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Confidence in Cosmetic Claims

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The Cosmetic Toiletry and Perfumery Association (CTPA) is the trade association for the UK cosmetic and personal care industry.

The Association's role is to advise manufacturers, distributors and suppliers about the strict legal framework for cosmetics, to represent industry views to UK government, and external stakeholders and help promote information to the media on issues relating to the safety of cosmetic products. The CTPA acts as the voice of the UK industry and provides the most up-to-date interpretation of, and guidance on, regulatory matters affecting cosmetic products in Europe.

Why join the CTPA?

CTPA membership gives companies access to experienced regulatory, scientific and technical staff to help them market safe, effective products that provide a wide range of consumer choice both in the UK and overseas. Membership provides companies with peace of mind with easy access to:

- up-to-date legislative references;
- guidance on compliance;
- confidential one-to-one advice;
- labelling advice, including claims;
- advice on best practice;
- advance knowledge of upcoming changes;
- global updates on key issues;
- media and consumer information; and
- 24/7 online resources accessible worldwide.

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Introduction

In this guidance note, we will cover cosmetic claims in detail.

We will first have a look at the horizontal, overarching legislation covering different sectors - the Directive 2005/29/EC of the European Parliament and of the Council of 11 May 2005 concerning unfair business-to-consumer commercial practices in the internal market and associated guidelines.

We will then focus on vertical legislation covering cosmetic claims (Cosmetics Regulation (EC) No. 1223/2009 and Regulation (EU) No. 655/2013 - Common Criteria for Justification of Claims) as well as relevant guidelines and the technical document, and finally, we will discuss advertising codes.

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1. Unfair Commercial Practices Directive (UCPD)

The Directive is horizontal in nature and protects the economic interests of consumers. The objectives of the Directive are to protect the consumer from unfair commercial practices by protecting the consumer to make an informed decision and preventing misleading actions and omissions that can be given verbally, in writing, by an illustration or by implications and relate to the main characteristics of the product.

- Commercial practices listed in Annex 1 are in all circumstances considered unfair. For example, pyramid schemes, false use of limited offers, etc.

- Misleading practices: either through action (giving false information) or omission (leaving out important information). For example, misleading information about the country of origin of the product, or an oversized packaging for a small container inside (also known as deceptive packaging).

- Aggressive commercial practices: that aim to bully consumers into buying. For example, cases of harassment, coercion (also physical force) or undue influence.

Misleading practices and aggressive commercial practices are assessed on a case-by-case basis and will be done by considering:

- the **average consumer expectations**; and
- whether the misleading practice has resulted in a **transactional decision** - a decision to purchase the product.

The Directive is breached if the average consumer alters a transactional decision because of an unfair commercial practice.

2. Article 20 of Cosmetics Regulation (EC) 1223/2009 (CPR)

In addition to the UCPD, cosmetic claims should comply with Article 20 of the Cosmetics Regulation which states *"claims shall not imply products have characteristics or functions which they do not have … the Commission shall establish an action plan regarding claims used and fix priorities for determining common criteria justifying the use of a claim …The commission shall adopt a list of common criteria for claims which may be used in respect of cosmetic products"*

Article 20 covers:

- packaging / labelling;
- the way of making available a product on the market (e.g. presentations at a stand, at the point of sale); and
- advertising.

The scope of Article 20 also covers all the different formats of claims made available to the average consumer such as:

- text;
- names (e.g. if a cream has the word 'anti-acne' in its name, this is regarded as a claim and therefore is covered by Article 20);
- trademarks;
- pictures; and
- figurative or other signs.

3. Common Criteria for Cosmetic Claims

As described in the text of Article 20, the European Commission has adopted in 2013 the Common Criteria for the justification of claims used in relation to cosmetic products as well as EU Guidelines for their application.

The text establishes that the Common Criteria apply only to cosmetics and should not to be used as an aid in 'borderline' decision-making. Therefore, any such question must already be resolved before these criteria are applied.

It establishes who is responsible for compliance with Article 20:

- the Responsible Person (RP); and
- the distributor in case they have modified the claims [Art 4.6] (for example translations).

It encourages a **common** approach across the EU.

The Common Criteria are not aimed at defining and specifying the wording that can be used for cosmetic product claims.

