

## Introduction

Eucomed welcomes the opportunity to comment on the Commission's consultation paper. We set out below as detailed a response to the Commission's proposals as time has allowed. We are working on further data which we hope will be of assistance to the Commission: in particular a more thorough analysis of the economic impact of a number of the proposals and an analysis of the likely impact on patients and clinical practice. We trust that this response will be received as a positive contribution to the Commission's process. We would welcome the opportunity to engage in a dialogue with the Commission on these and other matters.

Before answering the questions raised by the Commission, we hope it may be helpful to make the following points.

1. Recognising the importance of public confidence in its products and services, the Medical Device Industry has long supported strong and effective regulation in its sector. In the late 1980s, it was as a result of submissions by Industry to the Commission that the medical device industry was added to the programme to complete the Internal Market by 1992, and Industry collaborated constructively with the Commission in devising the necessary legislation. Industry has also taken a very active role in all the subsequent development of the original Device Directives as they have been adapted to technical progress. At the same time, Industry is very clear that device regulation needs to be proportionate and appropriate. The device technology has a quite different basis and the methods of design from the pharmaceutical industry; development, manufacture, testing and control of devices are equally different.<sup>1</sup>  
One of the things to be celebrated is that the European Medical Device Directives introduced not only a harmonised regulatory regime, but a new international paradigm for device regulation. It is a system that has strongly influenced regulation in other countries to the benefit of Europe. Above all it is a system that has been proven over 14 years effectively to protect the public interest without unnecessarily impeding Industry. There is no evidence of which we are aware that the level of protection enjoyed by patients under the European regulatory system is any less than that enjoyed (for example) by American patients under Food and Drug Administration (FDA) regulatory controls.  
The European model is a successful approach to regulation, which ensures a high level of patient and user safety while simultaneously enabling innovation and access to life enhancing devices, and has acted as a regulatory model throughout the world through the Global Harmonization Task Force (GHTF). As we illustrate below, the European system has given patients access to new medical technology years ahead of the US and Japanese systems.
2. In this context, we are concerned at the numerous assertions in the Commission's consultation document that there are substantial problems with the regulation of devices in Europe and the repeated indications that the Commission considers these problems can be addressed by submitting a substantial section of the Industry (e.g. some Class III and active implantable devices) and substantial aspects of the regulatory regime (borderline products

---

<sup>1</sup> The medical device industry is broadly based on engineering technology, whereas the pharmaceutical industry is based on chemistry and pharmacology. The effect of a medical device can be ascertained very reliably laboratory testing and evaluation. Blind comparative Clinical investigation may not be allowed ethically. Where clinical trials of devices are appropriate, they are conducted on a different scale and a different basis than trials of pharmaceutical products. The clinical performance of a device can be assessed with a small patient population. For example, in the absence of systemic effects to be analysed, a smaller number of patients are sufficient to confirm the clinical performance of a hip implant. On the other hand, issues of relative performance or longevity of such devices can only be determined by means of post market surveillance after many years of use. No company or clinician would engage in a clinical trial lasting ten years and involving thousands of patients before releasing a new hip implant onto the market. On the other hand, if post-market surveillance indicates unforeseen problems with a particular device, there may be reason to restrict its use after launch or even to require its withdrawal from the market. In contrast, the efficacy and side effects of a pharmaceutical compound are usually not obvious from laboratory experiment and can often only be determined by extensive clinical trials carried out prior to launch. Post-market surveillance will still be required, but pre-market clinical evaluation is normally mandatory. The economic profiles of the two industries are also relevant. The costs of research and development of a major new pharmaceutical are now c. € 1b. The time required completing the development and pre-market approval of such a product is typically in excess of 11 years. Once such products have been developed, the manufacturer will not lightly make changes to them.

In contrast, the development of a significant new medical device will cost in the region of € 5-10m and will take around 3 years to complete. The manufacturer will constantly upgrade that development because new generations of medical device technology are introduced at approximately 3 year intervals.

and device vigilance) to EMEA. Not only does the Device Industry think that this would be entirely detrimental to the interests of the public as well as the industry, but it sees no evidence of either the alleged problems or the reasons why EMEA would present the appropriate solution if those problems did indeed exist. This is all the more a matter of concern since two of the Device Directives (MDD and AIMDD) underwent an extremely long and thorough review, culminating in a report in 2002, in which no such problems were identified. On the contrary, while a number of improvements were identified, the report confirmed that overall the Directives had worked well, and that the areas that needed enhancement were relatively limited. We are unaware of any more recent information that suggests otherwise.

