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UNDERSTANDING THE PROMOTION OF MEDICAL DEVICES IN THE EUROPEAN UNION

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UNDERSTANDING THE PROMOTION OF MEDICAL DEVICES IN THE EUROPEAN UNION

Understanding the rules governing the promotion of medical devices in the European Union (EU) can be complex for many reasons. Unlike medicinal products, for which a specific chapter on promotion is dedicated in Directive 2001/83/EC¹, EU legislation does not contain much in the way of direct rules and guidance that are specific to the promotion and marketing of medical devices.

However, this does not mean that the promotion of medical devices is not regulated. Their promotion is governed by several EU Directives of general application, by the national legislation of the EU Member States and industry codes of conduct and professional rules governing healthcare professionals. The challenge can be to identify applicable provisions, and the purpose of this article is to shed light on this regulatory framework.

Medical Devices Directive

Council Directive 93/42/EEC concerning medical devices², as amended (commonly known as the Medical Devices Directive, MDD), contains some basic rules regarding the promotion of medical devices.

As a general principle, Article 2 of the Directive provides that the manufacturer of a medical device may market and promote only medical devices that are CE marked in accordance with the provisions of the MDD. Moreover, devices may only be promoted for their intended purpose as defined by Article 1(2)(g) (i.e. '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').

As a basic consequence, if a device is not CE marked, it cannot be promoted in the EU. Moreover, even if the device is CE marked in accordance with the provisions of the MDD (or whichever of the two other basic Directives that are relevant to an individual medical device^{3,4}), any promotion must be limited to the purposes for which the device has been CE marked.

Promotion of the off-label use of medical devices is excluded.

However, while the promotion of medical devices that have not been CE marked is excluded, the MDD does permit their exhibition in specified circumstances. Article 4(3) of the Directive permits non-CE marked medical devices to be exhibited at trade fairs, exhibitions and demonstrations. However, devices used for this purpose must be accompanied by a visible sign clearly indicating that they cannot be marketed or put into service until they have been made to comply with the requirements of the Directive as regards to placing on the market (i.e. until they are validly CE marked).

An additional provision of the MDD that has an indirect impact on the promotion of medical devices is the provision of Article 4 governing language. This provision permits the national authorities of the EU Member States to impose on manufacturers an obligation to provide all information related to a medical device in the national language(s) of the territory or in another EU language. In practice, all of the EU Member States have exercised the power given in this provision and begin from the requirement that all information concerning medical devices be in their national language(s). However, some (but by no means all) Member States provide a derogation from national language requirements for medical devices that are intended for professional use only.

To protect EU patients and healthcare professionals against medical devices that are not marketed in compliance with the MDD, Article 17(3) of the Directive prohibits the attachment to medical devices of marks or inscriptions which are likely to mislead third parties with regard to the meaning or the graphics of the CE marking. This means that, although other marks may be affixed either to the device, to the packaging, or to the Instructions for Use, these must not reduce the visibility and legibility of the CE marking.

In addition to the rules established by the MDD, manufacturers must also comply with a number of more general provisions provided in other Directives governing the advertising of products in the EU.

Misleading and Comparative Advertising

Directive 2006/114/EC concerning misleading and comparative advertising⁵ aims to protect traders against misleading advertising and its unfair consequences. It is not specific to the advertising of medical devices but it applies directly to their promotion. Article 2(b) of this Directive defines 'misleading advertising' 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 those reasons, injures or is likely to injure a competitor'.

When determining whether an advertisement related to a medical device is to be considered misleading, account shall be taken of all its features, in particular any information the advertisement contains concerning, among other things, the characteristics of goods or services and the nature, attributes and rights of the advertiser. 'Comparative advertising' is defined in Article 2(c) of Directive 2006/114/EC as:

'any advertising which explicitly or by implication identifies a competitor or goods or services offered by a competitor'.

Such advertising is permitted provided a number of requirements are met. According to Article 4, the comparative advertising should:

- not be 'misleading';
- compare goods meeting the same needs or intended for the same purpose;
- objectively compare one or more material, relevant, verifiable and representative features of a good, which may include price;

- not discredit or denigrate the trade marks, trade names, other distinguishing marks, goods, services, activities, or circumstances of a competitor;
- not take unfair advantage of the reputation of a trade mark, trade name or other distinguishing marks of a competitor;
- not present goods as imitations or replicas of goods bearing a protected trade mark or trade name; *and*
- not create confusion in the area of trade marks and names.

As the EU law governing misleading and comparative advertising is in the form of a Directive, it is the responsibility of the EU Member States to implement the requirements of the Directive into their national law. Although Member States are required to achieve the aims of any Directive, the manner in which these are achieved can vary from Member State to Member State. As a result, review of the national implemented legislation of individual Member States is important.

