

SUE REPORTING GUIDELINES

1. Introduction

Regulation (EC) No. 1223/2009 on cosmetic products ('Cosmetics Regulation')¹ created the basis for a uniform approach to the management of serious undesirable effects (SUEs) attributable to the use of cosmetics. It provides for notification of SUEs without delay to the Competent Authorities of the Member State where the effect in question occurred, as well as the notification of any corrective measures taken by the Responsible Person or Distributor. Data on SUE become part of the Cosmetics Product Safety Report (CPSR)² and have to be made available to the public³.

In order to facilitate the implementation of Article 23 of the Cosmetics Regulation, which constitutes an essential part of a cosmetovigilance⁴ system, and to establish a management and communication system on SUE throughout the EU, the Commission, in conjunction with Member States and industry, established the following guidelines describing the system. Their aim is to ensure harmonized notification of SUE by the Responsible Person or Distributor and follow-up on SUE notifications by Competent Authorities, Responsible Persons or Distributors.

2. Notification and transmission of SUEs

2.1 Definitions

The Cosmetics Regulation defines undesirable effects as “adverse reactions for human health attributable to the normal or reasonably foreseeable use of a cosmetic product”.⁵

Serious undesirable effects are defined as “undesirable effects which result in temporary or permanent functional incapacity, disability, hospitalisation, congenital anomalies or an immediate vital risk or death”⁶.

Taking into account the definition of an SUE, the word "serious" is not synonymous with severe. "Severe" is used to describe the intensity (severity) of the effect as in mild, moderate or severe. Seriousness is used to describe the patient/event outcome or action.

¹ OJ L 342, 22.12.2009, p. 59

² Annex I of Regulation (EC) No. 1223/2009 on cosmetic products

³ Article 21 of Regulation (EC) No. 1223/2009 on cosmetic products

⁴ Cosmetovigilance is defined by the collection, evaluation and monitoring of spontaneous reports of undesirable events observed during or after normal or reasonably foreseeable use of a cosmetic product. Together with other tools, cosmetovigilance contributes to post market surveillance.

⁵ Article 2 1. (o) of Regulation 1223/2009

⁶ Article 2 1. (p) of Regulation 1223/2009

As a consequence, before the notification or the transmission of the SUE, Responsible Persons, Distributors and Competent Authorities must ensure that the undesirable effect meets the seriousness criteria.

2.2 Causality assessment

Causality assessment is an analysis of causal association, on a case-by-case basis, in an attempt to determine the probability that a serious undesirable event⁷ is attributable to a well identified product used by an end user.

The causality assessment method described in the Annex 1 to this guideline provides a state-of-the-art approach to determine whether a notified serious undesirable event is considered to be attributable to the use of a cosmetic product.

The causality assessment relates to the effect on an individual end user; it does not provide any evaluation of the risk of a product to the general population. The likelihood of causality should be obtained from the use of a standardized method for causality assessment (see Annex 1).

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

In order to perform the causality assessment, information is needed on the serious undesirable event and on the product. To this end, an exchange of all the relevant information between the Responsible Person, the Distributor and the Competent Authority is crucial.

Notifications by the Responsible Person should include a causality assessment, which should be reviewed by the Competent Authority.

Notifications by the Distributor should, if possible, include a causality assessment, which should be reviewed by the Competent Authority. In any event, the Distributor should gather all the available information on the case in order to allow the Responsible Person and/or Competent Authority to make the causality assessment.

Causality assessments for cases reported directly to Competent Authorities should be made preferably by the Authorities. If this is not possible, the Authorities should inform the Responsible Person and exchange all available information to allow a causality assessment to be performed by the Responsible Person without delay.

The person responsible for the causality assessment should be someone who is experienced in complaint handling and who has an appropriate professional background. In certain cases it may be advisable to seek the support of an external or in-house healthcare professional in making the causality assessment in order to obtain a high degree of confidence in the result.

