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An Overview of EU Rules on Consumer Advertising of Over-the-Counter Products in the Life Sciences Sector


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Commentary on EU life science advertising regulation frequently focuses on the rules applicable to advertisements for prescription products directed to healthcare professionals. Less is written about other types of products that form part of the EU healthcare market, and the advertising restrictions that exist in relation to the marketing of these products to consumers. While advertising restrictions on over-the-counter (OTC) products are not, generally speaking, as detailed and stringent as those which exist in relation to prescription medicines, it is nevertheless important to be aware of the regulatory framework that applies to consumer advertisements for such products. This chapter is, therefore, intended to provide a summary of the overarching EU regulatory framework for consumer advertising of:

- **non-prescription medicines available OTC**, including herbal and homeopathic products;
- **self-care medical devices**, i.e., products that treat or prevent ailments by a physical (rather than pharmacological, immunological or metabolic) mode of action, such as emollients, eye drops and nasal sprays; and
- **foods supplements**, i.e., foodstuffs, the purpose of which is to supplement the normal diet and which are concentrated sources of nutrients or other substances with a nutritional or physiological effect, alone or in combination.

The European market for these OTC consumer healthcare products is made up of over 2,000 companies.[1] We summarise here the general framework of law and industry codes of practice that exist at EU level to regulate the advertising of these categories of products to consumers, with examples from national approaches and commenting, where relevant, on recent developments.

General Consumer Advertising Requirements That Apply to All OTC Healthcare Products

At EU level, Directive 2005/29/EC on unfair commercial practices[2] (the UCP Directive) governs business-to-consumer commercial practices relating to all kinds of products and services including medicines, medical devices and foods. In particular, the UCP Directive contains a broad prohibition on misleading and aggressive advertising. For these purposes, advertising is misleading if it contains false information or in any way (including through overall presentation) deceives or is likely to deceive the average consumer (even if the information is factually correct) and causes or is likely to cause him to take a transactional decision that he would have otherwise not taken. Aggressive commercial practices include advertising that applies undue influence, or pressure, in a way which significantly limits the consumer's ability to make an informed decision. There are also restrictions on comparative advertising set out in Directive 2006/114/EC[3] which apply to advertising directed at consumers. The EU law provisions, as implemented in national laws, are enforced nationally through varying mechanisms; in some Member States it is possible for companies to bring direct actions against competitors, whereas other countries require actions to be brought only by regulatory authorities. National laws may contain additional restrictions on both general and product-specific consumer advertising.

Several pan-European industry bodies represent the interests of manufacturers of consumer healthcare products. These include the Association of the European Self-Care Industry (AESGP), which represents manufacturers of non-prescription medicines, food supplements and self-care medical devices in Europe, and the European Federation of Associations of Health Product Manufacturers (EHPM), which represents specialist health product manufacturers in Europe. Individual companies may be affiliated with these European bodies directly or indirectly through national associations. For example, the Dutch association representing manufacturers of self-care products (Neprofarm) is a member of AESGP while its trade association for operators concerned with food supplements (NPN) is a member of EHPM. Some national industry bodies are charged with operating self-regulatory systems of advertising control, and have their own enforcement mechanisms in place. For example, in the UK, advertisements issued by companies who are members of the Proprietary Association of Great Britain (PAGB) will, in the first instance, be supervised by the PAGB, whereas companies which have not agreed to abide by the PAGB's Codes of Practice will be supervised directly by the Medicines and Healthcare products Regulatory Agency. In addition to sector-specific enforcement agencies, advertising and promotion of consumer health products is also subject to enforcement by bodies who enforce advertising standards generally, such as the UK Advertising Standards Agency (ASA).

Non-Prescription Medicinal Products

The advertising to consumers of medicines not subject to prescription is regulated by the general advertising rules outlined above, and by Directive 2001/83/EC (the Directive) as implemented into national laws. In addition, guidance is sometimes available at a national level from regulatory authorities,[4] independent advertising bodies,[5] and industry associations.[6] There does not currently exist any pan-European industry code of conduct applicable to the advertising of non-prescription medicines,[7] although AESGP represents the interests of manufacturers of non-prescription medicines at European level.