There are 6 Common Criteria of equal importance that Member States have agreed to follow:

- **Legal compliance:** for example, it is not possible to claim 'this product is in compliance with the Cosmetics Regulation' since all products placed on the EU market must comply.

- **Truthfulness:** for example, 'silicon-free' claim shall not be made if the product contains silicone.

- **Evidential Support:** all claims need appropriate support; with the exception of hyperbolic claims such as 'this perfume gives you wings', as no average consumer would take it literally and expect to grow wings.

- **Honesty:** for example, the claim 'one million consumers prefer this product' shall not be allowed if based only on the sales figure of one million units'.

- **Fairness:** for example, it is not fair to compare the anti-wetness properties of an anti-perspirant against a deodorant as the two are different products with different functions.

- **Allow informed decisions:** claims must be clear, understandable and provide enough information to allow the average consumer to make an informed decision.

The second section of the Common Criteria consists of the 'best practice for claim substantiation evidence', aiming at defining best practices specifically related to the type of claim support.

Claims can be substantiated by using either: formula, experimental studies, consumer perception tests and/or published information or, a combination of these.

Experimental studies need to be based on:

- reliable and reproducible method;
- protocol;
- monitoring system;
- data processing and interpretation of the result.

Consumer perception tests need to be based on appropriate:

- statistical principles;
- study protocol;
- ethical principles;
- wording of the questionnaire;
- data processing and interpretation of the result.

The use of published information should be relevant to the cosmetic product and the claim made.

4. Technical document

The technical document on cosmetic claims was agreed by the EU Sub-Working Group on Claims (3 July 2017). The aim of the document – which is meant to be a collection of best practices - is to provide guidance for the case-by-case application of the Common Criteria.

The Technical Document is not legally-binding and does not reflect an official position of the European Commission. Only the European Court of Justice (ECJ) can give authoritative interpretation. However, it does reflect a common understanding of national competent authorities, several of which have already indicated their intention to apply the guidance given in this document. Annexes I and II (published in 2013) are already being applied; Annexes III and IV are bringing new elements which apply as of 1 July 2019. This document is also work in progress and subject to modifications.

Part 1 'Free-From' Claims

Annex III looks at how the six Common Criteria apply to 'free-from' claims (including claims with a similar meaning).

Legal Compliance:

- 'Free from *prohibited ingredients*' claims are not permitted, e.g. the claim 'free from corticosteroids' is not allowed as corticosteroids are banned by EU cosmetics legislation.

Truthfulness:

- 'Free from a *functional group of ingredients*' (e.g. colorants, preservatives) is only allowed if there is no ingredient of that group present.

- If a specific ingredient is referred to, it must not be present or released, e.g. 'free from formaldehyde' is not allowed if the product contains a formaldehyde-releasing ingredient (such as diazolidinyl urea).

Evidential support:

- The absence of the specific ingredient or ingredients should be demonstrated by adequate and verifiable evidence. Annex II of this document covers best practices applying to experimental studies and should be consulted for advice.

Honesty:

- 'Free from' claims should not be allowed when they refer to an ingredient which is typically not used in the particular kind of cosmetic products, e.g. fine fragrances usually contain such a high amount of alcohol that the additional use of preservatives is not necessary. It would be dishonest to highlight that a certain fine fragrance does not contain any preservative.

- 'Free from' claims should not be allowed when they imply guaranteed properties of the product, based on the absence of an ingredient, which cannot be given, e.g. the claim 'free from allergenic/sensitising substances' is not allowed. A complete absence of the risk of an allergic reaction cannot be guaranteed and the product should not give the impression that it does.

- 'Free from' claims addressing functional groups of ingredients should not be allowed if the product contains ingredients with multiple functions and among these is the function that the product is claimed to be free from. Exceptions may be possible (e.g. based on challenge test results of the formula without the particular ingredient).

    - The claim 'free from preservatives' should not be made when the product contains an ingredient showing a protective effect against micro-organisms and which is not included in Annex V of the CPR 1223/2009. If the Responsible Person has evidence that the particular ingredient or combination of ingredients does not contribute to product protection, it might be appropriate to use the claim.

    - The claim 'free from perfume' should not be used when a product contains an ingredient which exerts a perfuming function in the product, regardless of its other possible functions in the product.

