12

MEDICINES, MEDICAL DEVICES, HEALTH-RELATED PRODUCTS AND BEAUTY PRODUCTS

Background

The rules in this section are designed to ensure that marketing communications for medicines, medical devices, treatments, health-related products and beauty products receive the necessary high level of scrutiny. The rules apply to marketing communications and not the products, which are regulated by health regulators such as the Medicines and Healthcare products Regulatory Agency (MHRA), www.mhra.gov.uk, Veterinary Medicines Directorate (VMD), www.vmd.defra.gov.uk, the European Medicines Agency (EMA), www.ema.europa.eu, and the Department of Health, www.dh.gov.uk. Marketing communications for those products must comply with the rules and professional codes of conduct of relevant professional bodies.

Scope

The rules in the first part of this section apply to all marketing communications for medicines, medical devices, treatments, health-related products and beauty products. The rules in subsequent parts apply to marketing communications for specific products and/or services. If relevant, the rules in this section also apply to claims for products for animals.

As they could apply to medicinal products for human use, the rules should be read in conjunction with the relevant sections of the Human Medicines Regulations 2012. This is particularly the case in relation to the definition of a marketing communication. Rules in this section apply to marketing communications, as set out in the Scope of the Code, that are also subject to the Regulations. Other activities defined as advertising in the Human Medicines Regulations 2012 that are outside the remit of the Code, specifically those listed in Regulation 7(2), are not covered by this section.

As they could apply to medicines for veterinary use, the rules should be read in conjunction with the Veterinary Medicines Regulations. For more information, please see Veterinary medicines Guidance Note 4, Controls on Advertising at www.vmd.defra.gov.uk/public/vmr_vmgn.aspx.

Definition

For the purposes of this Code, "licence" includes certificate, authorisation or registration.

For more information, see CAP Help Notes, especially those on: Substantiation for Health, Beauty and Slimming Claims; Health, Beauty and Slimming Advertisements that Refer to Medical Conditions; Cosmetic Surgery Marketing and Use of Experts by the ASA and CAP.

Rules

12.1 Objective claims must be backed by evidence, if relevant consisting of trials conducted on people. Substantiation will be assessed on the basis of the available scientific knowledge.

Medicinal or medical claims and indications may be made for a medicinal product that is licensed by the MHRA, VMD or under the auspices of the EMA, or for a CE-marked medical device. A medicinal claim is a claim that a product or its constituent(s) can be used with a view to making a medical diagnosis or can treat or prevent disease, including an injury, ailment or adverse condition, whether of body or mind, in human beings.

Secondary medicinal claims made for cosmetic products as defined in the appropriate European legislation must be backed by evidence. These are limited to any preventative action of the product and may not include claims to treat disease.

12.2 Marketers must not discourage essential treatment for conditions for which medical supervision should be sought. For example, they must not offer specific advice on, diagnosis of or treatment for such conditions unless that advice, diagnosis or treatment is conducted under the supervision of a suitably qualified health professional. Accurate and responsible general information about such conditions may, however, be offered (see rule 12.11).

Health professionals will be deemed suitably qualified only if they can provide suitable credentials, for example, evidence of: relevant professional expertise or qualifications; systems for regular review of members' skills and competencies and suitable professional indemnity insurance covering all services provided; accreditation by a professional or regulatory body that has systems for dealing with complaints and taking disciplinary action and has registration based on minimum standards for training and qualifications.

12.2.1 Marketing communications for medicinal products must not offer to provide a diagnosis or suggest a treatment by correspondence, for instance, by post, by e-mail or by other means of an electronic communications network.

12.3 Marketers offering individual treatments, especially those that are physically invasive, may be asked by the media and the ASA to provide full details together with information about those who supervise and administer them. Practitioners must have relevant and recognised qualifications. Marketers should encourage

consumers to take independent medical advice before committing themselves to significant treatments, including those that are physically invasive.

12.4 Marketers must not confuse consumers by using unfamiliar scientific words for common conditions.

12.5 Marketers inviting consumers to diagnose their minor ailments must not make claims that might lead to a mistaken diagnosis.

12.6 Marketers should not falsely claim that a product is able to cure illness, dysfunction or malformations.

12.7 References to the relief of symptoms or the superficial signs of ageing are acceptable if they can be substantiated. Unqualified claims such as "cure" and "rejuvenation" are not generally acceptable, especially for cosmetic products.

12.8 Marketers must hold proof before claiming or implying that a minor addiction or a bad habit can be treated without effort from those suffering.

12.9 Marketers must not encourage consumers to use a product to excess and must hold proof before suggesting their product or therapy is guaranteed to work, absolutely safe or without side-effects (subject to rule 12.19).

12.10 Marketing communications must not suggest that any product is safe or effective merely because it is "natural" or that it is generally safer because it omits an ingredient in common use.

