

BVMed comments to the proposed modifications to the MDD (status 05/04/2005)

Foreword

BVMed welcomes the opportunity to comment on the proposed modifications to directive 93/42/EC, and, as already indicated during the preparation period, is generally happy with the proposed amendments.

We would nevertheless like to highlight some points, which are either not acceptable to BVMed as presented or need to be clarified.

We would have liked to see in the text published by the Commission for public enquiry the following:

- Explanatory memorandum
- The recitals (justifying the modifications),
- The provision for amending other directives (namely 90/385, for which, in the accompanying impact assessment, the intention of alignment with the revised 93/42 was presented) and
- The indication of a possible timetable for implementation and, in particular, for transitional measures for devices conforming to the 1993 version of the Directive, taking into account the explanatory or complementary character of the amendments.

Due to the incompleteness of the text published on the Commission website, BVMed considers the present document as a first attempt to give its input to the revision of the Medical Devices Directive and retains the right to comment again once the final draft is available.

A. General Remarks

BVMed notes how some of the proposed modifications are related to articles or annexes, which belong to the general structure of the so-called New Approach; in particular those on Post Marketing Surveillance, on the safeguard clause and on the modules describing the various conformity assessment procedures.

The Commission is currently reviewing the New Approach and we wonder what impact this will have on the revised Medical Devices Directive (since the amendments are unlikely to take place simultaneously).

While we welcome the various clarifications introduced in the new proposal, we would welcome some rationale for the legislative modifications introduced in the text and an explanation on how these modifications are likely to affect those products already on the market.

It has been noted that the current text refers several times to the use of the Article 7(2) procedure. BVMed considers that the Art. 7(2) procedure should be triggered only when duly justified. We question whether the Commission has to rely on this procedure every time that a Commission measure or interpretation is needed. Recent experiences with art. 7(2), particularly taking into account the objective difficulties in handling and controlling 20 different language versions, have shown that the art. 7(2) procedure might not be the most effective and rapid tool.

BVMed suggests that the Commission could consider applying the Art. 7(4) procedure for the elaboration of an authoritative opinion.

The experience gained in several years of application of the Medical Devices Directive has highlighted the need to add some more definitions of terms, which have been source of different interpretations. The new document also includes some new concepts, which would benefit from a clear definition. In particular, we have identified the following:

- ❖ BVMed does not understand the meaning of the term **"lifetime of the device"**: some implantable devices (dental implants, for example) are going to stay in the patient for ever! Would not be more appropriate to define this as "x" years after the production of the device has been ceased?
- ❖ BVMed feels that, for the sake of transparency, the Commission should clarify the exact meaning of the expression **"duly substantiated"**. We understand that this is likely to be dealt within a guidance document, the need for which, in our opinion, is extremely urgent.
- ❖ Reference to **"state of the art"** is also sometimes confusing and deserves a clear definition for the sake of the appropriate interpretation of the directive (state of the art applies at design level).
- ❖ It is BVMed's understanding that the term **"animal"** must be defined as "vertebrates" excluding the Homo Sapiens
- ❖ We would also welcome appropriate amendments to differentiate the term **"classification"**, as referred to the classification system at Annex IX and "classifica-

tion" as referred to the compliance of a product with the definition of "medical device"

We also take this opportunity to introduce some other issues, which have not been taken into consideration in the current text, like this one:

- ❖ We would like to have the Commission's guidance of the term "***a given number of products***" as used in Annex II, Annex V and VI, each time under point 2, 2nd sentence; cf. the specific comments under **B XV** and an explanation, if there is a different meaning of the wording in Annex II "***... a given number of the products manufactured ...***" compared to Annexes V and VI "***... a given number of identified specimens of the products manufactured ...***"

B. Specific comments

The following specific remarks are the result of consultation among BVMed members. Where no comment is made, BVMed accepts the proposed changes.

I.

1.2.a

BVMed agrees with the addition, provided that it is made clear that the definition applies exclusively to standalone software, which is intended to:

"be used for human beings for the purpose of:

- ***diagnosis, prevention, monitoring, treatment or alleviation of disease,***
- ***diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,***
- ***investigation, replacement or modification of the anatomy or of a physiological process,***
- ***control of conception".***

II.