Fairness:

- 'Free from' claims should not be allowed when they imply a denigrating message, notably when they are mainly based on a presumed negative perception on the safety of the ingredient or group of ingredients.

    - E.g. certain parabens are safe when used in accordance with the CPR. Considering the fact that all cosmetic products must be safe, the claim 'free from parabens' should not be accepted, because it is denigrating the entire group of parabens.

    - E.g. phenoxyethanol and triclosan are safe when used according to the CPR. Hence the claim 'free from' these substances should not be accepted because it is denigrating authorised substances.

Informed decision-making:

- 'Free from' claims should be permitted when they allow an informed choice to a specific target group or groups of end users. Therefore, the following claims should be permitted if they also comply with the other common criteria:
  - o 'free from alcohol' in a mouthwash intended as a family product;
  - o 'free from animal-derived ingredients' in products intended for vegetarians;
  - o 'free from acetone' in nail polish for users wishing to avoid its particular smell.

Summary:

- 'Free-from' includes claims with a similar meaning, whether in text or another format.
- 'Free-from' claims are not all prohibited – some may be acceptable.
- Some Member States may take particular interest in these claims.
- Decisions will be taken nationally on a case-by-case basis (competent authority – national courts – European Court of Justice).

Part 2 Annex IV – Hypoallergenic Claims

Annex IV covers hypoallergenic claims and establishes that such claims can only be used where the cosmetic product has been designed to minimise its allergenic potential.

The Responsible Person should have confirmatory evidence:

- that is scientifically robust;
- statistically reliable;
- may include post-market surveillance data;
- the assessment should be updated continuously in the light of new data.

The presence of known allergens should be totally avoided, including those:

- identified as sensitisers by the SCCS;
- identified as skin sensitisers by other official risk-assessment committees;
- classified as category 1A or 1B skin sensitisers under CLP;
- identified by the company on the basis of consumer complaints;
- generally recognised as sensitisers in the scientific literature; or
- for which relevant data on their sensitising potential are missing.

This is a very high hurdle and would mean that a company will have difficulty to be able to substantiate a hypoallergenic claim, but the use of this claim is not mandatory; it is a choice.

Also, the document insists on the fact that the use of a hypoallergenic claim does not guarantee complete absence of sensitisation and therefore the product should not give the impression that it does. Companies should consider whether consumers understand the claim and if necessary, should make further information available.

The document also refers to the Scientific Committee on Consumer Safety (SCCS) 'Memorandum on the use of human data in risk assessment of skin sensitisation' SCCS/1567/15, 15 December 2015.

5. Advertising Codes

Advertising codes are established at Member States level and have a horizontal approach as different sectors are covered. In some Member States, such as in the UK, the Advertising Standards Authority (ASA) also provides specific rules for cosmetics.

The advertising codes lay down rules for advertisers, agencies and media owners and are separated out into codes for broadcast (radio and tv) and non-broadcast advertising.

There are three codes related to the cosmetics sector, and these are:

- the Committee of Advertising Practice (CAP) Code;
- the Broadcast Committee of Advertising Practice (BCAP) TV Code; and
- the BCAP Radio Code.

These codes cover a broad scope of advertising materials:

- broadcast,
- non-broadcast advertising,
- website (including Facebook and other social media). **It is important to mention that these codes do not cover the claims on pack, unless used in advertising material on a website (a picture of the packaging online)** or an advertisement.

6. Advertising & Claims Guidelines

A guide to advertising claims was developed by CTPA in 2008 and revised in 2018. The guide is endorsed by the ASA. The document is divided in three sections:

- Framework of common understanding
- Building blocks of claims support
- Practical guide to good study design

Part 1 Framework of Common Understanding

The legislation ensures that key principles apply when it comes to protecting the consumer over misleading claims. There is no prescriptive list of requirements detailing specific types of proof, test or result for certain claims. However, companies are expected to have sufficient data to substantiate their claims.

Owing to the nature of cosmetic products and the fact that the UK industry is a key driver for advertising, CTPA works closely with the ASA to ensure common understanding.

This guidance document applies to cosmetics not medicines and this is not a document to discuss the borderline. The Medicines and Healthcare products Regulatory Agency (MHRA) is the only competent authority in the UK to decide if a product is a medicine.

