Central Administration of Pharmaceutical Care
General Administration for Pharmaceutical Vigilance

EDA Cosmetovigilance Guidelines

For cosmetic products companies

Year 2022

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Contents

1 Introduction

What is a cosmetic product?

A “cosmetic product” shall mean any substance or preparation intended to be placed in contact with the various external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance and/or correcting body odors and/or protecting them or keeping them in good condition.

What is Cosmetovigilance?

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.

Cosmetic products placed on the Egyptian market have high standards of safety and quality. Undesirable effects as a result of normal or reasonably foreseeable use 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.

Each Product owner (Cosmetic products company) should specify the name of one person to be in contact with the general administration for pharmaceutical Vigilance (EPVC), and provide his/her contact details.

The Egyptian Pharmaceutical Vigilance Center (EPVC)

The Egyptian Pharmaceutical Vigilance Center (General administration for pharmaceutical vigilance) has been established in December 2009 in line with the global trend to strengthen the rules governing pharmacovigilance.
It is the national center in Egypt responsible for monitoring the safety of pharmaceutical products, medical devices and cosmetics throughout its life cycle. It also represents the regulatory body for pharmaceutical companies for subjects related to the field of pharmaceutical vigilance.

1.1. Foreword

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.

Following these guidelines will allow responsible entities and distributors to demonstrate compliance with the legal requirements and provide the public and the Egyptian Drug Authority 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.

1.2. Definition of terms

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, and any other individuals to have occurred during or after normal or reasonably foreseeable use (exclude misuse and abuse) 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 precise 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– as long as they are sufficient to enable the product’s specific identification.)

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

1.2.2. Undesirable Effect (UE)

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 multifactorial 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).

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 doctor.

'Serious undesirable effect' *means an undesirable effect which results in temporary or permanent functional incapacity, disability, hospitalization, congenital anomalies or an immediate vital risk or death.'*

Seriousness Criteria:

- ***Temporary or permanent functional incapacity***

  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.

- ***Disability***

  "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.

- ***Hospitalization***

  "Hospitalization" refers to inpatient hospitalization 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.

- ***Congenital anomalies***

  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.

- ***Immediate vital risk***

  "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.

- ***Death***

  It 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

Causality assessment is the analysis of the probability that a well identified product used by a consumer is responsible for a genuine undesirable event, i.e., whether the event is attributable to the use of a cosmetic product and should therefore be considered as an Undesirable Effect. A causality assessment is done for a specific use of the product by an individual consumer. It does not give an evaluation of the risk of a product to the general population.

1.2.6. Spontaneous report

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.

1.3 Roles and responsibilities

The cosmetic company placing a cosmetic product on the Egyptian market (i.e. the Product owner) has the following responsibilities:

- Make clear to consumers how they can contact the company
- 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
- Maintain records of all reported UEs on cosmetics marketed in Egypt and to readily provide access to the information upon request, to the Egyptian drug authority (EDA)
- 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
- Make sure that their personnel are appropriately informed and trained about their Cosmetovigilance obligations
- Establish a clear relationship between Product owner and Distributor regarding the management and reporting of SUEs
- Make available to National regulatory Authority (EDA) the contact facilities of the Product owner and set up internally the appropriate processes for the management and reporting of SUEs
- 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
- Ensure the monitoring of subsequent actions, if any
- Update the Cosmetic Product Safety Report (CPSR) considering the available data on the UEs and SUEs to the cosmetic product
- 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 EDA.

2 Scope

Compliance with Egyptian Guidelines for cosmetics requires the identification of the possible sources of information on UEs and SUEs. Individual SUEs that occur within Egypt are required to be reported to the Egyptian drug authority (EDA) via E-mail: pv.cosmetic@edaegypt.gov.eg

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 post-market surveillance studies or any epidemiological studies commissioned by a manufacturer/brand owner or requested by EDA , 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 Egypt, any SUEs identified would not be reportable but those data attributable to the products would be expected to form part of the Product owner's records, accessible **when necessary.**

Similarly, if studies are conducted in Egypt, published SUEs in scientific and medical literature, the data would be expected to be reported; 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 Product owner's company files.

The screening policy of scientific and medical literature is determined by each company, but should be proportionate. SUEs reported in Egyptian 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 Product owner and/or distributor should ensure that an appropriate management system of suspected 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 EDA (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 Product owner 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 EDA 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 EDA and/or the public under the requirements of the Regulation

3.1 Reception

Individual reports from consumers, EDA, 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. 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 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 healthcare 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 misuse 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 and 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.

