

POSITION PAPER Joint Medical Device Industry Contribution To Public Consultation on Recast of the Medical Devices Directives¹

The Medical Device Industry represented in Europe through the following European Trade Associations – COCIR, EDMA, EHIMA, EUCOMED, EUROMCONTACT, EUROM VI and FIDE, represents 95% of the European Market.

The Medical Device Industry has always supported strong and effective regulation in its sector and has always taken a very active role developing regulations at national, European and global level through the Global Harmonization Task Force.

The European Medical Devices Directives (MDDs), based on the New Approach, have influenced the regulatory framework at the international level over the years. This European Model has proven its efficiency, ensuring a high level of patient and user safety while simultaneously enabling innovation and timely access to devices critical for healthcare.

The Medical Device Industry believes that the current consultation will provide an excellent opportunity for trade associations, their members and other stakeholders to strengthen the acknowledged aims of ensuring the functioning of the internal market, avoiding unnecessary national technical barriers and ensuring devices provide a high level of safety and efficacy while at the same time protecting human health.

The Medical Device Industry would like to stress that the existing European Regulatory framework for Medical Devices, consistent with the GHTF principles, is working well and contributes to patients' timely access to safe and innovative medical technology.

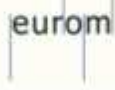
The Medical Device Industry considers that enhancements introduced in the European Directive 2007/47/EC will strengthen the current system further.

The Medical Device Industry believes that the European Commission together with relevant stakeholders can agree to proceed to further changes, using the existing structures and procedures to improve the overall performance of the European Medical Device legislative system.

The Medical Device Industry is supportive of the full implementation of a European database and considers this tool will be key to the future of the European Regulatory System.

Finally, the Medical Device Industry does not see any substantiated evidence that there is a need for a centralized European Agency for Medical Devices.

¹ http://ec.europa.eu/enterprise/medical_devices/consult_recast_2008_en.htm



DETAILED BRIEFING

I. Principle of Recast

The European Medical Device Industry does not see any evidence-based justification of the need for a recast for the following reasons:

- the 2003 report of the European Commission on the functioning of the Medical Devices Directives concluded that the existing legal framework was stable and sound,
- European Directive 2007/47/EC was adopted in September 2007 to introduce minor changes,
- Based on the current timing, those changes will be implemented in March 2010,
- Once the changes have been implemented, stakeholders will need more time to evaluate the effectiveness of the adopted New Directive 2007/47/EC, prior to the next review which is likely to be in 2015.

In addition, the Medical Device Industry considers the proposal to recast is the Medical device legislation is premature, especially as the impact of several changes must be assessed, such as:

- Implementation of the New Approach revision, to be published in the near future,
- The impact of the enhanced clinical evaluation requirements,
- The stronger Notified Body involvement in dossier evaluation (class II),
- The implementation of the European Medical Device Database by March 2010 (at the latest). Today, this database is voluntarily used only by 13 Member States only.

II. EU Regulatory Consolidation

The European Medical Device Industry considers the following points important:

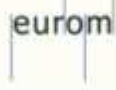
- In principle EU Regulatory Consolidation is acceptable for the AIMDD and the MDD, but not for IVDD because it is significantly different in structure.
- This is consolidation, not simplification. The European Commission has committed to simplify legislation wherever possible.

The European Commission also has an obligation to make sure that implementation of the current Directive provisions are enforced (e.g. implementation of a European database, elimination of national deviations). In addition, the European Commission should ensure consistent and enhanced application of national use of European Guidelines (MEDDEVs).

III. GHTF Model

The European Medical Device Industry is convinced that it is essential for any future proposal from the European Commission for amendments to the Medical Devices Directives that these should ensure consistency and adoption of the GHTF Global Regulatory Model:

- Harmonisation with the GHTF Model would have a number advantages especially when all Founding Members adopt the GHTF Model,
- Any proposal for pre-market approval should remain consistent with the GHTF Model.
- Appropriate transition periods for any changes will be required in Europe.



IV. Classification and borderline issues

The European Medical Device Industry suggests that the existing mechanism be strengthened and applied to issues relating to the classification of medical devices and to questions arising about the borderline between the medical device legislation and other legislation. The current procedures for arriving at opinions should be extended so that the opinions are converted to binding decisions (for example using the Article 7.1 Committee).

In the case of the proposed special category of "highest risk" devices, this mechanism must ensure:

- Transparency in terms of which products will be affected; and
- Decisions must be based on sound scientific evidence

There is neither need nor reason for a new centralised body to take on this role.

V. Pre-market approval of "highest risk" devices

The European Medical Device Industry suggests that existing mechanisms be applied if it is necessary for Competent Authorities to have direct input in pre-market approval of certain "highest risk" devices.

The mechanism introduced in Directive 2003/32/EC (TSE) is suitable for this purpose.

There is neither need nor reason for a new centralized body to take on this role.

VI. Notified Bodies

The European Medical Device Industry confirms that Notified Bodies should remain central to the European system (in accordance with the New Approach and the GHTF Model).

The Notified Bodies should remain under the Member States' responsibility. However:

- The Notified Bodies accreditation process should be made consistent and be strengthened. The existing accreditation procedures will be a suitable basis for this;
- The Notified Bodies supervision should be harmonized and consistent. The role of NBOG in the coordination of Notified Bodies should be enhanced.

There is neither need nor reason for new centralized bodies to take on these roles.



VII. Post-market activities

The European Commission's proposals are inconsistent with its recent recommendations relating to post-market activities.

The European Commission should pursue implementation of the currently established system for vigilance:

- Implement the European Database,
- Implement the relevant EU guidance documents consistently in all Member States,
- Make efficient use of the coordinating Competent Authorities system to ensure a consistent level of patient safety.

The European Commission should develop and implement a harmonized electronic reporting system.

There is neither need nor reason for a new centralized vigilance system to take on these roles.