
COSMETICS EUROPE

GUIDELINES ON THE MANAGEMENT OF UNDESIRABLE EFFECTS AND REPORTING OF SERIOUS UNDESIRABLE EFFECTS IN THE EUROPEAN UNION

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1. Introduction

Cosmetic products placed on the European Union (EU) market have high standards of safety and quality. Undesirable effects as a result of normal or reasonably foreseeable use¹ of cosmetic products are rare and are typically mild in nature and completely reversible. Each company will have procedures to enable it to react appropriately to all reports of undesirable effects covering their recording and assessment and understanding their nature and future prevention. For companies, this plays an important role in the post-marketing surveillance of cosmetic products and their performance in the marketplace.

1.1 Foreword

The EU Cosmetics Regulation (EC) No. 1223/2009, hereafter referred to as the Regulation, has created a basis for a uniform approach to the management of Serious Undesirable Effects caused by the use of cosmetics (Article 23, Chapter VII). The previous requirements of the Council Directive 76/768/EEC on Undesirable Effects regarding their inclusion in the Product Information File and the access to certain information for the public have been kept in the new Regulation and modified, integrating reporting requirements on Serious Undesirable Effects. (Respectively Article 21, Chapter VI and Annex I, Part. A).

The main purpose of Market Surveillance is to maintain the protection of health of cosmetics users by monitoring the occurrence and reducing the likelihood of reoccurrence of Undesirable Effects (UE). The Cosmetovigilance System includes the evaluation of Serious Undesirable Effects (SUEs) and, where appropriate, the dissemination of information which could be used to prevent such repetitions, or to alleviate the consequences of such effects. The Cosmetovigilance System is intended to facilitate a direct, early and harmonized implementation of such action across the Member States where cosmetic products are used, in contrast to action taken on a country by country basis.

Therefore, Cosmetics Europe, representing the European cosmetics industry, proposes these guidelines both for the management of UEs and the reporting of SUEs to Competent Authorities to promote a consistent procedure. Following these guidelines will allow responsible persons and distributors to demonstrate compliance with the legal requirements and provide the public and Competent Authorities with confidence on the credibility and accuracy of the data supplied, whilst at the same time protecting the privacy of the healthcare professional and their relationship with the individual consumer.

These guidelines update and supersede the earlier Colipa² Guidelines on the Management of Undesirable Event Reports (2005). These have been updated, ensuring harmonized industry practice in handling Undesirable Effect reports. They are in line with those issued by the representatives of National Competent Authorities and Commission Services, titled “SUE Reporting Guidelines” after joint work with industry and other interested parties in the Market Surveillance sector (Appendix I).

These guidelines will be revised and amended as necessary to take account of developments in science, technology and regulation.

¹ For more information, see Commission Implementing Decision of 25 November 2013 on Guidelines on Annex I to Regulation (EC) No 1223/2009 (2013/674/EU)

² Colipa is the former name of Cosmetics Europe

1.2 Definition of terms

For the purpose of these guidelines and according to the definitions given in the Article 2 of the Regulation, the following definitions shall apply.

1.2.1 Undesirable or adverse event

An undesirable or adverse event is defined as any human adverse health event which is:

- Voluntarily reported by consumers, healthcare professionals, Competent Authorities, and any other individuals to have occurred during or after normal or reasonably foreseeable use (exclude misuse and abuse)³ of a cosmetic product.
- Not necessarily related to the product.

Every reported undesirable event is to be considered as an alleged undesirable event. It will be considered as a genuine undesirable event only when the four following criteria are fulfilled:

- *An identifiable reporter (initials or age or gender) plus the name and address if the reporter is a Health Professional*
- *An identifiable consumer - one or more of the following qualifies the consumer as identifiable: date of birth, age (or age category, e.g. adolescent, adult elderly), gender, initials*

NOTE: The term identifiable in this context refers to the verification of the existence of a reporter and a consumer. Reporter and consumer identity is important to avoid case duplication, detect fraud, and facilitate appropriate case processing.

- *The precise nature of the event with a description of the reaction (complete verbatim with the symptoms; "reaction" alone should not be considered as a genuine UE) and the date of onset of the event (year at the minimum)*
- *An identified cosmetic product. (This can be established by the exact commercial name and/or a combination of other identifying elements such as brand name, category, type, batch number, notification number (CPNP number) – as long as they are sufficient to enable the product's specific identification.)*

An alleged undesirable event is clearly defined as quite distinct from anecdotal consumer complaints of a non specific nature or reports of sensorial perceptions which can be expected from the normal and reasonably foreseeable use of a specific cosmetic product.

³ Misuse and abuse - product use which is not in accordance with the intended purpose and the correct conditions of product use and/or with the directions of use and/or with specific warnings mentioned on the product.

1.2.2 Undesirable Effect (UE)

Article 2.1 (o): *'Undesirable effect' means an adverse reaction for human health attributable to the normal or reasonably foreseeable use of a cosmetic product.*

Undesirable Effects include but are not limited to irritant or allergic reactions that can affect the skin, eyes or mouth.

Undesirable effects caused by product misuse and abuse are not included in this definition.

Causality assessment is extremely difficult in case where a complaint links a chronic disease with application of a particular cosmetic product. Such health impairments are known to have a multi-factorial etiology and/or need multiple insults over a prolonged period of time (i.e. chronic hand eczema)

1.2.3 Undesirable effect medically confirmed

Any undesirable effect which has been confirmed and validated as attributable to the suspected product(s) by a healthcare professional (e.g. physicians, dentists). It is important to differentiate between medical confirmation of the presence of a particular health impairment (diagnosis) and substantiation of a suspected cause, which is only relevant if based on scientifically robust information (e. g. a diagnostic Patch Test identifying an allergen).

