Multi-jurisdictional advertising of medical devices – the legal framework in Germany, the Netherlands and the UK

Alex Denoon, *Erik Vollebregt* and *Mathias Klümper* examine the rules on promoting medical devices in Europe.

Unlike the EU directive on medicinal products, the directives on medical devices do not regulate the promotion of medical devices *per se*. Consequently, the legal landscape for the promotion of medical devices in Europe is fragmented and derives from a variety of disparate sources.

The primary requirement of the Medical Devices Directive (93/42/EEC), as amended by Directive 2007/47/EC, is that a medical device must have a CE mark if it is to be placed on the market[1]. In this context, a medical device may only be promoted for its intended purpose as set out in the instructions for use, labelling and promotional materials[2]. While there are limited exceptions for exhibiting at trade fairs, exhibitions and demonstrations[3], a visible sign displayed at those events must clearly indicate that the device cannot be marketed until the device is validly CE-marked.

An interesting question is whether the MDD prohibits the advertising of a product before the product has a CE mark.

Some commentators take the view that the MDD absolutely prohibits the promotion of a medical device without a CE mark. A more robust view is that so long as the product is not "placed on the market" in Europe, promotional activities alone are permissible as long as they do not suggest that the device can already be placed on the market lawfully.

As a result, promoting a medical device immediately prior to receipt of a CE mark to announce its arrival onto the market should not offend the MDD, provided that the device is not offered for sale in Europe and it is clear that the product is not available in Europe. In short, so long as the product is not placed on the market, the MDD will not apply to the promotional activities[4]. This more robust interpretation is supported by guidance issued by the European Commission in November 2010[5].

It is axiomatic, but worth emphasising, that if the promotional material includes or suggests a medicinal claim (eg that the product has a pharmacological, immunological or metabolic means of action), then the full force of Medicinal Products Directive (2001/83/EC) applies. This can be very challenging for a combination product where the primary mode of action is (say) physical, but the secondary mode of action is (say) pharmacological. In such cases, promotional material must emphasise the primary mode of action.

Also, even if the MDD does not prohibit advertising for medical devices, national rules in EU member states may impose constraints. As long as the subject has not been harmonised under EU law, member states remain competent to instate national rules on the subject, provided that these rules are in conformity with the Treaty on the Functioning of the European Union provisions on the free movement of goods and the free provision of services[6].

Other constraints

Even if there are no rules that prohibit advertising of medical devices *per se*, there are other rules that affect how certain devices may be advertised. For example, the Court of Justice of the EU recently addressed national rules on e-commerce for medical devices in the *Ker-Optika* case and held that since Directive 2000/31/EC on e-commerce does not exclude medical devices from its scope, it applies to medical devices in its entirety[7]. In our view, this would also include online advertising rules as Directive 2000/31/EC makes specific exceptions for medicinal products but not for medical devices[8]. It is, as far as we can predict, not presently envisaged that the recast of the medical device directives will change this by enacting rules with respect to advertising of medical devices.

Shedding light on advertising

There are multiple sources of law that prohibit misleading advertising, including national consumer protection laws. However, for the purposes of this article, we have focused on the Unfair Commercial Practices Directive (2005/29/EC), applicable to business-to-consumer advertising, and the Misleading and Comparative Advertising Directive (2006/114/EC), applicable to business-to-business advertising. These directives are designed to protect consumers and to protect traders against competitors engaging in unfair conduct by issuing misleading and/or unlawful comparative advertising.

Informational versus promotional

There is a critical distinction between informational and promotional materials. However, the courts are shrinking the "safe harbour" of "informational" material. The *Damgaard* case[9] concerning a journalist without ties to the manufacturer writing about an unauthorised medicinal product shows how wide the scope of the definition of "advertising" is interpreted by the EU court.

The CJEU (then known as the European Court of Justice or ECJ) in *Damgaard* held that to determine whether a message is considered to be advertising under the medicinal products directive, the purpose of the message as such counts.

Every communication, even if it were (a) not disseminated in the context of commercial or industrial activity or (b) disseminated by a third party, that may influence consumers' behaviour and encourage them to purchase a medicinal product falls within the scope of advertising. The EU court justifies this interpretation on the basis that information supplied to users should provide a high degree of consumer protection, in order that medicinal products may be used correctly on the basis of full and comprehensible information. In this light, it is not relevant who disseminates the information and for what purpose.

