medicaldeviceslegal

Medical devices legal and regulatory blog

To place on the market (or not)

That is the question. It is in fact on of the core questions of the three medical devices directives (the Medical Devices Directive, the In Vitro Diagnostics Directive and the Active Implantable Medical Devices Directive), which make the crucial acts of "placing on the market" and "putting into service" subject to compliance with the regulatory requirements under these directives.

With very little publicity (I saw a link under the News heading on the DG Consumer Affairs website to it only on 29/11/2010) the Commission published a new interpretative document on **"Placing on the market of medical devices"** dated 16/11/2010.

This document is very important for any medical devices company. The document discusses how the definition of "placing on the market" in the three directives must be interpreted by reference to English, German and French language versions of the directives and subsequently with a lot of references to the new market surveillance rules as well as old CE marking *acquis* when there is placing on the market in two scenarios that are treated very distinctly by the Commission:

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

It also discusses import of devices by private persons for personal use (point 19); rather obviously that does not count as placing on the market.

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.

(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."

For imported products on the other hand

"(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."

Although the Commission refers to the **Blue Guide** in point 10 of the document, it is remarkable how well this corresponds with the European Court's view of the concept of what placing a product on the market for the purpose of the interpretation of the EU product liability directive in the **O'Byrne case** . In that case the European Court spent quite some words 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.

In my view the interpretative document has the important – and perhaps unintended – possible consequence that advertising of a non-CE marked medical device does not constitute (or may likely not constitute) placing on the market of that medical device. Some have argued that medical devices must be CE compliant before any 'offer to transfer' may be made or before they can promoted lawfully on the EU market, by reference to the MDD or IVDD only. If we look at the interpretative document however the Commission fixates on the actual placing on the market (and not just advertising that this may happen at some point in time when CE marking has been completed). 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). In my 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, 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* (it rather gives a non-exhaustive list of ways to advertise a device: "trade fairs, exhibitions, demonstrations, etc."). I am aware that this interpretation may seem very controversial, but it can be defended under the concept of placing on the market as clarified by the Commission in the interpretative document. Before you get your hopes up as manufacturers and distributors: don't forget also that there may be national law in EU member states that regulates advertising of non-CE marked devices. However, insofar as that would go contrary to the MDD under in the interpretation defended here, it is contrary to EU and should not be enforced. A lot more can be said about this. Discussion, anyone?

Advertising, Placing on the market

30/11/2010

3 Comments

3 comments

Do you want to comment?

Comments RSS and TrackBack URI

1.
basdr.
In my personal opinion (even without the interpretative document) it is clear that the mere promoting of a non-CE marked device does not constitute 'placing on the market'. (But do include a statement that the product is indeed not yet CE marked).

Under the interpretative document a 'placing on the market' MUST involve a Transfer of the ownership, the possession (or any other right in rem) …….and it is hence NOT merely triggered by (i) a binding offer to sell the non-CE marked device or even (ii) the formation of a contract of sale for such non-CE marked device.
In most Member States, the ownership (legal title) is NOT transferred "automatically" upon formation of a contract of sale itself. A separate 'delivery' (e.g. leveringshandeling) would be required. Absent that, ownership (legal title) does not transfer.
Secondly contracts of sale often contain standard 'retention of title language' which -if the relevant conditions are not triggered- would prevent the ownership (legal title) from transferring anyhow.
Without such Transfer (of either the physical device itself, or of the ownership, the possession or any other right in rem in such device) no 'placing on the market' would occur.
If I today enter into a contract of sale for a non-CE marked device that I plan to deliver only 6 months from now, at which time it would be CE-marked ….and I would e.g. start manufacturing that individual device only in 5 months from now, I cannot see why I should be seen a having 'placed on the market' anything TODAY. The device does not exist. The ownership and/or the possession in it have not yet been transferred.
Do you or others see this differently?

Permalink, Reply
14/03/2011 ***15:35***

Erik Vollebregt
Dear Bas,
Many thanks for this observation. I am not sure I agree with your argumentation on all points, but it certainly provides for an interesting extra dimension with your reference to the differences in contractual transfer of title under different systems of contract law.

