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PERSPECTIVE

A Critical Overview about Cosmetic Labeling Claims

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Abstract: ***Background*:** In several countries, still there is no standardized regulation on the use of claims. However, there are some guideline materials and content that are used by regulatory agencies.

***Objective*:** The goal of this manuscript is to provide an approach to the understanding of the thematic of cosmetic claims to dermatologists and general practice physicians. The objective is to discuss the definition, regulatory framework and tips to help them on how to use this knowledge to guarantee an assertive indication.

***Results*:** Knowing the appropriate tests for the substantiation of claims allows the physician to indicate the most appropriate dermocosmetic for the skin condition of each patient.

***Conclusion*:** For a more critical and assertive indication or suggestion, it is recommended that the physician observe the product packaging and know how to understand and interpret the terms on the product label.

Keywords: Cosmetic claims, labeling claims, patient care, prescription, sensorial tests, instrumental tests.

1. INTRODUCTION

The growing and aggressive cosmetic marketing is increasing the participation of the cosmetics products on costumers' lives, even during the current COVID 19 pandemic [1]. A study about Opinion Box indicated that 43% of the interviewed participants were thinking more about their personal care during this period [2]. Due to marketing strategies, the access to information is also amplified and it is possible to see that costumers are increasingly concerned about the products' components they are using, considering quality, efficacy, safety, and sustainability [3]. As we live in a "planet" of cosmetics and dermocosmetics, it is relevant when addressing efficacy and quality to pay attention to the cosmetics claims. Cosmetic claims are marketing tools, characterized by clear, direct, and concise information that highlight functions, characteristics, benefits and differentials of products and services. These sayings are present on product labels, promotional advertisements, advertising campaigns, slogans, and other forms of communication [4]. It is important to highlight that to be identified as a claim, this element must be substantiated. Finally, it should be acknowledged that claims are not only essential ways of differentiating between products, but also contribute to stimulate innovation and foster competition.

Labelling is also the way by which the cosmetics manufacturers present products to consumers. Cosmetic products must have specific information on their containers and packaging to be made available on the market. This information includes the name and address of the responsible person, the nominal content at the time of packaging, the date until which the product will remain effective (date of minimum durability), and any necessary precautions for use. The date of minimum durability must be clearly expressed and can consist of either the month and year or the day, month, and year. Products with a minimum durability of more than 30 months do not require a date of minimum durability but must indicate the safe period for use after opening. The packaging must also include the batch number or product reference, the product's function (unless obvious from presentation), and a list of ingredients preceded by the term "ingredients" [5]. However, buyers may find the terminology confusing, since it is often exaggerated, miracle-claiming, or containing scientifically and legally vague terms, such as 'natural', 'biologic', physiologic, and 'organic' [6]. On the other hand, physicians often find this form of communication annoying, unless products are sold through the pharmaceutical channel [6]. There is no global consensus on the regulation of claims. Some countries, such as Brazil, do not have specific legislation about this topic, leaving free use of claims that are unrealistic or that may bring doubts to physicians. The regulation about the use of claims in cosmetic products communication is not so clear to professionals that work with cosmetics development [7] and

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probably to dermatologists. There are many products that do not display their composition on the packaging, making it difficult for doctors to recommend them. In this context, the present article aimed to survey cosmetic claims information, didactically demonstrate the necessary criteria for a communication element to be characterized as a claim; the legal issues and scientific methodologies involved in formulating a claim and how dermatologists and general practice physicians can use this knowledge to ensure a more assertive indication, with a greater chance of guaranteeing the efficacy and safety of the suggested product.

2. COSMETIC CLAIMS REGULATION

There are differences in the rules in claims regulations, all over the world. Therefore, it is important to check each local regulation. Nevertheless, the recommendations help to understand concepts that must be taken into consideration when dealing with cosmetics safety and trustworthiness [8]. The Food and Drug Administration (FDA) from United States provides recommendations on claims, monitors cosmetics on the market and acts against companies that break the laws it enforces. In addition, while the FDA regulates cosmetic labelling claims, the Federal Trade Commission regulates advertising claims [9]. In Brazil, rigorous regulation should also be followed according to the Brazilian Regulatory Agency (ANVISA) guidelines. One of the requisites that manufacturers must comply to place a product on the market is to present the evidence of substantiation of the claims included in the labelling. ANVISA has made available a guide for Evaluation of Safety of Cosmetic products, containing the methodologies that should be followed to support the claims [10]. In Europe, although all EU member countries follow Regulation 1223/2009, each member state has a competent national agency that monitors the market, including verification of labelling claims. They are based in Regulation (UE) N° 655/2013, laying down common criteria for the justification of claims of cosmetic products. This regulatory framework aims to ensure the protection for consumers, from misleading claims, whilst contributing to prevent distortions in the internal market and potentiate cooperation between EU members national authorities involved in the enforcement of consumer protection laws.

