11

MEDICINES, MEDICAL DEVICES, TREATMENTS AND HEALTH

Background

The rules in this section are designed to ensure that advertisements that include health claims (please see Section 13 for health claims made on foods) and advertisements for medicines, medical devices and treatments receive the necessary high level of scrutiny. Health claims may, for example, relate to the therapeutic or prophylactic effects of products, including toiletries and cosmetics.

The rules apply to advertisements and not the products or services, which are regulated by health regulators such as the Medicines and Healthcare products Regulatory Agency (MHRA), the Veterinary Medicines Directorate (VMD), the Care Quality Commission (CQC) and the Department of Health and Social Care.

Advertisements for those products or services must comply with the rules and professional codes of conduct of relevant professional bodies.

Medical advisory panels

For television advertisements, Clearcast retains a panel of consultants to advise it on health and medical aspects of products or services before they are advertised. For information, see "Contact us" at www.clearcast.co.uk.

For radio advertisements, Radiocentre retains a panel of consultants to advise it on health and medical aspects of advertising.

The ASA or BCAP may seek a medical opinion if there is a significant challenge to an advertisement that has been accepted by a broadcaster on the advice of a member of the panels.

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. ASA (Broadcast) 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 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 applicable requirements, 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 section, "licence" includes certificate, authorisation or registration.

“Applicable conformity marking” means conformity marking required by the legislation set out earlier in this section, under “Law”. For more information on the conformity marking requirements for medical devices, please refer to:

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

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

Rules

11.1 **Radio Central Copy Clearance** – Radio broadcasters must ensure advertisements subject to this section are centrally cleared.

11.2 If they are necessary for the assessment of claims, broadcasters must, before the advertisement is broadcast, obtain generally accepted scientific evidence and independent expert advice.

11.3 Advertisements 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 (see rule 11.9). That does not prevent advertising for spectacles, contact lenses or hearing aids.

11.4 Medicinal or medical claims and indications may be made for a medicinal product that is licensed by the MHRA, the 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.

11.5 These are not acceptable in advertisements for medicinal products:

11.5.1 Presentations, by doctors, dentists, veterinary surgeons, pharmaceutical chemists, nurses, midwives and the like that imply professional advice or recommendation

11.5.2 statements that imply professional advice or recommendation by people who are presented, whether directly or by implication, as being qualified to give that advice or recommendation

11.5.3 references to approval of, or preference for, any relevant product or their use by the professions covered by rule 11.5.1.

11.6 Advertisements other than those for medicinal products may feature or refer to health professionals covered by rule 11.5.1, if those professionals are suitably qualified in the relevant subject.

11.7 Unless it is obvious from the context, advertisements that include a health professional must make clear if he or she has a direct financial interest, or equivalent reciprocal interest, in the sale of the advertised product or service.

11.8 Testimonials or endorsements by health professionals must be genuine and supported by documentary evidence. Fictitious testimonials must not be presented as genuine. Any statement in a testimonial that is likely to be interpreted as a factual claim must be substantiated.

11.9 **Services including Clinics, Establishments and the like Offering Advice on, or Treatment in, Medical, Personal or other Health Matters** – Advertisements are acceptable only if the advertiser can provide suitable credentials, for example, evidence of: relevant professional expertise or qualifications; systems for regular review of their 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.

11.10 Advertisements for hypnosis-based procedures (including techniques commonly referred to as hypnotherapy), psychiatry, psychology, psychoanalysis or psychotherapy are acceptable subject to rule 11.9. Broadcasters must take particular care over advertisements for publications employing those techniques.

11.11.1 Advertisements for services offering advice on unplanned pregnancy must make clear in the advertisement 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, advertisers may wish to seek legal advice before advertising.

11.11.2 **Radio Central Copy Clearance** – Radio broadcasters must ensure advertisements for family planning centres are centrally cleared.

11.11.3 Rule removed on 30 April 2012

11.12 **Television only** – Teleshopping for these products or services is not acceptable:

11.12.1 medicinal products that are for human use and that are subject to a marketing authorisation within the meaning of Directive 2001/83/EC (as amended by Directive 2004/27/EC), as implemented by the Human Medicines Regulations 2012, and are on the General Sale List (GSL) as a pharmacy medicine (P) or as a prescription-only medicine (POM)

11.12.2 veterinary medicinal products that are subject to a marketing authorisation within the meaning of Directive 2001/82/EC (as amended by Directive 2004/28/EC), as implemented by the Veterinary Medicines Regulations, and are available as an authorised veterinary medicine on the General Sales List (AVMGSL) as a non-food animal medicine from a veterinarian, pharmacist or

suitably qualified person or as a prescription-only medicine from a veterinarian (POM-V) or from a veterinarian, pharmacist or suitably qualified person (POM-VPS)

11.12.3 medical treatments for humans or animals.

