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Advertising of Medical Devices and *In Vitro* Diagnostic Medical Devices in Europe Following the New EU Legislation


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This publication is focused on the advertising of medicinal products. In contrast, this chapter addresses the advertising of medical devices and *in vitro* diagnostic medical devices ("IVDs") in Europe. The regimes are separate and free-standing and, while there are some similarities, on the whole, the regime in relation to devices is much less developed compared to medicines. We set out below an overview of the relevant legal frameworks, as well as comment on some specific areas where questions frequently arise.

The EU Legal Framework Relevant to Medical Devices and IVDs

In contrast to the EU law on medicinal products, Directive 93/42/EEC on medical devices ("MDD") and Directive 98/79/EC on IVDs ("IVDD") (collectively, the "Directives"[1]) included no provisions relating to control of advertising, save for the general requirement that a medical device should be supplied only in accordance with its intended purpose, defined as "*the use for which the device is intended according to the data supplied by the manufacturer on the labelling, in the instructions and/or in promotional materials*". Significantly, there was no express prohibition on the promotion of medical devices and IVDs to consumers.

Regulation 2017/745 ("MDR"),[2] applicable from 26 May 2021, maintains this broad position, but also introduced a new Article 7 specifically addressing promotional and non-promotional activity concerning medical devices. This Article states:

> "*In the labelling, instructions for use, making available, putting into service and advertising of devices, it shall be prohibited to use text, names, trade marks, pictures and figurative or other signs that may mislead the user or the patient with regard to the device's intended purpose, safety and performance by:*
>
> *(a) ascribing functions and properties to the device which the device does not have;*
>
> *(b) creating a false impression regarding treatment or diagnosis, functions or properties which the device does not have;*
>
> *(c) failing to inform the user or the patient of a likely risk associated with the use of the device in line with its intended purpose;*
>
> *(d) suggesting uses for the device other than those stated to form part of the intended purpose for which the conformity assessment was carried out.*"

Regulation 2017/746 ("IVDR"),[3] applicable from 26 May 2022, includes equivalent provisions in relation to promotional and non-promotional activity concerning IVDs.

These provisions concerning advertising and promotion of medical devices and IVDs in the MDR and IVDR are drafted in high-level terms and provide only limited detail to assist manufacturers. The general principle under the MDR and IVDR reflects that under the Directives, Member States should ensure devices are placed on the market only if they comply with the requirements of the legislation (e.g. when supplied and properly installed, maintained and used in accordance with their intended purpose). Compliance with the general safety and performance requirements is demonstrated by the CE mark affixed to the device following an appropriate conformity assessment, which takes place before it is placed on the EU market. Provided that promotional claims are consistent with the CE mark and in line with the intended purpose, the information within the technical file should satisfy the requirement for substantiation, as the conformity assessment will have been based on a critical evaluation of the relevant scientific literature relating to the device and/or any clinical investigations.

EU-Wide General Advertising Requirements

Given the high-level nature of the provisions addressing promotional activity in EU medical device legislation, general EU rules on advertising must also be taken into account, particularly Directive 2006/114/EC on misleading and comparative advertising[4] (the "Misleading Advertising Directive") and Directive 2005/29/EC on unfair commercial practices directed at consumers[5] (the "Unfair Commercial Practices Directive").

The Misleading Advertising Directive is intended to protect traders against misleading advertising and to lay down the conditions for comparative advertising. It defines advertising as "*the making of a representation in any form in connection with a trade, business, craft or profession in order to promote the supply of goods or services, including immovable property, rights and obligations*". These voluntary representations should be distinguished from mandatory labelling requirements and instructions for use contained in labelling or packaging, or factual, scientific information that may be disseminated about a product. Misleading advertising is defined as "*any advertising which in any way, including its presentation, deceives or is likely to deceive the persons to whom it is addressed or whom it reaches and which, by reason of its deceptive nature, is likely to affect their economic behaviour or which, for these reasons, injures or is likely to injure a competitor*". In order to determine whether advertising is misleading, it is necessary to take into account the characteristics of the goods or services, the price and the conditions governing the supply of the goods, and the nature, attributes and rights of the advertiser. In addition to setting out minimum and objective criteria for determining whether advertising is misleading, the Misleading Advertising Directive defines the conditions for acceptable comparative advertising, defined as "*any advertising which explicitly or by implication identifies a competitor or goods or services offered by a competitor*"; such advertising should compare goods or services meeting the same needs or intended for the same purpose, should objectively compare one or more material, relevant, verifiable and representative features of those goods and services, and should not discredit or denigrate the trademarks or other distinguishing marks of a competitor.