It establishes also that it is difficult for the industry to discuss **specific words or claims** as, when taken in isolation, this might prejudice the use of the same claim or words used in a different context.

It also establishes the **general principles and the key questions that should be part of the assessment:**

- What has been claimed?
- Is the claim substantiated based on all available information?

It also highlights that the substantiation should be available at the time of the claim not after.

Part 2 Building Blocks of Claims Support

The building blocks approach takes into consideration the class of the claim and the level of evidence. It establishes that, depending on the claim, the level of evidence as well as the data will vary.

A) The class of the claim

The class of the claim should be established taking into consideration the meaning of the claim (including implied claim) for the average consumer. Claims should therefore be clear and specific.

'With added XXX' can be interpreted in different ways and therefore it is advised to be very specific to avoid challenges. Also, some factors may modify the sense of a claim:

- multiple claims;
- mix of speech, text, music, and imagery in advertising.

Looking at the cosmetics industry, the CTPA guide establishes five types of claims:

- Performance
- Ingredient
- Sensory and/or aesthetic
- Combination
- Comparison

B) The level of evidence

Once a company has determined the class of the claim the second step is to assess the level of evidence:

1. Is it a claim widely accepted to be established?
2. Is it a claim with established rationale but requiring product or ingredient specific evidence?
3. Is it a claim that is based upon a significant advance in science or technology?

The first level is when a claim is considered widely accepted, where the rationale is consistent with the status of current knowledge commonly accepted within the scientific communities, as applicable to cosmetic science and related disciplines. It could be because of a common use of an ingredient proven to provide a particular effect: for instance, the use of surfactant in shampoo. But there is no definitive list of "well-known ingredients" a case-by-case assessment should be followed. Also, the concentration of the ingredient should be considered.

The second level of evidence is when there is a widely accepted claim, but specific support or substantiation might be needed. The claim may be:

- highly dependent on formulation factor(s);
- for a product type or format not normally associated with the established claim;
- dependent on factors described in guidelines, industry recommendations or scientific reviews outlining the need for specific test(s);
- an enhancement or quantification of an established claim; or
- targeted to particular populations.

For instance, Sun Protection Factor (SPF) claims should be based on appropriate test measurements not predictions based on formula. The same principle will apply for fluoride toothpaste.

The highest level of evidence is based upon the advances in the science and technology behind it, not simply that the words used in the claim have not been used before. For example, where the claim is based upon:

- the action of an entirely new type of ingredient;
- an entirely new consumer benefit;
- an entirely new sensory property;
- an entirely new means of qualifying or quantifying the product's effects on the substrate; or
- a new insight into the biology of the body part to which the product is applied.

E.g. 2-in-1 shampoo and conditioner.

Part 3 Practical Guide to Good Study Design

The last part of the guidance provides information on good study design. When it comes to performing a study, it should be relevant to the claims being made and based upon reliable and scientifically valid methodologies, the study should be:

- well-designed and executed and accurately reported;
- data should be processed and interpreted in a fair manner and should not overstep the limits of the study's relevance; and
- evidence should not be selected or presented so as to give a falsely positive or misleading view.

Studies involving human volunteers must respect sound ethical principles and be based on informed consent by the participants, consistent with the type of study under consideration. It is important that the person conducting the study has the appropriate training and experience in the field of the proposed study.

Experimental design is a complex subject which necessarily requires knowledge and awareness of statistical principles in both the design of the study and in the analysis of the data obtained. To ensure studies reach scientifically valid conclusions, an adequate understanding of statistics is necessary on the part of the person responsible for the study.

The guide also provides further information on digital advertising, social media and e-commerce. A decision tree illustrating the key principles for claims substantiation and borderline considerations is also available as an Annex to the guide.

The CTPA Guide on Advertising Claims is freely available from www.ctpa.org.uk.

Cosmetic Claims in a Nutshell

- Claims are regulated by a mix of legislation, self-regulation and industry best practices
- Cosmetics are not medicines
- The understanding of the average consumer should be considered
- Difficulty for the cosmetics industry to discuss specific words or claims – the overall presentation should be considered
- The substantiation should be available at the time of the claim and will depend on the class of the claim and on the level of evidence needed

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