The common criteria established under this regulatory framework are:

1. Legal compliance: the claim cannot take benefit from characteristics which every product must have. For example: “safe product” since all products must be safe; it is not a perk to be used with the purpose to attract customers.
2. Truthfulness: the claim may not declare that the product does not have some ingredient if it is present (for example: “vegan product” if it has animal ingredients). Furthermore, if it assures that the product has a specific ingredient, it must contain it and promote the announced effect (for example: “with vitamin C” - the product really needs to contain vitamin C in the formulation and produce its expected function).
3. Evidential support: the tests must be done following adequate scientific methodology.
4. Honesty: it is not allowed that the claims include a special feature that is presented by all other similar products (for example: “sulfate free conditioner” - all conditioners are sulfate free, there is no difference among them).
5. Fairness: the cosmetic product claims need to be clear and cannot harm competitor brands images (for example: “30 times more powerful than competitor”).
6. Informed decision-making: the claim must communicate in a comprehensive and adequate way for an average consumer.

It should also be highlighted that labelling claims strongly affect the way a formulation is classified, since cosmetics often border on other products, namely, medicines, food, biocides, medical devices and even toys. Borderline products are products with doubts about their classification, whether composition, application area, labeling and mentions. Often, borderline products end up being evaluated by the most demanding legislation. Thus, for example, in the cosmetic/medicines border, products must be evaluated by the legislation applicable to medicines. In many cases, a decision on which regulatory framework applies is made by the national competent authorities on a case-by-case basis, and considering all characteristics of the product, such as the presentation, ingredients, mode of action and claims. The European Sub-Group on Borderline Products (integrated in the Working Group on Cosmetic Products) has produced a “Manual on the scope of application of the Cosmetics Regulation Nº 1223/2009 (art. 2(1)(a)”. Despite not being legally binding, it is a useful compilation of their views on products, or categories of products, which have raised doubts in the past, showcasing a case-by-case application of EU legislation by the member-states [11].

3. DIFFERENT TYPES OF SCIENTIFIC TESTS FOR COSMETIC EFFICACY EVALUATION AND CLAIM SUBSTANTIATION

Different methodologies can be used to provide information that helps to evaluate cosmetic products’ efficacy. The scientific tests are listed below. To be able to properly choose which test would be more adequate, it is important to comprehend the studies’ purposes and the information required to prove the products’ efficacy [12].

3.1. Sensorial Tests

Sensorial tests for claim substantiation are based on observation of the product’s efficacy and can be classified as self-consumer evaluation or trained expert panels evaluation.

3.1.1. Self-evaluation

The tests are performed by the customers who report their perception about the product’s efficacy, based on parameters related to visual observation or touch after use. There are two types: blind tests, with no information that can cause bias on costumers’ opinion or use tests that are connected to communication elements; the goal is to evaluate if the costumer’s perceptions matches with the communication presented on the product’s package.

3.1.2. Sensorial-evaluation Tests by Trained Panels

These are made with a panel of trained experts following a specific protocol and the goal is to evaluate pre-defined characteristics of the product.

3.1.3. Tests Under Medical Supervision

The tests are maintained under medical supervision, with parameters evaluated by clinical observation. These tests are compared to initial results, a placebo, untreated control, or a reference product.

3.1.4. Tests Under the Control of other Professionals

Beyond the medical accompaniment, it is also possible to perform the use test under evaluation of other professionals, such as aestheticians, hairdressers, or others. Here, the objective is to evaluate the product's efficacy by observing tactile and visual perceptions by using an established and validated scale. Self-evaluation by volunteers can also be used combined with these tests to evaluate if the perceptions are similar.

3.2. Instrumental Tests

These are executed with adequate non-invasive measurement instruments according to a defined protocol. Two types are used: 1) Laboratory instrumental tests performed by a trained technician, using specific equipment, in controlled laboratory conditions. For example: hydration, firmness, sun protection factor, *etc*.; and 2) Instrumental measurements associated with an evaluation by professional experts; they are similar sensorial tests made by experts, but in this case the use of equipment to measure the results is required. Example: measurement of hydration and skin's mechanical properties.

3.3. *Ex-vivo* / *In-vitro* Tests

Ex-vivo tests are performed with biological substrates taken from a living organism, without changing its intrinsic properties. The goal of this test is to measure the results or compare them without the use of the product being tested. For example: use of human hair to evaluate its mechanical properties after using a shampoo. *In-vitro* tests are performed at the industry laboratory, with artificial media, in a controlled environment. These tests are usually executed during the products development process to check and prove its expected results. These tests do not use a biological material.

4. COSMETIC CLAIMS CLASSIFICATION AND HOW TO DEMOSNTRATE

There is no world consensus about cosmetic claims classification. The guidelines for cosmetic product claim substantiation reviewed in 2019 have classified them following its characteristics and substantiation's needs. Below, there is an adapted interpretation of the analyses, ranked in eight different classifications.