Art.11.11

BVMed is not clear whether the suggested amendment implies that the "maximum five years" applies to the totality of the extensions or whether each extension shall be each time of maximum five years. BVMed suggests in any case deleting the term "***maximum***". If necessary, other specific maximum time limits might be introduced via NBOG for specific product families.

III.

Art. 12

BVMed has evidence of inconsistent application of the requirements of Art. 11 and 12 for procedures packs. BVMed urges the Commission to consider the drafting of appropriate guidance.

IV.**Art.12.3**

BVMed believes that it would be appropriate to slightly amend the text the penultimate paragraph to read:

"The application of the abovementioned Annexes and the intervention of the notified body are limited to the aspects of the procedure relating to the obtaining and maintaining of sterility for the shelf life of the device or until the sterile package is opened or damaged."

V.**Art. 13.1.d**

BVMed suggests the deletion of this article since the responsibility for interpreting the Directive and, in particular, its scope should remain within the Commission's remit and, ultimately, with the European Court of Justice

VI.**Art. 15.2**

BVMed believes that the justification for the decision should also be reported and that, in any case, the report should be made only when the refusal is due to safety issues.

VII.**Art. 20.2**

While we are in favour of the creation of publicly available list of class I devices manufacturers, we think that a clarification should be made to specify that points b) and c) are limited to the exchange of information between Member States and do not imply dissemination to the general public. The general public should be informed by another means (see below). In any case, if a Member State considers that information should or may be released in a publicly-available medium, the manufacturer shall be consulted in advance. Commercially confidential information shall be redacted from the material released to the public.

VIII.**Art. 21 and art.22**

See initial remarks.

IX.

Annex I, point 1

BVMed, while not opposing the modification in principle, believes that it is necessary to clarify what is meant by “by virtue of the technical knowledge, experience, education or training of the intended user”. We agree that a device intended to be used by a lay person shall be made in such a way as to take into account the lack of appropriate “technical knowledge, experience, education or training”. We suggest changing the above text by the following:

"taking into consideration, in particular, whether the device is intended for professional use or not".

X.

Annex I, point 12.1.b

BVMed is still unclear on the reasons for the inclusion of this ER. The principles of validation apply to all aspects of the design and not exclusively to software. We believe that this new ER is unnecessary and might even introduce some contentious issues between the manufacturer and the NB or the CA, particularly on the meaning of the term ***"validated according to the state of the art"***. (See also comment to Article 9.3)

XI.

Annex I, point 13.1

BVMed agrees on the basic principle introduced by this modification; however the term "properly" might generate confusion. The manufacturer is responsible for the intended use of the product and not beyond. We would appreciate the term "properly" being amended to ***"as intended"***. We also would welcome to exchange the word "accompanied" by the term ***"provided"*** in the light of our proposal - see below our comment to section 13.7.

The new point 13.1 should then read:

"13.1. Each device must be provided with the information needed to use it safely and as intended, taking account of the training and knowledge of the potential users, and to identify the manufacturer."

This information comprises the details on the label and the data in the instructions for use.

As far as practicable and appropriate, the information needed to use the device safely must be set out on the device itself and/or on the packaging for each unit or, where appropriate, on the sales packaging. If individual packaging of each unit is not practicable, the information must be set out and supplied with one or more devices.

Instructions for use must be provided for every device by a state of the art information delivery system. Providing instructions for use by other means than paper format shall

only be considered for medical devices intended for use by a healthcare professional in health care facilities. In such a case the manufacturer must afford health care facilities the opportunity to request the information in paper form in a timely manner. By way of exception, no such instructions for use are needed for devices in Class I or IIa if they can be used safely without any such instructions."

XII.

Annex I, point 13.3.a

BVMed agrees, in principle, with the need to include the name of the Authorised Representative (see, however the comments on art. 14). However we would urge the Commission to allow reasonable transition period for introducing this requirement. Modifications to the content of a label could be extremely expensive if appropriate time for stock exhaustion is not permitted.

XIII.

Annex I, Point 13.7

BVMed would like to reinforce and amend our previously submitted proposal to adapt the wording and intention of the MDD requirements on medical device labelling to allow instructions for use to be provided by "state of the art information delivery systems" such as, for example, electronic labelling instead of paper manuals in the European Union.

