Annex I, part 15

GUIDE MANUAL FOR ADVERSE EVENT REPORTING

1. DEFINITIONS AND TERMINOLOGIES

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

ii. 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

2. WHO SHOULD THE INDUSTRY REPORT TO?

The CNH shall report to the NPRA when an adverse event occurs, regardless of the source of the report (consumer, healthcare professional, etc.).

3. WHAT SHOULD BE REPORTED?

i. 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 1 (ii). The expression “reasonable suspicion” is meant to convey in general that there are evidences to suggest a causal relationship or an association.

ii. 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 NPRA. 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 NPRA.

4. WHEN TO REPORT AN ADVERSE EVENT?

i. Fatal or Life Threatening Adverse Events

Fatal or life threatening adverse event qualify for very rapid reporting to the NPRA, 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 1) within an additional 8 calendar days and providing any other information as may be requested by the NPRA.

ii. Other serious Adverse Events

All other serious adverse events (as defined in section 1 (ii)) 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.

APPENDIX 1

To:
Deputy Director,
Centre of Compliance and Quality Control,
National Pharmaceutical Regulatory Agency,
Ministry of Health Malaysia,
Lot 36, Jalan Universiti (Jalan Profesor Diraja Ungku Aziz),
46200 Petaling Jaya,
Selangor, Malaysia.

FOR OFFICIAL USE ONLY
Date received:
Notification No:

ADVERSE COSMETIC EVENT REPORT FORM

I. Company Particulars

Name & 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 Manufacturer	
Expiry or Manufacturing Date	
Batch No.	

III. Details of Adverse Event

Name/Initial 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:_____) □ Death (Date:_____) □ Not yet recovered □ Unknown			
Source of report	□ Healthcare professional □ Consumer □ Other (specify)		

…….. ……..
Signature of Person Making Report Date of Report