1.2.4 Serious Undesirable effect (SUE)

In very rare cases an undesirable effect could be serious. The term serious is not synonymous with severe. Severe is used to describe the intensity (severity) of the effect as in mild, moderate or severe. In case of doubts, the seriousness of the undesirable effects should be confirmed by a medical doctor⁴.

Article 2.1 (p): *'Serious undesirable effect' means an undesirable effect which results in temporary or permanent functional incapacity, disability, hospitalisation, congenital anomalies or an immediate vital risk or death.'*

- ***temporary or permanent functional incapacity***

NOTE: this criterion corresponds to a substantial disruption of a consumer's ability to carry out normal physical, or occupational life functions for a significant span of time.

Such disruption may for example be caused by severe and prolonged impacts on sensory or physiological functions. Impairment of body functions is considered as a relevant seriousness criterion only if assessed on the basis of objective, medical criteria. Such functional incapacity should be demonstrated, for instance on the basis of a medical certificate, in order to confirm that a report of adverse effect qualifies as an SUE.

⁴ General instructions for completing notification of SUE by Responsible Person or Distributor to Competent Authority (SUE form A)

- **disability**

NOTE: “Disability” corresponds to a permanent damage or disruption in the patient body structure or function, or in activity limitation. It should be documented by providing a medical certificate with an objective percentage of disability, in order to confirm that a report of an undesirable effect qualifies as an SUE.

- **hospitalisation**

NOTE: “hospitalisation” refers to inpatient hospitalisation that includes initial admission to the hospital on inpatient basis. The admission to hospital requires the production of an admission note. An emergency room visit, examination or treatment delivered as an outpatient, which does not result in admission to the hospital, does not qualify for this outcome. In cases where sufficiently precise information for judgement is not available, a duration of hospitalisation of at least 24 hours may be used as a simple criterion.

- **congenital anomalies**

NOTE: this criterion refers to a physiological or structural anomaly that develops at birth or before, and is still present at the time of birth. This excludes hereditary diseases.

- **an immediate vital risk**

NOTE: “vital risk” refers to an event/effect in which the consumer was at risk of death at the time of the event/effect if no medical intervention had been taken. This condition is fulfilled if an emergency medical intervention took place and can therefore be documented. “Vital risk” does not refer to an event/reaction which hypothetically might have caused death if it were more severe.

- **or death**

NOTE: should be considered as seriousness criterion if the undesirable event/effect is the direct cause of death. Death may be totally incidental to the appearance of a suspected undesirable event/effect.

1.2.5 Causality assessment

The causality assessment is the result of the analysis of causal association, on a case by case basis, as an attempt to determine the probability that a well identified product used by a consumer is responsible for a genuine undesirable event, which can therefore be possibly considered as *attributable* to the cosmetic product and therefore considered as an Undesirable Effect.

The causality assessment is therefore strictly individual and relates to the effect on individual consumers. It does not give any evaluation of the risk of a product to the general population. The likelihood of causality is obtained from the use of a standardized method which has been adopted by stakeholders of the European system of cosmetovigilance (see enclosed method in the appendix of the European Commission Guidelines on Reporting of SUEs, Appendix I).

The aim of this method is to provide a basis for a common understanding and uniform approach to the performance of causality assessments for genuine undesirable events to cosmetic products.

At the time of report, the undesirable event is to be considered as an alleged undesirable event. It will only become a genuine undesirable event when there is evidence that the event has indeed happened. A non-genuine undesirable event would be characterized, in particular, by the impossibility to obtain information that should be considered as evidence (i.e. consumer or health care professional identity and contact details, description of the reaction, symptoms and delay of onset, complete product identification, etc.) Care must be taken to exclude the possibility of malicious reports by consumers.

Once non-genuine undesirable events have been excluded, the causality assessment needs to be carried out, regardless of the source of the information (i.e. consumer contact reports and healthcare professional reports). Throughout the gathering of further information, the assessment of whether a reported event is genuine or non-genuine may change. In which case, the reported event may be subsequently excluded from the final causality assessment.

It is important to note that a useful causality assessment can only be performed if there is sufficient minimum information on the case history (in particular symptoms and chronology). If this minimum information is not obtained, the case should be considered as unassessable. As long as additional information can be reasonably expected to be obtained, which could change the assessment of the case, the case report is considered as not closed. It is, however, possible to close a case report as 'not-classifiable' after a minimum of two documented contacts without any additional information.

As a rule, the method must be used separately for each cosmetic product, without taking into account the level of causality of the associated products. The level of causality is determined using a decision table in which the scores are combined. The method offers five levels of causality assessment: very likely, likely, not clearly attributable, unlikely and excluded.

1.2.6 Spontaneous reports, Cosmetovigilance, Signal

Post Marketing Surveillance includes a set of methods and technical tools allowing the surveillance and evaluation of the safety profile of a given cosmetic product in user populations and contributing to the decision-making process for risk management. Together with other tools, cosmetovigilance, based on the management of spontaneous reports, contributes to the detection of signals and to post marketing surveillance.

