

Cosmetic evidence is the new black



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ABSTRACT

The development of high-performing or active cosmetics has become to the means for satisfying the most demanding consumers. However, rational and evidence-based formulating in the area of natural cosmetics goes way beyond mere regulatory and technological principles. The ultimate goal, which is an informed and satisfied consumer, can only be achieved by intertwining of actual cosmetic effects, and substantiated and truthful advertising claims.

Keywords: active cosmetics, claims, cosmeceuticals



COSMETIC PRODUCT, MEDICINE OR BOTH?

Modern cosmetic formulating is heading in the direction of combining science and activity, which is a reflection of increasingly demanding consumers. Consequently, marketing claims are becoming more and more daring, making it sometimes hard to distinguish between cosmetics and medicines. However, this frequently happens without a true rationale behind a cosmetic product's composition.

Whether a product is classified as a **cosmetic or a medicine (drug)** under the law is primarily determined by a product's intended use (1–3). A substance or a combination of substances **presented** for treating, alleviating or preventing disease through pharmacological, immunological or metabolic action is considered a medicine, as are products **used** with the aim of restoring, correcting or modifying physiological functions through the exertion of a pharmacological, immunological or metabolic action. On the other hand, the main purpose of a cosmetic product is cleaning, perfuming, changing appearance, correcting body odours, and protecting or maintaining the skin in good condition. However, maintaining the skin in good condition does not include the prevention of disease. The regulatory definition of a cosmetic product is clear and strict. In the event of violation, the US FDA issues warning letters to companies that place unsubstantiated health or drug claims on products placed on the market as cosmetics, while national authorities respond through the respective inspectorates in the European Union.

COSMETIC ACTIVITY AND ACTIVE COSMETICS

A typical cosmetic product therefore exhibits activity 'only' by **supporting the skin's barrier function**, and its ingredients typically penetrate 'only' into the lowest layers of the epidermis. And this is precisely where marketing claims often forget science-based facts, as you have probably often read or heard claims such as deep penetration, highly effective treatment or high-performance active ingredients. Exhibiting activity 'only' through the skin's barrier support may sound like a modest mechanism of action. However, if

we understand the basics of skin physiology, we know that this is usually enough or even the best in terms of a common skin care routine.

(Modern) cosmetic products, however, can go beyond exhibiting a 'single' activity. Cosmetology as a science, and the cosmetic industry and cosmetics in general have become focused on the development of so-called **active cosmetics**. Active cosmetic products have an added value: they target the specific needs or conditions of the skin and therefore place priority on individuals' needs and preferences. That level of advancement in knowledge, technological innovations and new or improved cosmetic ingredients has led to a shift from conventional to high-performance cosmetic activity.

This is when **cosmeceuticals** entered the cosmetics world, meaning hybrid products explained by the Cambridge English Dictionary as **cosmetics** that contains the qualities of medicines (**pharmaceuticals**) (4). In other words, a cosmeceutical means a cosmetic product that contains a biologically active ingredient that expresses a pharmaceutical or therapeutic effect on the skin, for example antioxidants, retinoids, alpha and beta hydroxy acids, peptides and proteins, etc., all exhibiting activity in deeper layers of the skin, as well. However, we should be aware that the term has no meaning under the law, as those products have not undergone rigorous studies by manufacturers and regulatory agencies to ensure therapeutic effectiveness, safety and quality, which are the three defining characteristics of a medicine (5, 6, 7).

Nevertheless, the term is very attractive for advertising. However, promises of sometimes almost miraculous activities often lack substance. This is where we, as educated consumers and professionals, should be very critical. This is also an aspect incorporated into the concept of the **CosmEthically ACTIVE certificate** (8).

Cosmetic activity is intrinsically linked to a well-planned product, including the incorporation of **cosmetically active ingredients in evidence-based concentrations** (1). The importance of using an ingredient at an active concentration, i.e. a concentration that is high enough to be able to express a desired cosmetic effect, such as moisturising or antioxidative effect, is

backed by extensive scientific research, and stands in deep contrast to cosmetic formulations containing the same cosmetically active ingredients but incorporated in insignificant concentrations. The latter is an example of **empty advertising claims**.

On the other hand, formulating active cosmetics should not mean putting more and more into the bottle to satisfy the almost endless and insatiable desire for eternal youth. In contrast, **excessive ingredients should be considered a burden** to the skin or hair (and the environment). Even antioxidants with proven effects can turn into pro-oxidants when their concentration is increased (9). Indeed, rational formulating, particularly with ingredients of natural origin, is a challenging task and requires a great deal of knowledge, research and experience.

ADVERTISING CLAIMS

Finally, considering the high number of cosmetic products available, it should be of great importance to provide consumers with specific, understandable, accurate and reliable information, enabling them to make informed choices, compare products on the market and find those that best suit their needs and desires. Unfortunately, the cosmetic industry frequently seems to leave consumers with advertisement-based information that is vague and often omits information necessary to help consumer decision making (10, 11).