The Unfair Commercial Practices Directive applies to all business-to-consumer transactions and aims to protect consumers from certain unfair commercial practices that harm their commercial interests, without prejudice to the laws of contract or to EU or national rules relating to the health and safety of products. The commercial practices that are prohibited are those that are contrary to the requirements of professional diligence (the standard of special skill and care that a trader may reasonably be expected to exercise towards consumers, commensurate with honest market practices and/or the general principle of good faith in the trader's field of activity) and those that materially distort or are likely to materially distort the economic behaviour with regard to the product of the average consumer whom it reaches or to whom it is addressed. The Unfair Commercial Practices Directive sets out the commercial practices that will be viewed as misleading, including the provision of false information, or are likely to deceive the average consumer, even if factually correct, and likely to cause him to take a transactional decision that he would not otherwise have made. Advertising may also be viewed as misleading if it omits material information that the average consumer needs in order to take an informed transactional decision.

National Legislation

Member States are able to implement specific requirements relating to the advertising of medical devices and IVDs, and may impose stricter requirements than EU legislation, provided that such provisions do not impede the free movement of goods. However, most Member States have not introduced specific legislation addressing the advertising of medical devices, but instead apply general advertising laws, particularly in relation to misleading and comparative advertising, consistent with the position at EU level.

There are some exceptions; in particular, Italy and Spain both have specific regulations on medical devices. In Italy, devices that are subject to a prescription or that must be used with the assistance of a medical practitioner may not be advertised to the general public and all advertisements for devices directed to the general public require prior approval. Similarly, in Spain, advertising to the general public of devices available through the national healthcare system or used by healthcare professionals is prohibited. Again, any advertisements for devices directed to the general public must be pre-approved.[6]

In France, ANSM has issued guidance supplementing the legislative provisions. For example, advertising of high-risk IVDs to healthcare professionals is subject to prior approval by ANSM. Where devices are reimbursed by the national health system, these may be advertised to the general public only if they fall within class I or class IIa. Advertising of self-diagnostic IVDs to the public is subject to prior approval by ANSM. Non-reimbursed devices may be advertised to the public, although advertising of higher-risk devices also requires prior approval.[7] The guidance also specifies a list of information in relation to the device that must be included with any advertisement.

Position in the UK

The withdrawal of the UK from the EU was completed before the MDR and the IVDR became applicable in the EU and therefore the new EU regime for medical devices and IVDs is not applicable in Great Britain (England, Wales and Scotland) and medical devices and IVDs are controlled by the Medical Devices Regulations 2002, which implemented the Directives in the UK, as well as national law that implemented the Misleading Advertising Directive and the Unfair Commercial Practices Directive. However, as a result of the Northern Ireland Protocol to the Withdrawal Agreement, EU legislation on medical devices and IVDs, including the MDR and IVDR, continues to apply in Northern Ireland.

Codes of Practice

As is the case with medicinal products, industry Codes of Practice can provide useful guidance on standards of advertising practice. The largest medical device manufacturer's industry association, MedTech Europe, issues a Code of Business Practice (the "MedTech Code"),[8] which imposes requirements that go beyond the obligations imposed through applicable legislation. The MedTech Code does not contain specific provisions on advertising. Instead, it is focused on events and interactions with healthcare professionals and seeks to ensure that: (a) interactions between member companies and healthcare professionals do not involve the offer or acceptance of undue or improper advantages that could influence purchasing decisions; (b) interactions are transparent and comply with national and local laws; (c) services performed by healthcare professionals for or on behalf of member companies are remunerated at a level commensurate with the value of the services performed; and (d) the arrangements for services performed by a healthcare professional on behalf of a member company are fully documented in a written agreement.

National Codes of Practice implement and, to a large extent, mirror the MedTech Code. Some national Codes also go further and include guidance on advertising and promotion, but the level of detail varies. Many national Codes simply contain provisions that are in line with the general EU legislation, requiring companies to ensure that all promotional claims and comparisons are accurate, balanced and unambiguous, can be justified by appropriate evidence, and are not misleading.

The Danish Code includes specific guidance on advertising of medical devices,[9] as does the Dutch Code.[10] For example, in relation to comparative advertising, the Danish Code states that it must be clear which medical devices are being compared, and should cover all corresponding products with the same scope of use (except products with a small market share of up to 2–3%).