Article 8 of the Directive allows EU Member States to retain or adopt provisions to ensure more extensive protection against misleading advertising. However, this is limited only to the protection against misleading advertising and does not apply to the protection against comparative advertising where Member States cannot go beyond the provisions of the Directive.

Direct-to-Consumer Promotion of Medical Devices

Although it is not specified in legislation adopted at EU level, the promotion of prescription-only medical devices is largely prohibited in the EU Member States.

The increasing consumer interest in lifestyle products, some of which are classified as medical devices, has led to an increase in promotion of such devices to consumers by manufacturers and distributors. Although limited in application, the Unfair Commercial Practices Directive 2005/29/EC⁶ influences the promotion to consumers of such medical devices.

The Unfair Commercial Practices Directive permits the national authorities of EU Member States to retain or introduce restrictions and

prohibitions on commercial practices on grounds of the protection of the health and safety of consumers in their territory. [Article 2(d) defines commercial practices as 'any act, omission, course of conduct or representation, commercial communication including advertising and marketing, by a trader, directly connected with the promotion, sale or supply of a product to consumers'. Article 2(a) defines a consumer as 'any natural person who, in commercial practices covered by this Directive, is acting for purposes which are outside his trade, business, craft or profession'.] These laws will apply irrespective of where the manufacturer is based. The national authorities of Member States can monitor and sanction commercial practices affecting consumers in their territory even if the manufacturer of such devices is based in another Member State or outside the EU.

'Unfair practice' is defined in Article 5 of the Unfair Commercial Practices Directive as a commercial practice that is contrary to the requirements of professional diligence and that:

'materially distorts or is 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, or of the average member of the group when a commercial practice is directed to a particular group of consumers'.

Unfair commercial practices include:

- misleading practices by act or omission;
- aggressive practices; *and*
- blacklisted practices.

'Misleading acts' are defined in Article 6 as:

- containing false information or deceiving or likely to deceive the average consumer, even if the information is factually correct;
- any marketing, including comparative advertising, which creates confusion with any products, trade marks, trade names or other distinguishing marks of a competitor;
- non-compliance with commitments contained in codes of conduct by which the trader has undertaken to be bound.

'Misleading omissions' are defined in Article 7 as actions omitting, hiding or providing in an unclear, unintelligible, ambiguous or untimely manner material information that the average consumer needs to take an informed transactional decision, or failing to identify the commercial intent.

Activities falling within the 'blacklist' mentioned above include, among other things:

- using editorial content in the media to promote a product where a trader has paid for the promotion without making that clear;
- making a materially inaccurate claim concerning the nature and extent of the risk to the personal security of the consumer or his family if the consumer does not purchase the product;
- including in an advertisement a direct exhortation to children to buy advertised products or persuade their parents or other adults to buy advertised products for them.

Non-Binding Rules

Medical device manufacturers are represented at EU level by Eucomed, the European medical technology industry association. Eucomed's members are national trade and pan-European product associations and internationally-active manufacturers of all types of medical technology. Eucomed has established a Code of Business Practice⁷ (the Code) which includes a set of non-binding rules which should be adhered to by the companies that make up its members.

The Eucomed Code requires that members should ensure that all promotional presentations, including product claims and comparisons, are accurate, balanced, fair, objective and unambiguous. These should be justified by appropriate evidence, and statements should not mislead the intended audience.

The Code also excludes companies that make up Eucomed members from directly or indirectly offering, making, or authorising payment of money or anything of material value where this is intended to unlawfully influence the judgment or conduct of any individual, customer or company.

The Eucomed Code imposes strict conditions on sponsorship by companies of product training and education or to support

third-party educational conferences. It also includes guidance for manufacturers wishing to meet with healthcare professionals to discuss product features, contract negotiations, or sales terms, and some important provisions regarding gifts are also laid down. On this latter point, the Code provides that gifts may be provided to healthcare professionals but only when they are modest in value and in accordance with the regulations of the country where the healthcare professional is licensed to practice.

The compliance and enforcement of the Code lies with the Eucomed members. Although many national member bodies have implemented the provisions of the Code into their national codes of practice, there is an element of inconsistency in the approach of some national bodies.

Conclusion

The framework applicable to the promotion of medical devices is a complex mix of EU and national rules with both specific and general scope. This framework is implemented, enforced, interpreted and complied with by 27 EU Member States with 27 national authorities and a number of industry bodies. Promotional activities are closely monitored by those players. The need for compliance cannot, therefore, be underestimated.

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