Although the medical device directives do not contain their own definition of advertising, in our view it is likely that a court would hold that the interest of information being disseminated about a device being correct and comprehensible applies equally to medical devices. For example, Mr Damgaard made a promotional statement about a product that may have been available but could not be placed on the market legally. He did not include a disclaimer that the product concerned could not be placed on the market lawfully. If he had made it clear that the product could not be purchased lawfully, the case, in our view, would have been decided differently.

Because promotional statements by third parties can constitute advertising under the *Damgaard* theory, it is obviously important to control the promotional statements made at different levels of the supply chain. Contracts with distributors should, therefore, give the manufacturer the right to control the promotional statements made by the distributor in order to avoid an adverse result from a prosecution of the distributors.

A trickier and less obvious category of statements are those made by third parties without a commercial interest but with a therapeutic interest in a device, eg prior to receipt of a CE mark. They may be prone to making statements intended to influence the behaviour of others and encourage them to purchase the device (or request prescription thereof), which could constitute unlawful advertising of the product. Therefore,

manufacturers should ensure that each patient group with whom they work is transparent about the status of a medical device that they discuss, particularly if the group wants to promote the device.

Misleading advertising

Directive 2006/114/EC (ie MCAD) 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.*

It is worth emphasising that the advertisement is to be taken as a whole, including all of its features, its context and the intended public. Thus, a claim that a product is similar to an existing product may not be misleading (if justified). However, if the headline of the same advertisement was "well balanced" and prominently used an equally balanced set of scales, it could well be misleading as it implies that the products were identical[10].

A useful touchstone in this regard is offered by the World Health Organization, which states that advertisements should be factual, fair and capable of substantiation[11]. These concepts are also reflected in the Eucomed code of ethical business practice, which states that:

> *Members should ensure that all promotional presentations, including product claims and comparisons, are accurate, balanced, fair, objective and unambiguous. They should be justified by appropriate evidence. Statements should not mislead the intended audience.*

The required substantiation will generally follow from the label (as defined in the MDD), as this determines the scope of the intended purpose of the device concerned.

Furthermore, advertising outside the scope of the intended purpose will normally constitute not only misleading advertising but also off-label advertising, which is usually prohibited and a serious offence. Generally speaking, one can further say that consumers will be more easily misled by advertising about a medical device because they will be more inclined to believe the factual information presented in advertising for lawfully marketed medical devices.

Comparative advertising

Comparative advertisements are common in the medical devices arena and, as a result, are also a regular source of dispute in the sector. Common complaints include allegations of incomplete or hanging comparisons, selective use of information, use of data from ongoing trials, comparison of products with different functionality, denigrating use of the other party's brand equity and use of a competitor's own product numbers in a comparison.

The concept of comparative advertising has a very wide scope. It is defined as any advertising that explicitly or by implication identifies a competitor or goods or services offered by a competitor.

Thus, the "identification" does not even require a comparative context or comparative intent: an indirect reference can be sufficient. Further a "competitor" can be any company active on the same relevant market (including potential market entrants) or with a possibly competing therapy[12].

MCAD provides that comparative advertising shall be permitted when the following conditions are met:

- the comparison is not misleading;
- it compares goods or services meeting the same needs or intended for the same purpose;
- it objectively compares one or more material, relevant, verifiable and representative features of those goods or services;
- it does not create confusion in the market place between the advertiser's trademarks, trade names, other distinguishing marks, goods, services, activities or circumstances of a competitor;
- for products with designation of origin, it relates in each case to products with the same designation;
- it does not take unfair advantage of the reputation of a trademark, trade names or other distinguishing marks of a competitor or the designation of origin of competing products; and
- it does not present goods or services as imitations of goods or services bearing a protected trademark or trade name.

Target audience

Under CJEU case law, "the national court must take into account the presumed expectations which it [the advertisement] evokes in an average consumer who is reasonably well-informed and reasonably observant and circumspect.