Spontaneous report: in Vigilance systems, this refers to unsolicited communication by a member of the public or by healthcare professionals to a company and/or its supply chain (e.g. manufacturer, importer distributor, retailer, salons, ...), regulatory authority or other organization that describes one or more suspected health related events in a person who has used one or more cosmetic products.

Cosmetovigilance is defined as the collection, evaluation and monitoring of spontaneous reports of undesirable events (including SUE) observed during or after normal or reasonably foreseeable use of a cosmetic product.

Spontaneous reporting gives meaningful indication on reporting rates, which are useful indicators to identify and describe possible signals.

A safety signal may be defined as the onset of new information which might modify the safety assessment on the product or require further investigation. A signal usually arises from an unexpected modification of a pre-existing level of reporting rates and includes qualitative or quantitative considerations. The validation of one identified signal and the measure of its impact require further investigations using other sources of information, the identification of possible risk factors and the characteristics of the population exposed.

1.3 Roles and responsibilities

The cosmetic company placing a cosmetic product on the EU market (i.e. the Responsible Person – RP) has the responsibility:

- To make clear to consumers how they can contact the company
- To establish and maintain an adequate internal post marketing surveillance system to ensure that any information about a suspected UE reported to the personnel of the company is collected and collated in order to be analyzed
- To maintain records of all reported UEs on cosmetics marketed in the EU and to readily provide access to the information upon request, to the Competent Authority in the Member State where the Product Information File is kept
- To encourage, if appropriate, consumers to consult a Healthcare Professional when they notice a UE suspected of being linked with the use of a cosmetic product
- To make sure that their personnel are appropriately informed and trained about their cosmetovigilance obligations
- To establish a clear relationship between Responsible Person and Distributor regarding the management and reporting of SUEs
- To make available to National Competent Authorities the contact facilities of the Responsible Person and set up internally the appropriate processes for the management and reporting of SUEs
- To identify when possible a contact for each country who will be the contact person for the National Competent Authority in case of local enquiry or action plan
- To set up an internal process and methodologies allowing to identify from their cosmetovigilance data any potential change in the safety profile for their product and take preventive/corrective action if appropriate
- To ensure the monitoring of subsequent actions, if any
- To update the Cosmetic Product Safety Report (CPSR) considering the available data on the UEs and SUEs to the cosmetic product
- To ensure that information on UEs and SUEs resulting from use to the cosmetic product are made easily accessible to the public by any appropriate means
- Communicate any subsequent actions resulting from the SUEs to the Competent Authorities

2. Scope

Compliance with Article 23 and Article 10 and 11 (Annex I, Part A) requires the identification of the possible sources of information on UEs and SUEs.

- Individual SUEs that occur *within the EU* are required to be reported to the Competent Authorities
- Knowledge of spontaneous reports of SUEs will be assured from some sources, as legally required under Article 23: End users, Competent Authority, Health Professionals, Distributors and Responsible Person.

Article 23.1.a mentions any SUEs which are reasonably expected to be known to the RP. Other sources of information than spontaneous reporting may include published studies, scientific literature or media. It would be expected that any data on UEs or SUEs attributable to the products and revealed as part of Europe-based post-market surveillance studies or any epidemiological studies commissioned by a manufacturer/brand owner, would be kept in their Cosmetic Product Safety Report (CPSR). Any SUEs identified by such studies would also be expected to be reported.

If the above such studies were conducted outside of the EU, any SUEs identified would not be reportable under Article 23 of the new Regulation but those data attributable to the products would be expected to form part of the responsible person's records, accessible when necessary.

Similarly, if studies on EU based SUEs are published in scientific and medical literature, the data would be expected to be reported under Article 23; but irrespective of the study location, any UE or SUE information likely or very likely to be attributable to use of a specific cosmetic product should form part of the CPSR and/or responsible person's company files.

The screening policy of scientific and medical literature is determined by each company, but should be proportionate.

Information available in the press and on social media sites is far more nebulous and may be purely anecdotal. SUEs reported in EU national media should be followed up and reported as necessary and the information form part of the CPSR. It is unlikely, nor is it necessary, that companies in the supply chain should monitor external websites or blogs. If a company becomes aware of UEs or SUEs being discussed in such forums, action should be taken on a case-by-case basis.

3. Management of Undesirable Effects

Each responsible person and distributor should ensure that an appropriate management system of alleged undesirable effect reports is in place, in order to ensure responsibility and accountability for its cosmetic products and that appropriate action can be taken, when necessary. Considering the time frame for reporting SUE to the National Competent Authority (NCA) (20 calendar days, see Section 3.4.3), the process of the management of SUEs should be clearly described in the company system.

It is in particular the responsibility of each responsible person to:

- record all contacts in relation to undesirable events
- determine which undesirable events are genuine undesirable events (see section 1.2.1)
- document, investigate, validate and evaluate cases that fulfill the criteria to be classified as undesirable effects in accordance with the Regulation
- classify these documented reports in terms of causal relationship
- identify the cases that fulfill the criteria to be classified as Serious and report SUEs to the NCA in accordance with the Regulation
- store the documentation of each report
- evaluate this information in terms of frequency, medical significance and causes
- ensure that healthcare professionals' and/or consumers' privacy protection is maintained
- include updated and substantiated relevant information into the Cosmetic Product Safety Report
- be in position to answer questions addressed by the NCAs and/or the public under the requirements of the Regulation

3.1. Reception

Individual reports from consumers, National Competent Authorities, or healthcare professionals can be reported to a company by different ways (mail, e-mail, telephone, direct contact) and received by different employees.

