DIRECTIVE 2007/47/EC: WHAT ARE ITS IMPLICATIONS FOR EXISTING MEDICAL DEVICES?

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The regulatory framework governing medical devices in the European Union (EU) and, more particularly, the three basic Medical Devices Directives,[1] have been amended on a number of occasions since their adoption. The most recent technical revision to the Directive on Active Implantable Medical Devices and the general Medical Devices Directive was through Directive 2007/47/EC,[2] which was adopted in September 2007. This Directive makes no change to the Directive on *In Vitro* Diagnostic Medical Devices.

On 21 March 2010, the modifications provided for in Directive 2007/47/EC will enter into force in the 27 EU Member States. The impact of this revision on certain types of medical devices currently on the EU market is unclear. However, given that the Directive introduces a number of important modifications to the current EU regime governing implantable medical devices and devices governed by the Medical Devices Directive,[3] it merits close examination and, arguably, clarification concerning its implications.

The new obligations introduced by Directive 2007/47/EC will require modifications to current manufacturing and technical processes for some types of medical devices. These modifications may, in some instances, lead to a modification of the existing certificates of conformity issued by Notified Bodies. Although not intended to be exhaustive, the main changes to the existing framework include the following:

- Technical documentation related to all medical devices must include a clinical evaluation document containing all the clinical data to support the declaration of conformity. This document must be actively updated and must incorporate relevant post-marketing surveillance data.

- Clinical investigation is required for all implantable and Class III devices unless reliance on existing clinical data is duly justified.

- Clinical investigations must be conducted in relation to surgically invasive devices intended specifically for use in direct contact with the central nervous system (reclassified from Class IIa to Class III).

- The definition of central circulatory system has been extended and now includes the vessel aortic arch (*arcus aortae*) and descending aorta (*aorta descendens*) to the aortic bifurcation (*bifurcation aortae*).

- Clinical investigation will be required when an initial clinical evaluation concludes that the available clinical data does not allow for the full evaluation of the clinical effectiveness and/or safety of the medical device.

- Medical devices that are specifically used for disinfecting invasive devices will in the future be classified in Class IIb (instead of Class IIa).

- The definition of continuous use will be expanded to include situations in which a medical device, upon discontinuation or removal, is replaced immediately by the same or with an identical medical device.

- Software, whether stand alone or incorporated into a medical device, will be classified as a medical device.

- Medical devices will be classified by their primary mode of action and not their intended use.

- For borderline products which are medical devices and personal protective equipment, the requirements of the Medical Devices Directive and the relevant part of Annex II to the Personal Protective Equipment Directive must both be

1) Council Directive 90/385/EEC of 20 June 1990 on the Approximation of the Laws of the Member States relating to Active Implantable Medical Devices (OJ 1990 L189/17 of 20 July); Council Directive 93/42/EEC of 14 June 1993 Concerning Medical Devices (OJ 1993 L169/1, 12 July); Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *In Vitro* Diagnostic Medical Devices (OJ 1998 L331/1, 7 December).

2) 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 (OJ 2007 L247/21, 21 September).

3) Council Directive 93/42/EEC of 14 June 1993 Concerning Medical Devices (OJ 1993 L169/1, 12 July).

met. Manufacturers of products that are classified both as machinery and as medical devices must also comply with the requirements of Annex I to the Machinery Directive and the Medical Devices Directive.

- With the entry into force of Directive 2007/47/EC, Member States may require information on Class IIa devices.

- Specific requirements are introduced concerning the safety, labelling and information of high-risk medical devices, namely devices containing phthalates.

Are there implications for the validity of current certificates of conformity?

Directive 2007/47/EC does not include any transitional period during which medical device manufacturers would be required to implement the obligations to which its provisions gives rise. Neither are there any references in the Directive to the continued validity of existing certificates of conformity granted in relation to facilities or devices which will require modification as a result of the entry into force of its provisions. The entry into force of Directive 2007/47/EC, therefore, raises the question of the validity of existing certificates of conformity for those medical devices that are likely to be directly impacted by its provisions.

The existing Medical Devices Directives require that a manufacturer inform the Notified Body that approved the quality system related to a medical device of any plan for 'substantial changes' to the quality system or to the product range covered by an existing certificate of conformity. Such substantial changes will often require a modification of an existing certificate of conformity.

It would appear likely that, as a result of the entry into force of the provisions of Directive 2007/47/EC, manufacturers of some medical devices will be required to make modifications to their quality system or product range. However, nothing in the Directive provides any indication as to which, if any, of these modifications should be considered 'substantial'. Moreover, there are no indications as to how any substantial changes required as a result of the entry into force of the Directive will impact current certificates of conformity.

