

The Last Word

Ms Rozina Ali argues for greater clarity in the definition of the term 'cosmeceutical'

In 1984, Dr Albert Kligman coined the phrase 'cosmeceutical' to describe, "A topical preparation that is sold as a cosmetic but has performance characteristics that suggest pharmaceutical action."

At the time, Dr Kligman was conducting clinical studies to confirm the efficacy of topical vitamin A in improving ageing skin, whilst at a similar time, Dr Eugene Van Scott and Dr Ruey Yu were working on developing alpha hydroxy acids (AHAs) for skincare.¹

According to Oxford Dictionaries, 'Cosmeceutical' is a blend of the words 'cosmetic' and 'pharmaceutical', and is a cosmetic that has or is claimed to have medicinal properties. The American version adds an extra definition to medicinal properties, stating, 'especially anti-ageing ones.'² However, contrary to popular use, the US Federal Food, Drug, and Cosmetic Act (FD&C), states clearly that 'cosmeceutical' is not a recognised term. They claim a product can be a drug, a cosmetic, or a combination of both, but the term 'cosmeceutical' has no meaning under US law.³ There is therefore an evident mismatch between the terms commonly used within the industry and the strict definition of the regulatory authorities. With the global cosmeceuticals market estimated to increase at a compound annual growth rate (CAGR) of 8.62% from 2014 to 2019,⁴ a clear definition is crucial. What, therefore, classifies as a cosmeceutical?

A 'cosmetic' product is any substance or mixture intended to be placed in contact with the various *external* parts of the human body with a view exclusively or mainly to clean them, perfume them, change their appearance and/or correct body odours and/or protect them or keep them in good condition.⁵ In the UK, the legal implications of this are that cosmetics are governed by The EU Cosmetics Directive. The fifth recital of the directive, 'the Cosmetic Directive', foresees cosmetic products having a secondary preventative (but not curative) purpose.⁶ Pharmaceuticals, on the other hand, are prescription-only medicines (POMs) designed and rigorously proven to cure, treat and improve a described condition. As such, they must be prescribed for use, and are governed by The Medicines and Healthcare Products Regulatory Agency (MHRA), which is an executive UK government agency,⁷ regulating both medicines and medical devices nationally. Interestingly, like the FD&C, neither the European body nor the MHRA uses or refers to the word 'cosmeceutical'. In short, the term 'cosmeceutical' is not recognised as a legal category, yet it has become an accepted term in the industry. The original definition by Kligman has been lost in the world of free-markets, margins and promotions; companies have realised that there is no legally-binding definition of the word, therefore anyone may call their product or brand a 'cosmeceutical'. The dermatology-based research and development companies established during the 1980-1990s that used the term 'cosmeceutical'

to describe their newly discovered active ingredients and synergistic formulations, such as alpha hydroxy acids and vitamin A, now find themselves with patents expired and generic ingredients flooding the market. Newcomers are now able to use any ingredient, at any dose, in any formulation – as long as the EU Cosmetics Directive has approved the ingredient. This, in my mind, has caused confusion, and requires an urgent and incisive move for clarity. One of the ways of doing so, aside from legislation, is to discuss with patients the claimed versus proven benefits of skincare. Many practitioners may 'prescribe' a skincare regimen, but this does not necessarily mean that they are prescribing POMs, and this must be understood by the patient. 'Prescribing' skincare implies to them that they are getting something that is clinically proven to be effective, when in fact the practitioner may simply be supplying goods under the EU Cosmetics Directive. This requires only that they be deemed 'safe' with the manufacturer responsible for product safety. All products do, however, need to be registered in the Cosmetic Products Notification Portal (CPNP).⁵ In order to clarify this, I strongly believe it would be beneficial to have a specific category classifying ingredients or formulations that are clinically proven to exert a positive effect on the epidermis, dermis or components of either. Cosmeceuticals may then be further subdivided into those exerting effects on skin health, skin rejuvenation or skin healing. Reproducible, reliable clinical evidence is key. As medical practitioners familiar with clinical studies and levels of evidence, we will find remarkably few randomised, double blind, placebo-controlled (or even better vehicle-controlled) studies on cosmetic ingredients and formulations. Marketing material tells me nothing useful professionally – it's only when I am offered scientific and/or clinical data that my antennae is alerted and I am primed to investigate an ingredient, product or range more closely. I am, however, heartened by the increasing number of single ingredient and formulation studies now being conducted. The serious players in the industry have recognised the value of an evidence-based unique selling point. As we fast approach the oncoming 'cosmeworld', we need to make sure we understand the terminology used by manufacturers, and take the time to decipher, by reading the studies and verifying exactly what ingredients, and in what strengths, we are delivering in the product choices we recommend to our patients.



Ms Rozina Ali is a consultant reconstructive and aesthetic surgeon with an interest in facial aesthetic surgery. Graduating from St Thomas' Hospital Medical School with first class Anatomy BSc honours, she later undertook additional postgraduate surgical training at the cranio-facial unit at Great Ormond Street Hospital.

REFERENCES

1. Patricia Farris, *A critical look at the term cosmeceutical: Descriptive or deceptive?* (US: Dermatology Times, 2013) <<http://dermatologytimes.modernmedicine.com/dermatology-times/content/tags/cosmeceutical-products/critical-look-term-cosmeceutical-descriptive-o?page=full>> [Accessed 9 April 2015]
2. Oxford Dictionaries, *Cosmeceutical* (UK: Oxford University Press, 2015) <<http://www.oxforddictionaries.com/definition/english/cosmeceutical>> [Accessed 9 April 2015]
3. The Food and Drugs Administration, *Federal Food, Drug and Cosmetic Act (FD&C Act)* (US: The Food and Drugs Administration, 2010) <<http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCA>> [Accessed 9 April 2015]
4. RNR Market Research, *Global Cosmeceuticals Market to Grow at 8.62% BAGR by 2019* (US: WhatTech, 2014) <<http://www.whatech.com/market-research-reports/press-release/consumer/37005-global-cosmeceuticals-market-to-grow-at-8-62-cagr-by-2019>> [Accessed 9 April 2015]
5. The Cosmetic, Toiletry & Perfumery Association (CTPA) *Information Centre* (UK: The Cosmetic, Toiletry & Perfumery Association, 2015) <<http://www.ctpa.org.uk/content.aspx?pageid=233>> [Accessed 9 April 2015]
6. European Union, *Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products* (EU: Official Journal of the European Union, 2009) <<http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ.L:2009:342:0059:0209:EN:PDF>> [Accessed 9 April 2015]
7. Gov.uk, *The Medicines and Healthcare Products Regulatory Agency* (UK: gov.uk 2015) <<https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency>> [Accessed 9 April 2015]