CONFERENCE PAPER

Drug Safety 2008; 31 (5): 437-439
0114-5916/08/0005-0437/$48.00/0



# Cosmetovigilance
## The 'Beautiful' Risk

*Ugo Moretti* and *Giampaolo Velo*

Clinical Pharmacology Unit, University of Verona, Verona, Italy

## Abstract

A cosmetic is classically defined as any preparation that is applied to the skin, eyes, mouth, hair or nails for the purpose of cleansing, enhancing appearance, giving a pleasant smell or giving protection. Unlike drugs, which are used to treat or prevent a disease in the body, cosmetics are not thought to change or affect the body's structure or functions. However, the distinction between drugs and cosmetics is sometimes not clear.

Regulations for cosmetic products primarily address the safety of products that may be used by large populations of healthy consumers. However, the efficacy and safety of cosmetic products are not reviewed or approved by national authorities before they are sold to the public.

The identification and analysis of adverse effects related to cosmetic products is a process that is currently still, to a large extent, industry driven. It is the responsibility of manufacturers to determine that products and ingredients are safe before they are marketed, and then to collect reports of adverse reactions. However, although the manufacturers do their best to monitor the safety profile of their products, we should consider that there is always a potential inherent conflict of interest.

### 1. Not Only Cosmetics

The European Cosmetic Directive 76/768/EC defines a cosmetic product as "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 odours and/or protecting them or keeping them in good condition".[1] On the other hand, the Federal Food, Drug, and Cosmetic Act (FDCA) defines a cosmetic as "articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance".[2] Comparing the above definitions, it could be noted that the latter includes the possibility to introduce the 'cosmetic product' into the human body, recalling the fact that drugs could be used as cosmetics. For instance, aminophylline, used in the treatment of asthma, is present in many thigh cream products for cellulite; tretinoin and other acne medicines are used for wrinkle reduction; botulinum toxin, used to treat torsion dystonias and other involuntary movements, is also used for smoothing facial lines and wrinkles. The cosmetic use of bleaching products is a common practice among dark-skinned African women; the use of corticosteroids as depigmenting agents is also very common in this population.[3] Furthermore, corticosteroids are used in

Moroccan Saharawi women for fattening purposes.[4] With the possible exception of botulinum toxin, cosmetic use of drugs is off-label.

The word 'cosmeceuticals', which has no legal definition, is often used by the cosmetic industry to indicate products that can be considered both drugs and cosmetics. Cosmeceuticals represent a marriage between cosmetics and pharmaceuticals, since they include substances that are topically applied (such as cosmetics), but that influence the biological function of the skin (such as drugs).

Herbal products are often used as cosmetics; propolis and its extracts or lavender essential oils are present in many cosmetic products. Herbs and cosmetics, like drugs, have the potential to cause adverse reactions; therefore, pharmacovigilance, phytovigilance and cosmetovigilance, which are generally considered three separate worlds, may overlap.

## 2. Adverse Reactions to Cosmetics and Cosmetovigilance

Cosmetic products are generally well tolerated but adverse reactions, mainly affecting cutaneous system, can occur. Fragrance allergy is relatively common; most recent estimates show that between 1.7% and 4.1% of the general population are sensitized to fragrance ingredients.[5]

Adverse reactions to cosmetics constitute a small but significant proportion (10%) of contact dermatitis cases. This proportion represents only the tip of the iceberg, as most patients who experience reactions to cosmetics seldom consult a physician, but merely discontinue use of the cosmetic.[6]

In November 2006, the Council of Europe's Committee of Ministers adopted a resolution on a vigilance system for undesirable effects of cosmetic products ('cosmetovigilance') in Europe.[7] This resolution is aimed at monitoring the occurrence of undesirable effects caused by cosmetic products, evaluating the risk for public health, and establishing procedures for taking corrective actions.

This resolution resulted from a pilot study carried out in 2004–5, which evaluated attitudes towards monitoring, reporting and following up on the undesirable effects of cosmetics.[7] According to the study, only a minority of consumers (25–36%) who experienced even very unpleasant undesirable effects consulted a physician. Under-reporting was also shown to be be significant, even though 15% of the cases were serious. Allergic contact dermatitis would be the most frequently reported adverse effect (76.5–83.9%). The study also showed that skincare products, hair dyes and hair preparations were the most frequent causal product categories.