There is, from a legal perspective, an interesting conundrum here. Where, as a matter of choice, a manufacturer introduces substantial changes to either its quality system or to its product range, it can be expected to accept the related consequences of such changes for existing certificates of conformity.

However, the question arises as to what obligations a manufacturer faces where substantial changes that will be required in relation to its quality system or product range are imposed by legislation rather than by choice. To suggest that the entry into force of new legislation, such as Directive 2007/47/EC, imposes a requirement that an existing quality system or product range, as well as related certificates of conformity, should be revised is arguably giving retrospective effect to the legislation in question. However, in the absence of any guidance to the contrary, it might equally be argued that a manufacturer is required to respect obligations imposed by regulation as these enter into force, particularly in relation to products having a potential impact on patient health. Following this line of argument, a manufacturer would be required to ensure that an existing quality system or product range be modified to reflect obligations laid down in Directive 2007/47/EC and related certificates of conformity revised by 21 March 2010 at latest.

The European Commission published an interpretative document[4] in the matter on 5 June 2009. The document, according to the European Commission, 'shall guide a uniform practice throughout the EU'.

Although the European Commission interpretative document is arguably somewhat arcane on certain points, it has the merit of making it clear that medical devices that are to be placed on the EU market or put into service after 21 March 2010 must comply with the new requirements of Directive 2007/47/EC. Moreover, from this date Notified Bodies will be required to carry out their conformity assessment activities in accordance with the new provisions.

The interpretative document makes a distinction between medical devices in relation to which changes must be notified where they are *significant*[5] and active implementable medical devices for which *any* modification of the quality system or design should be approved by the Notified Body. The document underlines that this is the usual regime regarding change control.[6]

It is arguable that medical devices that have been lawfully placed on the EU market in respect of existing EU medical device legislation should continue to be marketed without the need for a new certificate of conformity. However, even following publication of the European Commission's interpretative document, it is far from clear that this is the correct conclusion.

4) http://ec.europa.eu/enterprise/medical_devices/guide-stds-directives/transitionalperiod_2007-47-EC_guidance_final.pdf.

5) Annex II point 3.4 of the Directive 93/42/EC uses the qualifier 'substantial', while in Annex II point 4.4 there is no qualifier and it simply states 'changes to the approved design ...'. It is interesting to note that in its document the Commission used the qualifier 'significant'. Maybe 'significant' is the chosen qualifier between 'substantial' and the absence of qualifier.

6) Points 3.4 and 4.4 of Annex II, point 6 of Annex III, point 3.4 of Annex V or point 3.4 of Annex VI of Directive 93/42/EEC; point 3.4.and 4.4 of Annex 2, point 6 of Annex 3 or point 3.4 of Annex 5 of Directive 90/385/EEC.

The European Commission interpretative document notes that new certification will be necessary for medical devices in case of changes to the approved design of the medical device or the approved quality system of the manufacturer, triggered by the new requirements introduced by Directive 2007/47/EC. It does not, however, clarify whether such obligations will take effect on expiry of existing certificates or whether they take effect on 21 March 2010 on entry into force of the Directive.

The European Commission's interpretative document states that certificates of conformity for medical devices placed on the market before 21 March 2010 and delivered in accordance with the current version of Directive 93/42/EC shall, in principle, remain valid until their expiration date[7] or a renewal (in case of change to the quality system or the design).

However, where, due to the new requirements introduced by Directive 2007/47/EC, a medical device falls within a new class of devices[8], it is unclear from the interpretative communication whether or not the manufacturer needs to obtain a new certificate of conformity to continue to market its product in the EU after 21 March 2010. The interpretative document acknowledges that manufacturers may have an interest in anticipating compliance with the new legislation where, for example, they bring a new device type on the market for which the new requirements have been respected from the beginning. However, it also advises such an approach

> '*where a device falls in a different class requiring another conformity assessment procedure, or where the adaptation to the new requirements introduced by Directive 2007/47/EC requires changes to the approved design of a medical device or to the approved quality system of the manufacturer which are subject to prior assessment by the responsible Notified Body*'.

This statement could be interpreted as advising that, after 21 March 2010, where the quality system or product ranges are subject to substantial change as a consequence of the entry into force of Directive 2007/47/EC, related certificates of conformity should be revised. There would appear to be nothing in the communication to permit a conclusion to the contrary.

If there is legitimate doubt in the reading of the document, it would appear advisable that the advice of a Notified Body is sought concerning the continued validity of an existing certificate of conformity.

7) A certificate of conformity has a maximum validity of five years.

8) That is, from Class IIa to Class III, such as medical devices intended specifically for use in direct contact with the central nervous system, or from Class IIa to Class IIb, such as medical devices that are specifically used for disinfecting invasive devices.