



## RECAST OF THE MEDICAL DEVICES DIRECTIVES PUBLIC CONSULTATION

As a medical professional organisation, the European Society of Cardiology (ESC) welcomes the opportunity to comment on the Commission's consultation paper. Our specific comments are presented below. We trust that this response will be received as a positive contribution to the Commission's process. The European Society of Cardiology would welcome the opportunity to engage in a dialogue with the Commission on these matters.

As an introduction, the European Society of Cardiology would like to call European policy makers to restore the involvement of Health Professionals in their decision processes.

The European Society of Cardiology would like to insist on the importance of maintaining a balance between ensuring safety of new devices and keeping sufficient space for true innovation.

The heterogeneity of Notified Bodies across Europe, with requirements varying widely from one country to another, may be detrimental to patient safety, while it also constitutes a barrier to the development of new devices by not providing a clear and "universal" frame. There is a strong need for more coordination between Member States and their Notified Bodies for medical devices regulation and vigilance. A unified coordinating body would be welcome.

The ESC is also concerned about the possible risk of creating a bureaucratic giant paralyzing the market and the availability of Medical Devices for patients. Coupling competence and feasibility is critical, otherwise the new system might penalize both patients and industries. Protecting the patients is the ultimate goal, but a way to do so also consists in facilitating and strengthening the creative activity of the industry by creating a fluid regulatory process.

More specifically, the ESC recommends a systematic control of preclinical and clinical findings for Medical Devices' approval. For clinical data, we strongly advice to adopt rules defining the appropriate size of controls required for Medical Devices approval (eg follow-up years) and post marketing surveillance.

Objective Performance Criteria (OPC) of Medical Devices such as those applied by the FDA since 1994, should be implemented and regularly updated by appropriate European bodies.

The ESC also reiterates the need for clinical research on Medical Devices to be reinforced in Europe.

### 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)?

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**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?

A risk-based classification system would be preferable to the current list system. For diagnostic imaging, risk assessment should include long-term consequences of ionizing radiation. There are also risks from making a wrong diagnosis and so accuracy of different techniques should be considered.

Special attention should be kept in mind regarding monoclonal antibodies imaging agents linked to isotopes (There is a strong dependence between the efficacy of the medicinal product and the technical equipment used to create the image. This should be taken into consideration in relation to the radioactive dose administered with the antibody).

For invasive/ implantable devices, risk assessment and consequent classification is of paramount importance for information of the operators and public health protection. This should be mainly based on clinical trials: testing both efficacy and safety of Medical Devices.

**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?

**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.);



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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?

**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?

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

- a) in general?
- b) for non viable tissues and/or cells and/or their derivatives?
- c) for 'quasi medical devices'?
- d) to make medical devices more robust to technology change?

What new essential requirements could be needed and why?  
Please also estimate the socio-economic impact of the changes in each case.

For diagnostic imaging, within each technical industry, standard phantoms should be used so that the performance of one machine can be compared against another. Such phantoms should be developed by industry with the Notified Bodies. The results of phantom testing should be publicly reported.

When manufacturers change the construction of their imaging equipment, or the methods of processing the signals, or the software that is used to produce measurements, these changes should be publicly stated; and a log of such changes should be accessible to clinical users. Thus, there should be much greater transparency in the performance of any particular system against industry standards. The new regulations should determine an acceptable level of accuracy.

It is impractical to propose that medical diagnostic imaging equipment should not be introduced until the manufacturer can cite clinical trials that have demonstrated that use of this equipment leads to a measurable benefit on morbidity or mortality. Nonetheless, international standards for clinical guidelines now recommend that all imaging technologies should be evaluated in such clinical trials, with hard clinical end-points.