However, Community law does not preclude the possibility that, where the national court has particular difficulty in assessing the misleading nature of the statement or description in question, it may have recourse, under the conditions laid down by its own national law, to a consumer research poll or an expert's report as guidance for its judgment"[13].

According to the CJEU, in B2B circumstances one has to "take into account the perception of an average individual who is reasonably well informed and reasonably observant and circumspect. Account should be taken of the type of persons at whom the advertising is directed"[14]. When that person is a specialist trader, the risk of being misled may be significantly lower.

In Germany, the relevant target audience is considered to be a normally informed, observing and sensible average consumer. However, when marketing material is exclusively targeted to a healthcare professional, then one can assume a higher level of understanding in keeping with professional requirements.

The Dutch courts take a similar approach to the target audience. However, they emphasise that the manufacturer, when providing promotional material about medical devices, has a duty to be extra critical about the factual correctness of the material (even if the target audience comprises experts).

In the UK, there is no specific guidance about the target audience when marketing medical devices. However, this will be assessed on a case-by-case basis and less leeway will be afforded to a factually incorrect statement.

The Netherlands

In the Netherlands, one may bring a direct suit against a competitor for unlawful comparative advertising as unlawful comparative advertising constitutes a tort under article 6:194a of the Civil Code. In practice, many cases are brought alleging unlawful comparative advertising, including in the medical devices industry. A claimant can obtain an enforceable judgment from a Dutch court in injunction proceedings normally within approximately three weeks from service of a writ of summons until receipt of the judgment.

Complaints can also be brought before the self-regulatory body KOAG/KAG, whose code includes specific provisions on comparative advertising[15]. Furthermore, a complaint can be brought before the Advertising Code Commission (Reclame Code Commissie), which is not specialised in medical devices but will hear comparative advertising complaints in the sector[16].

Germany

In Germany, competitors, in practice, take action directly through the civil courts and seek to obtain injunctive relief against unlawful advertisements. They generally seek injunctive relief to stop advertisements violating their rights on the basis of the Act Against Unfair Competition (Gesetz gegen unlauteren Wettbewerb). In addition, competitors can request a corrective statement or the communication or publication of the judgment to third parties. Apart from this, a claimant can also sue for damages and compensation, and can request an account of any profit made. However, it is not only direct competitors that

may take direct action through the civil courts, but also associations promoting commercial interests (Wettbewerbsvereine), and consumer associations. Industry and chambers of commerce are also entitled to such claims.

In practice, the competent authorities would rarely take action against an advertisement that it considers to be unlawful. While they do have the power to stop further publication of such an advertisement, they have no legal power to force a medical device company to publish a corrective statement. Competent authorities take action only in very serious cases.

UK

In the UK (unlike in Germany or the Netherlands), one cannot bring an action directly against a competitor as a result of a misleading advertisement that breached MCAD. Rather, the Office of Fair Trading and local Trading Standards Services enforces MCAD[17]. Consequently, claimants often seek to characterise a claim as trademark infringement or malicious falsehood claims.

In practice, advertising in the UK is primarily controlled through codes of practice. In the case of advertisements in the non-broadcast media, the Advertising Standards Authority oversees and acts to ensure compliance with the non-binding CAP Code[18]. In essence, the code requires advertisements to be legal, decent, honest and truthful and to be prepared with a sense of responsibility to consumers and society at large.

While the OFT has a duty to investigate complaints, these matters are often resolved through the self-regulatory systems. Where these fail to prevent advertisements that mislead or that do not comply with the conditions under which comparisons are permitted, the OFT will act. The OFT can seek fines and may try to injunct publication of an advertisement. The OFT could seek a prison term for officers involved in breaches[19].

Traditionally, the OFT initially seeks assurances from an advertiser to modify or not repeat an offending advertisement.

Trademark infringement in comparative ads

As mentioned above, an additional or alternative basis of claim is for trademark infringement. Trademark use in comparative advertising is permitted, provided that the comparative advertising meets all requirements[20].

In many EU member states (but not in the UK), the courts tend to find that comparative advertising using a trademark of a competitor constitutes automatic trademark infringement when the comparative advertising does not meet the standards for lawful comparative advertising.