The Commission's notice says that the transfer that gives rise to the 'placing on the market' does not need to be a physical transfer and may also be a legal transfer (see point 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.").

In point 14 of the notice it says : "However, in certain circumstances, a device which physically is still in the manufacturer's warehouse can be considered as placed on the market. For example, this may be the case where the ownership or another right of a certain product has already been transferred to either a distributor or the end user but the product is still stored by the manufacturer on their behalf. A case-by-case assessment is required and the manufacturer would have to be able to demonstrate that the product is singled out for being distributed."

That means in my view that the Commission considers it certainly possible that a legal transaction while the product has not been physically supplied yet can constitute 'placing on the market'. The problem is – and that is where your examples are very valuable – what type of legal transactions will give rise to placing on the market. The Commission seems to hint that it considers legal transactions where a specific product "is singled out for being distributed". I agree that your example of a device (certainly relevant to large and complicated devices delivered as a system) that has not been built yet is a good example of a device that in my view would not be placed on the market yet. Things get more complicated when a device is present in a warehouse in a stage where it only needs to be assembled (e.g. in case of devices that are always assembled on location). MEDDEV 2.1/1 states that a device does not need to be in a final state to be considered a medical device. That reasoning may also be used to say that a device that is always assembled on location is put on the market if it is present in a warehouse in disassembled state.

I don't think you could prevent a device from being 'placed on the market' by selling and delivering it under retention of title, because that would make this criterion too easy to circumvent.

I agree with you though that different modalities of physical supply and legal transfer of title complicate things a lot. So, many thanks for your comment. If you want to continue the discussion, I'll be happy to.

Permalink, Reply
15/03/2011 ***21:06***

2.
basdr.
Thank you for this response. I also don't think you could prevent a device from being 'placed on the market' by selling and delivering (!) it under retention of title …as in that scenario the device has indeed (physically; in the sense of 'possession') Transferred.

The question indeed is what type of legal transactions (i.e. those where there is NO delivery) will give rise to placing on the market? My personal view is that it is only those transactions where the ownership or possession (or any other right in rem) is 'Transferred' as part of that transaction. I'd really like welcome views on that.

As an aside, point 14 in the Commission's notice seems to have been mainly written for the following (inverse, I would say) situation: manufacturer has a warehouse full of devices that it wants to 'place on the market' asap i.e. prior to new legal requirements coming into force. Manufacturer now urgently sells these devices to customers (or into its distribution channel) but adds; 'we'll keep them in our warehouse for you'. A bill-and-hold situation that the manufacturer seems to have had most interest in (i.e. because of such new requirements coming into force and the manufacturer's need to 'place on the market' prior to that occuring).
In THAT situation the Commission's notice makes it clear that this type of transaction could indeed constitute a placing on the market provided the product has been singled out. In my view the Commission's justification for it would be based on the fact that ownership or any other right in rem has indeed 'Transferred' as part of that transaction.

As a related aside, point 11 in the Commission's notice reads: "…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…." I am not convinced that the use of the word 'sold' by the Commission is intended to mean that the mere act of selling itself would always and automatically lead to the Transfer. I think the ennumeration here is simply repeated to indicate that all these actions (selling, leasing, renting

etc.) are each capable of leading to a ‘placing on the market’.
Point 14 in the Commission’s notice would simply not have been needed if Point 11, by using the word ‘sold’, made it clear that ANY sale would ALWAYS trigger the Transfer and would therefore always lead to a ‘placing on the market’. The Commission’s view seems to be; you need (i) a sale (ii) a transfer (of ownership or of another right) and (iii) the product having been singled out for being distributed.

My view is that in many cases of a mere ‘sale’ (i.e. a legal transaction where there is no delivery) the other two criteria are often not (yet) met.
Would welcome views; has anyone asked the Commission? What is the ‘industry standard/practice’ as to A. promoting, B. offering, C. selling (but not D. shipping/delivering!) of non CE-marked devices?

Permalink, Reply
16/03/2011 ***09:00***