EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Consumer Affairs
Cosmetics and Medical devices

Brussels, 16 November 2010
SANCO/B/2/PBE/pdw Ares(2010) 332016

INTERPRETATIVE DOCUMENT OF THE COMMISSION'S SERVICES[1]

PLACING ON THE MARKET OF MEDICAL DEVICES

Background

(1) In the context of the implementation of Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007 amending Council Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices, Council Directive 93/42/EEC concerning medical devices and Directive 98/8/EC concerning the placing of biocidal products on the market[2], questions have been raised concerning the interpretation of the notion "placing on the market" and in particular as to when a medical device should be considered as being placed on the EU market.

(2) Directive 2007/47/EC does not modify the definition of "placing on the market" as provided in Directives 90/385/EEC[3] and 93/42/EEC[4]. But as of 21 March 2010, the date of application of the national transposition measures, medical devices must comply with the new legal requirements when they are placed on the market[5]. The concept of placing on the market, which refers to each individual product, is fundamental for the application of the medical devices directives regardless of legislative changes. Since Directive 98/79/EC[6] on *in vitro* diagnostic medical devices uses the same concept of 'placing on the market' as Directives 90/385/EEC and 93/42/EEC, the following interpretation as regards the moment when a product is placed on the market applies to all three medical devices directives.

---

1 This interpretative document is not legally binding. The ultimate interpretation of Union law lies with the European Court of Justice.

2 OJ L 247, 21.9.2007, p. 21.

3 OJ L 189, 20.7.1990, p. 17.

4 OJ L 169, 12.7.1993, p. 1.

5 See Interpretative document of the Commission's services of 5 June 2009, http://ec.europa.eu/consumers/sectors/medical-devices/files/guide-stds-directives/transitionalperiod_2007-47-ec_guidance_final_en.pdf

6 OJ L 331, 7.12.1998, p. 1.

Legal definitions

(3) Article 1(2)(h) of Directives 90/385/EEC and 93/42/EEC, respectively, and Article 1(2)(i) of Directive 98/79/EC define the term "placing on the market" as follows:

> "*'placing on the market' means the first **making available** in return for payment or free of charge of a device […], with a view to distribution and/or use on the Community market, regardless of whether it is new or fully refurbished*" (emphasis added).

(4) Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93[7] defines the term "placing on the market" in Article 2(2), which reads as follows:

> "*'placing on the market' shall mean the first **making available** of a product on the Community market*" (emphasis added).

(5) In addition, Article 2(1) of Regulation (EC) No 765/2008 introduces a definition of the term "making available". This provision is worded as follows:

> "*'making available on the market' shall mean any **supply** of a product for distribution, consumption or use on the Community market in the course of a commercial activity, whether in return for payment or free of charge*" (emphasis added).

(6) In the German version of Directives 90/385/EEC, 93/42/EEC and 98/79/EC, "Inverkehrbringen" is defined as "*erste entgeltliche oder unentgeltliche **Überlassung** eines Produkts […]*" or "*[…] eines Geräts […]*", respectively. This definition differs slightly from the definition of "Inverkehrbringen" in Regulation (EC) No 765/2008 which is the following: "*die erstmalige **Bereitstellung** eines Produkts auf dem Gemeinschaftsmarkt*", whilst "Bereitstellung" is defined as "*jede entgeltliche oder unentgeltliche **Abgabe** eines Produkts zum Vertrieb, Verbrauch oder zur Verwendung auf dem Gemeinschaftsmarkt im Rahmen einer Geschäftstätigkeit"* (emphasis added).

(7) The French versions of Directives 90/385/EEC, 93/42/EEC and 98/79/EC define the "mise sur le marché" as "*première **mise à disposition** à titre onéreux ou gratuit d'un dispositif*", whilst "mise à disposition" is defined in Regulation (EC) No 765/2008 as "*toute **fourniture** d'un produit destiné à être distribué, consommé ou utilisé sur le marché communautaire dans le cadre d'une activité commerciale, à titre onéreux ou gratuit*" (emphasis added).

---

[7] OJ L 218, 13.8.2008, p. 30.

Interpretation

(8) The question has been raised whether a medical device may already be considered as being placed on the market when the manufacturing process is finished, or whether additional steps need to be taken towards its distribution or use.

