Annex 1, Part 11

A GUIDE MANUAL FOR ADVERSE EVENT REPORTING.

Introduction:

Pursuant to the ASEAN Cosmetic Directive, Article 3 (1) and the Discussion Paper on Post Marketing Surveillance/Product Safety, adopted by the ASEAN Cosmetic Committee in its second meeting held in Bangkok June 7-8, 2004, it is important to harmonize the mechanism to gather and, if necessary, take action on important safety information arising from post marketing surveillance of cosmetic products.

Thus, agreed definitions and terminology, as well as procedures, will not only ensure uniform standards in the adverse event reporting process but will also facilitate product safety information sharing among ASEAN Regulatory Authorities.

There are two issues within the broad subject of safety data management that are appropriate for harmonization at this time:

- The development of standard definitions and terminology for key aspects of adverse event reporting, and
- The appropriate mechanism for handling adverse event reporting

This Guide shall be revised as necessary, to take into account technical progress and regulatory developments.

Definitions and terminologies

a. Adverse Event:

Any genuine harmful or unintended event reasonably attributable to the normal or foreseeable use of a given cosmetic product.

b. Serious Adverse Event:

A serious event is any untoward medical occurrence that:

• Results *in death,*
• Is life threatening *(*the term life threatening refers to an event in which the person was at risk of death at the time of the event;
• Requires in-patient hospitalization*, or*
• Results in persistent or significant disability/incapacity

Who should the industry report to?

The company or person responsible for placing the cosmetic product in the market shall report to the regulatory authority of the ASEAN Member State where the adverse event occurred, regardless of the source of the report (consumer, healthcare professional, etc).

What should be reported?

a. Every cases of serious Adverse Event:

All serious adverse events should be reported. Non-serious adverse events are not required to be reported.

Whenever there is reasonable suspicion that the cosmetic product might be the cause of the reaction, reporting is necessary for all serious adverse events as defined in section 2.2 The expression "reasonable suspicion" is meant to convey in general that there are evidences to suggest a causal relationship or an association.

b. High incidence of Adverse Event (Non-serious/severe reactions)

There are "non-serious" adverse events that occur at a high incidence (as defined by the ratio of events to units sold) of a single "severe" reaction type that may necessitate rapid communication to the regulatory authority. However, appropriate medical and scientific judgment should be applied for each situation of non-serious, single "severe"[1] adverse reaction that has a high incidence before reporting to the regulatory authority.

When to report an Adverse Event?

a. Fatal or Life Threatening Adverse Events

Fatal or life threatening adverse event qualify for very rapid reporting to the regulatory authority, which shall be notified (e.g. by telephone, facsimile transmission, email or in writing) as soon as possible but no later than 7 calendar days after first knowledge, followed by completing the Adverse Cosmetic Event Report Form (Appendix I) within an additional 8 calendar days and providing any other information as may be requested by the regulatory authority.

b. Other serious Adverse Events

All other serious adverse events (as defined in section 2.2) that are not fatal or life threatening must be reported as soon as possible, but no later than 15 calendar days after first knowledge.

1 To ensure no confusion or misunderstanding between the terms "serious" and "severe", which are not synonymous, the following note of clarification is provided:
The term "severe" is often used to describe the intensity (severity) of a specific event (as in mild, moderate, severe reaction); the event itself, however, may be of relatively minor significance (such as skin irritation, headache). Seriousness, not severity, serves as a guide for defining regulatory reporting obligations.

COSMETIC PRODUCT [CONFIDENTIAL]

APPENDIX 1

To:
Name & Address of the Regulatory Authority
Department
Telephone no,
Fax no.
Email address

FOR OFFICIAL USE ONLY
Date received:
Product Notification No.

REPORT FORM FOR ADVERSE COSMETIC EVENT

I. Company Particulars

Name and address of Company		
Name & designation of person reporting		
Tel No.:	Fax No.:	Email:

II. Product Particulars

Product Name (as in product notification)	
Ingredient listing & pack size	(Please attach a separate list)
Product Type/Intended use	
Name of Manufacturer & country of manufacture	
Expiry or manufacturing date	
Batch No.	

III. Details of Adverse Event

Name/ Initials of person			
Identification or Passport no.			
Age		Sex	
Ethnic group / Nationality			
Date of onset of adverse event			
Description of adverse event (please use and attach a separate report if necessary) Delay between last application of the product and onset of symptoms: ___ min(s) ___hour(s)____day(s) How was the product used:			
Is the person hospitalised due to the adverse reaction?		□ Yes	□ No
Did person seek medical attention?		□ Yes	□ No
Outcome	□ Recovered (Date:_____) □ Not yet recovered	□ Death (Date: _____) □ Unknown	
Source of report	□ Healthcare professional	□ Consumer	□ Others (specify)

[Signature of person making report & date of report]