Regulations for cosmetic products primarily address the safety of products that may be used by large populations of healthy consumers. However, the efficacy and safety of cosmetic products are not reviewed or approved by national authorities before they are sold to the public.

Regulators require cosmetic companies to declare ingredients on the label or exterior wrapping in all their products. The purpose of cosmetic ingredient labelling is to improve public safety by making available to users information concerning the composition of cosmetics. A list of banned ingredients is regularly updated in both the EU and the US.

The identification and the analysis of the adverse effects related to cosmetic products is a process that is currently still to large extent industry driven. It is the responsibility of manufacturers to determine that products and ingredients are safe before they are marketed, and then to collect reports of adverse reactions. However, the 7th Amendment of the European Cosmetic Directive states that existing data on undesirable effects on human health must be easily accessible both to the competent authorities and to the public. Although manufacturers do their best to monitor the safety profile of their products, we should consider that there is always a potential inherent conflict of interest.

In January 2007, the European Commission launched a public consultation on the simplification of the Cosmetics Directive. The document published by the Commission to introduce the consultation reports the concept of "uncompromised safety". This means that, in principle, a risk to consumer safety in cosmetics cannot be balanced against the benefit of the product. This is the crucial difference

from regulation of medicinal products, where a risk-benefit analysis is conducted.

One of the replies to the consultation came from the European Cosmetic Toiletry and Perfumery Association (Colipa). In August 2005, this trade association issued the 'Guidelines on Management of Undesirable Event Reports' as a tool for harmonizing industry regarding the collection and evaluation of adverse event reports. Part of this document is devoted to the discussion of the evaluation of the causality assessment, the causal association between the undesirable event and the use of a cosmetic product.

Causality assessment is one of the key practical points and is a very complex issue to discuss. The knowledge base upon which effects are labelled or not labelled for each cosmetic product may affect the causality assessment of reported reactions. On the other hand, if a cosmetic company states that certain effects are labelled, it could be considered liable, with implications from a legal point of view.

## 3. Conclusions

Although much work has been carried out over the last few years to improve the safety monitoring of the cosmetic products, an effective and independent evaluation of the safety of these compounds is still lacking.

In recent years, national cosmetovigilance systems have been set up in some European countries; however, a European-level network is still missing. These systems should be associated with an effective and independent evaluation of the risk-benefit profile of a cosmetic both before and after marketing.

## Acknowledgements

No sources of funding were used to assist in the preparation of this conference paper. The authors have no conflicts of interest that are directly relevant to the content of this conference paper.

## References

1. EU Cosmetics directive 76/768/EEC art.1
2. Federal Food, Drug, and Cosmetic Act. Chapter II, section 201
3. Ly F, Soko AS, Dione DA, et al. Aesthetic problems associated with the cosmetic use of bleaching products. Int J Dermatol 2007 Oct; 46 Suppl. 1: 15-7
4. Rguibi M, Belahsen R. Fattening practices among Moroccan Saharawi women. East Mediterr Health J 2006 Sep; 12 (5): 619-24
5. Johansen JD. Fragrance contact allergy: a clinical review. Am J Clin Dermatol 2003; 4 (11): 789-98
6. Mehta SS, Reddy BS. Cosmetic dermatitis: current perspectives Int J Dermatol 2003; 42 (7): 533-42
7. Council of Europe. The Council of Europe recommends a vigilance system for undesirable effects of cosmetic products ("cosmetovigilance") [online]. Available from URL: http://www.coe.int/t/dc/press/NoteRedac2006/20061109_cosmetovigilance_en.asp [Accessed 2007 Dec 12]

Correspondence: Dr *Ugo Moretti*, Clinical Pharmacology Unit, University of Verona, Policlinico GB Rossi, Piazzale LA Scuro, 37134 Verona, Italy.
E-mail: umoretti@sfm.univr.it