1. Sensorial related (sticky, greasy, easily absorbed product): These claims can be substantiated with sensorial tests made by trained expert's panel.
2. Function related (reduces up to 30% of the spots in 30 days): In this case, it is necessary to prove the product benefits. It can be done by using sensorial, instrumental or *in-vitro*/*ex-vivo* tests.
3. Ingredient related (moisturizes your skin with hyaluronic acid): these claims can use bibliographic references that prove the function of the ingredient. In this case, it is necessary to make an instrumental test to prove that the product has enough ingredient to reproduce the desired effect.
4. Consumers perception claims (soft skin feeling): these claims can be substantiated with sensorial and performance tests made by consumers.
5. Comparative claims (guarantees the smoothest hair): These claims refer to comparisons between before and after use of a product, as well as comparisons made with competing products. It can be done by using sensorial, consumers, instrumental or *in vitro*/*ex vivo* tests.
6. Environmental claims also termed "green claims" (eco-friendly, energy efficient, neutral, low carbon, pollutant-free): Refer to environmentally beneficial qualities or characteristics of their goods and services.
7. Claims related to life-style choices, personal values and beliefs (vegan, halal, natural or organic): Certification according to private standards and compliance with other sectorial regulations can strengthen the substantiation of such claims.
8. Communication strategies that are not classified as claims - Hyperbolic/Puffery claims ("feel your beauty"): As mentioned in the introduction, to be classified as a claim, the communication strategy needs to be provable. Therefore, a different classification is used for this category, including communicative elements that have the objective of sensitize the final costumer.

5. EXPLAINING CLINICAL APPEALS

Products that contain claims considered clinical appeals and have messages about the acceptability of the product are also common. In these products, acceptability tests are conducted, and its objective is to confirm the absence of sensitizing risk (also known as allergy). These tests need to follow the conditions determined by the producer and must be realized at least in 30 participants, for 3 weeks, under dermatological supervision [10]. From the Table **1** it is possible to observe some examples of clinical appeals, their means and which tests can prove them. This knowledge is important to understand which premises need to be followed for the product to be considered safe and acceptable [10].

6. HOW TO GET A CRITERIAL AND CRITICAL APPROACH

Putting together all the discussed topics, the existence of many ways to guarantee a truthful and high-quality product to the costumer is evident. To fully understand what is behind the claims, it is always a good idea to take a good look at the

Table 1. Explanation of clinical appeals according to the Guide for Cosmetic Product Safety Assessment [10].

Clinical Appeal	Meaning	Test to be Realized
Ophtalmologically tested	Evaluation of the use of the product in humans, under ophthalmologist evaluation and with the accompaniment of a dermatologist.	Use tests, which objective is to evaluate the products acceptability on eyes area, by testing ophthalmological parameters.
Clinically tested	Evaluation of the use of the product in humans, under dermatologist evaluation or another professional if it is necessary.	Use tests which objective is to evaluate the cutaneous acceptability in real conditions of use.
Dermatologically tested	Evaluation of the use of the product in humans, under dermatologist evaluation.	Use tests which objective is to evaluate the cutaneous acceptability and/or compatibility in real conditions of use.
Sensitive skin related products	Evaluation of the use of the product in humans that were previously diagnosed with sensitive skin, and the test is realized under dermatologist evaluation.	Use tests, which objective is to evaluate the products compatibility in general population and its cutaneous acceptability in people that have sensitive skin.

Table 2. Cosmetic disclaimers interpretation.

Claim	Disclaimer Message on Package	Disclaimer Message Meaning
Moisturizes and restores softness	With the use of a shampoo and a conditioner compared to the use of a shampoo without moisturizing ingredients.	In this case, when analyzing the disclaimer, is possible to observe that the product presents the action described in the claim after a use test comparing the use of the shampoo and the conditioner to a shampoo without moisturizing ingredients.
Shinier hair in one week	With the use of a shampoo and a conditioner of the same brand.	In this case, the result was obtained after the use of both products together, and if it is not followed, the results cannot be as expected.
More elastic skin in 30 days	Based on volunteers' opinion.	In this case, a perception test with costumers or with professionals was performed and they give their opinion about the results.

product packaging. Sometimes, claims can bring asterisks indicating a disclaimer. This is a legal tool that can be used in products with the objective of alerting the costumer about a specific situation. Additionally, by looking at its label, it is possible to see what it really denotes, such as: the test that was used to do its substantiation, the need to use another product at the same time to get the expected result, as well as the time necessary. Table **2** shows examples of claims, disclaimers message and meaning.

Regulatory agencies in countries are important for standardizing functional claims on cosmetic labels in the current globalized world, we live in, we believe that these agencies will increasingly act together to achieve a more uniform standardization.

CONCLUSION

Through a critical interpretation of the cosmetic claims and communication elements the dermatologist and clinical practice physicians will be able to better indicate the ideal product to customers. It is necessary to know the definition, regulation rules and tips about cosmetics use to guarantee an assertive indication or suggestion and obtain the expected results.

ABBREVIATION

FDA = Food and Drug Administration

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CONFLICT OF INTEREST

The author(s) declare no conflict of interest, financial or otherwise.

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