ADVANCED TECHNOLOGY CONFERENCE

The definition of a cosmeceutical

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Introduction

What on earth is a cosmeceutical? Is it an attempt to convince the consumer that their skin care product is really a topical medicine without a proper licence, or is it a genuine category that is an attempt to provide a **mild** product that has undergone more stringent testing than a normal skin care product?

Examining the definitions

In order to unravel this tangle, we must look at several pieces of information and the UK perspective has been taken as the viewpoint.

The following definitions are presented:-

1. The Royal Pharmaceutical Society of Great Britain. Number 12, April 1994. "Medicines, Ethics and Practice - a guide for pharmacists".

Cosmetic means any substance or preparation intended to be applied to the various surfaces of the human body including epidermis, pilary system and hair, nails, lips and external genital organs, or the teeth and buccal mucosa wholly or mainly for the purpose of perfuming them, cleansing them, protecting them, caring for them or keeping them in condition, modifying their appearance (whether for aesthetic purposes or otherwise) or combating body odours or normal body perspiration.

A **dispensed medicinal product** includes a medicinal product prepared or dispensed by a practitioner (doctor, dentist or veterinarian) or prepared or dispensed in a registered pharmacy by or under the supervision of a pharmacist, either in accordance with a specification furnished by the purchaser (for example, a customer's receipt) or in accordance with the pharmacist's own judgement as to the treatment required for a person present in the pharmacy (that is, counter-prescribing).

Medicinal product means any substance or article (not being an instrument, apparatus or appliance) which is manufactured, sold, supplied, imported or exported for use wholly or mainly in either or both of the following ways, that is to say:

- use by being administered to one or more human beings or animals for a medicinal purpose;
  use as an ingredient, by a practitioner or in a pharmacy or in a hospital or in a business comprising the sale of herbal remedies, in the preparation of a substance or article which is to be administered to one or more human beings or animals for a medicinal purpose.

Medicinal purpose means any one or more of the following purposes, that is to say:

- treating or preventing disease;
- diagnosing disease or ascertaining the existence, degree or extent of a physiological condition;
- contraception;
- inducing anaesthenia
- otherwise preventing or interfering with the normal operation of a physiological function, whether permanently or temporarily, and whether by way of terminating, reducing or postponing, or increasing or accelerating, the operation of that function or in any other way.

2. The Consumer Products (Safety) Regulations 1989 SI 2233

Cosmetic product means any substance or preparation intended to be applied to any part of the external surfaces of the human body (that is to say, the epidermis, hair system, nails, lips and external genital organs), or to the teeth or buccal mucosa wholly or mainly for the purpose of cleaning, perfuming or protecting them, or keeping them in good condition or changing their appearance or combating body odour or perspiration except where such cleaning, perfuming, protecting, keeping, changing or combating is wholly for the purpose of treating or preventing disease;

"cosmetic products intended to come into contact with the mucous membranes" means a cosmetic product intended to be applied in the vicinity of the eyes, on the lips, in the oral cavity or to the external genital organs, and does not include any cosmetic product which is intended to come into only brief contact with the skin;

3. The Medicines Act 1968. Chapter 67

Medicinal product means any substance or article (not being an instrument, apparatus or appliance) which is manufactured, sold, supplied, imported or exported for use wholly or mainly in either or both of the following ways, that is to say:

- use by being administered to one or more human beings or animals for a medicinal purpose;
- use, in circumstances to which this paragraph applies, as an ingredient in the preparation of a substance or article which is to be administered to one or more human beings or animals for a medicinal purpose.

In this Act **"a medicinal purpose** means any one or more of the following purposes, that is to say:

- treating or preventing disease;
- diagnosing disease or ascertaining the existence, degree or extent of a physiological condition;
- contraception;
- inducing anaesthenia
- otherwise preventing or interfering with the normal operation of a physiological function, whether permanently or temporarily, and whether by way of terminating, reducing or postponing, or increasing or accelerating, the operation of that function or in any other way.

The similarities in the definitions can give a great deal of confidence to the marketing company both from a scientific and legal perspective.

However, there is another document that has recently been published by the Medicines Control Agency in the UK, which puts into a new perspective much of the original interpretation that many of us placed on these definitions. The Medicines Act is supported by a number of Medicines Advice Leaflets (MALs) which are presented to give advice and guidance to pharmaceutical companies. These are not legally binding documents, but they do clearly show the views of the regulating authorities. The latest MAL 8 (issued in December 1995) is the leaflet that covers the borderline between drugs and cosmetics.

A selection of the major heading are reproduced for consideration:-

Medicine Act Leaflet

A guide to deciding what is a medicinal product

Introduction

1. The Medicines Control Agency (MCA) regulates medicinal products for human use in the UK in accordance with the Medicines for Human Use (Marketing Authorisations, Pharmacovigilance and related matters) Regulations 1994 ("the Regulations") and the Medicines Act 1968 ("the Act").

2. It is the responsibility of the person marketing a product to do so in accordance with the relevant legislation, and in particular only to market a medicinal product in accordance with the Regulations. The latter provide that, unless otherwise exempt, a medicinal product may not be placed on the UK market without a marketing authorisation or product licence. This is granted by the Licensing Authority when it is satisfied that the product meets the prescribed standards for safety, quality and efficacy.

3. The status of many products occupying the "borderline" area between medicines and, for example, nutritional or cosmetic substances can be difficult to determine. These guidelines have been drawn up to explain the MCA's policy and practice on borderline products, and the principles on which they are based.

4. These notes are for general guidance only, and should not be taken as a complete or definitive statement of the law.

What is a "Medicinal Product"?