It is possible that the outcome of an initial assessment may change at a later stage in the process as a result of additional information obtained from detailed

⁷ Event is a noxious and unintended reaction that occurs in humans using or exposed to a cosmetic product without prejudging in advance of a link between a cause and an effect.

questionnaires or from medical investigation. A causality assessment should only be considered “final” if it is unlikely that further information will be obtained which might change the assessment.

2.3 Scope of notification of SUEs

The Cosmetics Regulation requires the notification by the Responsible Persons and Distributors of all serious undesirable effects which are known to them or which may be reasonably expected to be known to them.

Due to their potential medical seriousness, all SUE cases, except those classified as ‘excluded’ in causality assessment within the timeframe indicated in section 2.4.3, should be notified and the information on these cases should be kept available by the Responsible Person for the Competent Authority of the Member State in which the Responsible Person is established.

The act of notifying a SUE to a Competent Authority is not to be construed as an admission by the company of liability for the SUE and its consequences.

2.4 Requirements for notification and transmission of SUEs

2.4.1 Notification /Transmission Forms

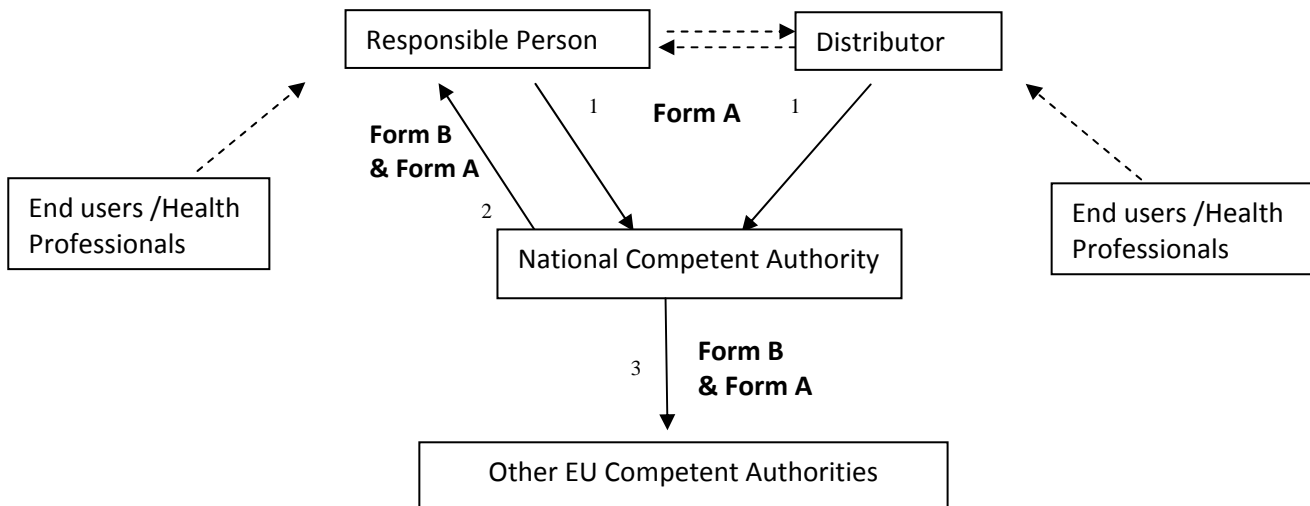
Three different forms were drawn up, enabling a structured and harmonised submission of all important factors related to the SUE, as well as relevant ancillary information (report reference number, outcome of causality assessment, status of notification: initial vs. follow-up, etc.)

The use of the following forms (see Annex 2) is strongly encouraged:

- SUE Form A: Responsible Persons or Distributors notifying SUEs to the Competent Authorities;
- SUE Form B: This form is completed by the Competent Authority and attached to SUE Form A to provide a brief summary and perspective of the case when the Competent Authority transmits SUE Form A to other Competent Authorities and to the Responsible Person. The transmission to the Responsible Person is mandatory when the initial notification comes from a Distributor and it is highly recommended in follow-up and final transmissions when the initial notification comes from the Responsible Person; and
- SUE Form C: Competent Authorities transmitting SUEs reported by health professionals or end users to other Competent Authorities and the Responsible Person.

