# RECAST OF THE MEDICAL DEVICES DIRECTIVES
# PUBLIC CONSULTATION

## GENERAL COMMENTS

A number of the questions that appear in the public consultation document appear to suggest that high risk medical devices should be regulated in a similar manner to pharmaceuticals. I do not support this argument.

The structure of medical devices industry is completely different from that of the pharmaceutical industry with the domination of SME's and, through them, continuous technical innovation. Products are regularly improved through the introduction of new technology and/or features and satisfying user demands. This results in short product lives (for example, new versions of ventilators, vial signs monitors and baby incubators are launched every two to three years) and a very competitive market place. The industry already struggles with the cost of global regulatory compliance and can not support the high costs of a regulatory approach that moves closer to that for pharmaceuticals. It is notable that none of the other established regulators of medical devices are moving in such a direction (i.e. the USA, Canada, Australia, Japan).

Despite the tone of the consultation document (e.g. in Section 2(a) Emerging Weaknesses), I would argue that the three medical device directives continue to be enormously successful in safeguarding public health for the approximately 18,000 device types that are regulated as medical devices. They have had enormous positive influence on global medical device regulations. The Commission's previous surveys confirmed this view and led to relatively minor changes to the MDD when it was revised recently. This consultative document offers no evidence to the contrary. Is appears to be based on apocryphal evidence alone or the prejudice of those who believe that the New Approach is an inadequate regulatory regime for medical devices.

There will always be occasional well publicised problems with a few medical devices that will lead to calls from politicians for a strengthening of the regulations but this occurs under all regulatory approaches and, I would contend, the regulatory approach applied to pharmaceuticals has not eliminated such problems.

As an active participant in the GHTF, where I am Secretary of Study Group 1, I can offer the following insight to the opinion of non-EU regulators:

a) Most of the vital aspects of GHTF guidance are based on the groundbreaking approach embodied within EU directives (e.g. the role of essential principles of safety and performance, risk-based classification, definition of a medical device, use and oversight of third party bodies for conformity assessment, adverse event reporting, regulatory data exchange, the role of technical standards) and these are promoted to countries with emerging medical device regulations by all participants, including the US Department of Commerce.
b) Regarding conformity assessment, other regulators are not comfortable with the EU's "type evaluation" option. They do not believe it is as effective as a quality management based system (Annex II).
c) Regarding Notified Bodies, there is no fundamental objection to their use, provided the Regulatory Authority has the competence and determination to operate a proper accreditation and oversight regime (even the FDA is now using some independents organisations to review 510(k)s). The UK, Germany, France and some other RAs have international creditability in this respect, others do not.

d) The failure of the MRA negotiations is due primarily to (b) and (c).
e) All counties have difficulty in collecting adverse event reports and the UK is seen as the most successful regulator in the World as far as generating reports from device users. Surveys suggest the pharmaceutical regulators have an equivalent problem.
f) If the proposals incorporated into this consultation document with respect to the involvement of the EMEA are accepted, there will be a fundamental divergence from GHTF guidance documents.

Finally, the consultation document has been given wide international exposure. It includes negative statements unsupported by evidence. Where does this leave those of us who have supported the "European approach" to the regulation of medical devices over many years? Where does it leave Europe's contribution to the Global Harmonisation Task Force? What will patient representative groups think? How will industry answer the implied criticisms when it competes against devices that comply with US or Japanese regulations?

## SPECIFIC RESPONSE TO QUESTIONAIRE

### 1. Scope

**Item 1 Legal simplification:** Do you see any positive or negative impacts of merging the nine texts into one legal text?

*I see no great advantage in doing so and see it as a low priority measure.*

*The GHTF guidance documents suggest the AIMD and MDD may be easily merged. The IVDD directive would need significant changes before it could be merged (e.g. elimination of CTSs and the adoption of risk based classification).*

**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?

*Yes.*

*GHTF guidance is a risk-based classification system. No fundamental problems were raised during the extensive consultation process for the guidance document.*

**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?

*There are some medical devices that may have both a medical and non-medical use and carry the same risks in either role (e.g. breast implants, contact lenses for cosmetic purposes). I see an advantage in extending the medical device regulations to incorporate them – not by changing the definition of a "medical device" but by adding a clause that says, for example: "for the purpose of this directive, contact lenses for cosmetic purposes will be subject to the same requirements as contact lenses with a medical purpose".*