Similarly, the UK Association of British Healthcare Industries ("ABHI") Code of Business Practice implements the provisions of the MedTech Code. It also governs the promotion of medical devices and IVDs addressed solely or primarily to healthcare professionals. The Proprietary Association of Great Britain ("PAGB") Code covers the promotion of non-prescription medical devices and IVDs to members of the public. In addition, advertising to the public may be enforced under the UK Code of Non-broadcast Advertising and Direct and Promotional Marketing ("CAP Code")[11] and the Code of Broadcast Advertising ("BCAP Code"),[12] both of which contain provisions on health products.

Promotion of Devices in Particular Circumstances

Promotion of devices before CE marking

Generally speaking, a device should not be promoted in the EU and UK if it is not CE-marked. This restriction has been strengthened as a result of the MDR and IVDR, which explicitly provide that advertising should not suggest uses for the device other than those stated to form part of the intended purpose for which the conformity assessment was carried out. However, some commentators consider that, if a device is not placed on the market, it can be marketed as long as it is made clear that the device is not available, and therefore it would be possible to advertise a device prior to grant of the CE mark if the status of the product is stated. The legislation does allow devices to be "shown" at trade fairs, exhibitions, demonstrations, etc., even

when they do not conform to the requirements or have a CE mark – provided that a visible sign clearly indicates that the device cannot be marketed until it does comply.[13]

Promotion of companion diagnostic devices

Companion diagnostics are, inevitably, closely linked to a specific medicinal product. Any activity that promotes the companion diagnostic may, indirectly, act to promote the associated medicine and must, therefore, comply with the requirements of Directive 2001/83/EC[14] and national Codes of Practice relating to medicinal products. By way of example, communications and activities involving healthcare professionals that may promote the use of a companion diagnostic may not be permissible if the relevant medicinal product linked to such use has not been authorised or if the use of the product associated with the companion diagnostic is "off-label".

Further, the link between companion diagnostic IVDs and the associated medicinal product also limits the promotion of the relevant IVD to members of the public. The medicinal product will, in most cases, be a prescription-only medicine, which may not, in accordance with EU legislation governing advertising of medicinal products, be promoted to the general public.[15] In practice, communicating with patients about a companion diagnostic is likely to constitute indirect promotion of the medicinal product associated with the diagnostic test. The risk that communications in relation to the companion diagnostic would be found to be promotional are particularly high in those cases where the result of the test indicates that the patient is likely to respond well to the medicinal product in question.

In cases where companies promote or offer their companion diagnostics to patients that are already being treated with the medicinal product linked to the diagnostic test, it may be possible to maintain an argument that such communication does not influence the prescribing decision of the doctor, particularly as the result of the test may be, in some cases, to convince the patient (and his doctor) to discontinue use of the medicinal product. However, these arguments are not strong enough to justify the promotion of companion diagnostics directly to the public in many jurisdictions.

Promotion of devices placed on the market under the MDD

The MDR became applicable on 26 May 2021. The MDD was repealed with effect from that date.

As a general rule, Article 5 of the MDR states that only devices that are in conformity with the MDR can be placed on the market after the date of application. As there are no "grandfathering" provisions under the MDR, whereby devices that are lawfully on the market under the MDD are automatically deemed to be compliant with the new rules, this provision applies to all medical devices.

However, for a limited amount of time, the MDR explicitly permits manufacturers to continue to place products on the market after 26 May 2021 under a valid MDD certificate, provided that a number of requirements are met. In particular, under Article 120(2), certificates issued by notified bodies as part of the conformity assessment procedure, which are issued in accordance with the MDD from 25 May 2017 to 26 May 2021, remain valid until the end of the period indicated on the certificate. However, all certificates become void at the latest on 27 May 2024.

In order to benefit from these transitional provisions, Article 120(3) of the MDR provides that certain requirements must be met, including that no significant changes in the design or intended purpose of the medical device are made after 26 May 2021, and that the requirements of the MDR in relation to the registration of economic operators and of devices, post-market surveillance, market surveillance and vigilance shall apply and be in place on 26 May 2021.

It is, therefore, lawful for manufacturers to place products on the market under these transitional provisions. If a device is lawfully on the market under these transitional provisions, the device can be promoted in line with the applicable rules, notwithstanding the fact that other (updated) devices may also be available on the market. In such cases, companies will need to ensure they have detailed tracking provisions in place to ensure that the correct provisions apply to the appropriate version of the product. It will also be important to review and update materials to explain that further MDD products are no longer being placed on the market, and that MDR products are available.