3. A number of changes have been introduced to the device regulatory regime as a result of the 2002 Report and the legislation implementing these changes was only published by the Commission in 2007. In our view it is necessary to allow these changes to become established and to assess their effect before further change is made.
4. The Device Industry is sensitive to the need to keep any regulatory regime up to date with technological development as well as to substantive changes in the regulatory expectations of society. There is no resistance to debating and participating in the development of appropriate changes to the current laws. We also share certain of the Commission's concern – for example about technical barriers to trade created by particular requirements unilaterally introduced by certain Member States and the opportunity to improve further the operation and co-ordination between Notified Bodies. However, that does not mean that we see justification for the Commission's proposal to introduce EMEA into the regulatory system for devices or to adopt policies similar to the pharmaceutical system rather than device regulatory controls. Instead we set out alternative proposals for building on the institutions already existing in the device field (article 7 committees, for example) which, in our view, could better address the concerns that we understand the Commission to have.
5. We are also concerned to avoid unnecessary increases in the cost of regulatory compliance. There is no resistance on the part of the Device industry to increased costs which are essential to a proper regulation of the Industry. However, we think that many of the proposals in the Commission's paper would lead to a substantial increase in the cost of regulation (both to the Device Industry and to regulators) that is not justified and that would damage the ability of companies – particularly SMEs – to develop the new products that patients and society in general need. It is our view that, if the Commission's proposals were enacted, the likely result would be to slow innovation and even to make unviable the development and introduction of a significant number of new devices.
6. We are also concerned that, although the Commission repeatedly states that it wishes to preserve the New Approach as the basis for device regulation, many of the proposals in the Commission's paper would significantly erode the New Approach and replace it with a quite different regulatory regime. Indeed, we would recommend that the Commission awaits the outcome of the separate, parallel review of the New Approach that is currently in progress, before it considers what, if any, changes might be necessary.
7. We are concerned at the emphasis on centralisation of control through EMEA that is contained in the Commission's paper. We fully accept – and indeed have repeatedly encouraged – the need for the flexible use of expert groups staffed by individuals with the necessary range of technology expertise. A structure for such groups already exists, although a clear definition of skills (both in terms of science and public health) needs to be defined and is referred to in our submission below. We would urge the Commission to support these existing initiatives rather than to seek to erect new regulatory structures.
8. We would urge the Commission not to view EMEA as currently structured as a suitable means of regulating the Device Industry or coordinating the current device regulatory system.
9. EMEA at present does not itself possess any significant expertise in device technology and would have considerable difficulty in identifying the experts with the necessary knowledge and experience of medical devices and device regulation that it could use for this purpose. Even in the pharmaceutical field, EMEA has limited technical capability of its own. To a great extent, EMEA delegates the task of appraisal and assessment of new pharmaceutical products to technical experts in the Member States' own national pharmaceutical regulatory bodies. Such an approach would not be possible in the device field. With few exceptions, the Member States do not themselves employ technical device experts to assess and regulate medical device companies and products. Instead, that work is done by the Notified Bodies designated by the Competent Authorities for that purpose. The Notified Bodies are

commercial organisations, and by virtue of its own rules (which forbid them to use commercial organisations) EMEA could not delegate work to Notified Bodies. We believe that EMEA would have great difficulty in identifying appropriate experts in device regulation, even if it were desirable for them to do so. To the extent that expertise exists outside the Notified Bodies (for example in universities and research organisations) it is already open to use by the Member States' Competent Authorities or by the Notified Bodies themselves. There is no need to involve EMEA to give it the ultimate task to act as a secretariat for these existing experts groups.

10. We would also urge the Commission to consider the effect on the Notified Bodies' business models if the appraisal of highest risk devices were removed from those organisations as suggested for example at option 1 of Item 11. The leading Notified Bodies have developed resources to deal with new device technology, and (although not on a par with EMEA's charges for the assessment of pharmaceutical products) those Notified Bodies earn significant sums from the assessment of highest risk devices. If that income stream were removed, we would expect that many of the Notified Bodies would face real difficulty in continuing their current activities. They would either have substantially to increase other charges or they would reduce their areas of activity. In addition current agreements between the EU, Australia and Canada should then be renegotiated.
11. We also comment below on the Commission's proposals to combine into a single legislative instrument all of the Device Directives. There are, of course, advantages in such consolidation. At the same time, we do not believe those advantages should be exaggerated. More important, for the reasons set out below, we do not support consolidation of the IVD Directive with the other two Medical Devices Directives.  
In more general terms, this recast shall be consistent with the Commission Communication of March 2005, which specifies that simplification means making things easier for operators. Any such action should not go beyond what is necessary to achieve the policy objectives pursued. It needs to be cost efficient and take the lightest form of regulation called for. In this respect, simplification intends to make legislation at both Community and national level less burdensome, easier to apply and therefore more effective in achieving their goals.
12. We have sought in our response to support wherever possible useful developments of the current regulatory regime. At the same time, we have made clear that we regard many of the Commission's proposals as having a potential negative impact on patient access and questionable added value to patient safety. We would urge reconsideration and open collaboration with all stakeholders, including Industry, to ensure that device regulation in Europe remains proportionate and appropriate. If this should not be the case, patient care and access to new medical technology is, in our view, likely to suffer. The international competitiveness of the Europe-based industry would also be reduced.
13. In any system there is always scope for improvement and we think that the recent legislative changes made as a result of the review of the Medical Device Directives addresses several concerns raised by the Commission in the present consultation and should be given time to prove themselves. We also recommend that the Commission support and build on the European regulatory structures that have been established by the Competent Authorities, and which in our view have considerable potential to deal with the concerns expressed by the Commission. As set out below, we would also support the establishment of a central registry for medical device (making the various national databases redundant). Above all, we would like to see the Notified Bodies Operations Group (NBOG) and the MD Compliance and Enforcement Group given more resource and authority. In particular, we recommend that (under the aegis of NBOG) a multi-national audit body be established that would engage with all the Notified Bodies to help spread best practice and give a greater assurance that the Directives are interpreted and enforced in a consistent fashion from country to country.

Eucomed would like to have the opportunity to submit supplementary comments once the text of the revision of the new approach legislation has been published. We will try to provide that additional input within one month of the measures being published

## QUESTIONNAIRE

**Item 1 Legal simplification: Do you see any positive or negative impacts of merging the nine texts into one legal text? Can you give an estimate of the costs of those impacts both in absolute terms and in terms of a breakdown of those cost components (e.g. per year or in man days)?**

There is an obvious attraction in having as few documents to which to refer in connection with any particular area of legislation. However, any exercise in consolidation needs to be considered in terms of the resource required, the time involved and the likely benefit to be derived. The directives are referenced often in the Technical documentation, the Declaration of Conformity, Certificates and other documents. Changing this reference will increase the workload for manufacturers and Notified Bodies to update their documentation.

We note that the statutory review of the IVD Directive is still underway. We see no advantage in seeking to merge the IVD Directive with the other Device Directives while this review is still in progress. In any case, the structure of the IVD directive is significantly different and it may not be possible to incorporate it in a consolidated text.