*Other devices to consider are: tampons, lasers with a cosmetic application, equipment providing medial gases to a hospital bed.*

**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?

*I support none of these options – see answer to Item 3.*

**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?

*Until the changes to the New Approach are finalised, I can not offer an answer to this question.*

**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.

*GHTF SG1 is about to review its document that lists "Essential Principles" and has a number of suggestions for change to consider. These include changes incorporated into the revised MDD and the changed role for the EU's Machinery Directive. The outcome of this work will be available to the EU.*

**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'?

*The balance between the directives and technical standards works well and the occasional difference of interpretation is of no practical problem. The approach has been adopted by the GHTF.*

*The inclusion of technical requirements directly into the IVDD directive was unnecessary and has not offered benefits.*

**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);

*I see little benefit unless there is consistency in the contents of an annual report. The Commission would need to specify what form such annual reports would take.*

**Proposal 2**

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

*I disagree with this proposal since, if the CA is providing proper oversight of their NBs this is unnecessary. The fundamental problem is inconsistent oversight.*

**Proposal 3**

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

*I support this proposal. Each CA must be involved in the designation and auditing of its own NBs and not sub-contract the task to a national accreditation organisation. I suggest some audits (say every second year) include experts from other CAs who have acknowledged expertise in this area (e.g. UK and Germany).*

**Proposal 4**

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

*I disagree with this proposal. The directives already provide the CAs with the necessary powers if they choose to use them.*

**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;

*I disagree with this proposal and do not believe it is a significant problem. New Approach directives allow the manufacturer to choose which NB it appoints and this helps control the cost of the work done.*

**Proposal 6**
To create an automatic link between accepted Safeguard Clauses and the withdrawal of certification for the related medical devices.

*I disagree with this proposal. The directives already provide the necessary powers. Where is the evidence that the Safeguard Clause is inadequate?*

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;

*See answer to Item 8 Proposal 3. I suggest a panel of experts in the designation and auditing of NBs be selected from those CAs with a record of success in this area (e.g. Germany and UK) and that members of this panel be included in the activities of the CAs (including Germany and the UK etc.) in respect to the designation and auditing of their NBs. Training sessions should be provided, also.*

*A method of openly reporting on outcomes of this approach should be agreed.*

*Also, the requirements on NBs have been strengthened in the recent revision of the MDD. Is there <u>evidence</u> that the changes are insufficient?*

**Option 2**
A centralised system of final designation and of control of monitoring by the Commission with the assistance of experts.

*I believe Option 1 is a better way to proceed. Responsibility and involvement must remain with the CAs.*

**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.

*I see no advantage to the proposal. There is no evidence presented that the directives are inadequate for the regulation of high risk medical devices. Have the Safety Alerts issued by CAs been analysed to demonstrate that high risk devices are a particular problem? In any event, the EMEA has failed to prevent well publicised problems with medicines, despite the enormous regulatory burden it represents – why would they do better with medical devices?*

*The involvement of the EMEA should be avoided. Industry can not afford the cost of involving the EMEA or the delays while it completes its tasks (see General Comments, above). Patients can not afford the inevitable consequences of such a change.*

*The EMEA has no expertise with medical devices. The medical device "component" would never have an "equal footing" with medicinal products. You only have to look at the effect on merging MCA with MDA within the UK, to predict the outcome.*

What in your opinion is an appropriate timeframe for the assessment and approval of a highest risk category device?

*90 days.*

**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?

*The involvement of the EMEA should be avoided. Industry can not afford the cost of involving the EMEA or the delays while it completes its tasks (see General Comments, above). If they do become involved, the devices designated will be those where innovation slows down, selling prices increase and market entry is delayed. Is this what patients are asking for?*

*If its "logical to also submit 'nonviable' tissues to approval via the same expertise and process as viable ones", why wasn't this done under Regulation (EC) No 1394/2007? Clearly, the difference in viability was believed to be crucial – what has changed?*

**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;

*I disagree with this option. It would have an adverse influence on NB income and therefore their viability for no gain in terms of safeguarding public health.*

*Cost to the manufacturer would be significantly increased and timescales would increase to an unacceptable extent.*

