

What is Cosmetovigilance and Why is it Important?

What is Cosmetovigilance?

Cosmetovigilance is the collection, evaluation and monitoring of adverse reactions observed during or after normal or reasonably foreseeable use of a cosmetic product.



Why is Cosmetovigilance important?

To protect consumer health by monitoring the occurrence and reducing the likelihood of reoccurrence of adverse reactions.



Definitions within Cosmetovigilance

'Undesirable Effect (UE)' means an adverse reaction for human health attributable to the normal or reasonably foreseeable use of a cosmetic product.



Definitions within Cosmetovigilance

'Serious Undesirable Effect (SUE)' means a UE that has resulted in one of the following outcomes: temporary or permanent functional incapacity, disability, hospitalisation, an immediate vital risk or death.



Definitions within Cosmetovigilance

The **'Causality assessment'** is the analysis of the probability that a cosmetic product used by a consumer is responsible for a genuine undesirable event.



How does Cosmetovigilance work?

Implement a system to receive and assess consumer contacts on possible adverse reactions; evaluate if it's a UE or SUE, and carry out the causality assessment; record in PIF; if SUE, report it to the authorities!



Who is Cosmetovigilance for?

Both the Responsible Person (RP) or the distributor have the obligation to report SUEs to authorities. A distributor may wish to contact the RP of the relevant product if a consumer reports an adverse reaction to them.



CTPA has a handy e-learning which provides a comprehensive training on cosmetovigilance and companies' related obligations.

Free for CTPA member companies, £75 for non-members

Cosmetovigilance Step-by-step

The below flowchart shows what to do step-by-step upon receipt of a consumer contact about an adverse reaction. For the details of the assessment between UE/SUE, the causality assessment and how to report SUEs please see available guidance or take the CTPA Cosmetovigilance e-learning.



Receipt of a consumer adverse reaction



Investigate the reaction with a consumer questionnaire



Consumer identification, nature of the adverse reaction, date of onset, chronology, identification of the cosmetic product



Is it a UE or an SUE?



Carry out the causality assessment



If UE and causality is excluded

No obligations



If UE and causality is not excluded

Record the UE in the CPSR



If SUE

Report the SUE to authorities and record in the CPSR

Available Resources

- [CTPA Cosmetovigilance e-learning](#)
- [UK Government SUE reporting](#)
- [EU Commission Guidance on causality assessment](#)
- [Cosmetic Europe Guidelines management of UEs and reporting of SUEs](#)

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