Particular attention should be paid to avoid the introduction of unintended changes during the consolidation exercise.

It is noted that directives are addressed to Member States, which have in some cases already merged the requirements (e.g. Germany); harmonization at European level will not necessarily mean harmonization at national level.

Many other directives apply to medical devices, like the Machinery Directive, environmental directives and regulations (WEEE directive, RoHS directive in the future, batteries directive, mercury directive, REACH, detergents...). It is much more difficult for manufacturers to keep oversight of these requirements than to comply with the different medical devices directives. We encourage the Commission to look into this issue and come with possible solutions, which would represent a great improvement towards simplification.

A particular manufacturer/division normally has reference to only one medical device directive and to the supporting guidance (depending on the type of device he makes). We have found no significant difficulty in dealing with the legislation in its current form.

**Item 2 Risk-based classification: In your opinion is such a risk-based classification system more desirable than the current European List system? Are you aware of any consequences for the protection of public health? Can you give an estimation of the costs or savings that would result from a change-over to this GHTF classification system?**

Eucomed does not have a position on this issue, which is of pertinence to EDMA

**Item 3: To your knowledge, are these the only medical devices currently not regulated at an EU level? Can you indicate others? Is the definition as given above accurate to describe these medical devices? Can you suggest an alternative definition?**

*All products that come within the current definition of “medical device” in the Device Directives are covered by regulation, unless the Directive in question contains specific exemptions. In the case of the general MDD (93/42/EEC), the only exemptions are certain products incorporating blood derivatives (which are already separately regulated) and certain products containing human tissue or cells and/or viable animal tissue or cells.*

The definition proposed in the Commission document needs to be expanded to include situations where materials and derivatives of human origin are utilised during the manufacture of a medical device. (This would be equivalent to the term ‘utilised’ in the animal materials legislation.)

*During the development of the Advance Therapy Medicinal Products Regulation, we argued that all tissue/cell engineered devices should be properly regulated under the MDD given certain amendments to the essential requirements and the testing required. Many of these products are now covered by the ATMP. With regard to those devices that are neither within the ATMP or the Device Directives, the MDD should now be amended or supplemented in order to cover the products concerned*

Alternatively, we would recommend that another approach should be considered whereby specific legislation is developed to cover these products rather than expand the MDD.

We have not identified any other types of medical devices that are not already regulated under the MDD.

**Item 4: In your opinion is it necessary to ensure full protection of public health to regulate these products as 'quasi medical devices'? Assuming that a Notified Body assessment would be necessary for these implantable or invasive 'quasi medical devices', can you estimate the impact in terms of cost for each of the three following options (per product, per year, man hours)?**

**The delimitation of these products can be done in different ways:**

**Option 1: Regulate as 'quasi medical devices' all implantable or invasive products which are not covered by another specific Community legislative regime (medicinal products, cosmetics, medical devices);**

**Option 2: Regulate as 'quasi medical devices' those products which belong to a category of products which also includes products with a medical purpose (for example, cosmetic contact lenses, as there are some contact lenses intended to be used for medical purposes, cosmetic wrinkle fillers, as there are some wrinkle fillers intended to be used for medical purposes, etc.);**

**Option 3: Regulate as 'quasi medical devices' those products that would be listed exhaustively in an Annex to the future Medical Devices Legislation.**

**What would be the socio-economic impact of these options?**

**Can you suggest any other options?**

Eucomed will respond on this issue of quasi-medical devices separately. It will not be possible to do so before the initial closing date for comments.

**Item 5:**

**– Which aspects of the revision of the New Approach do you consider of particular relevance to the medical devices sector, and why?**

**It could be necessary to deviate, modify or add requirements, as compared to the New Approach, to reflect the peculiarities of the medical devices sector, as unlike other industrial products, medical devices have a direct effect on the health and safety of citizens. What deviations, modifications or additional requirements would you recommend, and why?**

Eucomed does not consider that it can properly comment on the effects of the revision of the New Approach legislation on the medical device directives before the final text is made available..

Eucomed does not agree that the MDD is the only New Approach directive that addresses products that 'have a direct effect on the health and safety of Citizens'. All products covered by New Approach legislation can affect health and safety.

## **Item 6: In your opinion what changes are needed to the essential requirements:**

### **a) in general**

The latest revision of the MDD has just been completed after an exhaustive process, and the changes to essential requirements and other aspects of the Directives are now being transposed by the member states into national law. At this stage, no experience has been gained with those changes some of which were intended to address Commission concerns.

There is currently no evidence that further changes are required to the essential requirements. We accept that the position should be kept under review and further change may become necessary in the years to come. But in our view, change now would be premature.

We also note also that the current essential requirements are closely aligned with the GHTF essential principles of safety and performance, thereby promoting international regulatory convergence.

### **b) for non viable tissues and/or cells and/or their derivatives**

The provisions of the current legislation relating to animal tissues and derivatives (including the essential requirements) are seen as adequate.

*Non-viable animal tissues and their derivatives are already covered by the Device Directives and this control is well established. We are not aware of any evidence that the current essential requirements need to be amended with regard to such products, and we do not see the need for any such amendment*

Should non-viable human materials and their derivatives be added to the MDD there will need to be a review of the essential requirements – taking into account the relevant requirements already included for animal tissues – and there it is likely that minor amendments to the labelling requirements will be necessary so that the use of human materials in the product or its manufacture ('utilised in') – i.e. the presence of the human derivative in the product or the use of it during the manufacturing process – are declared in the labelling.

As we have stated above, the alternative is to craft specific legislation covering human materials and their derivatives to the extent that they are not included in the ATMP Regulation.

### **c) for 'quasi medical devices'**

Eucomed will respond to this issue separately.

### **d) to make medical devices more robust to technology change**

We are not aware of any need to modify the current wording of the essential requirements apart from removing the wording which currently do not allow the use of alternative labelling. They are drafted in general terms which allow for their application to novel technologies – e.g see the outcome of the recent review relating to nanotechnologies.