Similar issues arise in relation to IVDs that continue to be placed on the market under the IVDD after 26 May 2022, the date of application of the IVDR.

Enforcement

In general, the rules relating to medical devices are less well enforced than those on medicinal products. Where legislation exists, it is usually focused on advertising to patients, and therefore advertising to healthcare professionals is addressed through national Codes of Practice, and enforced through industry bodies, and the regulatory authorities do not "enforce" the provisions; whether a competent authority will review and investigate a particular claim will depend on their capacity and interest in the products/issue. As such, the risk of a complaint will depend on the competitive landscape, and whether both parties are members of the relevant industry body with associated obligations to comply with the applicable Code of Practice. In many countries, enforcement decisions are not published, or the sanctions following an adverse finding are limited (although if a company has signed up to the Code, it will usually follow the outcome of any decision).

In some countries, competitors may bring court action, and the prospects of success vary across the EU. In some countries, this is a comparatively quick process. For example, in Denmark, a complaint filed with the Danish Medicines Agency is generally cheap and dealt with rapidly, with the authority having a practice of interpreting the rules related to the promotion of devices strictly. Similarly, in Germany, claims (for example, in relation to a breach of the advertising rules or unfair competition) can be made to the German court about advertising of medical devices, and decisions on those claims can be obtained quickly. An injunction can also be obtained preventing the advertising from being published. In the Netherlands, if the defendant is involved in misleading advertising not only in the Netherlands but also in other EU Member States, the Dutch court may grant a cross-border injunction preventing use of the advertising materials.

Endnotes

1. (i) Council Directive 93/42/EEC of 14 June 1993 concerning medical devices. There are also two other Directives relating to medical devices: Council Directive of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices; and (ii) Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* diagnostic medical devices.
2. Regulation (EU) 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.

3. Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices and repealing Council Directive 98/79/EC and Commission Decision 2010/227/EU.
4. Directive 2006/114/EC of the European Parliament and of the Council of 12 December 2006 concerning misleading and comparative advertising.
5. 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 Directives 84/450/EEC, 97/7/EC, 98/27/EC and 2002/65/EC and Regulation (EC) No 2006/2004.
6. Law 29/2006 and Royal Decree 1591/2009 of 16 October 2009.
7. ANSM guidance, https://ansm.sante.fr/vos-demarches/industriel/modalites-encadrant-les-demandes-dautorisation-de-publicite-pour-les-dispositifs-medicaux-dm-dmdiv.
8. MedTech Europe Code of Ethical Business Practice with Q&A – March 2022, https://www.medtecheurope.org/resource-library/medtech-europe-code-of-ethical-business-practice.
9. Guideline No 11357 of 29 December 2014, https://laegemiddelstyrelsen.dk/en/devices/legislation-and-guidance/legislation-for-medical-devices/~/media/C3E28514CC994543A8EF6DBBCD6D3C79.ashx.
10. Code of Conduct Medical Devices, 1 January 2012, http://www.gmh.nu/images/Gedragscode-GMH---english-January-2017.pdf.
11. https://www.asa.org.uk/codes-and-rulings/advertising-codes/non-broadcast-code.html.
12. https://www.asa.org.uk/codes-and-rulings/advertising-codes/broadcast-code.html.
13. Article 21(3) of the MDR and Article 19(3) of the IVDR.
14. Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community Code relating to Medicinal Products for Human Use.
15. Article 88(1) of Directive 2001/83/EC.

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Her practice focuses on the regulation of medicinal products, medical devices, foods and cosmetics, particularly in relation to clinical trials, marketing authorisations, pharmacovigilance and advertising and promotion issues, including legal proceedings arising from the decisions of regulatory bodies.

In the context of advertising, she frequently assists clients in relation to compliance issues, including the coordination of cross-border programmes based on the EFPIA Code. She provides representation in proceedings before the UK Prescription Medicines Code of Practice Authority and its Appeal Board arising from alleged breaches of the ABPI Code of Practice and advises on enforcement action by the MHRA.

Her practice also covers the pricing and reimbursement of medicines and medical products, including both statutory and voluntary pricing regimes 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), and equivalent bodies in Scotland and Wales. She represents clients at NICE appeal hearings and has acted on behalf of the manufacturer company in 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. Such litigation has often involved coordinating proceedings in multiple jurisdictions and advising on forum and other jurisdictional issues. She also represents clients at inquests and public inquiries as well as other investigations concerning allegedly defective products.

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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 Daniel A. Kracov in Washington, D.C., giving a combined team of over 40 lawyers.

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