SUE form A

General instructions for completing notification of SUE by Responsible Person or Distributor to Competent Authority

Form A is designed to be filled in by Responsible Persons or Distributors that are made aware of an serious undesirable effect (SUE), in order to transmit it to the Competent Authority of the country where the SUE occurred, and with the purpose of complying with the Article 23.1 of Regulation (EC) Nº 1223/2009 on cosmetic products ('Cosmetics Regulation').

If the fields do not provide adequate space, attach additional information as needed. Identify all attached pages as “page X of Y” of “Company report number: xxxxxxx”.

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

Field 1: Case report

Company report number: is the company-specific ID, which allows the company to identify its report. This company report number must be completed each time a SUE form A is sent to a Competent Authority.

Type of report:

- **Initial**: select this box if the information on a SUE is submitted to the Competent Authority for the first time.
- **Follow-up**: select this box if new, relevant information is provided to the Competent Authority 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 company: the date at which any employee of the company, 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.

Sending date to the Competent Authority: corresponds to the date of submission to the Competent Authority.

Field 2: Company

Select the box corresponding for the reporter (Responsible Person/Distributor).

Company name: enter the full name of the cosmetic company (Responsible Person/Distributor).

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

Field 3: Seriousness criteria

Select one or several options corresponding to the seriousness criteria as defined in Article 2 1. (p) of the Cosmetics Regulation.

In case of doubts, the seriousness of the undesirable effects should be confirmed by a medical doctor.

Field 4: Primary reporter

Select the box corresponding to the primary reporter.

Has the reported information been confirmed by a medical professional?: select this box when a practitioner (i.e. physician, dermatologist, dentist etc.) has confirmed directly to the company the information initially reported.

Field 5: End user

This refers to the person who experienced the SUE.

The end user is defined in article 2, point 1 (f) of the Cosmetics Regulation as a consumer or professional using the cosmetic product.

Code: enter a code or reference which would not enable users of the form the identification of the person ("pseudonanimisation").

Age: enter the end user's age in years at the time the clinical event occurred. For children less than 3 years old, enter age in months.

Sex: select the corresponding field.

Country of residence: corresponds to the country where the end user lives. This is not necessarily the country where the SUE occurred.

Field 6: Suspected product

a) Full name of the suspected product

Use the free text field to enter the corresponding information.

For the section "Category of product", refer to the corresponding Annex of the SUE Reporting Guidelines, which reflects the categorisation of products for the purpose of the notification of cosmetic products[1].

Notification number: is the European reference number of the notification of the suspected product attributed by Cosmetic Product Notification Portal which is only available to the Responsible Person.

b) Use of the product

[1] The categorisation was established for the Cosmetic Product Notification Portal (CPNP).

Date of first ever use: is the date of first ever use of the product by the end user affected by the SUE.

Frequency of use: enter the corresponding information.

Professional use: select the corresponding box.

Application site(s): free text field, enter the corresponding information.

Product use stopped:

- Select **Yes** if the use of the product was stopped following the occurrence of undesirable effects.
- Select **No** if the end user continued to use the product after the undesirable effect occurred.
- Select **N/A (Not applicable)** if the product was only applied once.
- Select **Unknown** if no information is available on the use of the suspected product after the undesirable effect occurred.

c) Re-exposure to the suspected product

This field refers to a further exposure of the end user to the suspected product under the same conditions of use, following the disappearance of the clinical signs/symptoms.

This box does not cover re-exposure from clinical skin tests, which are covered under field 12.

- Enter **Positive** if the clinical event recurred or similar sign/symptoms reappeared following the re-exposure to the suspected product.
- Enter **Negative** if the clinical event did not recur or if no similar sign/symptoms appeared following the re-exposure to the suspected product.
- Enter **Not performed** if the product was not re-used.
- Enter **Unknown** if no information on re-exposure is available.

d) Other suspected cosmetic products used concomitantly

When there are two or several cosmetic products reported as suspected, their full name should be listed in this field.

The information corresponding to fields 6a), 6b) and 6c) for the other suspected products, if available, should be attached to this form or described in the narrative section in field 13.

Field 7: Description of the SUE

a) Type of effect

Country of occurrence: country where the SUE occurred.

Date of onset: date at which the first signs/symptoms of the considered effect(s) appeared.

Time from the beginning of use to onset of first signs/symptoms: Unlike field 6b), this information does not refer to the first ever use but it corresponds to the time interval between the beginning of the most recent cycle of product use and the onset of the first signs/symptoms.

If the product has been used intermittently over a number of years, only the last cycle of use should be considered for this field.

Time from last use to onset of the first signs/symptoms: corresponds to the time interval between the last use of the product and the first signs/symptoms.

If the product was applied only once, the first use to onset and the last use to onset could be the same.

Reported signs/symptoms: provide all the signs/symptoms using the original reporter's words (or corresponding translation in English) used to describe the clinical event.