While advertising to the general public of prescription-only medicines is prohibited under the Directive, there is no such restriction in relation to non-prescription medicines. Provided they have a valid marketing authorisation and do not contain any narcotic or psychotropic substances, non-prescription

medicines (including non-prescription herbal medicines) may, therefore, be advertised both to healthcare professionals and the general public if they comply with the advertising requirements set out in the Directive, and with any further requirements contained in national law (discussed below). In addition to complying with the Directive's advertising rules applicable to prescription medicinal products, advertisements of non-prescription medicines to the general public must also:

- be set out in such a way that it is clear that the message is an advertisement and that the product is clearly identified as a medicinal product (avoiding any suggestion that the product is any other type of consumer product);
- include certain minimum information (e.g., information necessary for correct use of the medicinal product and an invitation to read carefully the instructions on the package leaflet or on the outer packaging);
- not give the impression that a medical consultation or surgical operation is unnecessary;
- not suggest that the effects of taking the medicine are guaranteed, are unaccompanied by adverse reactions or are better than, or equivalent to, those of another treatment or medicinal product;
- not suggest that the health of the subject can be enhanced by taking the medicine;
- not suggest that the health of the subject could be affected by not taking the medicine (except in relation to authorised vaccination campaigns);
- not be directed exclusively or principally at children;
- not refer to a recommendation by scientists, health professionals or celebrities;
- not suggest that the safety or efficacy of the medicinal product is due to the fact that it is natural; and
- avoid case history representations that could lead to erroneous self-diagnosis and refrain from using improper, alarming or misleading terms or pictorial representations to make recovery claims or disease representations.

Advertisements for herbal medicinal products authorised by a traditional herbal registration must be accompanied by a notice stating "traditional herbal medicine for use in specific indication(s) exclusively based on long-standing use".

Homeopathic medicinal products must comply with the general EU law advertising requirements applicable to non-prescription medicines, subject to additional limitations on the information that may be included in such advertisements. For example, advertisements for homeopathic medicines must include a statement that the products are "without approved therapeutic indications".

Further restrictions on non-prescription medicines advertising to consumers may be set out under national law and/or industry codes. For example, French law prohibits advertising of non-prescription medicines to the general public where the medicines are reimbursed under the national social security schemes. National industry codes of practice frequently set out detailed requirements specific to consumer advertising of non-prescription medicines. While compliance with such codes is not legally mandated, it is encouraged and represents industry best practice. Compliance with the codes, which typically reflect and often elaborate on the legal requirements, is usually a good indication of compliance with legal requirements and therefore helps to minimise enforcement action.

In some European countries, there is a requirement to obtain pre-approval from a regulatory body (e.g., the ANSM in France) or an industry body (e.g., the PAGB in the UK, where member companies' advertisements to consumers are concerned) before advertisements for non-prescription medicines may be issued. Obtaining such approval further reduces the risk of enforcement action for improper advertising.

Self-Care Medical Devices

There is little by way of EU law specifically directed towards medical devices advertising. Under the Medical Device Directive, only products that are CE-marked may be marketed in Europe, and only in accordance with their intended use. These principles extend to claims made in advertisements: to make a medicinal claim in an advertisement for a self-care medical device, the device must be CE-marked and the claim must be within the scope of the device's intended use. Enforcement actions taken at national level in relation to self-care medical devices often concern advertising that has made unauthorised use of medicinal claims.

The Medical Devices Regulation[8] introduces a specific prohibition on advertising that may mislead in relation to a device's intended purpose, safety and performance.

The position under national laws is patchy, with some countries having introduced laws to further regulate medical device advertising (including, in some cases, laws that specifically govern the advertising of self-care medical devices) beyond that of the EU-wide legislation.

In the context of industry self-regulation, it is important to note that the Code of Ethical Business Practice issued by the European medical device industry representative body, MedTech Europe, does not govern advertisements directed to consumers. However, several countries have issued national codes of conduct to this effect; for example, the UK's PAGB Medical Devices Consumer Code which is applicable to member companies' advertisements concerning self-care medical devices (those that treat or prevent a self-treatable condition).

