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, and the Department of Health and Social Care, 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 (as amended). 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 about how veterinary medicines can be advertised, please refer to:

https://www.gov.uk/guidance/legal-controls-on-veterinary-medicines.

Law

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. The ASA is obliged to consider complaints about breaches of Regulations 286 to 290, which have been incorporated into these rules. With the introduction of new or changed products, diverse licensing requirements and changes in medical opinion,

this Code cannot provide a complete guide to all requirements for health claims or the advertising of products or classes of medicines and treatments.

Advertisements for products subject to licensing under the Human Medicines Regulations 2012 (as amended) 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 medicinal products and treatments, see the MHRA's guidance, The Blue Guide: Advertising and promotion of medicines in the UK at:

https://www.gov.uk/government/publications/blue-guide-advertising-and-promoting-medicines.

The rules governing the advertising of medicines, treatments, medical devices and health claims are set out below; they apply also to advertisements for veterinary products and services. Directive 2001/82/EC on the Community code relating to veterinary medicinal products (as amended by Directive 2004/28/EC), which has been implemented in the UK via The Veterinary Medicines Regulations, contains provisions relating to the advertising of such products. The Veterinary Medicines Regulations are revoked and remade regularly. For more information about how veterinary medicines can be advertised, please refer to:

https://www.gov.uk/guidance/legal-controls-on-veterinary-medicines.

In Great Britain, medical devices are currently regulated under the Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002), which transpose into UK law, the directives: Directive 90/385/EEC on active implantable medical devices; Directive 93/42/EEC on medical devices; and Directive 98/79/EC on in vitro diagnostic medical devices.

Under the terms of the Northern Ireland Protocol following the UK's withdrawal from the European Union on 31 January 2020, certain products on the Northern Ireland market, including medical devices, are required to comply with relevant EU legislation as well as with UK law. The EU Medical Devices Regulation (2017/745) took effect in Northern Ireland, subject to transitional provisions, on 26 May 2021; the EU *in vitro* Diagnostics Medical Devices Regulation (2017/746) took effect in Northern Ireland from 26 May 2022.

The MHRA is the body responsible for ensuring medical devices in the UK meet the applicable standards of safety, quality and efficacy. From 1 July 2023, medical devices placed on the Great Britain market will be required to bear a UK Conformity Assessed (UKCA) marking to attest that they conform to the regulatory requirements. Manufacturers can affix a UKCA marking on a voluntary basis ahead of this date so long as the relevant regulatory

requirements have been met. Where third party conformity assessment is required for the UKCA marking, a UK Approved Body must be used. Devices that have been CE marked in conformance with the relevant EU legislation will be unilaterally accepted on the Great Britain market until 30 June 2023. Where third party conformity assessment is required for the CE marking, an EU-recognised Notified Body must be used. The UKCA marking is valid in Great Britain only and a CE marking continues to be required for the Northern Ireland market. For more information about the transitional arrangements relating to conformity marking, please refer to the following MHRA guidance: https://www.gov.uk/guidance/regulating-medical-devices-in-the-uk.

Marketers are strongly urged to take legal advice about relevant requirements applicable, including conformity marking and third party conformity assessment bodies, for medical devices placed on the markets for Great Britain and Northern Ireland, and to have due regard to available guidance from the MHRA, including the following:

https://www.gov.uk/guidance/regulating-medical-devices-in-the-uk

https://www.gov.uk/guidance/medical-devices-eu-regulations-for-mdr-and-ivdr

https://www.gov.uk/guidance/medical-devices-conformity-assessment-and-the-ukca-mark

Definition

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

"Applicable conformity marking" means conformity marking required by legislation set out earlier this section, under "Law".

“Disease” includes any injury, ailment or adverse condition, whether of body or mind.

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; and Cosmetic Surgery Marketing.

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 medical device with the applicable conformity marking. 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 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 prevent or treat disease or a malformation; restore, correct or modify a physiological function; or modify a person's appearance.*
(This rule reflects a prohibited practice from Schedule 20 of the DMCCA. See note in Section 3 for more details).

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 (as amended). 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:

https://www.gov.uk/government/publications/blue-guide-advertising-and-promoting-medicines.

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 about how veterinary medicines can be advertised, please refer to:

https://www.gov.uk/guidance/legal-controls-on-veterinary-medicines.

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:

https://www.gov.uk/government/publications/blue-guide-advertising-and-promoting-medicines.

12.14 Marketing 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:

https://www.gov.uk/government/publications/blue-guide-advertising-and-promoting-medicines.

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.

Cosmetic interventions

12.25 Marketing communications for cosmetic interventions must not be directed at those aged below 18 years through the selection of media or context in which they appear.

Cosmetic interventions mean any intervention, procedure or treatment carried out with the primary objective of changing an aspect of a consumer's physical appearance. This includes surgical and non-surgical interventions, both invasive and non-invasive. This does not include cosmetic products as defined in Regulation (EC) No 1223/2009. See Advertising Guidance: Cosmetic Interventions.