The company needs to ensure that all these reports are made available without delay to the appropriate person. During this first contact attempts should be made to obtain necessary information required for the opening of a case file.

- Obtaining relevant information

In recognition of the difficulties posed by the lack of detail in some consumer reports and the difficulty sometimes experienced in obtaining additional or sufficient information, it is important that the person who is in charge of the documentation and evaluation of the UE exercises judgment in relation to how such reports are recorded, classified and followed up.

A standardized questionnaire can be used in consumer contacts to ensure that the maximum information is obtained at the initial consumer contact (see example of questionnaire in Appendix II). When necessary, the initial consumer contact may be followed up by additional contacts with the consumer or the treating healthcare professional in order to complement the information initially available. It is recommended in some countries to obtain from consumers their formal authorization to contact their healthcare professional. All complementary information obtained during the initial or follow-up contacts needs to be documented, dated and included in the case file.

Whatever the types of documents obtained during the inquiry, protection on data privacy should be applied and verified (see Section 3.5).

Additional follow-up or medical confirmation may not be necessary for an apparently non-genuine undesirable event. A non-genuine undesirable event would be characterized in particular by the impossibility to obtain information that should be considered as evidence: consumer or health care professional identity and contact details, description of the reaction (symptoms and delay of onset), complete product identification, etc. (See definition Section 1.2.5).

If the undesirable event is considered as genuine, reasonable additional efforts should be made either to obtain voluntary informed consent to contact the treating healthcare professional or to have the consumer provide additional, medically relevant, information.

Reports linked to product abuse or misuse³ whilst they may provide information relevant for cosmetic manufacturers, fall outside the scope of this document and should be classified separately.

- Company assistance

When necessary, the consumer should be encouraged by the company to consult a healthcare professional. Information should be offered by the company to physicians, dermatologists, dentists or other healthcare professionals to aid in the diagnosis in terms of documentation and/or testing whenever requested.

3.2. Internal Recording

The recording procedure must include the date of initial receipt of the undesirable event; this is the date when the company has first been informed of the undesirable event, whatever the role and function of the first recipient of the information in the company. Procedures should be in place to ensure any such report is transmitted to the appropriate person or department within the company without delay.

A file is opened for each report of a genuine event and a specific company reference number should identify each case file. This reference number should be included on all the documents related to the case.

It is up to each company to define their numbering system. . As an example, the European identification system could be used (*OECD coding for the country of origin, the year of reporting, the code of company, and the serial number of the concerned case*).

It is up to each company to define their internal policy and a procedure regarding the data entry of their undesirable events but it is recommended to use a standardized listing or dictionary of medical terms providing a code for each symptom / diagnosis. For the product(s) concerned, the use of the category defined by the Commission for the notification purpose is recommended.

3.3. Causality assessment

The assessment of causality should be applied to cases which are considered as genuine and for which sufficient relevant information is available, regardless of the source of the information (consumer contact reports and healthcare professional reports).

A detailed description of the EU wide accepted method for causality assessment can be found in Appendix I.

It is possible that the outcome of an initial assessment changes at a later stage in the process as a result of additional information obtained from detailed questionnaires or from medical investigation. A causality assessment should only be considered final if it is unlikely that further information will be obtained that could change the assessment.

A person who is trained in complaint handling and has an appropriate background should be responsible for conducting the causality assessment. In certain cases, it may be advisable to seek the support of an external or in-house healthcare professional when conducting the causality assessment in order to obtain a high degree of confidence in the result. This should be recorded in the case file documentation and the product information.

According to the method, five levels of causality can be obtained: 'very likely', 'likely', 'not clearly attributable', 'unlikely' and 'excluded'.

It is possible that a cause other than the cosmetic product is clearly identified through the investigation and causality assessment. In this case, the relationship between the undesirable effect and the product is considered as 'excluded'. In the same way if there is an incompatible temporal relationship with the use of the product (e.g. adverse event occurring before the use of the product) the causal relationship should be considered "excluded".

3.4. Reporting of Serious Undesirable Effects to National Competent Authorities

3.4.1 General principles

Upon receipt of a report of a SUE the Responsible Person has to report it to the National Competent Authority (NCA) **of the country where the undesirable effect occurred**, using the standardised Serious Undesirable Effect Report Form.

In the case where the SUE is directly reported to a distributor, the distributor has legal obligation to notify the case to the Competent Authority^{5,6}

It is recognised that the initial notification may be incomplete and may take place before causality has been established. Both conditions can be clearly indicated on the initial Report Form.

The act of reporting a SUE to a NCA is not to be considered as an admission of liability for the SUE and its consequences.

It is highly recommended that all the exchanges regarding SUEs, those sent to the NCAs and those received from the NCAs should be appropriately stored according to a well-defined internal traceability process. (see section 7.1)

3.4.2 Criteria for an Undesirable Effect being reportable to NCA as a SUE

Both criteria of the definition of a UE and the seriousness as defined in Section 1 are required for a transmission of a case report to the NCA. Each initial report must also lead to a final report, unless the initial and the final report are combined into one report.

If the minimum information referred in Section 1.2.1 cannot be obtained, the notifier should continue to undertake all the reasonable efforts to obtain the information and notify without delay as it becomes available. In case the minimum information cannot be obtained, the existence of SUE cannot be confirmed.