Flowcharts for notification scenarios

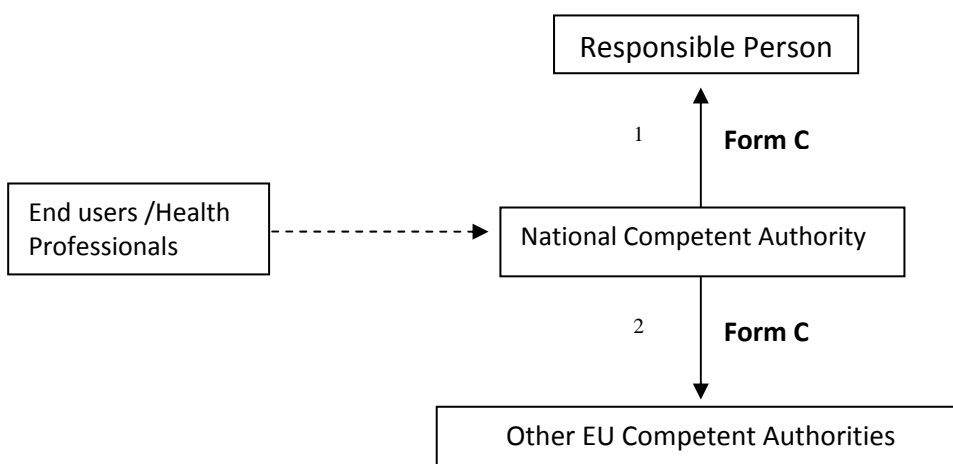
1. SUE initially received by the Responsible Person or the Distributor



SUE Form A: Responsible Persons or Distributors notifying SUEs to the Competent Authorities;
SUE Form B: Transmission Form for National Competent Authority (accompanying Form A to provide a brief summary and perspective of the case, when transmitting information to other EU Competent Authorities and the Responsible Person):

- to be sent to other EU Competent Authorities when received initially by the Responsible Person or the Distributor (recommended to be also sent to the Responsible Person)
- to be sent to the Responsible Person when the initial notification comes from the Distributor

2. SUE initially received by a National Competent Authority



SUE Form C: Competent Authorities transmitting SUEs reported by health professionals or end users to other Competent Authorities and the Responsible Person

The forms are designed not only for the initial notification or transmission, but also for follow-up and final conclusions. Not all the information listed in the forms may be available at the time of the initial notification. However, the initial notification should be carried out if the following minimum information is available:

- a) an identifiable reporter;
- b) the nature of the alleged SUE and the date of its onset; and
- c) the name of the cosmetic product concerned enabling its specific identification.

If the minimum information cannot be obtained, the notifier should continue to undertake all reasonable efforts to obtain the information and notify without delay as it becomes available. The existence of SUE cannot be confirmed unless a minimum amount of information can be obtained.

The list of Competent Authorities will be compiled and made available to the public by the European Commission⁸.

2.4.2 Identification /traceability of SUEs

Each Member State and the Responsible Person or Distributor should be able to unambiguously identify the cases which are forwarded to them.

A common European identification system should be used by Competent Authorities for their management of cases of SUEs when they first receive them (e.g. *OECD coding for the country of origin, the year of reporting and the serial number of the concerned case*). To avoid duplication, and to manage the follow up information of SUE appropriately, both the Company and Competent Authority Case Identification Numbers should be printed on the documents exchanged on these cases.

2.4.3 Timeframes

For the interpretation of the delays referred to in points 1 (without delay) to 4 (immediately) of Article 23 of the Cosmetics Regulation, the timeframes should be understood as being within 20 calendar days from the date on which any employee of the company or of the Competent Authority, whatever their role or function, becomes aware of the SUE.

2.5 Principles of interaction between the Responsible Person, Distributor and Competent Authorities

The Cosmetics Regulation makes provision for an exchange of information between the Member States' Competent Authorities and the company (Responsible Person or Distributor) whose product is concerned by the SUE notification.