11.13 Broadcasters may accept advertisements for services offering remote personalised advice on medical or health matters only if all staff providing that advice are suitably qualified and subject to regulation by a statutory or recognised medical or health professional body and the advice given is in accordance with its relevant professional codes of conduct (see rule 11.9).

11.13.1 Advertisements must not contain offers to prescribe or treat remotely (including by phone, post, e-mail or other means of an electronic communications network) unless the advertisers can demonstrate that the service offered complies with rule 11.9. Advertisements for medicinal products must not include such offers. That does not preclude advertisements containing offers to distribute general information on health-related matters, such as leaflets or information packs.

11.14 No advertisement may encourage indiscriminate, unnecessary or excessive use of products or services covered by this section.

11.15 Advertisements 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).

11.16 Unless authorised by the relevant product licence, the word "tonic" is not acceptable in advertisements that make health claims. Claims must not suggest that a product has tonic properties. That does not prevent the use of the word "tonic" in the description "Indian tonic water" or "quinine tonic water".

11.17 Jingles may be used. Those that incorporate a medical or health claim must be substantiated.

11.18 Advertisements for smoking deterrents:

11.18.1 must make clear that the indispensable factor in giving up smoking is willpower

11.18.2 must not claim that smoking is safer while the habit is being reduced. Harm reduction claims may be made, if authorised by the MHRA.

Medicines

11.19 Medicines must have a licence from the MHRA, the VMD or under the auspices of the EMA before they are advertised. Advertisements for medicinal products must conform with the licence. Advertisements must not suggest that a product is "special" or "different" because it has been granted a licence from the MHRA. For the avoidance of doubt, by conforming with the product's indicated use, an advertisement would not breach rule 11.3.

11.20 Advertisements for medicinal products which include a product claim (including legible on-pack product claims within a pack shot) must include this information:

11.20.1 the name of the product

11.20.2 the name of the active ingredient, if it contains only one

11.20.3 relevant wording such as "always read the label" or "always read the leaflet"

11.20.4 the indication (what the product is for).

Advertisements for traditional herbal medicinal products and homeopathic medicinal products must include mandatory information, which can be found in the MHRA Blue Guide at: www.mhra.gov.uk.

11.21 Advertisements for these are not acceptable:

11.21.1 medicinal products or medical treatments available only on prescription

11.21.2 Products for the treatment of alcohol or substance misuse or dependence. An exception is made for smoking deterrents (see rule 11.18).

11.22 No advertisement may suggest that a medicinal product is a foodstuff, cosmetic or other consumer product.

11.23 No advertisement for a medicinal product may claim its effects are guaranteed. That does not prevent the offering of refunds, if the advertisement does not suggest that efficacy is guaranteed.

11.24 No advertisement for a medicinal product or treatment may be directed at children. See also Section 5: Children and Section 32: Scheduling.

11.25 Advertisements must not, without good reason, make the audience anxious that they are or might be suffering from disease or ill-health or might do so if they do not respond to the advertisement.

11.25.1 Advertisements must not falsely suggest that a product is necessary for the maintenance of physical or mental health or that health could be enhanced by taking the product or affected by not taking it.

11.26 Advertisements must not, in improper, alarming or misleading ways, use images of changes in the human body caused by disease, injury or a medicinal product.

11.27 No advertisement for a medicinal product or treatment may include a recommendation by a person well-known in public life, sport, entertainment or similar or be presented by such a person. That includes persons corporate as well as singular and would prohibit, for example, recommendations by medical charities, patient groups and health or sport organisations.

11.28 No advertisement for a medicinal product may refer in improper, alarming or misleading terms to claims of recovery.

11.29 Advertisements for medicinal products must not contain material that could, for example, by description or detailed representation of a case history, lead to a wrong self-diagnosis.

11.30 Although it may refer to the likely absence of a specific side effect, for example, "unlikely to cause drowsiness", no advertisement for a medicinal product may suggest that a product has no side effects.

11.31 No advertisement for a medicinal product or treatment may suggest that the effects are better than, or equivalent to, those of another identifiable medicinal product or treatment.

11.32 No advertisement for a medicinal product may suggest that the safety or efficacy of the product is due to it being "natural".

11.33 Only homeopathic medicinal products that are registered in the UK may be advertised. Mandatory information for homeopathic advertisements can be found in the MHRA Blue Guide at: www.mhra.gov.uk.

11.34 A tension headache is a recognised medical condition; analgesics may be advertised for the relief of pain associated with that condition but no advertisement for a simple or compound analgesic may claim the direct relief of tension or refer to depression.