Responsible Persons and distributors should designate (a) person(s) qualified to assess the seriousness of the cases. In case of doubts, the seriousness of the undesirable effects should be confirmed by a medical doctor⁷.

Where there is a doubt about the reportability on SUE the case should be reported within the 20 days' time frame rather than waiting for complete information.

As long as the company has reason to believe that it is in the position to obtain additional relevant information, which could change the assessment of the case, the case report is considered as not closed.

SUEs resulting from an abuse or misuse of the cosmetic product are excluded from the reporting obligation as they are not part of normal or foreseeable use of the product.

If a report received refers to groups of unknown size, such as "some" or "a few" SUEs, the company should follow up to find out the number and then submit to the NCA a separate report for each identifiable consumer. Each case should be identified separately so that it is clear for the NCA it is not a duplicate report of a single SUE.

Due to the potential medical seriousness, all SUE cases, except those classified as "excluded" should be notified to the NCA where the SUE occurred. Information on the reported SUEs should be kept

⁵ EU Regulation 1223/2009 – Article 23 and European Commission "SUE Reporting guidelines" (version July 2013) http://ec.europa.eu/growth/sectors/cosmetics/market-surveillance/docs/sue_reporting_guidelines_en.pdf

⁶ Cosmetics Europe Guidelines on Roles and Responsibilities

⁷ General instructions for completing notification of SUE by Responsible Person or Distributor to Competent Authority (SUE form A)

available by the Responsible Person for the Competent Authority of the Member State where the Responsible Person is established.

It is up to each company to inform initial reporters, consumers or healthcare professionals of the transmission of their reported case to the NCA.

3.4.3 Time frames

For the interpretation of the time frames referred in Article 23 of the Regulation, “without delay” or “immediately” should be understood as within 20 calendar days⁸ from the date at which any employee of the responsible person or distributor becomes aware of the SUE, whatever their role or function. Thus, the notification by the company of the SUE to the NCA of the country where the SUE occurred should be carried out as soon as possible and in any case no later than *20 calendar days* following the date of initial receipt of the SUE. This is not necessarily the date of receipt by the person in charge of expediting the SUE form.

3.4.4 SUE Report Form

The reporting of a SUE to the NCA should be done using a harmonised Serious Undesirable Effect Report Form. Guidance on completing the form is enclosed in Appendix I along with the SUE report form.

If the case is not closed at the time it is initially reported, it should be clearly mentioned on the SUE report form.

The report form should be sent to the NCA by appropriate means to ensure confidentiality. An acknowledgement of the reception of the case should be sent back to the Responsible Person or the local national contact where the SUE occurred. This acknowledgment should be kept in the case file if received.

All subsequent communication on the SUE, including follow-up or exchange of information on the SUE between European Member States, should be kept in the case file with the company reference number.

When there are two or several cosmetic products reported as suspected, their full name should be listed in field 6d) in SUE reporting form A. To avoid duplicate counting of the same SUE, separate reporting on two reporting forms should only be considered if necessary by the specific case circumstances.

The information corresponding to fields 6a), 6b) and 6c) of SUE reporting form A for the other suspected products, if available, should be attached to the same form or described in the narrative section in field 13 of form A⁹.

⁸ European Commission “SUE Reporting guidelines” (version July 2013)
http://ec.europa.eu/growth/sectors/cosmetics/market-surveillance/docs/sue_reporting_guidelines_en.pdf

⁹ General instructions for completing notification of SUE by Responsible Person or Distributor to Competent Authority (SUE form A)

If a SUE involves more than one suspect cosmetic product, the NCA who receives the case should inform the other concerned responsible persons of the SUE. In this circumstance, the concerned companies should not re-send the case to their NCA.

All communications should refer the reference number of the initial report and great care should be taken to avoid duplicate reporting of the same case.

3.4.5 Follow-up

Whenever necessary, the initial report of a suspected SUE should be followed-up to obtain sufficient information for a complete and appropriate causality assessment; reasonable additional efforts should be made to obtain voluntary informed consent from a consumer to contact the treating healthcare professional or to have the consumer provide additional medically relevant information.

Complementary information when obtained should be registered in the report file with the date of their receipt. If the collected information has significant impact, such as the nature of the event, on the outcome or the assessment of the case, it should be sent to the NCA as a follow up using the same SUE report form as the one initially used, with the addition of the complementary information obtained and within the 20 calendar days following their reception. The company reference number should be clearly indicated to avoid the generation of a duplicate by the concerned NCA.

The causality assessment of each SUE should be performed by a suitably trained person within the company, or delegated if necessary, to an appropriately trained third party (see Section 3.3). The causality assessment is performed once there is sufficient information and no chance to receive further information on the case. The result of causality assessment will be transmitted to the NCA and the case then considered as closed.

3.4.6 Serious Undesirable Effect received from National Competent Authorities

According to the paragraph 2 of the Article 23 of the Regulation, when National Competent Authority is made aware of a SUE on its territory and whatever the source of information (distributors, end users or health professionals), they should transmit the case with all available details to the Responsible Person. It is therefore expected that the NCA will validate the seriousness criteria as defined in Section 1.2 before any onward distribution and obtain the required minimum level of information to identify the exact name/category/notification number of the marketed product, and thus the company responsible for placing on the market.

The “entry portals” for Competent Authorities to send their SUEs to the Responsible Person are the following: Notification by physical contact, the Contact details filled in via SUE Notification forms, Existing national contacts with local Authorities, Cosmetics Europe Website for Public Information.