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). Notifications by the Product owner should include a causality assessment, which should be reviewed by the Authority. The aim of this reproducible, rational, harmonized and standardized method is to assess cause-and-effect relationships between cosmetic products and given clinical and/or paraclinical effects. The method is based on *six criteria*, divided into *two groups*, which are used to calculate a **chronological score** and a **semiological score**. 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 method offers five levels of causality assessment: very likely, likely, not clearly attributable, unlikely and excluded. The vigilance process may serve various activities in various fields: improving knowledge, epidemiology, surveillance, signal detection and alerts. For a number of reasons, particularly on epidemiological grounds, it can be useful to list already known effects in order to determine their frequency and analyze thoroughly their determinants. By combining their frequency and severity, it is possible to determine the criticality of the undesirable effects, which is one of the central factors in risk management. However, it is essential to be able to identify undesirable effects irrespective of current scientific knowledge, particularly the scientific knowledge of the reporter and monitor. It is therefore vital not to reject reported undesirable effects on the ground that no causal link can be established.

As is the case for all causality assessment methods, implementation of this method:

- Is possible only once a minimum amount of information has been collected
- Must be conducted independently for each cosmetic product used before occurrence of the undesirable effect
- Might require specialist medical assessment — this is recommended in complex cases, or if the impact on the user's health is deemed serious.

The experts established a set of intrinsic criteria, involving no data other than those collected on the individual case, for calculating two types of scores:

- Chronological score
- Semiological score

Chronological score

The chronological score is calculated from the information on the time sequence between use of the cosmetic product and occurrence of the symptoms.

The time sequence between use of the cosmetic product and occurrence of the alleged undesirable effect may be:

- Compatible, i.e. usual given the reported symptoms;
- Only partially compatible, i.e. unusual given the reported symptoms;

- Unknown;
- Incompatible, whenever the clinical or paraclinical effect occurred before the cosmetic product was used or whenever the period before the observed symptoms appeared is too short.

If the time sequence is inconsistent, the undesirable effect cannot be attributed to use of the cosmetic product.

Semiological score

The semiological score is calculated from the information on the nature of the undesirable effect and on the results of any specific additional examinations that were performed or of re-exposure to the cosmetic product.

a) Symptomatology

Symptomatology is defined as a set of symptoms, recorded as exhaustively as possible during the case investigation, enabling a diagnosis to be put forward. Absence of diagnosis does not prevent use of this method.

It points to use of a cosmetic product whenever the symptoms observed are appropriate to the nature of the product or to its method of use in terms of location, effect or evolution.

It is otherwise only partially or not at all evocative (not suggestive of the product effect).

In certain cases, factors that might have contributed to the undesirable effect, i.e. to attenuating or accentuating its clinical expression, may come to light when this information is collected. Although these factors may play a significant role, for the sake of simplification they have not been taken into account in this method.

b) Additional examinations (AE)

Any additional examinations must be reliable and specific to the observed effect and must be performed by specialist physicians.

The results of these examinations are rated as follows:

- AE (+): positive;
- AE (-): negative;
- AE (?): if no examinations were performed or if the results were ambiguous.

c) Re-exposure to the cosmetic product (R)

After the decurrence of clinical signs, there are three possibilities if the effects recur after re-exposure to the cosmetic product, whether accidental or not:

- R (+, positive): the initial symptomatology recurs with the same intensity or with a higher intensity when the user is re-exposed to the product;
- R (?): there is no re-exposure to the product or the conditions of re-exposure are not identical to those of the initial exposure;
- R (-, negative): the effect does not recur when the user is re-exposed to the product.

For re-exposure to be considered negative, it must occur under similar conditions of use of the cosmetic product (identical product, identical procedure, identical duration, etc.) without causing

an identical undesirable effect (identical symptoms and location, identical time sequence before occurrence, etc.).

These scores, combined in a decision table (Table 1), produce five levels of causality: very likely, likely, not clearly attributable, unlikely and excluded.

In this decision table, in principle causality is 'excluded' if the time sequence before the effect appears is considered incompatible.

