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Editorial Open Access

Misleading Marketing of Cosmetics. Do the "Free from Parabens" and "Free from Allergenic Substances" Claims Really Make Sense?

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Editorial

In recent years, many cosmetics companies have been quick to turn into business opportunity the average consumers concerns on cosmetic products related to safety issues. With the complicity of misinformation, a new claim, the so-called "free from" claim, was born to reassure consumers, particularly in the case of parabens and allergic ingredients. Although much of this can be put down to misinformation and media hype, the blame does not totally lie at the door of ignorance and scarce stories. Furthermore, the increasing size of the market for "free from" products is inevitably fuelling, among consumers, the idea that such ingredients should be avoided. On one side, someone can except that "free from" claims could be useful to help consumer to be able to make an informed choice about whether they want to purchase paraben-containing products or not; on the other side, a wise man could except that there is no informed choice without correct information.

Article 20 of the Cosmetic Regulation EC no. 1223/2009 [1] clearly prohibits misleading marketing of cosmetic products. In this view, marketing has a broad definition and includes the product name, trademarks, pictures, figurative signs, and advertising. Since it is unrealistic to specify fixed rules defining misleading marketing, the European Commission has adopted common criteria for the justification of claims used in relation to cosmetic products [2]. The "free from" claims contradict the "truthfulness", "honesty", "fairness", and "informed decision-making" criteria laid down in the EU Regulation no. 655/2013, as follows: i) they are based on false and irrelevant information, ii) the evidences of the hazards associated to the use of particular substances go beyond the available supporting evidence, iii) they denigrate ingredients legally used and not prohibited to be used in cosmetic products, and iv) they contain information that are not understandable to the average consumer whose comprehension can be distorted by misinformation. Furthermore, "free from" claims contradict the "evidential support" criterion if the concerned ingredient was not deliberately added in the product formula but was in one or more of the ingredients used in the product formula. However, it is clear that the proposed common criteria are insufficient to regulate the "free from" claims. In order to put an end to this misleading practice, the EU Commission should clearly indicate that "free from" and similar claims raise a multitude of issues under the applicable legal framework and are likely to be considered misleading or illegal, by nature. Ultimately, the "free from" claims can materially distort or are likely to materially distort the economic behaviour (with regard to the product) of the average consumer whom it reaches or to whom it is addressed, or of the average member of the group when the commercial practice is directed to a particular group of consumers. In fact, the "free from" claims fall also within the jurisdiction of the Directive 2005/29/EC concerning unfair business-to-consumer commercial practices [3] and as a consequence, shall be prohibited.

What are the scientific evidences behind the "free from" claims? And what are the myths and reality behind the consumers concerns related to particular cosmetic ingredients? In the sections here below the scientific evidences will be discussed for both the "free from parabens" and the "free from allergenic substances" claims.

The "free from parabens" claim. In 2004 Darbre et al. [4] reported the presence of intact parabens (methyl paraben, ethyl paraben, n-propyl paraben, isobutyl paraben, n-butyl paraben, benzyl paraben) in the human breast tumours, igniting the concern that parabens can mimic oestrogens and thus are able to cause hormone disruption. However, these studies cannot identify either the source of the parabens or whether they entered the human body by an oral or by a topical route. Furthermore, the study was biased by the followings: i) lack of control tissue when measuring concentrations of parabens in breast tumours, ii) blank samples clearly contaminated with parabens, iii) high variability in individual blank values, iv) no study of the general therapeutic history of the tissue donors and no mention of the paraben-containing anti-cancer drugs the patients were using, v) no study of donors' exposure to consumer products containing parabens, vi) brief descriptions of tissue handling. As soon as after its publication, the European Commission asked the Scientific Committee on Consumer Products (SCCP) to assess if the data provided by Darbre and co-workers indicate a potential risk for the development of breast cancer in past users of underarms cosmetics containing parabens and if a concern that parabens when used up to the maximum authorized concentration in cosmetic products might pose a risk to the consumer health. After reviewing the data available in the scientific literature, the SCCS concluded that i) existing epidemiological data indicate the absence of an association between underarm cosmetics and breast cancer, ii) the most frequently occurring paraben in the study was the methyl ester, which had shown to have the lowest estrogenic activity in the *in vitro* and *in vivo* estrogenicity studies, and iii) the majority (>98%) of underarm cosmetics do not contain parabens as preservatives [5]. In 2014 a European amendment to EC no. 1223/2009 [6], in response to a SCCS opinion on parabens [7,8], added the longer chain parabens (isopropylparaben, isobutylparaben, phenylparaben, benzylparaben and pentylparaben) in the list of substances prohibited in cosmetics (annex II), since limited or no information was submitted by industry for their safety assessment. In USA, the CIR expert panel concluded that methylparaben, ethylparaben, isopropylparaben, butylparaben, isobutylparaben, and benzylparaben are safe as cosmetic ingredients in the practices of use and use concentration described in the safety assessment [9]. Based on the scientific evidences reported here above the concerns on the safety of use of parabens in cosmetics is a myth not

supported by facts. Therefore, the claim "free from parabens" is unfair and denigrating the cosmetic industry, since these ingredients can be legally approved to be used in cosmetic products.

The "free from allergenic substances" claim and the related "hypoallergenic" claim. Skin sensitization is a baseline, unavoidable, and acceptable undesirable (adverse) event associated to cosmetic products use, even if they can be still considered safe. The "free from allergenic substances" and the "free from a particular allergen" claims are highly misleading since unknown and unexpected ingredients can induce skin sensitization. In fact, both claims does not allow informed decision making to consumers concerned about skin sensitization or allergic to a specific ingredient. On the other side "which cosmetic manufacturer would add sensitizers to their products?". The answer is so obvious as to leave no scope for any reasonable doubt, no one would deliberately add a sensitizer in its cosmetic product. In this view the "free from allergenic substances" claim does not make any sense. Quite related but substantially different is the "hypoallergenic" claim. Hypoallergenic means that the product has been formulated to minimise its allergenic potential (low allergenic potential, reduced risk of allergy) and that the manufacturer has evidence to support the claim. Currently there is no formal definition of the term "hypoallergenic" and there are a variety of interpretations. In the near future, a clear definition of what "hypoallergenic" means would be the first step to correctly inform consumers concerned about sensitization. In any case, consumers who know they are allergic to a specific ingredient should always be made aware to check the absence of the ingredient from the ingredients list.

In conclusion, extol the virtues of what is inside a cosmetic product instead to claim what the product does not contain, it should be imperative for a responsible marketing of cosmetic products.

Conflict of interest

The author declares that there are no conflicts of interest. Dr Vincenzo Nobile is scientific member of Helvetic Association for Cosmetic Ingredients (HCI), Via Arch. R. Tami 2, Casella Postale 18, CH-6924 Sorengo (TI), Switzerland.

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