### **e) what new essential requirements could be needed and why**

**Anti-counterfeiting etc measures:** Eucomed believes that it timely to consider the issue of measures against counterfeiting. Auto-identification systems for unique device identification are being adopted increasingly and address this issue in part. Such systems are being introduced because of patient safety considerations, but often in an ad hoc manner and without reference to existing industry standards. This is occurring on a world-wide basis. Unless a standardised system is adopted the use of multiple coding systems is likely to confound the intended advantages and is already creating technical barriers to trade. Note that 'unique device identification' does not necessarily mean serialisation of individual devices.

**Item 7: Can you cite instances of Member States introducing their own national specific device, method or material requirements? Can you give an estimate of the costs arising from these differing specific device requirements? What would be the socio-economic impacts of the introduction of ‘harmonised specific requirements’?**

*We are not aware of any case in which “there is scientific agreement that a certain device, material or method is not safe” and in which there is no effective remedy open to the Competent Authorities. There are many cases in which there is scientific dispute about certain safety matters – for example the presence of certain plasticizers in a manufacturing process or the safety of certain sterilisation processes. However, these are not cases in which there is any clear scientific conclusion. In any event, if a Competent Authority has a real concern about the safety of a particular medical device, the Directives give it the power to intervene and to either require the product to be withdrawn from the market or for its supply to be restricted.*

*The fact that these powers are not frequently used does not mean that they are inadequate. It may rather be the case that there few occasions on which there is a need to use such powers*

There have been a number of national measures introduced in this area such as the French and Belgian application of the clinical trials directive, requirements for freedom from latex, specific labelling requirements, registration/listing requirements, etc. Eucomed would urge that such national deviations are addressed by the Commission under existing powers. Eucomed will be happy to assist by providing further information on these matters.

Eucomed will try to submit information on costs separately.

Eucomed is not aware of any evidence of a need for “harmonised technical specifications” in relation to devices, and we do not agree to their being introduced. If there are perceived deficiencies in standards, the Member States should engage more closely in the preparation of those standards, particularly where there is a mandate in force. Where there is a need for amendment of the standard and its requirement there is an existing mechanism for this in the directives.

**Item 8: The Commission intends to make some proposals concerning the functioning and the activities of the Notified Bodies, some of which could be cumulative. Furthermore two options could be put forward to strengthen the system. What is your opinion on each proposal and option and what would be an estimate of the impacts and costs involved?**

**Proposal 1**

**To increase transparency into the activities of Notified Bodies (e.g. obligation for the Notified Body to publish annual reports);**

*We have no objection in principle to the idea of annual reports. We understand that the Notified Bodies Operations Group proposed this some years ago, and to our knowledge, certain Notified Bodies already produce reports. However, we would need to know the detail of what might be proposed, before giving a full response.*

We would also observe that the EUDAMED system, complying with the current scope, and finalized, implemented and used, would ensure transparency into the activities of NB's without the need for separate publication of specific NB reports. For this reason, we emphasize the urgency of finalizing and implementing the EUDAMED system. This would not have an additional impact or costs for industry..

**Proposal 2**

**To develop a system of improved information exchange from Notified Bodies to Competent Authorities;**

Provided that such information would be well-structured and standardised, Eucomed supports, the idea of NB's to inform their respective CAs, but *we would need to understand the detail of any proposal before commenting fully.*

**Proposal 3**

**To ensure an improved cooperation between Competent Authorities with regard to the activities of Notified Bodies;**

In principle, Eucomed supports this proposal which would be complementary to proposals 1 and 2. Transparency of information covered by proposals 1 and 2 would result in greater opportunity for cooperation amongst CA with respect to the activities of NBs. This could support the ongoing monitoring of the activities of NBs and could contribute to the harmonization of NBs monitoring.

**Proposal 4**

**To impose the application by the Member States of sanctions and penalties where a Notified Body fails to act properly;**

Eucomed supports appropriate actions and /or measures with respect to NBs that fail to act properly.

At the same time, the outmost attention shall be paid to the consequences of any measure (e.g. suspension of notification) which may seriously affect all manufacturers which are using that Notified Body

**Proposal 5**

**To introduce measures to stop 'forum shopping' by manufacturers. Forum shopping is the informal name given to the practice adopted by some manufacturers of getting their products reviewed by the Notified Body thought most likely to provide a favourable opinion;**

Although the principles of the New Approach give the freedom to the manufacturer to chose (and change) any notified body "that has been designated to carry out the conformity assessment procedure in question according to the applicable directive", Eucomed has no evidence that "forum shopping" is applied to any great extent. In this respect, any potential for forum shopping would be eliminated by the increased transparency, ongoing monitoring of NB activities and increased cooperation amongst CAs as pointed out under proposals 1, 2 and 3.

## **Proposal 6**

### **To create an automatic link between accepted Safeguard Clauses and the withdrawal of certification for the related medical devices.**

Eucomed is in favour of appropriate implementation and application of Safeguard Clauses as defined by current MD directives. Considering the short lifecycles of devices, the timeline should also be short and well defined, and any actions taken should be based on scientific advice from the article 7.1 committee.

That said, we would not support an “automatic” link between use of the Safeguard Clause and withdrawal of certification. Each case should be considered on its merits. It may not be in the public interest for certification automatically to be withdrawn.

**The above proposals could be coupled with one or both of the following options:**

#### **Option 1**

**The reinforcement of controls on the nomination (including setting out and defining the role of accreditation) and monitoring of the Notified Bodies by Member States;**

Eucomed is strongly in support of option 1.