Table 1: Decision table

Symptom / Time sequence between exposure and occurrence of symptoms	EVOCATIVE			ONLY PARTIALLY OR NOT EVOCATIVE		
	R and/or AE +	R and/or AE ?	R and/or AE -	R and/or AE +	R and/or AE ?	R and/or AE -
Compatible	Very likely	Likely	Not clearly attributable	Likely	Not clearly attributable	Unlikely
Only partially compatible or Unknown	Likely	Not clearly attributable	Unlikely	Not clearly attributable	Unlikely	Unlikely
Incompatible	Excluded	Excluded	Excluded	Excluded	Excluded	Excluded

3.4 Reporting of Serious Undesirable Effects to EDA

3.4.1 General principles

Upon receipt of a report of a domestic SUE the Product owner has to report it to the **EDA** using the standardized 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 **EDA**

It is recognized 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 **EDA** 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 **EDA** and those received from the **EDA** should be appropriately stored according to a well-defined internal traceability process. (See section 6.1)

3.4.2 Criteria for an Undesirable Effect being reportable to EDA 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 **EDA**. 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.

Product owners 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 doctor.

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 **EDA** a separate report for each identifiable consumer. Each case should be identified separately so that it is clear for the **EDA** 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 **EDA**. Information on the reported SUEs should be kept available by the Product owner.

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

3.4.3 Time frames

Product owners and distributors are expected to report a domestic Serious Undesirable Effect (SUE) to the Authority (EPVC/EDA) as soon as possible but in no case later than 20 calendar days following the date of initial receipt by the company.

3.4.4 Reporting Form

The reporting of a SUE to **EDA** should be done using a harmonized Serious Undesirable Effect Reporting 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 reporting form should be sent to **EDA** by appropriate means to ensure confidentiality. An acknowledgement of the reception of the case should be sent back to the Product owner. 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 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 A . If a SUE involves more than one suspect cosmetic product, the authority should inform the other concerned Product owners of the SUE. In this circumstance, the concerned companies should not re-send the case to **EDA**. 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 EDA 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 EDA.

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 EDA and the case then considered as closed.

3.4.6 Serious Undesirable Effect received from the Egyptian Drug Authority

When EDA is made aware of a domestic SUE and whatever the source of information (distributors, end users or health professionals), they should transmit the case with all available details to the Product owner. It is therefore expected that EDA 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.

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

If there is no consensus on the final causality assessment of the SUE between the EDA and the Product owner, 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 EDA will be included in the record files of the Product owner. Such cases will have a double identification: the company reference number and the EDA reference number.

3.5 Data privacy protection and confidentiality issue

Consumers should not be identified by name or address when reporting SUE to the EDA. 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. In case of request for personal information, the transmission of personal data shall follow the provisions of the 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 Product owner and EDA, 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, 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 Product owner 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. Two main indicators are generally used for market monitoring:

- Reports number: the number of new cases reported during a given period of time
- 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. Corrective actions

When necessary, corrective actions should be undertaken by a Product owner 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.

5 Cosmetic Product Safety Report

The Cosmetic Product Safety Report (CPSR) 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 Product owner, except if the causality assessment qualifies the link between the product and the SUE/UE as 'excluded'. If there is a disagreement between the Product owner and the EDA on the outcome of a causality assessment, this should be mentioned. Different levels of details are expected for the inclusion of SUEs and UEs and it is therefore recommended to define each of them separately 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 EDA, should be included via a copy (physical or electronic) of the notification form(s) sent to the 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 Product owner's action and handling of the reported Serious Undesirable Effect should be stated. Corrective as well as preventive measures taken should be described.

The CPSR is submitted upon request from the EDA

6 Management system and data protection

6.1. Management system for handling of UE/SUEs

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 authority. Especially for multi-sited and/or multinational companies' clear interfaces and workflows should be described.

6.2. 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 EDA) should be clearly described. Written SOPs or workflow-diagrams are recommended to ensure transparency among the functions involved.

6.3. Legal compliance with the Egyptian Data Protection Rules

All company personnel involved in the processing of UE/SUEs should be familiar with the applicable regulations on data protection.

Appendices

Appendix I

SUE Form A

This form is to be filled in by Product owners or Distributors that are made aware of a SUE in order to transmit it to the Authority.