Food Supplements

Food supplements are regulated as foods under EU law. Regulation (EC) No 1924/2006[9] (the Claims Regulation), which is directly effective in Member States, places strict controls on the use of nutrition and health claims on food labelling and in advertising. Under the Claims Regulation:

- a nutrition claim is any claim which states, suggests or implies that a food has particular beneficial nutritional properties due to the energy and/or nutrients or other substances it provides or contains (e.g., "low fat"); and
- a health claim is one which states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health (e.g., "calcium is needed for the maintenance of normal teeth").

Under the Claims Regulation, only nutrition claims that are listed in the Annex to the Regulation, and/or health claims that have been authorised by the European Commission following a European Food Safety Authority scientific review are permitted. The only exception to these requirements is in relation to claims that are trade marks (or brand or "fancy" names) and general, non-specific health claims (e.g., "good for you"). These claims may be used without prior approval, provided they are "accompanied by" an approved claim (which, in the case of a general health claim, must be an authorised specific health claim, such as the calcium example given above).

The Claims Regulation is enforced at national level, and national regulators have to date taken varying approaches in their interpretation of its requirements. A recent decision by the European Court of Justice Case C-524/18 *Schwabe*,[10] which followed a referral from a German court, has helpfully clarified the meaning of the Claims Regulation's use of the phrase "accompanied by". The European Court held that the concept of "accompanying" includes both a substantive and a visual dimension. The substantive element requires that the content of the "general" health claim and the specific health claim match,

meaning that the former is fully supported in substance by the latter. In relation to the visual element, the Court held that this normally requires "spatial proximity or immediate vicinity" but that, exceptionally, a clear reference, such as an asterisk, between the two claims may suffice (e.g., in cases where the packaging of a food supplement contains a reference to general, non-specific health benefits of a nutrient or food on the front of the packaging, whereas the specific health claim intended to accompany it appears only on the back of that packaging). This is a more restrictive approach than that which was preferred by the Advocate General,[11] but will nevertheless help to inform a more uniform application of the relevant rules across Europe.

Also of importance to food supplements advertising in the EU is Directive 2002/46/EC (the Food Supplements Directive), which provides for specific marketing requirements relating to food supplements. These include that the labelling, presentation and advertising of food supplements:

- must not attribute to food supplements the property of preventing, treating or curing a human disease, or refer to such properties; and
- must not include any mention stating or implying that a balanced and varied diet cannot provide appropriate quantities of nutrients in general.[12]

There has been a recent flurry of activity by national regulators in some European countries in response to advertisements for food supplements that purport to prevent or treat infection with coronavirus/COVID-19. Such advertisements are contrary to the prohibition on medical claims contained in the Food Supplements Directive, as implemented in national laws. For example, the Finnish Food Authority issued a statement in April 2020, noting that marketing of foods (including food supplements) for the purpose of preventing or treating coronavirus had increased significantly on the internet and social media, that these must immediately cease, and reminding commercial entities of their legal duties in this regard.[13] In the UK, the ASA has issued several recent decisions which uphold complaints made in relation to advertisements claiming that various marketed vitamins, minerals and amino acids could help prevent or treat COVID-19. For example, statements such as "Help protect and prevent against the new strand of virus (known as the Coronavirus) with a REVIV Megaboost® IV Therapy containing a high dose of Vitamin C" were determined to be contrary to the applicable regulatory requirements and the advertiser was ordered to remove the material, and refrain from making unauthorised medicinal claims going forward.[14]