(9) According to the legal definitions, a product must be "made available" (*mis à disposition*, *überlassen*) with a view to distribution or use whilst making available is to be understood as the supply of a product (*fourniture*, *Abgabe*). The interpretation of these terms indicates that the mere termination of the manufacture is not sufficient for a product to be placed on the market. In addition, it must have entered into the distribution chain.

(10) The *Guide to the implementation of directives based on the New Approach and the Global Approach* ("Blue Guide")[8] states that the placing on the market takes place 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.

(12) According to the "Blue Guide", placing on the market is considered not to take place where a product, amongst others, is

- in the stocks of the manufacturer, or the authorised representative established in the Community, where the product is not yet made available, unless otherwise provided for in the applicable directives; or

- not (yet) granted release for free circulation by customs, or has been placed under another customs procedure (for example transit, warehousing or temporary importation), or is in a free zone.

(13) As regards the situation described in the first indent, it needs to be highlighted that a transfer of products does not yet occur when a device is merely put in the manufacturer's warehouse. Otherwise, manufacturers would have an incentive to produce quantities of products according to "old" legal requirements, stockpile them in their warehouse and sell them over a long period of time. In addition, European manufacturers may also produce specifically for export; these devices

---

[8] Published by the European Commission (1999), see http://ec.europa.eu/enterprise/policies/single-market-goods/files/blue-guide/guidepublic_en.pdf , in particular page 18.

are not required to comply with the EU legislation on medical devices and should therefore not be considered as being placed on the EU market when the manufacturer stores them in his warehouse.

(14) 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.

(15) As regards **imported products**, they must at least be released for free circulation in the internal market[9] before they can be considered as being placed on the EU market (see Articles 27-29 of Regulation (EC) No 765/2008). In particular paragraphs 1 and 2 of Article 29 of Regulation 765/2008 state that products which present a serious risk or which are not compliant with harmonised EU legislation, and which therefore shall not be placed on the EU market, shall not be released for free circulation. This requires a close cooperation between customs authorities and market surveillance authorities.

(16) The question is whether the placing on the market is deemed to coincide with the release for free circulation. For the placing on the market of imported products the same criteria must be applied as for EU manufactured products while the release for free circulation is determined by customs regulations.

(17) An importer is defined as the person established within the EU who places a product from a third country on the EU market (see Article 2(5) of Regulation (EC) No 765/2008). The importer can either be the authorised representative or another third person, who may belong to the non-EU manufacturer's own distribution network. 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.

(18) Under certain circumstances, however, the placing on the market of an imported medical device does <u>not</u> coincide with its release for free circulation, namely in cases where that product has not yet been transferred from the stage of manufacture to the distribution stage. For example, this would be the case

- where, in line with Article 29(2) of Regulation 765/2008, a market surveillance authority requires the importer to take appropriate action in order to ensure that the imported products are made compliant with EU legislation before they are placed on the market. There may be cases where the refusal to release a non-compliant product into free circulation would

---

9 The release for free circulation is regulated in Articles 79-83 of the Council Regulation (EEC) No 2913/92 establishing the Community Customs Code. The release procedure confers on 3rd country goods the status of EU goods.

not be appropriate (e.g. disproportionate), but the market authority could nevertheless require that the placing on the market is deferred until the product is made compliant with EU legislation; or

– where the non-EU manufacturer mandates another person within the EU (including its authorised representative) to carry out activities which are necessary to make the device compliant with the requirements of the directive (e.g. assembling, packaging, processing, labelling or the accomplishment of a conformity assessment); or

– where the product is transferred to a manufacturer’s (or the authorised representative's) warehouse as long as the product is not yet made available on the market. This includes the case where the goods are stored in the warehouse of a European manufacturer who has the product designed and manufactured outside the EU and markets it under his own name or trademark in Europe.

In these cases, the product is placed on the market when it is transferred to a distributor or end user in accordance with the general criteria determining the placing on the market.

(19) A medical device which a private person acquires in a third country and then brings it to the EU for his/her own **personal use** is not 'placed on the market' and is not required to conform to the requirements of the medical devices directives. If, however, a professional user buys a medical device in a third country, brings it to the EU and uses this device in the context of his/her professional activity, he/she puts this device into service. According to Article 2 of Directives 90/385/EEC, 93/42/EEC and 98/79/EC, respectively, a device put into service must comply with the requirements of the applicable directive.