BVMed understands the intention of the Commission to take into consideration the wishes of some Member States to introduce in a controlled mode such "***state of the art information delivery systems***". However, we do believe that the clause 13.7 procedure chosen might result in lengthy negotiation processes and a rather complex system of sub-regulations on various scenarios for medical device applications.

We once again suggest amendment of the current requirements on "instructions for use" to be provided in paper format only, within the limitation of some basic principles already established in other regulatory systems and which thus should also ensure the safe use of medical devices within their intended use in the health care environment in the EU today. BVMed therefore would welcome in particular the deletion of the term "***leaflet***" in point 13.1, sentence 4, which anyway represents an undefined term, from the text of the MDD. Instead we propose the above new wording of Annex I, point 13.1. Within this context Annex I, point 13.7 should be deleted

XIV.

Annex I, point 13.8

This is not an essential requirement and, therefore, should not be included in annex I. It is not clear what the role of the Art 7 committee is on a subject, which has been extensively discussed on the past and on which all stakeholders have reached a consensus. We believe that the Commission might have all the necessary elements to intro-

duce this practice without the need to get Art. 7 support. (See also comment to art. 13.1.d).

XV:

Annex II, point 2, 2nd sentence

(ditto: annexes V and VI, point 2, 2nd sentence each)

"The manufacturer must affix the CE marking in accordance with Article 17 and draw up a written declaration of conformity. This declaration must cover a given number of the products manufactured and be kept by the manufacturer."

This comment does not refer to an amendment under discussion, but it intends to change the current wording of the directive. This comment is also valid for Annex V and VI MDD.

In practice this requirement is not meaningful and as a matter of fact can only be fulfilled - e.g. for continuously manufactured single use devices - by formal paperwork without any benefit. It is much better to allow an "unlimited" CE conformity declaration, i. e. starting with a specified lot no. or a declared date.

Change to: ***"... a given number, the first lot number or the first putting into service date of the products / references manufactured ..."***

Note: The wording of Annexes II/V (point 2, 2nd sentence) and VI (point 2, 2nd sentence) is not congruent in this clause:

"... must cover a given number of the products ..." or "... must cover a given number of identified specimens of the products ..."

Rationale: National competent authorities are issuing free sales certificates depending on their individual interpretation of the term of "a given number of products". It may lead to unjustifiable price differences, if the individual understanding on what "a given number" means, diverges.

XVI.

Annex II, Point 3.3

The intent of the amendment, as understood and accepted by BVMed, is to clarify that, in the context of a full quality system assessment; NBs have the duty to confirm the appropriateness of the design procedure by evaluating sample design dossiers. The term "representative" might generate confusion. The term ***"selective"***, appropriately explained in a guidance document, could better serve the cause.

XVII.**Annex II, point 6.1¹**

BVMed is not clear on the meaning of the term "lifetime of the device": some implantable devices (dental implants, for example) are going to stay in the patient for ever! Due to the rapid developments within the medical devices sector, would not be more appropriate to set a maximum time limit after the production of the device has been ceased?

XVIII.**Annex IV, point 8.3**

This new point is in opposition with point 8.1 of the same annex and is de facto resulting in up-classification of all class IIa products in IIb with all the consequences, This activity shall remain a post market surveillance one and not within the pre-market approval process. BVMed opposes this addition.

XIX.**Annex V, point 6.2**

This new point is in opposition with point 6.1 of the same annex and is de facto resulting in up-classification of all class IIa products in IIb with all the consequences, This activity shall remain a post market surveillance one and not within the pre-market approval process. BVMed opposes this addition.

XX.**Annex VI, point 6.2**

This new point is in opposition with point 6.1 of the same annex and is de facto resulting in up-classification of all class IIa products in IIb with all the consequences, This activity shall remain a post market surveillance one and not within the pre-market approval process. BVMed opposes this addition.

