriptive characteristics (are the proposed technical regulations too prescriptive and are these inhibiting innovation?

GPR Principles and Benefits- WTO TBT and ASEAN Policy on S& C

Steps approach to development of technical regulations using the GPR Principles (11):

7. Reference to standards
8. Compliance (should a conformity assessment process be put in place to ensure compliance?)
9. Types of conformity assessment (Formal certification/ approval? Self declaration?)
10. Undertake conformity assessment
11. Mutual Recognition Arrangements (Equivalency)

GPR Principles and Benefits- WTO TBT and ASEAN Policy on S& C

Core trade principle

Standards, conformity assessment procedures and technical regulations need to be equally applicable to locally and imported good and service

WTO TBT and ASEAN Policy on S&C in the context of the ACD implementation- GMP

ACD requires that all cosmetic products be manufactured according to ASEAN Cosmetic GMP Guideline and self declaration by manufacturer is allowed . The following issues were raised and discussed:

- *What are the impacts of the GMP Requirements on imported cosmetics?*
- *Will GMP in country of manufacturing be considered equivalent to ASEAN GMP Guideline?*
- *What evidence would be required to demonstrate equivalency?*
- *How will audits of OS manufacturers be carried out?*

WTO TBT and ASEAN Policy on S&C in the context of the ACD implementation - GMP

Options on GMP for consideration

Option 1:

Compliance with the ASEAN GMP requirements or with any other national or regional well established GMP procedures (recognition of equivalency between ASEAN GMP or other GMP requirements)

Option 2:

Proof of compliance by formal issuance of certification by Conformity Assessment Bodies which are accredited by accreditation bodies

WTO TBT and ASEAN Policy on S&C in the context of the ACD implementation - GMP

Option on GMP for consideration

GMP audit of OS manufacturers if required during PMS, the cost of any audit required by the relevant regulatory authorities is to be born by the company responsible for putting the product in the market

ACD and Borderline Issues Between Cosmetics and Pharmaceuticals

: Appendix III - ASEAN Cosmetic Claim Guidelines

Products are determined to be either “cosmetic” or “drug” based on two factors:

- Composition of the products, and
- The proposed use of the products

- Composition: products containing ingredients that are not allowed in cosmetics (from Annex II) that are at concentration higher than that allowed or that are allowed but for a different purpose (Annex III) are automatically classified as “drugs”
- Proposed use: Cosmetics must only make cosmetic claimed benefits; and not medicinal or therapeutic claimed benefits. Any cosmetic claimed benefits shall be aligned with that is accepted internationally and shall be justified either by technical data and/or cosmetic formulation or preparation itself.

ACD and Borderline Issues Between Cosmetics and Pharmaceuticals

Current Situation in ASEAN

Most of Member Countries are facing difficulties in classifying borderline products.

Products are classified on the basis of the composition and intended use (claims). Some countries also use the presentation.

The same product can be treated differently in different countries

ACD and Borderline Issues Between Cosmetics and Pharmaceuticals

Treatment of Some Borderline Products – Current and Future Classification (ACD)
C = Cosmetic, D = Drug, B = Borderline *must not contain a scheduled poison, + Depends on concentration of active/composition,
& = depends on use/claims Good Agreement No clear consensus

Category/decision --- Country	Mouth wash C	Anti-Cavity Toothpaste C	Anti-dandruff C	Skin wash C	Antiseptic	Sunscreen C	Personal lubricant C	Nasal cleaner	Skin whitening C	Acne C	Banned Ingredient	Restricted Ingredient	Anti-hair loss C
Brunei	C - C	C - C	C* – C*	C - C	D - D	C - C	? - ?	D - ?	C* – C*	C* – C*	D - D	C* – C?	C* – C*
Cambodia													
Indonesia	C - C	C - C	C/D+ – ?	? - ?	C/D – C/D$^{\&}$	C - C	Device	? - ?	C - C	C/D – C/D+	D - D	D - ?	C/D – C/D
Lao	C - C	C - C	C - C	C - C	D - D	C - C	C - C	C - C	C - C	B - C	D - D	C - D	C - D
Malaysia	C/D – C$^{\&}$	C/D – C$^{\&}$	D - C	D - C	D - D	C - C	Not Controlled	C - C	C - C	C/D – C$^{\&}$	D - ?	C/D - C	D - C
Philippines	C - C	C - C	C - C	C - C	C - C	C - C	D -D	D - D	C - C	C/D – C$^{\&}$	D - D	D - D	C/D – C/D+$^{\&}$
Singapore	C* – C*$^{\&}$	C - C	C - C	C - C	C - C	C - C	C- Device	D - D	C - C	D - D	D - ?	? - D	C/D – C/D+$^{\&}$
Thailand	C/D - ?	C - ?	C/D+$^{\&}$ - ?	C - ?	C/D+$^{\&}$ - ?	C - ?	? - ?	D - ?	C/D+$^{\&}$ - ?	C/D+$^{\&}$ - ?	D - ?	C - ?	C/D+$^{\&}$ - ?
Vietnam	C - C	C - C	C - C	C - C	C/D – C/D+$^{\&}$	C - C	C - C	D - D	C - C	D - C	D - D	C - C	C - C
Industry View	- C	- C	- C	- C	- C	- C	- C	- C	- C	- C	Not Cosmetic	Not Cosmetic	- C

ACD and Borderline Issues Between Cosmetics and Pharmaceuticals

Based on Appendix III of ACD, the Workshop recommended the following categories to be treated as cosmetics:

1. Mouth wash
2. Anti-caries toothpaste
3. Anti-dandruff
4. Skin wash
5. Anti-bacterial including rinse off
6. Sunscreen
7. Skin Whitening
8. Acnes
9. Anti- Hair loss
10. Anti- Cellulite
11. Bust Countering Cream

ACD and Borderline Issues Between Cosmetics and Pharmaceuticals

Other products, subject to further consideration and discussion:

- Personal Lubricant
- Nasal cleaner
- Anti bacterial leave on
- Slimming products
- OTC Products containing ingredients from Annex II or Annex III (above the limits or for a different use) such as hydroquinone, subject to consultation with PPWG

Other observations and recommendations

It is recommended that the ACC consider:

- the setting up of proper databases to collect information (such as product notification, company inventory, consumer complaints, etc.);

- determine what information will be made available to the relevant parties i.e. manufacturers/ suppliers, regulatory authorities, wholesalers, retailers of cosmetics and the community at large. It should be decided what information can be available for the general public and what information should be confidential and to whom and how the databases will be kept up to date and accessed

Other observations and recommendations

- Establishing guidelines on:

  - Post Market Auditing

  - What should be included in the PIF

  - What to look for in the PIF

  - Illustrative list of unacceptable claims for cosmetic product

Thank You!