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## **Guideline on Cosmetic Claims**

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## **Cosmetic claims guideline**

### **1. Introduction**

#### ***What is a cosmetic claim?***

Claims for cosmetic products are statements made, usually in advertising, with regard to a product's functions (R. Schueller and P. Romanowski, C&T, January 1998)

Claims include texts, images, symbols used by brands to present the characteristics of a cosmetic product.

The evaluation of claims cannot be separated from consideration of whether a product is a cosmetic or not. One of the main factors in determining whether a product is a cosmetic or a medicine, is on the claims made for the product. There are also several indicators that a cosmetic product has a proposed therapeutic use. Intended use may be established in number of ways.

This guide provides a simple classification guide helping to identify products and claims as cosmetics. This has been prepared based on ASEAN guideline. The document also provides some unacceptable claims for cosmetic products based on the product type and other unacceptable claims in the local setting. **(Annex 1)**

### **2. Decision process to identify cosmetic products and allowable claims**

#### ***a. Composition of cosmetics***

The product should contain ingredients that comply with EU ingredient database (up to date) and should not contain any ingredients that are banned in EU data base / Reference authority. In situations which the particular material is not given in the Eu data base, any other standard approved by the authority should be considered.

#### ***b. Target site of application***

The product should be intended to be placed on external parts of the human body (eg. skin, hair, nails, and lips) or mouth (including gums, teeth and tongue).

The products that are ingested, injected or placed in contact with other parts of the body e.g., mucous membranes of nasal mucosa or the internal genitalia cannot be considered as cosmetic products.

#### ***c. Intended main function of cosmetics.***

The product is intended exclusively or mainly for cleansing, perfuming, or changing the body odour, changing the appearance or to keep or protect defined parts in good condition.

***d. Product presentation of Cosmetics***

The product should not have therapeutic claims. i.e., presented as treating, preventing, or diagnosing diseases.

The following features of the product should be taken into account:

- I. Product claims and the context in which the claims are made.
- II. Labelling packaging inserts (including graphics)
- III. Promotional literature, including testimonials and literature issued by third parties on behalf of the supplier.
- IV. Advertisements
- V. The product form and the way it is to be used e.g., capsule, tablet injection etc.
- VI. Particular target of the marketing information e.g., specific population groups with specific population groups with, or particularly vulnerable to, specific diseases or adverse conditions.

***e. Physiological effect of cosmetics***

Every product that has an effect on the functioning of the body also has an effect on its metabolism. Cosmetic products typically have effects that are not permanent and have to be used to maintain their effects.

***Other unacceptable claims:***

1. Good Manufacturing Practice (GMP)-

The use of symbol, logo or statement related to GMP certification is unacceptable (as it is a prerequisite for registration)

National Medicines Regulatory Authority- Cosmetic Regulatory Division

Refer Technical document on cosmetic claims 3<sup>rd</sup> July 2017.

(<https://ec.europa.eu/docsroom/documents/24847>)

Revision on free from claims 2018

## **Annex 02**

Best practice for claim substantiation evidence

## Annex 01

### Cosmetic claim guidelines

The claims that can be reasonably expected for the product types are given below:

Product type	Unacceptable claims
Hair care products	<ul style="list-style-type: none"> <li>❖ Eliminate, cure (or similar meaning)* dandruff permanently.</li> <li>❖ Seborrhoeic dermatitis*</li> <li>❖ Hair loss can be arrested or reversed*.</li> <li>❖ Alopecia*</li> <li>❖ Stimulate hair growth/hair cells/hair follicles *(Scalp)</li> <li>❖ Restore hair cells*.</li> <li>❖ Prevent/stop/cure/reverse*hair thinning.</li> </ul>
Depilatories	<ul style="list-style-type: none"> <li>❖ Stop/retard /prevent hair growth.</li> </ul>
Nail products	<ul style="list-style-type: none"> <li>❖ Reference to growth resulting from nourishing fingernails.</li> </ul>
Under eye care products	<ul style="list-style-type: none"> <li>❖ Acting on causes of discoloration (correct, modify physiological functions)</li> <li>❖ Remove eye bags.</li> </ul>
Skin products	<ul style="list-style-type: none"> <li>❖ Prevent/stop/eliminate/reverse* the physiological changes and degeneration changes brought about by aging.</li> <li>❖ Stop/reverse/eliminate/* pigmentation, results permanent change of skin color.</li> <li>❖ Skin whitening/depigmenting*</li> <li>❖ Bleach</li> <li>❖ Remove*scars permanently.</li> <li>❖ Prevent /heals/treats/stops* acne (or pimples/blemishes/comedones), Anti acne*</li> <li>❖ Numbing /analgesic effect*</li> <li>❖ Treatment of cellulite</li> <li>❖ Relieves abrasions/bites/inflamed skin/rashes*.</li> <li>❖ Loose centimeters/slimming/enhance body contours*.</li> <li>❖ Removes /burns*fat.</li> <li>❖ Reduces/controls*swelling puffiness or edema*.</li> <li>❖ Fungicidal/ antifungal*</li> </ul>

