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Guidelines for the Cosmetics' Efficacy Evaluation.

The cosmetic efficacy: myth or reality?

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Summary

Efficacy evaluation of a cosmetic is one of the most important passage in the research, development and marketing of a product and has to be included in the product information file.
Special attention, however, needs to be applied when sound scientific substantiation of claims might bring the cosmetic in the delicate borderline area. Guidelines to help manufacturers and regulators have been produced by the EU Commission but reference to case law need also to be taken into account.

Riassunto

La valutazione dell'efficacia di un prodotto cosmetico rappresenta il più importante compito della ricerca e sviluppo e del marketing dedicato al prodotto stesso e riportato nel suo file informativo.
E' necessario dedicare una particolare attenzione nel redigere messaggi divulgativi e pubblicitari di prodotti cosmetici presenti nella delicata area di confine tra cosmetici, farmaci e dispositivi medici.
A tal proposito la Commissione Europea ha redatto le linee guida per aiutare i produttori ma è necessario anche tenere in evidenza i diversi casi giuridici presenti nella letteratura legale europea su questo argomento.

INTRODUCTION

Looking and feeling good brings confidence and success in of our lives. Cosmetics help people taking care of themselves and play a role for a better quality of life by providing feelings of well-being (by using a shampoo, a makeup or a fragrance), protecting from climate impacts and consequent skin/hair damage (by applying sunscreens or skin moisturizers or hair conditioners) and ensuring good hygiene practices (by means of soaps and oral care products).

Colipa (The European Cosmetics Industry Association) guidelines and recommendations (e.g. on safety assessment, product information file, undesirable effects, cosmetic efficacy) represent an important tool for the industry, providing useful information on the practical interpretation and application of legal requirements (1).

Recently Colipa has published revised guidelines for the efficacy evaluation of cosmetic products (2). Methodologically sound research is essential for the efficacy evaluation and the guidelines offer an overview of the established different testing methodologies. providing data on the performance of cosmetics products.

Cosmetic claim substantiation is an integral part of product development and design and validated evaluation methodologies grant an appropriate and effective tool to assess the validity of product efficacy.

Moreover efficacy claims and the methods substantiating them need to be included in the product information file, by the person placing the product on the market, according to the current Cosmetics Directive (3) and the future Cosmetics Regulation (4).

However some product efficacy claims, even when scientifically substantiated, might fall outside the scope of the Cosmetics Directive. Concerning the delicate question of borderline products among the scope of the Cosmetics Directive and other pieces of EU Regulation, like the Medicinal Product, the Medical Devices, the Biocides, the Food and the General Product Safety Directives there are several guidelines produced by the EU Commission to help both the national Competent Authorities and the industry (5).

The Manual on the scope of the application of the cosmetics Directive (6) is the latest guideline and it is the result of the effort of a working group chaired by the Commission (DG Enterprise) and composed of representatives of all Member States of EU and EFTA, the European Organisation of Consumers (BEUC), the European Federation of Cosmetic Products (COLIPA) and other industry associations.

In the EU a product can have only one regulatory status at a time, as reiterated also in the Recital no. 5 of the Cosmetic Directive 76/768/EEC ' [the Cosmetic Directive] is not applicable to the products that fall under the definition of cosmetic products but are exclusively intended to protect from disease'.

Recognizing the existence of a borderline area with definitions overlapping to some extent did not, in any case, induced the regulators to introduce mid way categories (e.g. cosmetic/drugs) even in the recent recast of the Cosmetics Directive which ended with the approval of the new Cosmetics Regulation.

The EU Court of Justice in various judgements indicated that, in case of definitions overlapping, should be applied the most rigorous legal regimen.

Nevertheless the different Commission guidelines, published on its Internet site, contain principles laid down by case law:

- global assessment of the characteristics of the product (e.g. function, composition, method of use, frequency of application, application site, distribution, familiarity of the consumer with the product, potential risks, labelling, packaging, claims, target population etc.) must be taken into account in order to avoid

that a single characteristic is enough to arrive at a definite judgement;

- the intended main function of the product (i.e. cleaning, perfuming, changing appearance, correcting body odours, protecting, keeping in good condition) takes precedence when making a decision and a secondary, ancillary function for 'preventive' purposes does not necessarily classify a product as a drug or a biocide;
- the question whether a product or its substance(s) restores, corrects or modifies physiological functions by exerting a pharmacological, immunological or metabolic action has to be taken on a case-by-case basis. Cosmetics may modify physiological functions without affecting the metabolism in a significant way, i.e. not any minor modification of physiological function suffices to render a product a medicinal product by virtue of function;
- if a substance is also contained in a drug as active ingredient, it is not decisive for the classification of a product but this may be an indicator for a pharmacological, immunological or metabolic action of the substance independently of the question whether the product is ingested or used topically.

The EU Court of Justice (7) is of the opinion that: "As regards the meaning of 'restoring, correcting or modifying physiological functions', it is clear from the aim of health protection pursued by the Community legislature that the phrase must be given a sufficiently broad interpretation to cover all substances capable of having an effect on the actual functioning of the body. However, this criterion does not serve to include substances such as certain cosmetics which, while having an effect on the human body, do not significantly affect the metabolism and thus do not strictly modify the way in which it functions."

References

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