

EU revision of the Medical Devices Directive

The EU Commission, having consulted during the spring last year, has now published proposals for amendments to the Medical Devices Directive (which it is obliged to review regularly).

The first meeting of the EU Council to consider the proposed amendments to the Directive, as published on 22 December 2005, will be held on 23/24 January 2006. The MHRA will be attending and need input from industry so they can go armed with evidence of any amendments which will cause problems, and why.

The link below will take you to the page from which you can access the proposals:

http://europa.eu.int/comm/enterprise/medical_devices/revision_mdd_en.htm

If you cannot find your copy of the existing Directive, you can get it at:

http://europa.eu.int/eur-lex/en/consleg/main/1993/en_1993L0042_index.html

The changes that the Secretariat believes may cause members concern are outlined below, but please look at the whole thing carefully, as we may have missed something!

Clinical data:

The amendments seek to make it very difficult not to provide clinical data/clinical evidence for all medical devices (only Annex X 1.1e gives even a hint of a get-out clause). A new clause (k) has been added to Article 1.2 which defines “clinical data”.

We need examples from you of products where a requirement to provide clinical data would be impractical etc – perhaps product designs which have been on the market for many years without significant alteration; or where clinical evaluation would be nonsensical because the product is so simple/low value; or where it is not feasible to carry out a proper clinical trial because numbers will be too low... the more actual examples you can send in, the better. The MHRA will then be in a position to make the case that this should not be a requirement across the board.

New requirement to include on labels “the respective code of an internationally recognized generic medical device nomenclature” (Annex II, 13.3 b):

The MHRA already intends asking “why?”; if there is a compelling argument as to why this should be done, they will propose one nomenclature should be used (they will suggest the obvious one to use - GMDN = the Global Medical Devices Nomenclature).

However, the codes may be too broad to be meaningful, and there may be medical devices which cannot be coded using GMDN. Please let me know of any examples where this may pertain (and any compelling arguments why the principle in itself is a bad idea – perhaps in terms of practicality).

Info on GMDN can be found at:

<http://www.gmdn.org>

Single authorised representative:

For those of you who import (and may be an authorised representative), there are two clauses which you need to look at. The first is Article 14 (2) where it has been added that where a manufacturer who places devices on the market under his own name does not have a registered place of business in a Member State, he shall designate “a single” authorised representative.

This would mean that for a manufacturer outside the EU, all of their products would have to go through just ONE authorised representative. Would this be a problem? If so, please give examples.

Linked to this approach, Annex II 13.3 (a) says that information to be supplied on the label or outer packaging or instructions for use shall contain in addition, the name and address of the authorised representative “where the manufacturer does not have a registered place of business in the Community”.

(The thinking behind this is clearly to make it easier to trace who is responsible in the first instance when there are adverse incidents etc.)

Custom made devices:

Article 4 (2) brings in a new requirement that the statement called for in Annex VIII (about who the manufacturer is etc) “shall be provided to the named patient”.

It has been pointed out that in the case of, for example, dental technicians, they will manufacture the device, but the dentist will fit it and the technician has no control over whether the patient receives the statement. It would therefore be impractical to enforce or police. Would it cause problems for orthotics and prosthetics?

A new Section 5 has been added to Annex VIII which extends the requirement for post market surveillance and adverse incident reporting to custom made devices.

Lifetime of a product:

Throughout the document, new reference is made to the necessity to keep technical documentation for a period at least equivalent to “the intended lifetime of the product as defined by the manufacturer....”

Previously, it simply had to be kept for a period not less than five years. We anticipate that this requirement may present problems and we do not think it has been thought out properly. For example, do you have products out there, which are still going strong many years after they were first sold? (Perhaps, for example, a wheelchair frame – all the moving parts may have been replaced over time, but the frame itself is still going strong?) Is the lifetime of the product entirely dependent on proper maintenance? Please send in any examples where you would find it difficult to state the intended lifetime of the product, and/or difficult to keep the technical documents for that length of time. (The question has also been asked, is it intended life from the date of first sale?)

Other additions which, although self-evident, may give you pause for thought and perhaps necessitate an overhaul/revision of all your technical files, are:

Annex I 1 – devices must be designed and manufactured in such a way....”This shall include reducing, as far as possible, risks posed by user error due to the ergonomic features of the device and its intended user environment”.

Annex I 13.1 – each device must be accompanied by the information needed to use it safely and “properly, taking account of the training and knowledge of the potential users...”

Please return your comments by 18 January 2006, to:

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