	<ul style="list-style-type: none"> <li>❖ Virucidal/antiviral*</li> <li>❖ Antibacterial/bactericidal*only</li> <li>❖ Reference to disease causing organisms, kills pathogens, helps control infection, cleans cuts.</li> <li>❖ Keratolytic*</li> <li>❖ Rejuvenate/revitalize living tissues* (hair follicles living cells)</li> <li>❖ Promotes skin respiration/cellular respiratory factor*.</li> <li>❖ Relax muscles*.</li> </ul>
Deodorants and antiperspirants	<ul style="list-style-type: none"> <li>❖ Completely prevents sweating/perspiration*.</li> </ul>
Perfumes/fragrances/colognes	<ul style="list-style-type: none"> <li>❖ Any implication of hormonal attraction, reference to relieving stress or improving physical wellbeing.</li> </ul>
Oral or dental hygienic products including toothpastes and mouth washes	<ul style="list-style-type: none"> <li>❖ Any implication or effect below gum line</li> <li>❖ Treatment or prevention of dental abscess, gumboils, inflammation, mouth ulcers, periodontitis, pyorrhea, periodontal disease, sensitivity, stomatitis, thrush, or any oral disease or infection*</li> <li>❖ Whiten tetracycline- induced stains.</li> <li>❖ Antiseptic/kills pathogens/antibacterial/microbicidal</li> </ul>
Feminine and male hygienic products	<ul style="list-style-type: none"> <li>❖ Reference to sexual pleasure</li> <li>❖ Reference to male female vitality</li> <li>❖ Reference to preserve normal flora.</li> <li>❖ Tighten vaginal muscles.</li> <li>❖ Reference to infection and inflammation</li> <li>❖ To reduce vaginal discharge/leucorrhea</li> </ul>
Oil to assist body massage	<ul style="list-style-type: none"> <li>❖ Reference to body/muscle/joint pain/aches</li> <li>❖ Stomach wind</li> <li>❖ Arthritis</li> </ul>
Aromatherapy	<ul style="list-style-type: none"> <li>❖ Reference to any claim which is not cosmetic in nature such as for sleeping disorder, neurological effect, muscle/body/joint pain, immune system, aphrodisiac, blood circulation or other medical conditions.</li> </ul>
Sunscreen	<ul style="list-style-type: none"> <li>❖ Sunblock</li> </ul>

	<ul style="list-style-type: none"><li>❖ Sweat proof.</li><li>❖ Waterproof</li><li>❖ Reference to cancer</li></ul>
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\*or similar meaning

**Note:**

- Claim “Anti- dandruff” will only be accepted-if the product contains antidandruff agents according to EU regulations on cosmetic raw materials.
- This is not an exhaustive list and will be reviewed when necessary.
- During the evaluation need to consider case by case depending on the claims, active ingredients, and other relevant pharmacokinetics.
- Cosmetic Evaluation Sub Committee (CESC) of the National Medicines Regulatory Authority (NMRA) reserves the right to disallow any other words, phrases, or graphics for product label/information leaflets which in its opinion is misleading, improper or not factual.

**Allowed wordings:**

- ✓ Anti-hair loss, Anti- hair fall
- ✓ Anti-wrinkling
- ✓ Anti-aging

## Annex 02

### Guide on claim substantiation evidence for cosmetics

Claims for cosmetic products shall be justified by substantial evidence and /or by the cosmetic formulation or preparation itself. These claims, whether explicit or implicit, should be supported by adequate and verifiable evidence regardless of the types of evidential support used to substantiate them, including where appropriate, expert assessments. Different types of evidential support can be used to substantiate claims.

#### Common criteria (from EU)

The **European Commission** has published guidance to set out the minimum requirements that cosmetic claims should meet:

- **Legal compliance:** Presumed for all products circulating in the EU.
- **Truthfulness:** Concerning the presence of certain **ingredients** or properties in the **finished product**.
- **Evidential support:** All manufacturers should provide **proof of effect claimed** for their products, taking into account the state of the art at the moment when the product is marketed.
- **Honesty:** The effect claimed should not go further than the evidence available.
- **Fairness:** Different products shall not be compared to prove the benefits of one of them.
- **Informed decision making:** Claims and advertising shall be clear and understandable for the target audience.

It is usual to substantiate claims by using either:

- Experimental studies
- Consumer perception tests
- Published information.
- Or combination of these



## **Experimental studies**

- Should comprise methods which are reliable and reproducible.
- Should follow a well-designed scientifically valid methodology according to best practice.
- Should meet all necessary ethical requirement for an experimental study.
- Criteria used for evaluation of the product performance should be defined with accuracy and chosen in accordance with the aim of the test.
- Safety assessment by a suitably qualified person approved by the regulatory authority.

### **Different types of experimental studies on cosmetics:**

#### **Tolerance tested-**

means that the product underwent tests under the supervision of a scientifically qualified professional intended to study its tolerance in a target group and that the results of those tests show that the product was well tolerated by this group.