Causality assessment of the cases reported directly to NCA should be made preferably by the authorities; if this is not possible, they should inform the Responsible Person and exchange all available information to allow a causality assessment to be made by the Responsible Person without delay.

If there is no consensus on the final causality assessment of the SUE between the NCA and the Responsible Person, both causality assessments can be integrated in the file of the case and included in the consecutive documents or exchanges regarding the case.

SUEs initially transmitted by NCA will be included in the record files of the responsible person. Such cases will have a double identification: the company reference number and the NCA reference number.

The principles of interaction between the Responsible Person, Distributor and Competent Authorities on the management of SUEs and the notification /transmission forms used by the NCA are described in Appendix I, enclosed.

3.5 Data privacy protection and confidentiality issue

Consumers should not be identified by name or address when reporting SUE to the NCA. Instead, the company or the initial reporter, such as a healthcare professional should assign a code (e.g. consumer's initials) to each UE.

In particular, the company and its representatives should be familiar with and discharge obligations to the collection, use and disclosure of personal information in accordance with the national regulations transposing the EU Personal Data Protection Directive (Directive 95/46/EC). In case of request for personal information, the transmission of personal data shall follow the provisions of the EU Data Protection Directive and local laws.

In situations where a consumer explicitly withholds consent to the recording of his/her personal data, the person who is in charge of complaint handling should indicate in the case file that it is a consumer report and that the name and contact details have been withheld at the request of the consumer.

All communications about SUE between Responsible Person and NCA, or between different NCA, should guarantee the confidentiality of the information. The reception and the storage of the SUE report forms received from companies or health professionals should not be accessible to non-authorized persons.

3.6 Archiving

The company should define clear procedures for archiving records and for the destruction of old documents.

It is the responsibility of each company, based on legal requirements of each EU Member State, to specify their retention policy for the case files.

All information relevant for inclusion into the Product Information File has to be kept for 10 years following the date on which the last batch of the cosmetic product was placed on the market.

4. Monitoring of Undesirable Effects

It is the responsibility of each responsible person to define their policy for the market monitoring of their products and the types of summary documents they provided for their management review.

In addition to the inclusion of individual cases into the Product Information File, it may be useful to have reporting rates available in the company summaries/information, at the level of product classes, product categories or at individual product level. This can facilitate data analysis actions and the

identification of trends or signals. Similarly, separate analysis and evaluation of Undesirable Effects medically validated from with non-medically validated cases should be considered. (See definition Section 1.2.1)

Such reports/information will allow companies to manage in-house UE/SUE reports for their products in a transparent and easily accessible manner, demonstrating a high professional standard followed by the company.

A part of these summaries and statistical information will have to be included in the Cosmetic Product Safety Report and used for the information to the public (see Sections 5 and 6). Two main indicators are generally used for market monitoring:

- reports number: the number of new cases reported during a given period of time
- estimation of the reporting rate: the total number of reported cases observed during a given period of time, over the total number of cosmetic units sold (or the total number of users estimated from cosmetic units distributed) during the same period of time.

4.1 Signal analysis

Identification by a Competent Authority of a signal or a trend based on the report of SUEs could lead to a specific enquiry in the country concerned; the Responsible Person should be informed of the enquiry so that they can provide the investigating Competent Authority with the information needed to evaluate the trend or signal. The analysis of the signal should follow state-of-the-art risk assessment principles, e.g. those described by the International Risk Governance Council¹⁰.

If the Competent Authority decides to investigate further at European level, the Responsible Person and the European Commission should be informed.

Caution should be exercised in evaluating spontaneous reports, especially when comparison is made between different countries where the cosmetovigilance systems are recently implemented. The data accompanying spontaneous reports are often incomplete, and the rate at which cases are reported is dependent on many factors including the time since market launches, media attention or environmental / public health concerns. In order to minimize bias, breaking out analysis and evaluation of medically validated SUEs with non-medically validated cases should be considered.

Except in the case where immediate action is necessary on the grounds of a serious risk to human health, the Responsible Person should be given the opportunity to put forward his viewpoint before any decision is taken.

4.2 Corrective actions

When necessary, corrective actions should be undertaken by a responsible person or distributor following the assessment of the SUEs or the validation of a trend or signal. The appropriate corrective actions may, for example include a change in usage instructions, labeling, warnings, formula modification or any other action necessary to protect the health of the consumer. Measures taken should be proportionate to the nature and frequency of the Serious Undesirable Effect and be subject to a rigorous risk assessment.

¹⁰ Risk Governance, Towards an Integrative Approach, Geneva, International Risk Governance Council (IRGC), January 2006 (<http://www.irgc.org>).

5. Cosmetic Product Safety Report

Annex I of the Cosmetics Regulation, which describes the Cosmetic Product Safety Report, requires the inclusion of: *“All available data on the undesirable effects and serious undesirable effects to the cosmetic product or, where relevant, other cosmetic products. This includes statistical data.”*

This requirement affects all UEs and SUEs reported to the responsible person, except if the causality assessment qualifies the link between the product and the SUE/UE as ‘excluded’. If there is a disagreement between the Responsible Person and the Competent Authority on the outcome of a causality assessment, this should be mentioned.

Different levels of detail are expected for the inclusion of SUEs and UEs and it is therefore recommended to separate them in the Cosmetic Product Safety Report.