Medicines

Title VIII of European Directive 2001/83/EC (as amended) concerns “The Advertising of Medicinal Products for Human Use” and has been implemented in the UK by the Human Medicines Regulations 2012. Advertisements for products subject to licensing under the Human Medicines Regulations 2012 must comply with the requirements of the Regulations and any conditions contained in the marketing authorisation, certificate, licence or traditional herbal registration for the advertised product.

For more information on the advertising of medicinal products, see the MHRA’s guidance, The Blue Guide: Advertising and promotion of medicines in the UK at http://www.mhra.gov.uk/Howweregulate/Medicines/Advertisingofmedicines/BlueGuide.

For more information on medical treatments, go to www.cqc.org.uk.

Advertisements for products subject to authorisation under the Veterinary Medicines Regulations must comply with the requirements of the Regulations and any conditions contained in the marketing authorisation, certificate or registration for the advertised product.

For more information please see Veterinary medicines Guidance Note 4 Controls on advertising at http://www.vmd.defra.gov.uk/public/vmr_vmgn.aspx.

12.11 Medicines must have a licence from the MHRA, VMD or under the auspices of the EMA before they are marketed. Marketing communications for medicines must conform with the licence and the product's summary of product characteristics. For the avoidance of doubt, by conforming with the product's indicated use, a marketing communication would not breach rule 12.2.

Marketing communications must not suggest that a product is "special" or "different" because it has been granted a licence by the MHRA, VMD or under the auspices of the EMA.

12.12 Prescription-only medicines or prescription-only medical treatments may not be advertised to the public.

12.13 Marketing communications which include a product claim for a medicinal product (including legible on-pack product claims within a pack shot) must include the name of the product, an indication of what it is for, text such as "Always read the label" and the common name of the sole active ingredient, if it contains only one.

Marketing communications for a traditional herbal medicinal product or a homeopathic medicinal product must include mandatory information, which can be found in the MHRA's guidance, The Blue Guide: Advertising and promotion of medicines in the UK at

http://www.mhra.gov.uk/Howweregulate/Medicines/Advertisingofmedicines/BlueGuide.

12.14 Markting Communications for medicinal products must not:

12.14.1. use, in improper, alarming or misleading terms, images of changes in the human body caused by disease, injury or a medicinal product.

12.14.2. refer, in improper, alarming or misleading terms, to claims of recovery.

12.14.3. suggest that using or avoiding a product can affect normal health.

12.14.4. present a description or detailed representation of a case history that might lead to erroneous self-diagnosis.

12.15 Illustrations of the effect or action of a product should be accurate.

12.16 Marketing communications for a medicine must not be addressed to children.

12.17 Marketers must not suggest that a medicinal product is either a food or a cosmetic.

12.18 Marketers must not use health professionals or celebrities to endorse medicines.

12.19 Marketing communications for a medicine may not claim that its effects are guaranteed, that it is absolutely safe or without side-effects or as good as or better than those of another identifiable product.

12.20 Homeopathic medicinal products must be registered in the UK. Any product information given in the marketing communication should be confined to what appears on the label. Marketing communications must include a warning to consult a doctor if symptoms persist. Marketing communications for an unlicensed product must not make a medicinal or therapeutic claim or refer to an ailment unless authorised by the MHRA to do so.

12.21 Marketers of traditional herbal medicines may advertise for the indications listed in the product's summary of product characteristics and must include mandatory information, which can be found in the MHRA's guidance, The Blue Guide: Advertising and promotion of medicines in the UK at

http://www.mhra.gov.uk/Howweregulate/Medicines/Advertisingofmedicines/BlueGuide/.

Marketing communications for products that hold a Traditional Herbal Medicines Registration must not imply that registration is based upon clinical trials.

Cosmetics

12.22 Claims made about the action that a cosmetic has on or in the skin should distinguish between the composition of the product and any effects brought about by the way in which it is applied, such as massage. Scientific evidence must also make that distinction.

12.22.1 Some cosmetics have an effect on the type of skin changes that are caused by environmental factors. Marketing communications for them may therefore refer to temporarily preventing, delaying or masking premature ageing.

Hair and scalp

12.23 Marketers must be able to provide scientific evidence, if relevant consisting of trials conducted on people, for any claim that their product or therapy can prevent baldness or slow it down, arrest or reverse hair loss, stimulate or improve hair growth, nourish hair roots, strengthen the hair or improve its health as distinct from its appearance.

Services offering advice on unplanned pregnancy

12.24 Marketing communications for services offering advice on unplanned pregnancy must make clear if the service does not refer women directly for a termination. Given that terminations are lawful only in some circumstances, and are subject to particularly stringent requirements in Northern Ireland, marketers may wish to seek legal advice.