Unfair advantage

A common problem with comparative advertising is how far an advertiser may go in the use of a competitor's brand equity. This type of problem often occurs in cases where the advertiser has a less strong brand in the market and tries to gain market share by referring to the products and brand of the incumbent.

In the case law of the CJEU this is not considered as taking unfair advantage of the reputation attached to distinguishing marks of his competitor *per se*[21]. However, there is unfair advantage if that indication could cause the public to associate the incumbent's brands with the competing supplier, in that the public might associate the reputation of that manufacturer's products with the products of the competing supplier[22].

Whether that happens depends on the overall presentation of the advertising at issue, eg if the advertisement gives the public a false impression of the relationship between the advertiser and the trademark owner[23]. An example would be imitation products, as was recently confirmed by the CJEU in *L'Oréal v Bellure*[24]. Bellure promoted its "smell-alike" perfumes by reference to well-known registered trademarks.

L'Oréal successfully sued for infringement and won despite the court finding that the advertisement was not misleading and no sales were diverted. The court held that as Bellure's products were held out to be imitations or replicas, they were promoted by reference to, and took unfair advantage of, the L'Oréal brands. According to the court, where a third party attempts, through the use of a sign similar to a mark with a reputation, to ride on the coat-tails of that mark in order to benefit from its power of attraction, its reputation and its prestige, and to exploit, without paying any financial compensation and without being required to make efforts of his own in that regard, the marketing effort expended by the proprietor of that mark in order to create and maintain the image of that mark, the advantage resulting from such use must be considered to be an advantage that has been unfairly taken of the distinctive character or the repute of that mark.

Also sensitive in this respect are the "works with" and "fits on" claims that may be made in a comparative context, notably in the disposables markets.

Homing in on trademark use

In the UK, Section 10 of the Trade Marks Act 1994 addresses trademark infringement, while Section 10(6) provides limited protection in relation to comparative advertising:

Nothing in the preceding provisions of this section shall be construed as preventing the use of a registered trade mark by any person for the purpose of identifying goods or services as those of the proprietor or a licensee. But any such use otherwise than in accordance with honest practices in industrial or commercial matters shall be treated as infringing the registered trade mark if the use without due cause takes unfair advantage of, or is detrimental to, the distinctive character or repute of the trade mark.

There is no counterpart in the EU Community Trade Mark Regulation and no specific requirement in the Trade Marks Directive. Section 10(6) of the UK act is not an endeavour to implement MCAD, which is separately enforced by the OFT and the ASA. Of course, in some cases an advertisement will constitute trademark infringement under section 10(6) and breach the MCAD requirements.

The primary objective of section 10(6) is to permit comparative advertising. Justice Jacob has set out a 13-point summary of the proper meaning of section 10(6) and specifically the requirement of "honest practice in commercial matters"[25]. Without seeking to restate all of the requirements, it is worth noting that an advertisement that is significantly misleading is not honest for these purposes. The question should be considered from the perspective of the average consumer who is reasonably well informed and reasonably observant and circumspect.

Malicious falsehood/trade libel

In the UK, there is a novel cause of action, known as malicious falsehood or trade libel. The elements of a claim for malicious falsehood are that:

- the defendant has published words about the claimant that are false;
- the words were published maliciously; and
- special damage has followed as the direct and natural result of the publication.

Recently, Ajinomoto (the world's largest manufacturer of the sweetener aspartame) successfully sued[26] the supermarket chain ASDA for malicious falsehood as a result of ASDA's use of the following expression on a range of ASDA's own brand products: "No hidden nasties... no artificial colours or flavours and no aspartame".

The elements of the cause of action are relatively onerous and case law has established that the statement must (a) be intended to be taken seriously; and (b) specifically denigrate the claimant's goods. The leading text[27] gives a useful illustration of this point: while a statement that the defendant's goods are the best implies that a competitor's goods are not as good, it does not denigrate them. Further, general praise of the defendant's goods will

usually not be actionable even if it is false, damaging and made maliciously[28].

The requirement of malice would be satisfied by knowledge that the statement is false or without considering or caring whether the statement was true[29].

