

## NOTE

From the CTPA Guide to Cosmetic Advertising Claims. Chapter 3. Terms and Definitions  
<http://www.g-regs.com/downloads/UKCosCTPAguideadclaims.pdf>

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Article 2 of (EC) No 1223/2009.

A 'cosmetic product' means any substance or mixture intended to be placed in contact with the external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odours.

Article 2.2 states that "...a substance or mixture intended to be ingested, inhaled, injected or implanted into the human body shall not be considered to be a cosmetic product."

Recital (7) to the Cosmetic Products Regulation provides an illustrative list of products which are considered to be cosmetic products for example, face masks, anti-wrinkle products.

In addition, the Medicinal Products Directive (2001/83/EC) refers to other cases where products that might fall within the definition of cosmetic products are, nevertheless, to be considered as medicinal products. These are products that produce, or are intended to produce, a restoration, correction or significant modification of physiological function by pharmacological immunological or metabolic action. The notion of intent might be important and lack of efficacy would not be an acceptable argument if intent was demonstrable.

The Cosmetic Products Regulation defines what a cosmetic is and prohibits, or places restrictions on, certain ingredients within a product. The definition envisages that a cosmetic product may have a secondary preventative (but not curative), purpose. When deciding whether or not a product on the borderline between cosmetics and medicines is a medicinal product, the Medicines and Healthcare products Regulatory Agency (MHRA) will apply the tests set out in Directive 2001/83/EC. If a product falls within the definition of a cosmetic and within the definition of a medicinal product it will be classified as a medicinal product (Delattre 1991, C369/88). The regulatory status of products in other Member States will also be taken into account.

Note that the definitions are silent on the matter of time of effect; cosmetics are not required to have an immediate effect on application; neither are cosmetics required to have a durable effect; nor are cosmetics required to have a fully reversible action. Time is not one of the elements that determine whether or not a product is a cosmetic product. However, there may be a time element involved in the claims made for a cosmetic product and it is to be expected that such a claim would be supported in the appropriate manner.