XXI.**Annex VII, point 3**

BVMed is strongly against the deletion of the term "**where appropriate**". It must be kept in mind that this annex is applicable to class I products such as tongue depressors, cotton gauzes, walking sticks, spectacles frames and several others for which the collection of clinical data, as specified at article 1.2.k (highlighting the "*various aspects of the clinical safety and performance of the device*") is not only superfluous, but also impossible to gather. We doubt that it would be possible, for example, to get permis-

¹ This comment applies also to point 7.3 of annex III, point 7 of annex IV, point 5.1 of annex V, point 5.1 of annex VI, point 2 of annex VII and point 4 of annex VIII.

sion to make studies on well established materials such as cotton gauzes and even the extension of "*published and/or unpublished data on market experience of the device in question or of a similar device for which equivalence to the device in question can be demonstrated*" may give rise to endless discussions with the NBs or the CAs.

XXII.

Annex IX, point 1.3

BVMed disagrees on this deletion; see comment to new rule 6.

XXIII.

Annex IX, Point 1.4

We agree with the concept, but the sentence "*or being part of a medical device*" should be deleted.

XXIV.

Annex IX, point 2.6

Add to the end of this rule "*unless it can be demonstrated that such replacement eliminates the risks arising from a continued use of the device*". For instance, if risks arise from gradually increasing degradation or leaching of materials due to prolonged contact with the patient, then the risks might be mitigated by frequent changes using new materials.

XXV.

Annex IX, rule 5

There is no explanation for this addition; from a technical stand point, this does not make sense. BVMed opposes to the modification.

XXVI.

Annex IX, rule 6

- Could the Commission please duly substantiate the reclassification of these devices from Class I to Class IIa.
- Could the Commission please clarify what ends are intended by this reclassification.
- What alternatives to this reclassification has the Commission considered?
- Could the Commission please provide information on the costs of implementing this change for industry?

- What transition period has the Commission in mind should this reclassification go ahead?

BVMed is not aware of any rationale for this modification, which will result in a reclassification, not previously agreed, of several devices without justification. We believe that if need be to up-classify these products the appropriate procedures contained in the directive should be applied. If this amendment, however, is linked to the comment made in the Council report on some "inconsistencies" in the classification rules, then it is not clear why the general rule (class I) has been upgraded to a special rule (class IIa for single-use surgical instruments) and not vice-versa. It is important to note that the peculiar difference between reusable and non reusable instruments (e.g. sterility) would be evaluated by a Notified Body even if the single use surgical instruments are classified in class I sterile.

XXVII.

Annex IX, rule 15

BVMed is not aware of any rationale for this modification, which will result in a reclassification, not previously agreed, of several devices without justification. We believe that, if there is a need be to up-classify these products, the appropriate procedures contained in the directive should be applied. If this is linked to the comment made in the Council report on some "inconsistencies" in the classification rules, then it is not clear why the general rule (class IIa) has been upgraded to a special rule (class IIb for contact lenses) and not vice-versa. It is worth noting that the exception for contact lenses disinfecting solutions was triggered in the first place by the need to have more controls on products, which are commonly used by lay persons. BVMed proposes the omission of this addition.

XXVIII.

Annex IX, rule 17

BVMed does not understand why a previously accepted modification (to change "utilising" into "***incorporating or being made of***", as in the October text) has been dropped. The modification was aimed at aligning the text of the rule to the text of the relevant MEDDEV-document and to reduce the number of uncertainties in classifying products, which could, in their manufacturing cycle, have been in contact with animal origin materials. We cannot believe that the amendment is aiming at reclassifying a huge number of products into class III or to compel the industry to find alternative materials. The previous proposal should be reinstated.

XXIX.

Annex X

BVMed, recognizing that the proposed text is a faithful representation of the agreement reached at CETF level, maintain its support for its content. In the event that the text is modified as a consequence of the consultation procedure or of the discussion at Council level, we maintain the right to submit additional comments.

C. Further proposals.

BVMed regrets that the current text does not address the issues related to the practice of reprocessing devices intended by their manufacturers for single use only.

BVMed understands that the Commission services take the view that this activity is outside the scope of the directive since it happens after the placing on the market of the products.

BVMed is of the opinion that a lack of regulation in this field represents a threat for patients' safety, which is one of the prior objectives of the Medical Devices Directive (see recital 5 of the preamble).

Furthermore, due account should be taken of the European Commission's "Guide to the implementation of directives based on the New Approach and the Global Approach", where it is stated in Point 2.1 that **"A product, which has been subject to important changes that modify its original performance, purpose, and or type after it has been put into service, may be considered as a new product. Where a rebuild modified product is considered to be a new product, it must comply with the provisions of the applicable directives when it is placed on the market and/or put into service."**

Moreover, it is well known that reprocessing of single use devices takes place in certain Member States and such reprocessed products circulate within the internal market across Member State borders, which is an additional argument to justify the intervention of the European legislator.