1) Case report id	**2) Company**
Company report number: Type of the report: ☐ Initial ☐ Follow-up ☐ Final Date received by company: dd/mm/yyyy Sending date to EPVC: dd/mm/yyyy	☐ **Distributor** ☐ **Product owner** Company name: Address and local contact details:
3) Seriousness criteria *****	
☐ **Temporary or permanent functional incapacity** ☐ **Disability** ☐ **Hospitalization**	☐ **Congenital anomalies** ☐ **Immediate vital risk** ☐ **Death**
4) Primary reporter	**5) End user**
☐ Consumer ☐ Health professional ☐ Other (*specify*): Has the reported information been confirmed by a medical professional : ☐ Yes ☐ No	Age (at time of SUE): Date of birth: yyyy Sex: ☐ Female ☐ Male ☐ Unknown
6) Suspected product **Complementary information can be attached to the document /related in the narrative*	
a) Full name of suspected product …… Company: Category of product: Batch number: Notification number: Name and address of retailer of the product…….. **b) Use of product** Date of first ever use: dd/mm/yyyy Frequency of use: times per (day/week/month/year) Professional use: ☐ Yes ☐ No Application site(s): Product use stopped : ☐ Yes ☐ No ☐ N/A ☐ Unknown Date of stopping the product use: dd/mm/yyyy **c) Re-exposure to the suspected product** ☐ Positive ☐ Negative ☐ Not performed ☐ Unknown **d) Other suspected cosmetic products used concomitantly:**	

……
……

7) Description of serious undesirable effect (SUE)

a) Type of effect

- Country of occurrence:
- Date of onset: dd/mm/yyyy
- Time from the beginning of use to onset of first symptoms: (minutes/ hours/days/months)
- Time from last use to onset of first symptoms: (minutes/ hours/days/months)
- Reported signs/ symptoms:
- Reported diagnosis (if any):

b) Location of SUE

☐ Skin, area(s) concerned :

☐ Scalp ☐ Hair ☐ Eyes ☐ Teeth ☐ Nails ☐ Lips

☐ Mucosae, specify: ☐ Others, specify:

☐ SUE in area of product application ☐ SUE out of area of product application

8) Outcome of SUE(s)

☐ Recovered *If recovered, specify the time for recovering:*

☐ Improving ☐ Aftereffects (sequalae) ☐ Ongoing ☐ Unknown

☐ Other:

9) Relevant underlying conditions

☐ Yes ☐ No ☐ Unknown *If yes, specify* :

☐ Relevant treatment(s):

☐ Additional concurrent use of other products (drugs, food supplements, ...):

10) Relevant medical information / history

☐ Allergic diseases, specify: *If tests previously performed, specify the type and results*:

☐ Cutaneous diseases, specify:

☐ Other relevant underlying disease(s):

☐ Skin specificities including phototype:

☐ Others (*example: specific climatic conditions or specific exposure):*

11) Case management

a) <u>Treatment(s) of SUE</u> *(please include the name of the products (INN) used as treatment, dose and duration)*

b) <u>Other measure(s)</u>: Duration / complementary details:

c) Seriousness of undesirable effect

c-1) Functional incapacity *(if applicable)* Description:

☐ If temporary, specify the duration: ☐ Expert evaluation available ☐ Medical certificate available

☐ Corrective treatment of the functional incapacity:

c-2) Disability *(if applicable)*, specify the %:

Description:

☐ Expert evaluation available ☐ Medical certificate available

c-3) Hospitalization *(if applicable):*

Duration of hospitalization: Hospital name and address:

Corrective treatment received during the hospitalization *(please include the name of the products (INN) used as treatment, dose and duration, in addition to any other treatment measures after hospitalization)*

c-4) Congenital anomalies *(if applicable)* :

☐ Detected during pregnancy ☐ Expert evaluation available ☐ Detected after delivery

c-5) Immediate vital risk *(if applicable):*

Treatment and specific measures:

c-6) Death *(if applicable):*

Date: dd/mm/yyyy Diagnosis: ☐ Medical certificate available

12) Complementary investigations

☐ Yes ☐ No *If yes , specify* :

☐ **Allergic testing :**

☐ Skin test(s) performed with the suspected cosmetic product(s) :

Product(s) tested	Method(s) used	Readings on	Results

☐ Skin test(s) performed with the substances (*if available, attach the complete results to this form)*

☐ Other results of allergic testing: ……..

☐ Other additional investigation(s) (*specify, including results):*

13) Summary from Product owner or Distributor

a) Narrative

b) Follow-up

c) Causality assessment

☐ Very likely ☐ Likely ☐ Not clearly attributable ☐ Unlikely ☐ Excluded ☐ Unassessable

d) Corrective actions***

☐ Yes ☐ No *If yes , specify* :

e)	**Comments**……
	……
	……

Appendix II

Process for reporting SUE

Product owners and distributors are expected to report a Serious Undesirable Effect (SUE) to the Authority (EPVC/EDA) 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 Authority as a “follow up report”. Follow up reports should be sent to EDA 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.