Comparison with trademark infringement

In the context of a comparative advertisement, it is becoming increasingly common to bring an action based on section 10(6) and malicious falsehood. While an action based on section 10(6) has the significant advantage that there is no need to prove malice, this can lead to a Pyrrhic victory if the advertisement can be amended to remove the use of the registered trade mark. The claimant bringing an action based on 10(6) also runs the risk that the defendant may seek to revoke the trademark registration.

Table 1 provides some tips on what companies should consider when promoting a medical device.

Table 1. What to consider when promoting a medical device

	Do	Don't
Comparative advertising	Prepare evidence (and have dated copies available) supporting statements before. Consider in what jurisdictions to use comparative advertising. Using product numbers is permitted.	Use superlative terms ("best", "most accurate", etc) unless supported unequivocally. Use more brand equity of a competitor than necessary for the comparison.
Advertising medical claims	For combination products with a secondary "medicinal" mode of action, emphasise the primary mode of action.	Advertise outside the scope of the CE mark. Suggest a pharmaceutical mode of action or, if you do, make it clear that this is a secondary mode of action.
Advertising general	Ensure that the supporting scientific and clinical data is current. Always refer readers back to the approved documentation such as the instructions for use.	Use absolute statements such as SAFE. Make statements that could promote anxiety (eg by encouraging people to believe that without the product they will suffer).

References

1. *Article 2 of Directive 93/42/EEC*
2. *Article 1(2)(g) of Directive 93/42/EEC*
3. *Article 4(3) of Directive 93/42/EEC*
4. *Vollebregt E and Klümper M, To place on the market (or not)?, Regulatory Affairs Medtech, 17 January 2011*
5. *European Commission, Interpretative Document of the Commission's Services, Placing on the Market of Medical Devices, 16 November 2010, http://ec.europa.eu/consumers/sectors/medical-devices/files/guide-stds-directives/placing_on_the_market_en.pdf*
6. *Clinique, Case C-315/92, [1994] ECR I-317*
7. *Case C-108/09 of 2 December 2010. For an annotation see http://medicaldeviceslegal.wordpress.com/2010/12/05/eu-court-rules-on-internet-sales-restrictions-for-medical-devices/*
8. *See recitals 11 and 21 of Directive 2000/31/EC on e-commerce*
9. *Daamgard, Case C-421/07, [2009] ECR I-2629*
10. *AUTH/2357/9/10 – GP v Boehringer Ingelheim, www.pmcpa.org.uk/?q=node/874*
11. *WHO, Ethical Criteria for Medicinal Drug Promotion, Geneva 1988, http://apps.who.int/medicinedocs/en/d/Jwhozip08e/1.html*
12. *Landtsheer Emmanuel, Case C-381/05, [2007] ECR I-3115*
13. *Gut Springenheide, Case C-210/96, [1998] ECR I-4657*
14. *Toshiba/Katun, Case C-112/99, [2001] ECR I-7945*
15. *KOAG/KAG website, www.koagkag.nl/content/*
16. *Stichting Reclame Code website, www.reclamecode.nl*
17. *The Business Protection from Misleading Marketing Regulations 2008, www.legislation.gov.uk/uksi/2008/9780110811475/contents*
18. *The UK Code of Non-Broadcast Advertising, Sales Promotion and Direct Marketing (CAP Code), 12th edition, www.cap.org.uk/The-Codes/CAP-Code.aspx*
19. *OFT guidance brochure, www.oft.gov.uk/shared_oft/business_leaflets/general/oft1056.pdf*
20. *Recitals 14 and 15 of Directive 2006/114/EC*
21. *Toshiba/Katun, C-112/99 [2001] ECR I-7945*
22. *Ibid*
23. *Ibid*
24. *L'Oréal SA v Bellure NV, (C-487/07), 18 June 2009*
25. *Cable v Wireless, [1998] FSR 383*
26. *Ajinomoto Sweeteners Europe SAS v Asda Stores Ltd, [2010] EWCA Civ 609*
27. *Kerly's Law of Trade Marks and Trade Names, 14th Edition at 18-048*
28. *Hubbuck & Sons Ltd v Wilkinson Heywood & Clark Ltd, [1899] 1 QB 86*
29. *Kerly's Law of Trade Marks and Trade Names, 14th Edition at 18-068*

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