#### **Tested under medical supervision-**

indicates that the product underwent tests conducted under supervision of a medically qualified professional such as a medical doctor or a dentist. Depending on the presentation of the claim, it may, for example refer to a specific efficacy of the product or to skin tolerance.

#### **Dermatologically tested-**

Implies that the product was tested on humans under the supervision of a dermatologist. Depending on the presentation of the claim it may refer to specific efficacy or tolerance of the product. Consumer self-perception studies are not appropriate to substantiate such claims.

#### **Clinically tested-**

refers to expertise, process, or conditions under which the tests were carried out. "Clinically tested" means that the product was tested on humans under the supervision of a medically qualified professional or another scientifically qualified personnel according to a clinical protocol or in a clinical setting.

### **The report of the experimental study:**

- Should include clear identification of the product, enabling establishment of a link to the product available in the market.

- This report should also include:
  - ✓ Clear identification of the product (enabling to establishment of a link to the product available in the market)
  - ✓ The study's objective
  - ✓ Test schedule
  - ✓ Test protocol
  - ✓ Presentation of results and their interpretation
  - ✓ Statistics
  - ✓ Signature of the person in charge of the study

### **Consumer perception tests**

These tests evaluate consumer's perception of product efficacy and cosmetic properties based on parameters that they can observe or feel.

The experimental aspect of studies calls for reliance on knowledge and awareness of statistical principles in the design and analysis of the study. A study protocol should be drawn up and validated in order to enable the study to be conducted and monitored appropriately, thereby ensuring its quality.

The method should comply with the requirements given in the "**Technical Document on Cosmetic Claims**".

The report should include:

- Clear identification of the product (enabling to establishment of a link to the product available in the market)
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- Statistics
- Signature of the person in charge of the study

### **Published information.**

May include:

- Scientific publications
- Scientific state-of-art

➤ Market data

Scientific publications on ingredients or combinations of ingredients to substantiate a claim will be acceptable provided that they are relevant to the cosmetic product and the claim made.

Market data – should be relevant to the claim made and representative of the market in question. For further details refer the TGA document.

### **“Free from” claims**

More guidance is needed for the application of common criteria to provide adequate and sufficient protection of consumers and professionals from misleading claims.

The EU CPR states that **all** ingredients used in cosmetic products must be safe. Many 'free from' claims perpetuate myths on safe and legally allowed ingredients, fostering a negative perception around the safety and uses of cosmetic ingredients, which in turn has led to safe and effective ingredients no longer being used. The damage to the trust and reputation such action has on the industry should not be underestimated. Companies should follow the guidance of the Technical Document. We would encourage the use of claims that talk more positively about the ingredients being used and the innovative benefits they impart, rather than the absence of ingredients.

The absence of specific ingredient(s) should be demonstrated by adequate and verifiable evidence.

1. Free from claims/claims with similar meaning should not be made concerning ingredients prohibited for use in cosmetics in EU database or any other database recognized by the regulatory authority. eg “*free from corticosteroids*” is not allowed as it is prohibited in cosmetics
2. In claims in relation to absence of ingredients the product should not contain any ingredient belong to the relevant group. eg. the claim “*free from formaldehyde*” is not allowed if the product contains formaldehyde.
3. “Free from” claims or claims with similar meaning should not be allowed when they refer to an ingredient which is typically not use in the particular type of cosmetic

product.eg fine fragrances usually contain such a high amount of alcohol that the additional use of preservatives is not necessary. In such situations it would be dishonest to highlight the fact that certain fine fragrances do not contain any preservatives in a product.

4. Free from claims or claims with similar meaning should not be allowed when they imply guaranteed properties of the product based on the absence of (an ingredient(s) which cannot be given.eg. the ‘free from allergenic/sensitizing substances’ is not allowed as complete absence of the risk of an allergic reaction cannot be guaranteed. The product should not give the impression that it does.

For further details refer the **“Technical Document on Cosmetic Claims”**

### **Hypoallergenic claims**

This can only be used in cases where the cosmetic product has been designed to minimize its allergic potential. Evidence should be produced to support the claim by verifying and conforming a very low allergic potential of the product through scientifically robust and statistically reliable data.

Example: - reviewing post-marketing surveillance data etc.

If a cosmetic product claims to be hypoallergenic the presence of known allergens or allergen precursors should be totally avoided, in particular of substances or mixtures (refer p15 of **“Technical Document on Cosmetic Claims” document**)

The use of the claim “hypoallergenic” does not guarantee a complete absence of risk of an allergic reaction and the product should not give the impression that it does.

The companies should consider whether consumers understand the claim “hypoallergenic”. If necessary, further information or clarification regarding its meaning should be available.

References:

“Technical document on cosmetic Claims”  
(<https://ec.europa.eu/docsroom/documents/24847>)

European Commission Cosmetic Ingredient Database  
([https://ec.europa.eu/growth/sectors/cosmetics/cosing\\_en](https://ec.europa.eu/growth/sectors/cosmetics/cosing_en))

***\*\*This document is not exhaustive. CESC of NMRA reserves the right to request any additional information depending on the individual product.***