#### **Option 2**

**A centralised system of final designation and of control of monitoring by the Commission with the assistance of experts.**

Eucomed does not support option 2, but supports

- 1- a European accreditation organization to oversee and ensure harmonized operations of national accreditation bodies,
- 2- that potential notified bodies should be accredited by national accreditation bodies, and
- 3- that Member States shall remain responsible for the designation, notification and monitoring of the national Notified Bodies

**Item 9: What are the social and economic advantages and disadvantages of extending the role of EMEA in the medical devices legislative framework? If possible, and where appropriate, please express these social and economic advantages and disadvantages in terms of cost. What in your opinion is an appropriate timeframe for the assessment and approval of a highest risk category device? And**

Eucomed does not agree that there needs to be EMEA involvement in the manner suggested by the Commission. There are existing mechanisms to deal with the various roles proposed for the EMEA.

These include the availability of Article 7.1 committee mechanisms for dealing with urgent matters and the precedent of involving notified bodies (who prepare assessment reports) and competent authorities (who comment on the assessment report) as was done with medical devices containing animal materials. As far as Eucomed is aware, the latter mechanism was both effective in terms of member states' input to the process and the amount of delay before notified bodies could approve or reject products.

Should the Commission pursue the proposal to involve the EMEA without any involvement of Notified Bodies, the agency would need to be significantly restructured so that any medical device related functions were autonomous. By way of example, the FDA Centre for Devices and Radiological Health (CDRH), employs almost 400 people to administer and evaluate medical devices and IVDs. It is anticipated that a similar number of staff and external experts would be needed by the medical devices function of the remodelled Agency. Should the EMEA take up this role, for medical devices, there would need to be a significant shortening of processing times compared to those for pharmaceutical products.

We would try to revert with information on current costs at a later stage.

As previously advised, the expertise available to the EMEA does not currently extend to medical devices; the agency's (the CHMP) current statutory role in connection with medical devices is limited to devices containing stable human blood derivatives, and it is limited to the evaluation of safety and quality of such stable human blood derivatives. EMEA has also had a limited role in assessing the safety and quality of certain substances that may be incorporated in devices, being substances that could in other formulations be active medicinal substances.<sup>2</sup> There is a huge range of other types of medical devices to which the EMEA has had limited if any exposure to date. In addition, a very wide range of harmonized and other standards are referred to in the context of medical devices and the EMEA will have had extremely limited exposure to these documents.

Eucomed does not agree with the specific examples chosen by the Commission of "highest risk" devices. These examples are of products that have had considerable periods of safe use and it is not agreed that this type of products should automatically be presumed to be incorporated in the new category of "highest risk" devices. Eucomed suggests that this "highest risk" category be limited to truly innovative products where the risk assessment and risk management proposals identify particular unusual hazards. In addition, we urge that there be clear and transparent criteria by which medical devices would be deemed to fall within the proposed "highest risk" category, and an opportunity for affected manufacturers to present their views.

Moreover the current level of EMEA fees appears to us to be excessive compared to the current costs in the medical devices system. It is also pointed out that the number and frequencies of modifications to medical devices (equivalent to "variations" in the pharmaceutical sector) would put considerable strain on the agency's ability to process these in a timely manner.

---

<sup>2</sup> In this respect, Eucomed does not wholly agree with the Commission's description of EMEA's current involvement in the assessment of combination products. Under the Medical Devices Directive, EMEA is not responsible for evaluating devices "that are combined with an ancillary medicinal product". EMEA does not evaluate the device at all: that is the task of the Notified Body. The element in which EMEA is involved is the assessment of the safety and quality not of "an ancillary medicinal substance",.

**Item 10: If EMEA were to participate in the evaluation of highest risk category devices, which products should these be (e.g. medical devices consisting exclusively of non viable human cells and/or tissues and/or their derivatives and medical devices incorporating such cells and/or tissues and/or their derivatives with an ancillary action to that of the medical device, and certain products from the following categories: class III medical devices, devices using nano-materials, in vitro diagnostic and active implantable medical devices)?**

**As the EMEA expertise and approval process is already foreseen for 'viable' human tissues (under Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004), it would seem logical to also submit 'nonviable' tissues to approval via the same expertise and process. What in your opinion would be the social and economic impacts if this was the case?**

Eucomed does not agree with the Commission's linking of products controlled under a specific Regulation and those covered by separate and distinct medical devices legislation. Furthermore we cannot comment specifically to proposals related to "certain" class III medical devices without having a more specific list and rationale to consider. We would also suggest that IVD cannot be considered in general to be in the highest risk category particularly since there is no direct human exposure. Furthermore, Eucomed does not agree that AIMDs should be compared with viable human cells and/or tissues.

Concerning products containing non viable human tissues or cells, these have been specifically excluded from the ATMP since it was recognized that the ATMP system was not appropriate to cover these products, therefore the statement that **"it would seem logical to also submit 'nonviable' tissues to approval via the same expertise and process"** is at least questionable and surprising. The fact that EMEA has been given authority to review devices that incorporate viable cells or tissues is not a reason to give it authority to review devices that incorporate non-viable cells or tissues, which by definition cannot have any medicinal effect. We would point out the Medical Devices Directive has since its inception covered devices that incorporate non-viable animal tissue or derivatives thereof, and there is no evidence that this regime has in any way failed to protect the public interest.

Each device technology needs to be considered on its own right and a risk analysis needs to be carried out objectively to determine whether there are aspects of the technology that are not adequately covered by existing regulatory controls. In this context it is striking that (with the exception of viable cells and tissues) the recent review of the Medical Devices Directive and the recent debate over tissue engineering products did not identify any device that needed new or additional regulation. Indeed, in the field of nano-technology (cited as one example by the Commission) extensive research by regulatory authorities has concluded the devices incorporating such technology should be properly controlled under the Medical Devices Directive.<sup>3</sup>

If, in exceptional instances, there are grounds to believe that given devices would benefit from a closer relationship between the Notified Body and the competent authority, then a mechanism to endorse the conclusions of the NB by the relevant CA should be contemplated. Eucomed points out that such a mechanism was introduced under the animal material legislation and could be applied here. We see no reason to involve the EMEA in such consultation procedures.