- Data on UEs may be in the form of statistical data such as number and type of undesirable effects per year. It may be useful to make a distinction in the presentation between UEs that are medically confirmed and those based solely on consumer reports.
- Data on SUEs, which have been notified to the National Competent Authority, should be included via a copy (physical or electronic) of the notification form(s) sent to the Competent Authority.

Companies should have clear internal procedures for inclusion of this information, updating it and making available to the safety assessor, who may revise his assessment and/or take the information into account when assessing similar products.

The Responsible Person’s action and handling of the reported Serious Undesirable Effect should be stated. Corrective as well as preventive measures taken should be described.

For further information, refer to the comprehensive guidelines on the Cosmetic Product Safety Report (Annex I of the Regulation) issued by the European Commission¹¹

http://ec.europa.eu/growth/sectors/cosmetics/legislation/index_en.htm

and Commission’s Communication of serious undesirable effects including EC SUE guidelines and reporting forms:

http://ec.europa.eu/growth/sectors/cosmetics/market-surveillance/index_en.htm

6. Information to the public

Under Article 21 of the Regulation, it is foreseen:

“Without prejudice to the protection, in particular, of commercial secrecy and of intellectual property rights, the responsible person shall ensure that the qualitative and quantitative composition of the cosmetic product and, in the case of perfume and aromatic compositions, the name and code number of the composition and the identity of the supplier, as well as existing data on undesirable effects and serious undesirable effects resulting from use of the cosmetic product are made easily accessible to the public by any appropriate means.

¹¹ Guidelines on Annex I to Regulation (EC) No 1223/2009 (2013/674/EU)

The quantitative information regarding composition of the cosmetic product required to be made publicly accessible shall be limited to hazardous substances in accordance with Article 3 of Regulation (EC) No 1272/2008.”

6.1 When is this information to be made available to the public and by whom?

All the information concerned is already accessible to the Competent Authorities of the Member States under the specific requirements of Article 11 (Product Information File) of the Regulation. The key difference is that some of the information must also be made easily accessible to the public on their request. The obligation to make the information mentioned in Article 21 easily accessible to the public is clearly with the Responsible Person. This Responsible Person has also to keep this information readily accessible to Competent Authorities. Member States have to ensure that these obligations are fulfilled.

6.2 What information needs to be made accessible to the public?

- Qualitative composition – the list of ingredients of the product
- Quantitative composition – only required for hazardous ingredients classified under the EU Regulation for Classification and Labelling of Chemicals (EC No 1272/2008)
- Data on the Undesirable Effects and Serious Undesirable Effects resulting from use of the cosmetic product

6.3 Data on Undesirable Effects related to the product (Article 21)

All Undesirable Effects that are assessed as ‘very likely’ or ‘likely’ linked to the use of the product should be considered when the responsible person gives information to the public. The companies have the possibility to inform the public if Undesirable Effects have been medically substantiated or not.

Appropriate information on the frequency and nature of Undesirable Effects linked to the product placed on the market of the Member States must be provided. Companies have the possibility when informing the public to additionally compute a value for the number of undesirable effects per 1,000,000 units placed on the market.

6.4 How should the information be made accessible to the public?

The information outlined above has to be made accessible to the public upon request but it does not have to be published.

The Commission considers that members of the public who wish to access this information will have one or more of the following options:

- to write to the responsible person
- to telephone the responsible person
- to visit the responsible person’s website

For companies that do not have consumer help-line numbers or websites, the public will always have the option of writing to the address indicated on the package. In accordance with Article 19 (1) (g), the label of every cosmetic product placed on the EU market must bear the name or style and the address

or registered office of the Responsible Person marketing the cosmetic product who is established within the Community.

Moreover, in order to facilitate public access to the relevant product information, industry has made known to the Commission that it has created a central public directory of companies placing cosmetic products on the EU market. European Directory of public access: <http://www.european-cosmetics.info>. The directory is available on the internet and contains company names and contact details (address, telephone, fax, e-mail, website). The directory is a central listing of contact points, designed to enable the public to locate the companies, and is not the source of the information itself. Companies themselves will reply directly to the public.

In order to make the information easily accessible to the public, the party responsible for answering a request for information according to Article 21, should ensure that an answer is given promptly without unnecessary delay taking into account the nature and the volume of the information.

If a member of the public does not receive an answer from the company or if the answer is not complete, they may complain to competent authorities who may then contact the competent authorities of the Member State concerned.

The answer should be in a language easily understood by the public.

Companies should keep a record of all requests and answers given.

7. Management system and data protection

7.1. Management system for handling of UE/SUEs

To ensure a well controlled management of Undesirable Effects and to provide rapidly information when necessary, it is recommended to set up an appropriate system which ensures reception of all incoming information about UE/SUE, their fast and targeted transmission to the responsible function within the company, and a good traceability of the SUEs, including those sent by the Competent Authorities. Especially for multi-sited and/or multinational companies clear interfaces and workflows should be described.

7.2 Determination of tasks and responsibilities

The tasks and responsibilities from all company functions involved in the handling of UE/SUE (e.g. administrators, causality assessors, personal authorized for communication with NCA) should be clearly described. Written SOPs or workflow-diagrams are recommended to ensure transparency among the functions involved.

7.3. Outsourcing

When activities are outsourced partly or in total, the company should have written agreements with the third party, in which obligations, responsibilities and interfaces are fixed.

Due to the importance of the management of SUEs any outsourcing activity should be carefully selected, taking into account the know-how, resources and credibility of the third party.