Endnotes

1. https://aesgp.eu/who-we-are [Accessed 20 May 2020].
2. Directive 2005/29/EC of the European Parliament and of the Council of 11 May 2005 concerning unfair business-to-consumer commercial practices in the internal market and amending Council Directive 84/450/EEC, Directives 97/7/EC, 98/27/EC and 2002/65/EC of the European Parliament and of the Council and Regulation (EC) No 2006/2004 of the European Parliament and of the Council.
3. Directive 2006/114/EC of the European Parliament and of the Council of 12 December 2006 concerning misleading and comparative advertising.
4. For example, the UK Medicines and Healthcare products Regulatory Agency (MHRA) "Blue Guide".
5. For example, the UK Advertising Codes applied by the Advertising Standards Authority (ASA).
6. For example, the UK PAGB's Advertising Codes for Medicines.
7. The European Federation of Pharmaceutical Industries and Associations (EFPIA) Code of Practice does not apply to activities relating solely to non-prescription medicines.
8. Article 7 of Regulation (EU) No 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.
9. Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods.
10. Case C-524/18, *Dr. Willmar Schwabe GmbH & Co.KG v Queisser Pharma GmbH & Co. KG* (30 January 2020).
11. Opinion of Advocate General Hogan delivered on 12 September 2019.
12. Articles 6(2) and 7 of Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements.
13. https://www.ruokavirasto.fi/sv/foretag/livsmedelsbranschen/uutiset-elintarvikealalta/marknadsforing-av-livsmedel-for-att-forebygga-eller-behandla-coronavirussjukdom-maste-stoppas-omedelbart/ [Accessed 20 May 2020].
14. ASA Ruling on REVIV UK Ltd (22 April 2020). Similar decisions were issued by ASA on the same day in relation to advertisements by the Private Harley Street Clinic and Cosmetic Medical Advice UK Ltd t/a Dr Rita Rakus Clinic.

Adela Williams is a Partner in Arnold & Porter's London office.

Her practice focuses on the regulation of medicinal products, medical devices, foods and cosmetics in the UK and at EU level, particularly in relation to clinical trials, marketing authorisations and advertising and promotion issues, including legal proceedings arising from the decisions of regulatory bodies. She advises clients in relation to compliance issues and proceedings before the Prescription Medicines Code of Practice Authority and its Appeal Board arising from alleged breaches of the ABPI Code of Practice on promotion of medicines and related activities.

She also advises clients in relation to the pricing and reimbursement of medicines and medical products. This area of her practice includes both statutory and voluntary pricing regimes (VPAS) in the UK, the application of the Drug Tariff and all stages of health technology appraisals by the National Institute for Health and Care Excellence (NICE), the Scottish Medicines Consortium, and the All Wales Medicines Strategy Group. She frequently represents clients at NICE appeal hearings and has acted on behalf of the manufacturer company in two of the three applications for judicial review brought against NICE in the Administrative Court.

She has substantial experience representing pharmaceutical and medical device clients in product liability litigation (unitary actions and group litigation), including claims involving unlicensed medicines in the research context as well as marketed products. Such litigation has often involved co-ordinating proceedings within the EU and advising on forum and other jurisdictional issues.

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Louise Strom's practice focuses on matters affecting clients in the pharmaceutical, medical device, cosmetics and food sectors. Ms. Strom advises on a broad range of regulatory issues that arise in the course of the product life cycle, including clinical research, authorisation, manufacturing and distribution, labelling, pricing and reimbursement, and pharmacovigilance. She advises life science companies on the boundaries of the industry codes of practice, and on UK and EU legislation regarding advertising and promotion.

She is experienced in advising clients on health and nutrition claims, food product classification issues, novel foods regulatory requirements (including in relation to CBD products). She also advises on issues arising in connection with EU and UK regulation of acrylamide, pesticides and organic produce.

Ms. Strom assists clients with preparation and negotiation of various types of agreements, including licence and collaboration agreements, clinical study agreements, supply agreements and pharmacovigilance agreements. She also advises life sciences companies on their development and implementation of global and regional compliance programmes.

Before joining the firm, Ms. Strom trained and worked in the London and Brussels offices of a leading global law firm, where she focused her practice on dispute resolution. She has also worked in-house at a major financial institution and at a UK regulatory body.

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The EU life sciences team, headed by Ian Dodds-Smith and based in London, has unrivalled experience in advising on every aspect of the regulation of medicines, devices, cosmetics, foods and borderline products. The team includes a number of lawyers with scientific qualifications, including physicians. It is regularly ranked as the leading firm providing regulatory advice and specialist litigation services to the life sciences sector.

The team of lawyers specialising in this field in London is complemented by Arnold & Porter's highly regarded pharmaceutical and medical devices regulatory practice headed by Dan Kracov in Washington, D.C., giving a combined team of over 40 lawyers.

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