

**Polish Association of Cosmetics and Home Care Products Producers comments on
European Commission Working Document 13/SANCO/COS/WG/19
Proposal for criteria to determine a serious undesirable effect**

Since July 2013, industry is under the obligation to report serious adverse effects (SUE) following the use of cosmetic products. According to the Cosmetics Regulation, an undesirable effect is described as serious when it leads to one of the following consequences: - Death, Congenital anomaly, Immediate vital risk; Hospitalization; Temporary or permanent functional incapacity, Disability.

To facilitate the notification process the Commission, Member states and the industry jointly developed guidelines on Serious Undesirable Effects and finalized them in June this year.

However, recently France questioned the fact that 'there was no consensus definition, between industry and the Member States about the criteria to qualify as a serious effect' and proposed to introduce specific definitions for SUE. These criteria were discussed between European Commission and a limited number of Member States but industry was not part of these discussions.

Based on practical industry experience and taking into account divergences in health systems in different Member States we would like to stress that the proposed criteria to determine SUE seem too broad and in consequence do not allow to detect those cases, which require a follow up at European Level. This might lead to over reporting of irrelevant cases and might impact the rapid follow up on the truly relevant cases. In that regard we would like to provide, in particular, two comments:

1. SUE criteria for Hospitalization:

Commission Working group text:

Admission to the hospital, whatever the delay between the cosmetic use and the hospitalisation if a causal relationship is suspected. A treatment in an emergency room or a consultation in a hospital without admission are not considered as hospitalisation."

Polish Association of Cosmetics and Home Care Products Producers proposal:

"Admission to the hospital, on an inpatient basis whatever the delay between the cosmetic use and the hospitalisation if a causal relationship is suspected. The hospitalisation should be confirmed if possible with relevant medical documentation. In cases where sufficiently precise information for judgement is not available, a duration of hospitalisation of at least 24 hours or an overnight stay may be used as a simple criterion. An emergency room visit, examination or treatment delivered

as an outpatient which does not result in admission to the hospital are not considered as hospitalisation.”

This sentence was proposed taking into account the divergences between systems in different Member States and the practical experience from received consumers reports. It is important to note that while in some countries the “admission confirmation “is provided as a standard procedure, in other Member States patient do not receive the confirmation of admission to the hospital, which hinders the possibility to assess whether a hospitalization actually took place or consumers simply chose to go to hospital instead of GP/dermatologist. In some countries patients tend to go to the hospital instead of GP/dermatologists as the provided service is cheaper and advice can be given on the same day whereas the GP is not always available. In such cases few hours of waiting in the emergency room tend to be reported as hospitalization. To support our arguments before criteria to define SUE are finalized, we stand ready to conduct a survey amongst our members to determine how many cases a year the industry would submit with a very short stay in a hospital and how many of these would actually be relevant.

2. SUE criteria for Temporary and permanent functional incapacity:

Commission Working group text:

Temporary or permanent physical damage which can affect the quality of life and/or make impossible for the patient to exercise his/her usual occupation.

Examples:

- any adverse event resulting in significant changes in physical appearance (allergy reactions on face and body, hair loss, burns..) that are responsible for significant social discomfort for the patient and a loss of quality of life.
- a hairdresser who developed an allergy to hair coloring products and has to change their job
- respiratory problems requiring a medical surveillance ;
- all the adverse events which lead to a work stoppage or sick leave ;
- any important medical event for example a facial oedema requiring the patient to be under medical observation in an emergency room without an hospitalization thereafter.

Polish Association of Cosmetics and Home Care Products proposal:

Temporary or permanent physical damage which can significantly affect the quality of life and/or make impossible for the patient to exercise his/her usual occupation. Permanent functional incapacity should be documented by providing a medical documentation. Due to huge inter-individual variability, it is difficult to assess subjective reports on temporary social functional incapacity. Any case of temporary functional incapacity which is medically confirmed is a SUE. If the case is not medically confirmed, a global assessment of the entire case and its outcome for the consumer shall be performed with a medical and scientific judgment, on a case-by-case basis, to determine if the case is SUE or not.

Examples:

- any adverse event resulting in significant changes in physical appearance (allergy reactions on face and body, hair loss, burns..) that are responsible for significant social discomfort for the patient and a loss of quality of life.
- a hairdresser who developed an allergy to hair coloring products and has causing him to change theirhis job ;
- respiratory problems requiring a medical surveillance;
- all the adverse events which lead to a medically confirmed work stoppage or sick leave;
- any important medical event for example a facial oedema requiring the patient to be under medical observation in an emergency room without an hospitalization thereafter.

Defining of temporary functional incapacity is very difficult and can be subjective. To this end, a case-by-case assessment should take place of the entire case and its outcome for the consumer. It is important to ensure that consumers are not using these criteria as an excuse not to conduct normal life duties. Notably, the allowed duration of the sick leave without a medical confirmation is very different between Member States (1 to 5 days). Thus, it is important to seek any sort of confirmation (employer, school) and preferably medical to verify whether an actual SUE took place and to exclude fraudulent and irrelevant cases.

An aspect which we would like to address in particular is the social discomfort, which clearly is not an objective criteria. However, the actual effects (work stoppage, sick leave) are objective criteria. 90-95 % of reports collected by industry are reported by consumers themselves, thus sometimes and depending on reporter's perception the same event can be considered serious by one consumer but not by the other. Keeping very subjective, consumer reported, criteria will lead to:

- inconsistency of classification of a same reaction being once serious, once non-serious depending on the consumer words and objective behind the report (re-funding, work leave,...)
- inconsistency of classification of a same reaction between evaluators (within and between companies)
- a need for a significant communication campaigns and training for companies who are not fully aware of all details behind the definitions (including SMEs).
- big differences between cases received by e-mail (with low level of details) and those collected by phone (with full discussion about potential "minor" impairment in normal life activities/quality)
- a risk of dilution of more relevant, indisputable cases with clear temporary incapacity.