Due to a lack of enforcement in cosmetic marketing, manufacturers are left with the decision to respect the rules or not. In the US, the FDA regulates cosmetic labelling claims, while the US Federal Trade Commission (FTC) regulates advertising claims in print and other media, requiring them to be **substantiated, truthful and not misleading** (12). In the European Union, based on Regulation (EC) No 1223/2009, claims should not be used to imply that cosmetic products have characteristics or functions they do not have. With the aim of providing a high level of protection for end-users, Commission Regulation (EU)

No 655/2013 established six harmonized, common criteria to assess the justification of a claim, including (13):

- **Legal compliance.** Claims that convey the idea that a product has a specific benefit when this benefit is merely in compliance with minimal legal requirements shall not be allowed.
- **Truthfulness.** Claims shall not be based on false information; i.e. if it is claimed on a product that it contains a specific ingredient, that ingredient shall be present.
- **Evidential support.** Claims for cosmetic products shall be supported by adequate and verifiable evidence.
- **Honesty.** Presentations of a product's performance shall not go beyond the available supporting evidence.
- **Fairness.** Claims for cosmetic products shall be objective and shall not denigrate the competitors, nor shall they denigrate legally used ingredients.
- **Informed decision-making.** Claims shall be clear and understandable to average end users, allowing them to make an informed choice. Marketing communications shall be clear, precise, relevant and understandable.

Those are some of the cues that all of us involved in the cosmetics industry, from formulators, manufacturers, marketing experts to media, must keep in mind when communicating products and research, particularly to consumers. It's our responsibility and obligation to use cosmetic claims for what they should be: essential tools to inform consumers about the characteristics and quality of a product. Claims should always be based on the truth, which requires honest evidence. Honesty, in turn, requires fairness, which in the end ensures an informed and satisfied consumer (14). And that should be our ultimate goal, right?

REFERENCES

1. FDA, U.S. Food & Drug Administration: Is It a Cosmetic, a Drug, or Both? (Or Is It Soap?) [Internet]. [cited 2021 May 16]. Available from: <https://www.fda.gov/cosmetics/cosmetics-laws-regulations/it-cosmetic-drug-or-both-or-it-soap>
2. FDA, U.S. Food & Drug Administration: Cosmetics Labeling Claims [Internet]. [cited 2021 May 16]. Available from: <https://www.fda.gov/cosmetics/cosmetics-labeling/cosmetics-labeling-claims>
3. EUR-Lex, Access to European Union law: Document 52016DC0580, Report from the Commission to the European Parliament and the Council on product claims made based on common criteria in the field of cosmetics, COM/2016/0580 final [Internet]. [cited 2021 May 16]. Available from: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52016DC0580>
4. COSMECEUTICAL | meaning in the Cambridge English Dictionary [Internet]. [cited 2020 Sep 13]. Available from: <https://dictionary.cambridge.org/dictionary/english/cosmeceutical>
5. Janeš D, Kočevar Glavač N. Modern Cosmetics, Ingredients of Natural Origin, A Scientific View, Volume 1. 1st ed. Velenje: Širimo dobro besedo; 2018. <https://moderncosmethics.com/product/modern-cosmetics/>
6. Sörensen A, Landvall P, Lodén M. Moisturizers as cosmetics, medicines, or medical device? The regulatory demands in the European Union. In: Lodén M, Maibach HI, editors. Treatment of dry skin syndrome: The art and science of moisturizers. Berlin, Heidelberg: Springer-Verlag; 2012. p. 3-16.
7. Lupo MP. Cosmeceutical peptides. *Dermatol Surg.* 2005;31(s1): 832-836.
8. Modern CosmEthics. CosmEthically ACTIVE Certificate, Technical Document, Version 1.0 [Internet]. Velenje: Širimo dobro besedo [cited 2021 May 16]. Available from: https://cosmethicallyactive.com/wp-content/uploads/2020/12/Technical-Document_1.0_2020.pdf
9. Malinowska P, Gliszczyńska-Świątło A, Szymusiak H. Commercial plant extracts may act as antioxidants or pro-oxidants in cosmetic emulsions based on argan oil. *J Cosmet Sci.* 2017;68(2):147-158.
10. Fowler JG, Carlson L, Chaudhuri HR. Assessing scientific claims in print ads that promote cosmetics: How consumers perceive cosmeceutical claims. *J Advert Res.* 2019;59(4):466-82.
11. Yvon P. Back to basics: Product labelling, manufacturing and launch. *Cosmetics & Toiletries.* 2019; 134 (10):35-41.
12. Steinberg DC. Labeling Claims [Internet]. Allured Business Media: Cosmetics & Toiletries; 2013 [cited 2021 May 16]. Available from: <https://www.cosmeticsandtoiletries.com/regulatory/claims/premium-labeling-claims-212300281.html>
13. EUR-Lex, Access to European Union law: Document 32013R0655, Commission Regulation (EU) No 655/2013 of 10 July 2013 laying down common criteria for the justification of claims used in relation to cosmetic products, Text with EEA relevance [Internet]. [cited 2021 May 16]. Available from: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32013R0655>
14. A Closer Look at Cosmetic Claims [Internet]. [cited 2020 Sep 13]. Available from: <https://www.cosmeticsandtoiletries.com/regulatory/claims/A-Closer-Look-at-Cosmetic-Claims-561149991.html>