BVMed shares the view of most member States that it is appropriate to consider the status of "single use only" as part of the intended use as specified by the manufacturer. On this basis, whoever reprocesses a device intended for single use only and then renders the device available to the user for a new intended use (multiple instead of single use) is, in fact, putting the product into service for the "unintended re-use". This, according to article 2 of the directive, requires that the product complies "with the requirements laid down in the Directive when duly supplied and properly installed, maintained and used in accordance with the intended purpose [re-use]" (e.g. shall be CE marked). The reprocessor, however, may not be placing the product on the market, but will put it into service for re-use. Due to the specific risks and safety concerns inherent in the reprocessing of single use, and taking into account the impossibility for the reprocessor to CE mark the product, it is appropriate that a special set of requirements should be included in the Directive to cover this practice. We suggest that these reprocessed product should not bear the CE marking.

A tentative proposal could be along the following lines:

At the end of art. 1.2.f, to add the following:

"Reprocessor: Any legal or natural person which reprocesses a medical device (intended for single use only by its manufacturer) after its first use, to render it available for subsequent putting into service."

"Reprocessed device: any medical device, intended by its manufacturer for single use only, which has been subject, after its first use, to reprocessing being offered for subsequent putting into service."

At Art. 2 add:

"Without prejudice to the right of Member States to prohibit reprocessing of devices intended by the manufacturer for single use for the protection of public health, Member states may allow the reprocessing of such devices and the subsequent putting into service of such devices only if they meet the requirements set out in article 11.6.b."

At Art 11.6 add:

"11.6.b: When CE marked single use devices are reprocessed by any legal or natural person for their reuse, such reprocessed devices can only be put into service if the reprocessor has applied the relevant procedures outlined in Annex II. The reprocessed devices shall not bear the CE marking."

The requirements placed on manufacturers as outlined in Annex I and II are applied equally to reprocessors. The reprocessor shall confirm that the existing or modified design meets the requirements of this directive."

At article 14 add:

"14.5: Reprocessors shall notify to the Competent Authority of the Member State in which they have their registered place of business of the address of the registered place of business and the nature and type of devices reprocessed."

At annex I:

"13.1.b Reprocessors shall supplement the information provided with the original device, with the information referred to at points 13.3.o, 13.3.p and 13.6.q"

13.3.o reprocessed devices shall not bear the name or trade name and address of the original manufacturer, but the name or trade name and address of the reprocessor.

13.3.p reprocessed devices shall bear in a visible place on the label and in the instructions for use and in clearly legible font the following:

❖ ***the indication "REPROCESSED DEVICE",***

13.6.q Reprocessed devices shall be accompanied by appropriate instructions for use which shall contain, in addition to the information referred to above,

❖ ***the detailed description of any risks introduced by the reprocessing.***

❖ ***the indication that any incident involving a reprocessed devices shall be reported exclusively to the reprocessor and to the Competent Authority and***

❖ ***a statement indicating that the patient should be informed of the additional risks caused by the reprocessing."***

At annex II:

Point 1:

replace "the manufacturer"" with "***the manufacturer or the reprocessor***".

Point 2: add:

"Reprocessed devices shall not bear the CE marking

Point 9 (new) Application to reprocessed devices: the reprocessor shall in addition to the conformity assessment procedures prescribed by this Directive, for each device, submit the following data for evaluation to the Notified body:

- ***Data related to the design of the reprocessing process and its validation, with justification for the reasons for reprocessing.***
- ***A full risk management file with an independent critical analysis of the acceptability of any risks introduced by the reprocessing***
- ***Methods to identify design changes by the manufacturer and to validate the continued conformity to this directive***
- ***A description of the measures taken to maintain the conformity of the device to them after reprocessing.***
- ***Label and instructions for use.***

The Notified Body shall review the above documentation and issue a certificate of conformity to the relevant requirements applicable to reprocessed devices.

Changes to the approved reprocessing protocol must receive further approval from the Notified Body."

BVMed

Berlin, 24/06/2005