Reported diagnosis: provide all the information on the reported diagnosis. A diagnosis can be established only by a medical practitioner.

b) Location of SUE

Select the corresponding box(es) and specify where necessary.

Other: free text field to enter more specific information.

SUE in area of product application and/or **SUE out of area of product application**: select the corresponding box; both could be selected.

Field 8: Outcome of SUE(s)

This field refers to the outcome of the clinical event at the time of the last available information.

Recovered: select this box if the event resolved, and enter the time to recovery.

Improving: select this box if the sings/symptoms have significantly improved at the time of the last obtained information compared with the initially reported symptoms.

Aftereffects (sequelae): select this box if the clinical event resolved with sequelae, if the clinical event is permanently disabling, or if all the persisting signs/symptoms that can be related to the clinical event were considered as sequelae according to the last information obtained.

Ongoing: select this box if the clinical event is still present at the time of the last available information.

Unknown: select this box if no information on the outcome is available.

Other: other outcome can be described as: worsening, etc.

Field 9: Relevant underlying conditions

This section refers to any underlying medical condition, disorder or disease, to any medical or surgical procedure, or prophylactic measure (e.g. desensitisation) from

which the patient was suffering when the SUE occurred, or had suffered previously, if considered as relevant. Use the corresponding fields or the free text fields to enter the appropriate information.

Relevant treatment(s) and **Additional concurrent use of other products**: use these free text fields to enter cosmetic products, drugs, or dietary supplements used at the same time as the suspected product.

Field 10: Relevant medical information/history

This section refers to any significant medical past history which could be considered as a risk factor or could be linked with the occurrence of the SUE; complete the fields when relevant.

Field 11: Case management

a) Treatment(s) of SUE

Treatment is any therapy given to the patient to counteract one or several of the clinical effects. It includes medications or other prescribed treatment. For the medications the INN (International Non-proprietary Names) instead of marketing names should be entered.

b) Other measure(s)

Free text field to enter types of procedures or measure(s) taken which were not part of the medical treatments (e.g avoid sunlight exposure).

c) Seriousness of undesirable effect

If **Functional incapacity** is selected in section 3 of this form, this free text field is used to provide complete description of the functional incapacity supporting the seriousness criterion; select the corresponding boxes if medical certificate and/or expert evaluation are available.

If **Disability** is selected in section 3 of the form, this field is used to provide complete description of the disability as well as the percentage of the disabled function, supporting the seriousness criterion. If a medical certificate and/or expert evaluation are available, tick the corresponding box.

If **Hospitalization** is selected in section 3 of this form, this field is used to provide all appropriate information on the hospitalization: duration, corrective treatment including medication and/or procedures.

If **Congenital anomalies** is selected in section 3 of the form, this field is used to provide description of the anomalies; select the appropriate box regarding the period when the anomalies were detected.

If **Immediate vital risk** is selected in section 3 of the form, the specific treatment given for the event should be mentioned; the treatment could be different than the one mentioned in the subsection11a) of this form, as it concerns only the life threatening episode.

If **Death** is selected in section 3 of the form, complete the date and the cause of the fatal outcome. Select the option 'Medical certificate' if available.

Field 12: Complementary investigations

Specify all relevant information on tests and procedures. Include only the most pertinent investigations. The results should mention mainly what are the pertinent negative or positive results, considering the initial diagnosis hypothesis based on the reported symptoms.

Allergic testing

- **Skin test(s) performed with the suspected cosmetic product(s)**: enter the relevant information on the product tested, on the type of tests, methods, results of investigations with the finished product.
- **Skin tests performed with the substances** (e.g. patch tests): if available the detailed results should be provided on a separate document appended to this form.
- **Other results of allergic testing** (e.g. specific IgE): enter information on the type of tests and results.
- **Other additional investigation(s) (specify, including results)**: enter all the appropriate information on investigations other than allergy tests.

Field 13: Summary from the Responsible Person or Distributor

a) Narrative: this field is used to provide a structured and complete description of the case, including nature, timing, conditions surrounding the events, progression of the event, 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 known, the Competent Authority case identification number should be specified.

If a follow up is sent to a Competent Authority, the original information should be kept in the form and the additional follow-up information should be highlighted throughout the form and summarized in this field.

c) Causality assessment: should be completed when sufficient information is available. 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 'Comments' section (refer to "causality assessment of undesirable effects caused by cosmetic products[2]").

d) Management: it is possible that this case has already been reported to or is being reported in parallel to another Competent Authority**;** select the corresponding box as appropriate.

e) Corrective actions: if the reporting Responsible Person or Distributor took correctives actions as a result of the reported SUE, they should be specified in this field.

[2] Reference to Causality Assessment Method

f) Comments: this field is used to provide the Responsible Person's or Distributor's global assessment of the case based on all the relevant elements available.
The Responsible Person's or Distributor'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.

If additional information on an SUE is provided on separate documents, a complete listing of these attached documents should be added in this section.