Moreover, Eucomed will come at a later stage with its best evaluation of the incremental cost and delays in placing on the market should EMEA deal with the approval of devices.

---

<sup>3</sup> Reference to the N&ET report: [http://ec.europa.eu/enterprise/medical\\_devices/net/entr-2007-net-wg-report-nano-final.pdf](http://ec.europa.eu/enterprise/medical_devices/net/entr-2007-net-wg-report-nano-final.pdf)

**Item 11: Two basic considerations arise with an expanded role of EMEA in the evaluation of the highest risk category medical devices: (i) in what way does a file get submitted to EMEA for an opinion and (ii) What is the final decision making process? On both aspects some solutions can be proposed. Which ones, in your opinion, are the best ones and why? Can you suggest other modalities in order to involve EMEA in the evaluation of the highest risk category devices and to take into account the opinions delivered by EMEA?**

**(i) in what way does a file get submitted to EMEA for an opinion?**

**Option 1.**

**No Notified body involvement, thus obliging direct submission of manufacturers' files related to highest risk category devices to EMEA for an opinion;**

**Option 2.**

**A variation of option 1. Obliging manufacturers to directly submit their files related to highest risk category devices to EMEA, and EMEA then selects a Notified Body to act as a 'rapporteur'. The Notified Body 'rapporteur' then assesses the file and sends its recommendation to EMEA for a final opinion;**

**Option 3.**

**Maintain the Notified Body responsibility for the overall assessment of the files as it is at present, but oblige Notified Bodies to send their preliminary reports concerning highest risk category medical devices to EMEA for an opinion;**

**Option 4.**

**A variation of option 3. Keep the Notified Body responsibility for the overall assessment of the files but instead of a systematic assessment of the preliminary report by EMEA, oblige Notified Bodies to notify EMEA of all applications for evaluation of highest risk category devices and allow EMEA, on a public health interest basis, to select those evaluation reports on which they will give an opinion.**

**(ii) What is the final decision making process?**

**Two possibilities can be foreseen:**

**Possibility 1: For options 1 or 2 above, i.e. an EMEA opinion rather than a Notified Body certificate, the normal decision making process would be a Commission market authorisation based on a Comitology decision.**

**Possibility 2: For options 3 or 4 above, i.e. maintain overall responsibility with the Notified Body, then the system could continue as it is now, with the Notified Body issuing its certificate, but only if it had received a positive opinion from EMEA.**

Behind all of the Commission's proposals in this Section (and indeed in much of the rest of the Commission's paper) lays an assumption that EMEA would somehow be uniquely suited to bringing to bear an expertise on the evaluation of "highest risk" devices that would greatly enhance the situation and that this would not be possible in any other way. We reject such an assumption.

There is no evidence that the current system is not working. The Notified Bodies have already shown that they can cope with innovation. A more robust supervision of Notified Bodies (including their accreditation) would improve the system by reducing discrepancies between Notified Bodies.

A significant issue is where the technology expertise can be found that will be needed to address difficult questions about the introduction of genuinely novel and high risk technology.

In answer, we would suggest that such knowledge is found in notified bodies with specific device experience, in a relatively few specialist (typically university) research centres and within the companies developing the technology.

If it is required that the competent authorities are involved in this procedure of oversight it would be preferable to apply the system developed in the animal material directive.

Without in any way accepting the Commission's proposed options, we would comment further as follows:

Option 1 would de facto (if not de jure) remove the devices concerned from the New Approach which, as we understand, it would be contrary to the Commission's own intentions.

Such a result would be completely unacceptable.

With regard to Option 2, we see no advantage in the proposal. We do however note with alarm that the proposal would give EMEA the right to involve a Notified Body that was not of the manufacturer's choosing. Not only would this undermine another key element of the New Approach, it would

inevitably create significant confusion between the manufacturer's Notified Body and that chosen by EMEA.

Options 3 and 4 are similarly objectionable. They would undermine the New Approach and jeopardise the role of the Notified Body. They would introduce significant expense. In addition, this would require that a clear process is established to avoid uncertainty on what grounds Notified Bodies would refer issues to EMEA and ensure consistency between Notified Bodies.

It would seem that the Commission's concern is to guard against new technology being allowed onto the market without adequate scrutiny. In our view, the way to address this issue is not to throw away the current and well-proven system, but to build upon it. First, there needs to be an objective analysis of whether a new technology does indeed present significantly higher or different risk than existing technology. "New" does not equate to "high risk". Second, if there is a significant new risk to be addressed, there should be an objective assessment of where the necessary expertise can be found to analyse and advice on the risk. It is likely that the answer will lie in university or industry research centres that specialise in the particular technology in question. Such expertise is already available to Notified Bodies as and when required to help in the assessment of a particular.

Accordingly, we see more benefit in building on the work being done by the Notified Bodies Operations Group to maintain a horizon-scanning function and to identify the leading experts in particular technologies. This would enable Notified Bodies to call on such experts when appropriate, and for the Notified Bodies Operations Group to monitor whether this is in fact done. We would also observe that the involvement of industry in such horizon scanning would be both appropriate and highly beneficial. It is often industry that is at the forefront of such research. By involving industry, the identification of research centres would be facilitated, and the desirable exchange of information between industry and Notified Bodies in such matters would be encouraged.

**Item 12: Do you see any reason why the EMEA Medical Devices Committee should not also have the possibility to have access to all evaluation reports of the Notified Bodies in order to establish and monitor a high level of evaluation and to require corrective action where needed?**

We see no advantage in having EMEA involved in this procedure. Notified Bodies have shown their ability to ensure appropriate oversight of the products brought to them for evaluation. A more robust supervision of Notified Bodies (including accreditation), as proposed above would improve the system by reducing discrepancies between Notified Bodies.

