

	UNDESIRABLE EFFECT (UE) EVENT REPORTING FORM FOR COSMETIC PRODUCTS	Please email completed form to: kosmetyki@aflfarm.pl
<input type="checkbox"/> Initial	<input type="checkbox"/> Follow up	Page 1 of 2

(If you are completing this form by hand please write legibly in BLOCK CAPITALS)

Reporter:

- Consumer
- Health Professional
- Other

Full name

Contact data * (phone number and/or e-mail).....

Suspected product:

Full name of suspected product*

Batch number*

Shelf life/PAO*

End user affected by undesirable effect:

Full name*

Age (or age group: adult, elderly, child up to 3 years of age given in months)

Gender:

- Female
- Male
- Prefer not to say

Professional use, if applicable

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Country of residence

Address for correspondence

Phone number and/or e-mail*

Description of undesirable effect:

Date of starting the product use:*


Date of stopping the product use:*

Date of onset of symptoms:*

Was the product used for the first time? Yes No

Application site: *

- face
- scalp
- body
- other

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UE in area of product application? * Yes No

Type of effect *

.....

.....

.....

Re-exposure to the suspected product*: Yes No

Undesirable effects upon re-exposure, if any?*

.....

Allergic diseases: Yes No

Additional concurrent use of other products (example, cosmetic products, herbal products, food supplements)

If yes, specify

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Case management:

Has the reported information been consulted/confirmed with a medical professional? Yes No

If yes, provide date and place

.....

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Treatment of the undesirable effect: Yes No

If yes, specify (name(s) of prescribed medicines, dosage, duration, other measures if any)

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* required

.....
(Date and signature of the Reporter)

Company (to be completed by Aflofarm):

Case report number:			
Date received by Responsible Person	Responsible Person	Date received by Company	Signature of Responsible Person

Pursuant to Article 13 of the Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of individuals with regard to the processing of personal data and on the free movement of personal data, and repealing Directive 95/46/EC (General Data Protection Regulation; hereinafter 'GDPR') Aflofarm Farmacja Polska Sp. z o. o. organized and existing under the laws of Poland, seated in Pabianice 95-200 at Partyzancka 133/151, contact details : telephone +48 42 22 53 100, email address: aflofarm@aflofarm.pl (Aflofarm) shall be the Controller and processor of personal data obtained and collected as part of the spontaneous UE report. For unsolicited communication in case of reporting of any undesirable effects, the DPO (Data Protection Officer), designated by Aflofarm, can be contacted via standard mail to the above-said address or by sending an email to daneosobowe@aflofarm.pl. Unless explicitly consented otherwise, we will only collect and use your personal information in case of reporting non-serious undesirable effect event of a cosmetic product to comply with the legal obligations Aflofarm is subject to under Article 6 (1) (c) and (f) and Article 9 (2) (f) and (i) of GDPR, the processing of such mandatory personal information carried out for the legitimate interest of Aflofarm or determined in the legal basis for the compliance with the applicable regulations at all times to the extent required by law with respect to:

- a) safety of cosmetic products, including maintaining a record of reported adverse reactions events and reporting of SUE or ADR to national competent authorities with respect to:
 - health-related data when processing is necessary for reasons of public interest in the area of public health to ensure high standards of quality and safety of health care and of medicinal products for compliance with regulatory obligations under Article 10(1), Article 11(2) (b), Article 21 and Article 23(1) of the Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November on cosmetic products,
 - other personal information subject to mandatory processing by the Data Controller under Article 10(1), Article 11 (2) (b) Article 21 and Article 23(1) of the Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products Pharmaceutical Law of 6 September 2001;
- b) to the extent any such processing is necessary for the establishment, exercise or defence of legal claims that may arise between You and the Data Controller with respect to health data as special category data and other personal information, to which Article 9 (2) (f) and Article 6 (1) (f) of GDPR shall apply, respectively, i.e. where the processing is carried out in the course of legitimate activities or interest pursued by the Data Controller Administrator.

The recipients of personal data of the User shall be (1) appointed employees and associates of Aflofarm or authorised persons of any third parties contracted by Aflofarm and (2) entities acting for or on behalf of Aflofarm, including authorities competent for cosmetovigilance and pharmacovigilance, and national authorities or agencies or other governmental bodies or third parties authorised to the lawful processing of such data under the applicable law and regulations, in particular the Polish Chief Sanitary Inspector or respective equivalent authorities of other EU member states where cosmetic products are distributed by the Data Controller. Aflofarm represents to maintain any personal data for as long it is necessary or required under cosmetovigilance or relevant regulations on prescriptive period. Your personal information shall be stored for no longer than a year upon completion of handling the UE submission. After that time Aflofarm shall delete or anonymise any such personal data of the User. Should it be impossible to do so (for instance personal data have been saved in the backup archives), then the personal data will be re-identified, encrypted or pseudonymized for further processing until deleted on proviso that it is lawful and technically possible. Providing personal data to the Data Controller is voluntary, yet necessary to carry out investigation on safety of cosmetic products and maintain up-to-date register of adverse reactions to cosmetic products. At any time, you have the right to access, change and delete information we hold, including the right to rectify, delete (to the extent the processing of personal information is limited to the legitimate interest pursued by the Data Controller under Article 6 (1) (f) and Article 9 (1) (f) of GDPR), limit the processing, data portability (transfer) or the right to object to the processing (to the extent the processing of personal information is limited to the legitimate interest pursued by the Data Controller under Article 6 (1) (f) and Article 9 (1) (f) of GDPR). Personal data may not be deleted or subject to objection to processing, if the processing is carried out in the legitimate interest of the Data Controller under Article 6 (1)(c) and Article 9 (2) (i) of GDPR. If at any time you wish to change personal information that is inaccurate or out of date, please contact the DPO designated by the Data Controller via email at daneosobowe@aflofarm.pl and we will amend this record or take all reasonable steps to delete it unless we need to keep it for legal reasons. If you think your data protection rights have been breached, you can lodge a complaint with the supervisory authority (i.e. the President of the Personal Data Protection Office in Poland). The personal data provided will not be subject to any profiling or automated decision-making processes, nor will it be transferred to any third countries.