UK Comments on the proposed revision of MEDDEV 2.1/3

The UK has reviewed the proposed changes to the borderline MEDDEV and has discussed this with the UK Medicines Authority. We have the following comments:

Our main concern is that none of the discussions or determinations that have taken place over the past few years with relation to where products should be regulated as medicinal products or as medical devices have been incorporated into the document, nor have any example changes been made resulting from the redefinition of a medicinal product.

Comments on Specific sections

Cover section:

It is not clear why the title of the document has been deleted – the MEDDEV should have a title to indicate that it covers the borderline between medical devices and medicinal products. We suggest that 'pertaining to the demarcation between medical devices and medicinal products' should be added. It should also reference the fact that the document includes information on the consultation process for Class III devices containing medicinal substances.

Section A.

There should be some mention that there is separate guidance document available for IVD medical device borderlines (perhaps in section A1 or with footnote 4 in A2)

Section A2

The last paragraph under the heading *Medical device* Article 1 (2) MDD commencing '*These principles are subject to certain exemption….*': The current wording implies that antacids and some of the other examples currently listed in A. 4.2. do not fall within the definition of a medicinal product as they fulfil their function by physical or chemical means. Whilst this may be acceptable for in vivo diagnostic substances (for which the definition is clear) this could cause problems in the light of the redefinition of a medicinal product since it implies that such products do not work by pharmacological, metabolic or immunological means, which would exclude them from regulation as medicinal products. The revision of this document therefore needs to be made in the light of the re-definition of a medicinal product.

We consider that this paragraph should be modified and moved into the section covering non-cumulation – suggested wording:

> ***Due to the definition of "medicinal product", substances administered to human beings to make a medical diagnosis, even if they fulfil their function by physical or chemical means, and not by pharmacological, immunological or metabolic means in the sense as described above are considered to be medicinal products. The products listed in A.4.2 have been regarded throughout the EU as medicinal products within the meaning of Directive 2001/83/EC.***

The examples that could potentially cause problems should be moved to section A 4.1 (e.g. haemofiltration substitution solutions, solutions for peritoneal dialysis, antacids and fluoride dental preparations).

The first sentence at the top of page 5 : ' A product will thus be considered a medicinal product ……at least one of these two categories': This should be removed since it implies that a product only has to fall within one of the limbs of a definition of a medicinal product for it to be a medicinal product. A large majority of medical devices also fall within the first limb definition and thus according to the proposed wording would be transferred back to being medicinal products. In addition ECJ C-290/90 of 1992 referred to would no longer be fully valid since the introduction of the Medical Devices Directive.

Section A3 - 3.1

The note on antimicrobial substances should be expanded in order to clarify the impact on the classification of such products where the antimicrobial action could be considered ancillary to the main purpose of the device (rather than being considered a medicinal product).

Section A4 examples of medicinal products.

The example of topical disinfectants in section 4.1 should be expanded to include specific examples such as alcohol / disinfectant / antiseptic swabs, antimicrobial wound cleansers etc, since although there is general agreement that these are medicinal products, a large number of such products are accepted in various member states as medical devices. If they are to remain as medicinal products, specific examples should be given.

The item on in vivo diagnostic agents in section 4.2 should be expanded to include a comment that those products that are administered for an in vivo diagnostic purpose, but which remain inert and do not change their shape or form (or have any effect upon the body) are considered to be medical devices.

This section still includes some products where as a result of the redefinition of a medicinal product there was general agreement that such products would be acceptable as devices (provided that there was no pharmacological, immunological or metabolic action). Therefore the following items need to be removed from this section and placed in section 3.1:

zinc paste for dermatological use from section 4.1
artificial tears from section 4.2

The amended last sentence of section 4.2 is incomplete and does not make sense.

Section 4.3 – this section should be expanded to cover IVF media with metabolic action, which cannot be considered to be medical devices but may be considered as medicinal products in some Member States.

Section B
B.3 (p) - should this also mention the MEDDEV Guidance on clinical data?

Items to be added to the proposed revision.

1. There are a number of issues that have been discussed and determinations agreed over the past few years which are not reflected in the current proposed wording. The following should be added to the proposed draft:

    - The commission decision on ‘integral’ covering when a product consists of a ‘device’ element and a ‘medicinal’ element but are combined together prior to administration to the patient.

Examples of medical devices (to be included in section 3.1):

- Non-medicated dermatological creams
- Aluminium sulphate /salts for dental use as an astringent
- Products containing acids (see UK statement – copy attached)
- Zinc oxide products (with no pharmacological action)
- Artificial Tears (with no pharmacological action)

Examples of medicinal products:

- Products containing lactobacillus for the regulation of the pH of vaginal flora (considered to be medicinal products after discussion at CWG/MDEG) to be given as an example in 4.1
- Lung scintigraphy gas producers (graphite crucible) to be given as an example in 4.1
- Lissamine green ophthalmic strips to be given as an example in 4.2

2. There are also a number of items awaiting discussion / clarification that could usefully be included in the examples listings for medical devices / medicinal products once the relevant decision has been made (sections A3, A4 as appropriate). These include:

    - The regulation of eye drops indicated for environmental relief only (expand section A 3.3.1 entry on 'irrigation solutions (including those used in the eye) intended for mechanical rinsing')
    - The regulation of osmotic laxatives (add to 4.2 as examples of medicinal products)
    - The regulation of glycerine suppositories
    - The regulation of catheter flushing solutions containing medicinal substances (medical devices with ancillary medicinal action)
    - The regulation of solutions / powders/concentrates for on line haemodiafiltration (medicinal products)
    - The regulation of active coal solutions (medicinal products)
    - The regulation of products coated with antimicrobial agents (classification)
    - The regulation of IVF media that act metabolically (not medical devices)
    - The regulation of aqueous eosin solutions
    - The regulation of the laryngeal cough reflex product (medicinal product)

Additional comments:

The UK would greatly appreciate having sight of comments made by other Member States on this issue prior to the classification working group meeting in December.

We would also like to know the intended timescale for the revision and publication of this document and details of any plans to enable further discussion of the issues raised by ourselves and other Member States.

Since the proposed document includes reference to case law, will details of this case law be included on the commission website?

The UK would also appreciate some clarification on whether it is intended to further review and clarify this MEDDEV guidance after the revision of the MDD has been completed and what the plans are for the revision of the classification MEDDEV, since some of the issues raised in the discussions over this document will have an effect on the examples listed in MEDDEV 2.4/1