The Responsible Person or Distributor should exchange all available information that is relevant to the assessment of the case. Additional information deemed necessary by the Competent Authority should be provided on request.

⁸ Article 34 of Regulation (EC) No. 1223/2009 on cosmetic products

Prior to forwarding information to other Competent Authorities, the Competent Authority receiving a SUE notification should verify whether the case fulfills the seriousness criteria described in Chapter 2.1 and whether the required minimum level of information is available (Chapter 2.4.1).

Where several products are suspected, the Competent Authorities should involve all Responsible Persons concerned.

To ensure the efficiency of the system and to avoid duplication, it is recommended that the Responsible Person receives a copy of the transmission form disseminated to the other Competent Authorities. If other significant information relevant to the case, including its final conclusion, is exchanged between Competent Authorities, it is also recommended that the Responsible Person should be informed.

In particular, the Responsible Person should have the opportunity to review and comment on the causality assessment. If there is no consensus between the Competent Authority and the Responsible Person on the causality assessment, this disagreement should be noted in the transmission of the SUE to the other Competent Authorities.

It is recommended that any communication to the Responsible Person or between Competent Authorities on a notified SUE should be channelled through the Competent Authority which originally received the notification.

Distributors are under a legal obligation to notify to the authorities any SUEs that are reported to them. It is acknowledged that they may not have the same level of information on the product as is available to the Responsible Person and they may find it difficult to provide the full information expected in a SUE notification. The Distributor can inform the Responsible Person in order to collaborate on the SUE notification, provided that the timeframes referred to in Chapter 2.4.3 are respected.

3. Transmission of information on SUEs between Competent Authorities

3.1 Principles

The scope and objective of information exchange / transmission on SUEs between authorities is to facilitate post-market surveillance in order to ensure that the provisions of the Cosmetics Regulation are respected.

Prior to their transmission to all Competent Authorities, the causality of SUEs should be determined by means of the common method referred to in Chapter 2.2.

Likewise, any changes in the outcome of the causality assessment, based on relevant follow-up information to a case, should be transmitted to the Competent Authorities, including assessments which ultimately rule out a link between the product and the SUE.

3.2 Information Exchange Network among Competent Authorities

The information exchange concerning SUEs among Competent Authorities of the Member States will be carried out via the Information and Communication System for Market Surveillance (ICSMS).

3.3 Data privacy protection and confidentiality issues

All persons involved in SUE notification and transmission should be familiar with and discharge obligations with regard to the collection, use and disclosure of personal information in accordance with the national regulations transposing the EU Personal Data Protection Directive⁹. In particular, end users and / or notifiers (e.g. health professionals) should not be identified by their name or address when notifying a SUE or when disseminating a notification among Competent Authorities.

All communications concerning SUEs between Responsible Persons and Competent Authorities, between Distributor and Competent Authorities, between Responsible Person and Distributor, or between different Competent Authorities should guarantee the confidentiality of the information. The reception and the storage of the SUE forms received should be accessible to clearly identified authorized persons only, in accordance with internal Standard Operating Procedures.

4. Subsequent actions

The main purpose of subsequent actions is to maintain the protection of health and safety of cosmetics users by reducing the likelihood of recurrence of an SUE. This includes, where appropriate, corrective measures and the dissemination of information which could be used to prevent such repetitions and which should be proportional to the nature and/or frequency of the SUE.

It should be stated that notification of a SUE does not necessarily indicate a serious risk or non-compliance of the product.

Besides the evaluation of isolated cases, ideally the validation of a signal¹⁰ and the measure of its impact should be performed. This requires further investigations using other sources of information, the identification of possible risk factors and the characteristics of the population exposed.

Therefore, care should be taken when evaluating spontaneous reports¹¹, especially if a comparison is made between different countries or companies. The data accompanying spontaneous reports and the rate at which cases are reported is dependent on many factors. In order to minimize bias, a specific analysis and evaluation of medically validated SUEs should be considered and compared with non-medically validated cases.