**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;

*I disagree with this option. It would have an adverse influence on NB income for all of the NBs other than the one acting as a rapporteur and therefore their viability, with no gain in terms of safeguarding public health.*

*Cost to the manufacturer would be significantly increased and timescales would increase unacceptably.*

**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;

*I disagree with this option. Cost to the manufacturer would be significantly increased and timescales would increase unacceptably.*

*If it is decided that there is a need for a public health authority to be involved, it should be the CA with responsibility for the NB concerned. However, they are likely to charge the manufacturer for their opinion and the cost of approval will increase.*

**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.

*I disagree with this option.*

**(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.

*I disagree with this option.*

**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.

*I strongly disagree with this proposal. The NBs and CAs must retain responsibility for decisions reached.*

**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?

*I strongly disagree with this proposal. It destroys CA responsibility, has considerable cost implications and there is no gain in terms of safeguarding public health.*

**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?

*Where is the evidence that there is significant under-reporting? All counties have difficulty in collecting adverse event reports and the MHRA is seen as the most successful regulator in the World as far as generating reports from device users. It is neither surprising or unacceptable for different CAs to receive different numbers of adverse event reports. Provided one CA receives and investigates an adverse event report it will act on behalf of the whole of the EU. Unlike with medicines, a single report could be significant and we are <u>not</u> looking for statistically relevant trends to appear.*

*The exchange of data between RAs, as operated through GHTF guidance, is working well. It effectively pools the experience of the global regulatory community.*

*I would put more emphasis on post-market surveillance alongside the existing adverse event reporting requirements.*

*The EUDAMED system is not working. Rather than "reinventing the wheel" why not address this issue?*

**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;

*The FDA tried this approach and it didn't work. The MHRA system for generating reports from device users is voluntary and works well. The trust between the device user and the MHRA has taken years to establish.*

**Proposal 2**

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

*This should be happening already as part of a NBs QMS audit of the manufacturer. Where is the evidence that it isn't?*

**Proposal 3**

Mandate EMEA to coordinate vigilance reports and to detect signals;

*I disagree with this proposal. To carry out this role the EMEA would have to have expertise for all medical devices, not just high risk ones, and the cost of this additional resource would have to be recovered from manufacturers.*

*As well as these objections, I would ask for evidence that the EMEA does a good job for medicinal products.*

**Proposal 4**

Allow the Commission to impose restrictive measures, on the basis of the opinion of the

Medical Device Committee in EMEA.

*I disagree with this proposal. To carry out this role the EMEA would have to have expertise for all medical devices, not just high risk ones, and the cost of this additional resource would have to be recovered from manufacturers.*

**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.

*I agree with this proposal.*

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

- to have a central European registration system for devices;

*I agree but first you must demonstrate a central database can become operational. Experience is not encouraging.*

- to redraft and rationalise the rules on market surveillance;

*I agree with this proposal.*

- to strengthen the provisions related to the Commission on coordination; and,

*I agree with this proposal.*

– 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.

*I disagree with this proposal. As an alternative, form a group of experts selected from the experienced CAs and write a suitable operational procedure.*

Do you see any problems with these measures to increase the integrity of market surveillance?

Can you suggest other improvements?

*See details above.*

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**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?

*I disagree with this proposal.*

**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?

*I support the proposal for the EU to adopt <u>all</u> GHTF guidance documents. Documents that I recommend are: the Summary Technical File; Definition of 'manufacturer'; Classification of IVDDs, Conformity Assessment of IVDDs; Registration and Listing.*

*This will be of considerable benefit to industry and reduce the cost of gaining regulatory approvals throughout the world.*

*If the proposals incorporated into this consultation document with respect to the involvement of the EMEA are accepted, there will be a fundamental divergence from GHTF guidance documents.*

**8. Imports, Exports and Counterfeiting**
**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?

*Where is the evidence that the situation in the EU is any worse that that in other jurisdictions?*

**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.

*I agree with this proposal.*

**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?

*No.*

**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?

*The definition of a manufacturer.*

**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?

*I have no view on this suggestion.*

**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?

*I would support this suggestion. If type evaluation is retained, its application should be severely limited e.g. to where the annual production volume is limited to only a few devices.*

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**SUBMITTED BY**

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