An alternative approach that could be introduced as a new essential requirement, would be that manufacturers of diagnostic imaging equipment (in certain categories, which would need to be carefully defined but which might include machines with capability of producing harm if their

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accuracy is poor or if biological side-effects are possible) should only be granted continuing permission to market their devices after a period of time (such as 3 years), if they can then resubmit detailed evidence obtained from appropriate clinical trials. A new essential requirement such as this would ensure that manufacturers of expensive imaging equipment have the responsibility to demonstrate clinical benefit and not just diagnostic performance or accuracy. This point is particularly important as, up to now, there have been virtually no clinical trials in the field of cardiovascular diseases to assess the potential benefits or harms of diagnostic strategies or equipments. This requirement would not stifle innovation or the prospects for SMEs of expanding their company – but it would meet some of the perceived public health need to evaluate diagnostic imaging objectively and limit ineffective options by controlling the continued marketing of equipment that does not convey special benefit or carry non marginal risks (radiations).

For implantable devices the approval for the market introduction should be granted only on the basis of demonstration of efficacy and safety by clinical trials (sample size, duration and end-points of trials varying according to the type and scope of devices). Long term post-approval observational studies (Registries) should be strongly recommended or made mandatory in specific situations (heart valves, vascular stents). This is crucial in many instances, as the long-term safety of these devices can only be assessed in large observational cohorts.

No applications for minor revisions of implantable devices should be allowed within 1 year before the expiry of the patent for a device. Any such request should be treated as a de novo application. Strict definition of “minor modification” should be applied. In particular, at present according to the medical device legislation, the Notified Body has to consult one of the competent authorities of the Member States or the EMEA with regards to the quality, safety of the medicinal substance incorporated as integral part of the device, including the clinical benefit/risk profile of the (the device incorporation of the substance into the device. Guidance is needed with regard to the non-clinical and clinical data required for this evaluation.

**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’?

**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);

Proposal 2

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

Proposal 3

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

Proposal 4

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

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;

Proposal 6

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

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;

Option 2

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

Improved cooperation and coordination between all the Notified Bodies is desirable, as well as a certain level of centralisation.

Specifically:

Proposal 1: Yes

Proposal 4: Yes

Proposal 5: Yes

Proposal 6: Yes, but only between "certified" Notified Bodies

An additional option would be for a European authority to grant a "certification" to National Bodies.

Option 2 looks preferable.

**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?

A Medical Devices division of the EMEA (or analogous body) assuming responsibility of approval and monitoring of highest risk category of devices is needed.

The advantage should be a better health protection, a disadvantage might be a bureaucratization of a field in rapid evolution with a drop of European innovation ability and competitive force. Separate divisions for each type of device might help combining the need of specific expertise and undertaking many processes in parallel.

The time frame may vary according to the type of medical device (see also response to item 6). There should be an obligation that the EMEA will adhere to set timelines and answers in writing when it fails to adhere to predefined timelines (<6 months).

**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?

Implantable cardiovascular medical devices should definitely be listed a high risk device. See also response to Item 9.

**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 of 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;

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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.

This question is difficult to answer not knowing the exact range and quality of competences of Notified Bodies and the areas of expertise that EMEA could cover.

Option 1: This effectively denies any function and then the very existence of Notified Bodies.

Options 2 to 4: The difference consists in the entity responsible for the “final” option. Option 2 seems more appropriate by considering Europe as a state in progress. Option 4 is an alternative in the case that, for political reasons, Notified Bodies should keep a role.

**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?

The risk in creating such a Committee would be create a bureaucratic giant, that would lengthen decision making processes due to the multitude of Medical Devices submissions, and consequently alter the innovation capacities of SMEs across Europe.

**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;

Proposal 2

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

Proposal 3

Mandate EMEA to coordinate vigilance reports and to detect signals;

Proposal 4

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

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.

Proposal 2 seems unpractical.

A combination of proposals 1 and 3 could be explored. However, many responses still remain unanswered, ie how would the Notified Bodies (which one? all?) cover the European continent? One answer could be to prospectively monitor sufficiently large cohorts of patients in whom a given device (or type of device) has been used.

**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,



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– 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?

**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?

As mentioned above, there is a risk of multiplying subjects involved, get different opinions and consequently lengthen decisional processes. For the benefit of the patients, it is essential that, while ensuring the safety of new devices, European administrative structures do not constitute a barrier to innovation, thereby delaying marketing of truly beneficial devices.

**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?

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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?

The EU legislation should indeed reflect all of the essential recommendations of the GHTF.

**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?

**Item 18:** For those cases where there is 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.

**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?

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**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?

**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?

**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?

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