7.4. Legal compliance with EU Data Protection Rules

All company personnel involved in the processing of UE/SUEs should be familiar with the applicable regulations on data protection (eg. the national transpositions of the EU Personal Data Protection Directive 95/46 CE).

European Commission Guidelines on the communication of SUEs

The European Commission guidelines on SUE Reporting, as well as their translation, are available here:

http://ec.europa.eu/growth/sectors/cosmetics/market-surveillance/index_en.htm

Three different reporting forms were prepared and are available via the links indicated below:

- **SUE Form A - To be filled in by Responsible Persons or Distributors** that are made aware of a SUE in order to transmit it to the Competent Authority of the country where the SUE occurred. The form is available here :
http://ec.europa.eu/growth/sectors/cosmetics/market-surveillance/docs/sue_form_a_en.pdf

Fill in instructions on Form A are available here :

http://ec.europa.eu/growth/sectors/cosmetics/market-surveillance/docs/sue_form_a_guide_en.pdf

- **SUE Form B - To be filled in by a Competent Authority and attached to SUE Form A** in order to transmit the information on SUE to the Competent Authorities of other Member States, when the information was reported by a Responsible Person or Distributor; or in order to transmit the information on SUE to the Responsible Person, when the information was initially reported by a Distributor. The form is available here :
http://ec.europa.eu/growth/sectors/cosmetics/market-surveillance/docs/sue_form_b_en.pdf

Fill in instructions on Form B are available here :

http://ec.europa.eu/growth/sectors/cosmetics/market-surveillance/docs/sue_form_b_guide_en.pdf

- **SUE Form C -To be filled in by a Competent Authority** in order to transmit to the Competent Authorities of other Member States and to the Responsible Person the information on SUE which has been reported by health professionals and/or end users. The form is available here :

http://ec.europa.eu/growth/sectors/cosmetics/market-surveillance/docs/sue_form_c_en.pdf

Fill in instructions on Form C are available here: .

http://ec.europa.eu/growth/sectors/cosmetics/market-surveillance/docs/sue_form_c_guide_en.pdf

National contact points can be found here:

http://ec.europa.eu/growth/sectors/cosmetics/market-surveillance/docs/sue_contact_points_en.pdf

Example of questionnaire for collection of information on a Undesirable Event

Date of contact

Consumer¹²

- Name or initials
- Contact details
- Sex
- Age (in particular if a child is involved)
- Baseline characteristics, including relevant medical history and relevant past cosmetic product use (e.g. history of allergy, a previous reaction with a cosmetic product)

Reporting person, if different from the consumer/end user

- Name,
- Contact details
- Qualification (e.g. physician, dentist, pharmacist, nurse, consumer or other non-healthcare professional)
- As far as information can be shared³: baseline characteristics of the consumer, including relevant medical history and relevant past cosmetic product use (e.g. history of allergy, a previous reaction with a cosmetic product)

Suspected product

- Product category
- Exact name
- Batch number (if possible)

Conditions of use

- Duration of application
- In case of an error in the product use (e.g. misuse), the sequence of events leading up to the error

Undesirable event

- Signs/symptoms
- Chronology (date of start of event, the time to onset/clearing of signs or symptoms)
- Seriousness of the event
- Diagnosis made by a health-care professional, if available.
- Results of medical investigation and/or re-exposure
- Clinical course of the event, including medical treatment, if any

¹² Important : Consumer related information needs to respect privacy and data protection, see Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995, on the protection of individuals with regard to the processing of personal data and on the free movement of such data.

Process for reporting SUE

Responsible Persons and distributors are expected to report a Serious Undesirable Effect (SUE) to the National Competent Authority of the country where the SUE occurred as soon as possible but in no case later than 20 calendar days following the date of initial receipt by the company. The company should submit SUEs using the Serious Undesirable Event Report Form as recommended in Appendix I.

Each report submitted should bear prominent identification as to its content i.e. as an “initial report” or as a “follow-up report”. A pending initial report has to be promptly investigated by the company. When complementary significant information regarding the case is received, even several weeks after the initial notification, it should be submitted to the National Competent Authority as a “follow up report”. Follow up reports should be sent to National Competent Authorities preferably within 20 calendar days following receipt of the information by the company.

If it is expected that the follow-up is not the last one, companies may consider it useful to indicate the status as “pending”. Likewise, if this is the last follow-up, the status to be indicated would be “closed”. If no additional information can be obtained despite two further attempts to contact the initial reporter, the case may be closed. These two contacts must be documented in the case file.

The final causality assessment should be indicated in the section “Comments of the company” of the report form. If this causality assessment cannot be done (unassessable) the reason should be given in this section.

INITIAL RECEIPT OF CASE REPORT IN THE COMPANY

↓ 20 calendar days

INITIAL EXPEDITED REPORT

Initial level of information incomplete:
Mark report as *'initial'*.

Initial level of information complete:

- Mark report as *'initial'*
- Indicate *'no further information will be obtained'* in comments field of SUE reporting form
- Indicate outcome of final causality assessment

Preferably within 20 calendar days

New, significant information

→ ↓

FOLLOW-UP REPORT- same SUE Report

If further information obtained, re-looped



Level of information remains incomplete:

- Mark report as *'follow-up'*
- If it is known then state that *'no further information will be obtained'*
- Indicate outcome of causality assessment

Level of information complete:

- Mark report as *'follow up'*
- Indicate *'no further information will be obtained'* in comments field of SUE reporting form
- Indicate outcome of causality assessment