4.1 Subsequent actions by a Responsible Person

4.1.1 Analysis of the data

A human health issue could be identified from one report or, more likely, from several similar SUE reports associated with the same product. Where necessary, a trend analysis that takes into consideration the nature, severity and/or frequency should be

⁹ OJ L 281 , 23.11.1995, p. 31

¹⁰ A signal may be defined by the onset of an unexpected modification of a pre existing level of reporting rates, including qualitative or quantitative modifications.

¹¹ In vigilance systems spontaneous report refers to unsolicited communication by end users or by health care professionals to a company, 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.

performed. Other factors could include possible predisposing factors on the part of the end users who had experienced the undesirable effect.

When a human health issue is thereby identified, further analyses should be carried out to establish, where possible, the potential mechanism of the undesirable effect.

4.1.2 Inclusion in the Cosmetic Product Safety Report

Annex I of Cosmetics Regulation requires inclusion in the Cosmetic Product Safety Report 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.”

Specific guidance on this matter is given in separate EC guidelines (ref: Annex I Guidelines)

4.1.3 Information to the public

The Cosmetics Regulation requires that existing data on undesirable effects and serious undesirable effects resulting from the use of the cosmetic product are made accessible to the public by any appropriate means¹².

Although that information has to be made accessible to the public on request, it does not have to be published. The contents should be presented in a consistent fashion and follow the recommendations described in the Guidelines for Information to the Public (reference to be updated).

Any communication on cosmetovigilance data should take into account the understanding level of the readers. Data should be provided on causality levels and levels of seriousness. To be meaningful, cosmetovigilance data should not be presented in isolation, but should be put into perspective with market data.

4.1.4 Corrective action

Where necessary, a number of actions may be undertaken by a company following assessment of the post marketing surveillance data, together with other sources of safety data. The measures taken should be proportional to the nature and/or frequency of the SUE and be subject to the same rigorous risk assessment exercise conducted by Competent Authorities (see below). These measures may include a change in usage instructions, labelling, warnings, changes to the formula, recall or withdrawal of the product, or any further action necessary to protect the health of the end user. If a SUE requires corrective measures, these have to be notified to the same Competent Authority to whom the SUE had originally been notified. This Competent Authority has to inform other Competent Authorities in the Union.

4.2 Subsequent actions by Competent Authorities

Actions subsequent to SUE notifications can be taken by Competent Authorities for the purposes of in-market surveillance, market analysis, evaluation, and end user information in the context of Articles 25, 26 and 27 (non-compliance and safeguard clause).

¹² Article 21 of Regulation (EC) No. 1223/2009 on cosmetic products

4.2.1 Evaluation of trend or signal detection

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 Council¹³.

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

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.

4.2.2. End user information by Competent Authorities

Periodic bulletins on post-marketing surveillance data from cosmetics may be issued by Competent Authorities, particularly on their respective websites. If data on SUEs including the outcome of causality assessments and statistical analysis are published through this medium, the Responsible Persons of the companies concerned should be duly informed ahead of such publication if the commercial name of the product is mentioned.

The risks of a dissemination of isolated cases of SUEs to the public should be carefully examined. Any communication on cosmetovigilance data should take into account the level of comprehension of the readers. In order to be meaningful, cosmetovigilance data should not be presented in isolation, but should be put into proper perspective. Data should be provided on causality levels and degree of seriousness.

Accurate and timely communication of emerging data on risk is an essential part of cosmetovigilance. Risk communication is an important stage in risk management as well as a risk minimisation activity. End users and healthcare professionals need accurate and effectively communicated information about the risks associated with the cosmetic products and other factors influencing these risks. Because of the importance of risk communication, it is recommended that appropriate experts should be consulted.

¹³ Risk Governance, Towards an Integrative Approach, Geneva, International Risk Governance Council (IRGC), January 2006 (<http://www.irgc.org>).