For example, to reduce discrepancies, NB should load in a common database the evaluation report of Class III devices. Such information shall be available to all CA who would be able to recommend corrective action in case of identified non conformities.

Eucomed suggests that consideration be given to the inclusion for the evaluation report for “highest risk” devices in the Eudamed.

**Item 13: One or more proposals to improve the vigilance system could be foreseen to be appropriate. In each case can you give an estimate of the socio-economic impact of the particular proposal?**

**Proposal 1**

**Establish an obligation for the medical institutions and healthcare professionals to report incidents and to invite patients to do the same, to introduce timelines for reporting and corrective actions, to give certain publicity to the corrective actions of the manufacturer;**

We would welcome an obligation for the medical institutions and healthcare professionals to report incidents but this would appear to be a matter of national responsibility and potentially could be seen to interfere with matters of professional conduct.

**Proposal 2**

**Create an obligation for the Notified Body to periodically review the manufacturer's vigilance system;**

This requirement is already contained in the existing Directive (e.g. MDD Annex II, IV, V, and VI) and applied by the Notified Bodies. In addition, the new version of the MEDDEV 2.12-1 Rev 5. Section 7 includes this particular request as part of the description of the role of the Notified Body.

We would be concerned that a case by case event assessment carried out by the notified body would duplicate and in some case contradict the risk / hazard assessment performed by the member states under the Vigilance system.

**Proposal 3**

**Mandate EMEA to coordinate vigilance reports and to detect signals;**

We see no role for EMEA in this matter.

Under the current regulatory system, a manufacturer is obliged to report all adverse incidents that (broadly) involve death or serious injury or which if repeated could involve death or serious injury. Further than this, the manufacturer's quality management system will oblige him to record and investigate every adverse event allegedly involving his products, whether or not such events are reportable to the authorities. All such incidents must be investigated by the manufacturer and corrective action taken as and when appropriate. As it is the manufacturer, in consultation with relevant Competent Authorities, who is responsible for taking appropriate corrective and preventive actions, the role and potential value of EMEA in this proposal is not clear.

**Proposal 4**

**Allow the Commission to impose restrictive measures, on the basis of the opinion of the Medical Device Committee in EMEA.**

Depending on the detail of such a system, Eucomed could agree that the Commission should be allowed to propose (but not impose) restrictive measures on the basis of sound scientific opinions and following an appropriate and transparent process. However Eucomed does not consider EMEA to be the appropriate body to deliver such opinion. The Article 7.1 committee should be consulted by the Commission in order to propose such measures based on scientific opinion

**Proposal 5**

**Also, remembering that the medical device market is very much a global one, should there be provision for exchange of information on incidents and corrective measures at an international level? This happens now voluntarily through GHTF but could be strengthened.**

Industry is in favour of such a proposal. However, the system should be consolidated to become robust enough to support this extension. Specifically it should be linked to a commitment by all GHTF members and associated National Competent Authority Reporting (NCAR) system participants to apply the notification system and GHTF guidance globally and to maintain confidentiality of the report

content. Also the documents to be circulated should be better defined and a permanent secretariat should be established and funded.

**Item 14: In order to reinforce market surveillance, it could be appropriate:**

- to have a central European registration system for devices;**
- to redraft and rationalise the rules on market surveillance;**
- to strengthen the provisions related to the Commission on coordination; and,**
- in cases where the Commission has to take a decision, to have the possibility to ask for a scientific opinion of the Medical Device Committee in EMEA.**

**Do you see any problems with these measures to increase the integrity of market surveillance? Can you suggest other improvements?**

- to have a central European registration system for devices;**

Eucomed strongly supports the concept of a centralised registration system, providing this system will totally replace existing national systems. The EUDAMED system was proposed to perform this purpose and should therefore be implemented without further delay.

- to redraft and rationalise the rules on market surveillance;**

Eucomed supports measures intended to rationalize rules on market surveillance. However we have not seen detailed proposals on how this would be implemented and therefore we are not in a position to give comments on this proposal

- to strengthen the provisions related to the Commission on coordination;**

Coordination at EU level of market surveillance activities is welcomed by industry.

- in cases where the Commission has to take a decision, to have the possibility to ask for a scientific opinion of the Medical Device Committee in EMEA.**

Eucomed see no role for EMEA in this procedure. It is suggested that the Article 7.1 committee be used for this purpose. The input of appropriate experts will be needed in these procedures

**Item 15:**

**The Medical Device Committee in EMEA could provide a joint opinion together with the Committee for Medicinal Products for Human Use (CHMP) on the appropriate qualification of a product.**

**It can also be envisaged that the Committee on Medical Devices in EMEA could provide an opinion on the classification of a medical device. Or indeed that EMEA could give scientific opinions or advice on other technical matters related to medical devices.**

**What would be the health or economic impact of such a system in your view?**

It is however agreed that a central system is required for decision-making and greater legal certainty on the status of particular products that will be applicable in all member states. *One of the reasons for changing the Article 7 procedure in the recent amendments to the Device Directives was specifically to achieve this objective.*

**Item 16:**

**It would be appropriate to evaluate the GHTF guidance documents and carry over as much as possible into the European framework. Can you (roughly) estimate the costs stemming from international regulatory divergences? What are the positive and negative impacts of Europe harmonising to the GHTF global regulatory model? To what extent should European legislation reflect the GHTF global model:**

**Fully?**

**Only where possible?**

**Please explain which areas are possible and why**

**Not at all? Please explain why**

**Which GHTF guidance documents would you recommend to be carried over into European legislation? If fully aligned, can you estimate the savings this would bring about for European businesses? What would be the added value in terms of protection of public health?**

Eucomed is generally supportive of moving to the GHTF model. However, careful consideration will need to be given to how individual measures will be changed – this is in particular because of differences in classification and the use of the STED. An appropriate transition period will need to be allowed where requirements and recommendations are amended. Both of these could have a significant impact on the cost of compliance in Europe. Harmonisation with the GHTF model would have advantages provided that all founder members also implement the GHTF recommendations.