5. The Regulations set out the current legal regime in the UK for the grant, variation, renewal, suspension and revocation of a marketing authorisation for a **"relevant medicinal product"**. This is defined as a **"medicinal product for human use to which Chapters II to V of Directive 65/66 EEC apply"**. Article 1 of Directive 65/66 EEC defines a "medicinal product" as:

"Any substance or combination of substances presented for treating or preventing disease in human beings or animals."

"Any substance or combination of substances which may be administered to human beings or animals with a view to making a diagnosis or to restoring, correcting or modifying physiological functions in human beings or animals is likewise considered a medicinal product."

The first limb of the definition describes a product which is medicinal by **presentation**, while the second describes a product which is medicinal by **function**.

MCA policy and practice

In the past the MCA has placed particular emphasis on the claims made for a product when deciding its status. However, changing circumstances, European Court of Justice (ECJ) judgements, the evolution of professional opinion and changes in marketing practices have required corresponding changes to the way the Agency assesses products whose status is in doubt. In particular, it takes full account of the ECJ view that competent authorities of Member States should consider all the characteristics of the product, and are obliged to consider what impression of the product "an averagely well-informed consumer" would be likely to gain.

7. In practice, the MCA considers all information with a bearing on the product's status. For example:

- the claims, implicit as well as explicit, made for the product, (including any made on linked "help-lines" or publications, or in the product's actual name);
- the ingredient(s) and any pharmacological effect(s) they have on human beings;
- the labelling, and the packaging/package inserts, including any graphics;
- the promotional literature (including testimonials and any other literature issued by third party on behalf of the manufacturer or producer), and advertisements (including those appearing in so-called "advertorials");
- the product form, (tablet, capsule etc.);
- the targeting of specific sections of the population or specific adverse conditions; whether there are similar **licensed** medicinal products on the market.

"Medicinal by function"

8. A product falls within this limb of the definition of a medicinal product if it has the potential to interfere with, modify, or restore a function, of the body. If it contains any ingredient(s) with a significant pharmacological effect, this will be a strong indicator that the product is medicinal by function.

9. Many herbs have well-established pharmacological properties; for example, as bronchodilators (*Ephedra*); as respiratory stimulants (*Lobelia*); or as sedatives (*Valerian*). The presence in a product of medicinal herbs like these, (and there are many more), will be considered as strong evidence that it is intended for a medicinal purpose.

10. A product presented as a nutritional substance or cosmetic may well still be a medicinal product if it contains ingredients which have a significant pharmacological effect.

“Medicinal by presentation”

11. The MCA looks at claims in the context of the product and its presentation as a whole - not in isolation. Nevertheless, the claims made for a product are normally a very strong factor in deciding whether it is medicinal by presentation. For example, the MCA may regard a product as licensable, even though it is presented as a nutritional substance or cosmetic, if “medicinal” claims (see paras. 13 to 16 below) are made for it.

12. It is impossible to produce a definitive list of the kind of claims that the MCA generally regard as acceptable or unacceptable for an unlicensed product. However, the following guidance may be helpful.

Medicinal claims

13. Claims to treat or prevent disease, or to interfere with the normal operation of a physiological function of the human body are regarded as medicinal. Claims of relief from symptoms, or to cure, remedy or heal a specific disease or adverse condition are similarly regarded as medicinal. (In some contexts, protect or avoid may have the same meaning as prevent.) Stress, anxiety and nervous tension are all adverse conditions, and claims to cope with or manage them are also regarded as medicinal.

14. **“Maintenance”** claims are likely to be regarded as medicinal when made for a product targeted at a vulnerable section of the population, if there is an implication that it will restore, or help to restore, a specific bodily function or organ to a normal healthy state.

15. Particular words which are generally regarded as indicating or implying a medicinal claim include:

restores; repairs; eliminates; controls; counteracts; combats; alleviates; clears; stops; removes; heals; heals; cures; remedies; treats; avoids; protects; prevents.

16. Particular phrases which are generally regarded as indicating or implying a medicinal claim include:

help with/may help with/is said to help with; traditionally used for; is said to benefit those who suffer from; lowers cholesterol; strengthens or boosts the immune system; fights gum disease; stops craving for; burns fat; increases metabolic rate; helps body adjust after crossing time zones (jet lag is an adverse condition)**; strips off sun-damaged pre-cancerous cells; at the first sign of a spot, use...; calms; calming; detoxifies; helps maintain normal water balance; stimulates the nervous system.**

Non-medicinal claims

17. **Generalised** claims to **"maintain"** or **"help to maintain"** health or a healthy lifestyle are unlikely to be considered medicinal, (but see para.12).

18. Provided that they are not used in connection with, or in the context of, a disease, illness or specific adverse condition, the following descriptions are not generally regarded as indicating or implying a medicinal claim:

beneficial; revitalising; relaxing (except for products containing sedatives)**; tonic; refreshing; invigorating; uplifting; soothing.**

Marketing Authorisations/Product Licenses

19. Guidance on marketing authorisations/product licences is provided in MAL 81 and should be read alongside the "Notice to Applicants" (Volume II of the Rules Governing Medicinal Products in the European Community, ref. III/5944/94, published January 1995). These can be obtained from MCA's Eurodirect Publications Office, Room 1207 Market Towers, 1 Nine Elms Lane, London SW8 5NQ (enquiries on 0171-273-0228 or 0348).

Conclusions

The reader is left to consider the implications of these definitions, however, with the harmonisation taking place between the various member states of Europe, one has to feel that the future is going to be very interesting and full of debate!