To place on the market (or not)?

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The definition of the term "placing on the market" is critical for medical device manufacturers whose products are marketed in the EU. It is in fact one of the core issues relating to the three EU medical device directives (the Medical Devices Directive – 93/42/EEC), the In Vitro Diagnostics Medical Devices Directive – 98/79/EC) and the Active Implantable Medical Devices Directive – 90/385/EEC), which make the crucial acts of "placing on the market" and "putting into service" subject to compliance with the regulatory requirements under these directives.

As reported in this issue, the European Commission adopted an "Interpretative Document of the Commission's Services: Placing on the Market of Medical Devices" on 16 November 2010[1,2]. This very important document discusses how the definition of "placing on the market" in the three directives must be interpreted when placing on the market occurs in two scenarios that are treated very distinctly by the commission. The scenarios relate to:

- medical devices that are manufactured in the EU (points 8-14); and
- medical devices that are manufactured outside the EU and subsequently imported (points 15-18).

The interpretative document discusses this issue with references to the English, German and French language versions of the directives; it also makes many references to the new market surveillance rules in Directive 2007/47/EC (the so-called amending directive) as well as the old CE-marking ***acquis***.

As an aside, the document also discusses the importation of devices by individuals for personal use (point 19); not surprisingly, that is not considered placing on the market for the purposes of the directives.

While the document allows for considerable flexibility for a manufacturer based in the EU to "play" with the moment when a medical device is placed on the market, such flexibility does not seem to be allowed for devices manufactured outside the EU and subsequently imported into the EU. For EU manufacturers a product is considered placed on the market:

> *(10) [...] when the product is transferred from the stage of manufacture with the intention of distribution or use on the Community market. Even though the term "transfer" is not used in the legal definition, the German term "Überlassung" in the definition of Inverkehrbringen as well as the term "supply" in the definition of making available (like "Abgabe" in Bereitstellung or "fourniture" in mise à disposition) underline that a certain type of transfer needs to take place.*
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> *(11) The transfer can consist in a physical hand-over and/or be based on a legal transaction. It can relate to the ownership, the possession or any other right transferred from the manufacturer to a distributor or to the end user. A transfer of a product is considered to have taken place, e.g., when it is sold, leased, given as a gift, rent out or hired. Where a manufacture operates an own distinct distribution chain, the transfer can also occur to that distribution chain.*

On the other hand, for imported products:

> *(15) [...] they must at least be released for free circulation in the internal market before they can be considered as being placed on the EU market (see Articles 27-29 of Regulation (EC) No 765/2008)*
>
> *and*
>
> *(17) [...] If the transfer of the finished device from the manufacturer (or a distributor) established outside the EU to the importer takes place prior to or during the customs procedure, its release for free circulation will also be the moment of its placing on the market.*

The commission refers in the interpretative document to the Blue Guide, one of its basic guidance documents on CE-marking for guidance on the concept of placing on the market. Although the interpretative document does not refer to it, the concept of placing on the market set out in point 10 of the document corresponds remarkably well to the Court of Justice of the European Union's view in the O'Byrne case on the concept of placing a product on the market for the purpose of the interpretation of the EU Product Liability Directive (85/374/EEC)[3]. In that case the CJEU spent quite some time defining where production ends and distribution begins in a complex multinational undertaking in which several subsidiaries are involved in the manufacturing process of a medicinal product.

Important promotion-related consequences

In our view, the interpretative document has the important – and perhaps unintended – possible consequence that the promotion of a non-CE-marked medical device does not constitute (or may likely not constitute) the placing on the market of that medical device.

This goes against the theory advocated by those have argued that medical devices must be CE-compliant before any "offer to transfer" may be made or before they can be promoted lawfully on the EU market, by reference to the medical device directives only. If we look at the new interpretative document, however, the commission focuses on the actual placing on the market (and not just the act of advertising that this may happen at some point in time when CE marking has been granted). This actual placing on the market is defined as a physical act or legal transaction-based handover pursuant to which a device is transferred from the stage of manufacture with the intention of distribution on the EU market (see points 10 and 11).

This interpretation is also consistent with the Blue Guide, which provides that[4] a:

> *product offered in a catalogue or by means of electronic commerce is deemed not to have been placed on the Community market until it is actually made available for the first time. In order to respect the rules and principles aiming to prohibit misleading advertising, a non-compliance of a product in- tended for the Community market should be clearly indicated.*

In our opinion, a promotional announcement that a particular device is in the pipeline, but is not yet available because the regulatory process is not yet completed, does not constitute "placing on the market" under the theory of the interpretative document. This would also fit in with the exception provided for in Article 4(3) of the MDD (the trade fair exemption), because this provision aims to create an exemption for advertising of a device that is not yet CE-marked, "provided that a visible sign clearly indicates that such devices cannot be marketed or put into service until they have been made to comply". In other words, there must be no misleading of the public about the regulatory status of the advertised device. This may be extrapolated to other forms of publicity, since the MDD does not limit this exemption to trade fairs only, but rather gives a non-exhaustive list of ways to advertise a device: "trade fairs, exhibitions, demonstrations, etc". We are aware that this interpretation may seem controversial, but it can be defended under the concept of placing on the market as clarified by the commission in the new interpretative document.

Conclusion

Before manufacturers and resellers raise their hopes, they should not forget that there may also be national laws in EU member states that regulate the advertising of non-CE-

marked medical devices. However, insofar as that would be contrary to the medical device directives under in the interpretation defended here, it is contrary to EU law and should not be enforced. The space that EU law leaves for member states to regulate advertising and other modalities of sale of medical devices is constantly shrinking. This has been shown by the recent *Ker-Optica* case about internet sales and advertising of medical devices[5].

References

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3. *CJEU, Case C-127/04, Declan O'Byrne v Sanofi Pasteur MSD Ltd, formerly Aventis Pasteur MSD Ltd, Sanofi Pasteur SA, formerly Aventis Pasteur SA, 9 February 2006, http://curia.europa.eu/jurisp/cgi-bin/gettext.pl?where=&lang=en&num=79939790C19040127&doc=T&ouvert=T&seance=ARRET*
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