Information on cost implications will be submitted separately.

**Item 17: Can you suggest any specific proposals to strengthen the European system against the criticism of having un-equal checking and control of imported versus domestic medical devices?**

We have no evidence to support this criticism. However if the designating authority responsible for monitoring of notified bodies' activities finds any indication of such practices, then they should be dealt with by the designating authority as appropriate, in particular ensuring appropriate control of sub contractors.

Furthermore, Member States shall ensure proper enforcement of Regulation 339/93 on controls of products entering the Community market.

We consider that additional requirements applicable to importers and distributors shall be considered

**Item 18: For those cases where there are no legal requirements in the importing country, a separate export certificate regime could be developing based upon the Directives, say requiring medical devices for export to be treated in the same way as medical devices for the Community market (affixed with CE marking) or requiring the manufacturer to have a quality management system (Device GMP). Please give your evaluation of such proposals in terms of social and economic impacts.**

Eucomed would point out to the Commission that the supply of products to third Countries not having their own national requirements applicable to medical devices is not a simple issue. In some cases, an export certificate would be useful because the CE marked product is to be supplied to the market concerned. However for a number of reasons, the product supplied to a third country might be an earlier version of a CE marked device for which the certificate is expired. This situation might require two parallel systems. The first would be for situations where the current CE marked product is to be exported when a conventional export certificate might be appropriate, the second case is when the product to be exported differs, and in which case some form of quality system evaluation would be more relevant.

Eucomed would like to discuss this further with the Commission before providing a definitive response.

**Item 19: Can you suggest appropriate measures within a future legal framework for medical devices that could help battle against the counterfeiting of medical devices?**

While the problem is still relatively limited in the medical devices area, we agree that preventive measures should be put in place to avoid proliferation of counterfeit products in Europe.

We suggest that, in the implementation of the rules for importers and distributors, special attention is given to this issue.

We would advocate and support the use of the GS1 system of standards to limit counterfeiting and also provide a useful traceability system.

**Item 20: Which elements in the Medical Devices Directives have given rise to particular legal uncertainty in regard to their application? Did this increase administrative burden, e.g. costs to get familiar and to understand the applicable legislation? Can these costs be quantified, e.g. by assessing the necessary man-hours? How can these costs be reduced without compromising the safety of medical devices placed on the market?**

We agree with the Commission on the potential issues coming from fragmented implementation of the directives, but we are unsure that the consolidation alone of the directives into one legal text would solve this problem. What is needed is a quicker procedure allowing the Commission to force member states to amend any implementing measure which does not conform to the directives. In any case we doubt that the IVDD can be merged successfully with the other two directives.

Concerning the uncertainties related to classification, we believe that the revised directives contain sufficient new requirements and means to address this issue and this revised regime should be evaluated first and only then, if appropriate amended.

The Directive itself does not contain issues which cause legal uncertainty. Conversely, the interpretation given by several Member states have given rise to discrepancies in the way NB operate and interpret the requirements.

All examples below generally do not hamper the free circulation of devices, but introduce an uneven playing field for manufacturers:

5-year renewal of the CE declaration of conformity decisions

Under Article 11.11 of the MDD it is provided that EC declaration of conformity decisions and EC type examination certificates have a period of validity of 5 years, which may be extended upon application for further periods of 5 years.

The requirements to extend the certification are not clearly defined and leading to bureaucratic and burdensome 5 years reviews often going beyond the initial review.

An alternative could be (similar to what has been done under the revision of the pharmaceutical legislation) to have once an issuance of a certificate combined with a duty to send a summary of vigilance findings (like the so-called PSURs, Periodic Safety Update Reports) together with an explanation of the risk management measures that have been taken by the manufacturer to mitigate risks and maintain appropriate risk/benefit balance. The current practice is a competitive disadvantage since other regulatory regimens do not require such extensive review of existing products in addition to post market surveillance mechanism.

Classification of medical devices

Reporting rules for vigilance

Freedom for member states to organise the notification of placing on their territories medical devices has generated a full set of requirements, which, although similar are slightly different and require an extensive administrative work for manufacturers. This is often used as a prerequisite for the access to public tenders.

**Item 21: Would it be preferable to regulate medical devices by means of a Regulation (i.e. a directly applicable legal act, cf. Article 249(2) of the EC Treaty)? What would be the socioeconomic impact of this option?**

The suggested transformation of the medical devices legislative instrument into a Regulation has some merit and needs to be carefully evaluated. Moving from a regime where some requirements are left to the national authorities, to something that will be clearly and consistently defined will require considerable effort. Care will need to be exercised to ensure that the process of developing such a new legislative instrument does not end up with the adoption of more specific and prescriptive requirements without due justification

The cost and impact of this can only be evaluated on the basis of a proposal.

**Item 22: It could be envisaged to collapse all the quality system conformity assessment modules into one module, analogous to the current Annex II module in Directive 93/42/EEC concerning medical devices. Would this be a simplification of the system? What would be the benefits in terms of administrative burden and cost? If certain conformity options are to be retained, which ones and why?**

**What are the convincing social and economic arguments to keep them? Can you estimate the negative impact if they are phased out?**

Eucomed is not convinced that there is any need to merge the modules on Quality management System into one module. .

It is agreed that Annex II should be available to all device manufacturers (at their choice). However it is important to maintain the different options within the Quality management systems. For some manufacturers a simpler quality management system may be perfectly adequate. In particular type examination may be perfectly acceptable for manufacturers of certain kinds of product – for example makers of customised devices such as central decontamination installations.