SUE form B

General instructions for completing transmission of SUE by Competent Authority to other Competent Authorities or Responsible Person

Form B is designed to be filled in by a Competent Authority in order to transmit the information on serious undesirable effect (SUE) to:

- the Competent Authorities of other Member States, when the information was reported by a Responsible Person or Distributor, with the purpose of complying with Articles 23.2 and 23.3 of Regulation (EC) Nº 1223/2009 ('Cosmetics Regulation').
- the Responsible Person, when the information was reported by a Distributor.

SUE Form A and any additional information on the SUE provided on separate documents must be attached to this form.

Form B should preferably be completed in English in order to facilitate the exchange of information among Competent Authorities.

Field 1: Case report

Competent Authority case identification number: is the Competent Authority-specific ID, which allows it to identify the case (OECD coding for the country of origin, the year of reporting and the serial number of the concerned case).

This Competent Authority Case Identification Number must be used each time an SUE Form B is sent to the Responsible Person and to the Competent Authorities of other Member States.

Type of report:

- **Initial**: select this box if the information on an SUE is submitted to the Responsible Person and to the Competent Authorities of other Member States for the first time.
- **Follow-up**: select this box if new, relevant information is provided to the Responsible Person and to the Competent Authorities of other Member States on an SUE **after initial submission.**
- **Final**: select this box if you think you will not receive any more information on this SUE.

Date received by the Competent Authority: the date on which any employee of the Competent Authority, whatever her/his role and function, becomes aware of an SUE. This is not necessarily the date of receipt of the SUE by the person in charge of expediting the SUE form.

Field 2: Competent Authority

Member State: enter the country where the Competent Authority is located.

Competent Authority name: enter the full name of the Competent Authority.

Address and local contact details: enter the name of the local contact within the Competent Authority considered as responsible for the national management of the SUE.

Field 3: Suspected product

Full name of the suspected product(s): Use the free text field to enter the corresponding information.

Notification number: is the European reference number of the notification of the suspected product attributed by Cosmetic Product Notification Portal.

Field 4: Competent Authority summary

a) Narrative

This field is used to provide a structured and complete description of the case including nature, timing, conditions surrounding the event, its progression, information on relevant medical history, possible risk factors, underlying/concomitant disease, results of re-exposure (if applicable), relevant tests, additional investigations and corrective treatments.

b) Follow-up

If a follow-up is sent to the Responsible Person and to the Competent Authorities of other Member States, the original information should be kept and the additional follow-up information should be summarized in this field.

c) Responsible Person causality assessment

This field should be completed when sufficient information is available (refer to "Causality Assessment of Undesirable Effects Caused by Cosmetic Products[1]"). The option "unassessable" should be chosen only in cases when the necessary information is not available to assess the causality. If the case is/remains unassessable, the reason(s) should be mentioned in the "Competent Authority comments" section.

d) Competent Authority causality assessment

Only when a Competent Authority does not agree with the causality assessment of the Responsible Person or Distributor this field should be completed (refer to "Causality Assessment of Undesirable Effects Caused by Cosmetic Products[1]"). If the case is/remains "unassessable", the reason(s) should be mentioned in the "Competent Authority comments" section.

e) Corrective actions

If the reporting Competent Authority took correctives actions as a result of an SUE, they should be specified in this field.

[1] Reference to Causality Assessment Method

f) Comments

This field is used to provide the Competent Authority global assessment of the case based on all the relevant elements available. The Competent Authority's overall clinical evaluation of the case may include comments on the reported signs/symptoms and diagnosis, the evaluator's opinion on etiological factors that could possibly be relevant to the potential causal role of the suspected product and on other issues which the evaluator considers as relevant.