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European Commission
Unit ENTR F/3, Cosmetics and Medical Devices
BREY 10/176
B-1049 Brussels
Belgium

Brussels, 28 June 2008

Concerning: European Commission Public Consultation on Medical Devices Directives

Dear Commissioner,

The European Federation of Nurses Associations (EFN) welcomes the opportunity to participate in the consultation process on the Medical Devices Directives, as a pan-European Organisation representing more than one million nurses from National Nursing Associations from 30 Member States. The EFN has strong alliances with the European Nursing Specialists groups ([ESNO](#)), the European Nursing Students Groups ([ENSA](#)) and the International Council of Nurses ([ICN](#)).

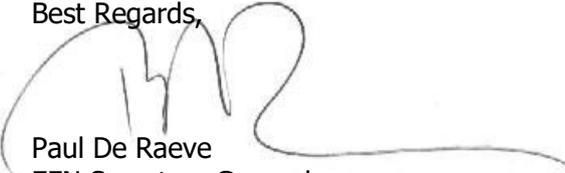
The mission of EFN is "To strengthen the status and practice of the profession of nursing and the interest of nurses in the EU and Europe". Therefore, within the context of this consultation, EFN has developed several positions supporting our input: [EFN Position Statement on Medical Devices](#), [EFN Position Statement on Prevention of Sharp Injuries](#) and [EU Action Aimed at Safer Needle Devices](#).

Furthermore, EFN answers to your extensive consultation questions takes into account EFN experiences in working with all relevant stakeholders within the EMEA, especially the health care professions, the European Public Health Alliance and the European Patient Forum.

Finally, EFN is an active partner in the DG Sanco [EUNetPaS](#) project on patient safety and EFN answers are inspired by this project which recently started with all EU Member States and NGOs.

I hope EFN input will support the Commission in its further developments.

Best Regards,


Paul De Raeve
EFN Secretary General

EFN RESPONSE TO THE SPECIFIC CONSULTATION QUESTIONS

1. Scope

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)?

Taking into account the experience of the "harmonisation" process of the Sectoral Directive 36 on Mutual recognition of professional qualification, between 2002 and 2005, it seems to EFN that the review process would take a great deal of effort and cost. Consultations and engagement are so costly and time consuming for NGOs. Based on EFN experience in the DIR 36 harmonisation, Member States are brought to court for not implementing the harmonised version. Infringements become a "trendy" process which is NOT helpful for the sustainability of the health care system. Furthermore, the harmonisation, merging process could lead to unexpected consequences. EFN strongly supports a bottom-up approach in stead of a top-down approach.

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?

The safety of patients and users is of paramount importance. The EFN supports the use of effective risk management processes, and classification of products by risk potential would seem to be the most logical approach.

Patients have the right to be informed when highest risk category products are being used for their treatment. Giving information to the patients is to enable them to choose to take the risk or not during their own treatment. A risk-based classification system could help patients to be more aware of the risk taken during the treatment and also to ensure an appropriate level of protection according to the risk. Defining such a classification requires nurses and patients' involvement.

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?

EFN is not aware of any other exclusions.

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)?

EFN suggests that there should be a separate regulatory process for these types of products, as they are not really medical devices as currently defined. We can not confuse more the system as it is already now the case.

2. Specific Update following the revision of the New Approach

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?

The overall umbrella legislative framework for industrial products so called the "New approach" is relevant for medical devices as it aims at improving public health safety by fighting counterfeiting medicines, reinforcing market monitoring and evaluation with strengthened regulation and CE labelling.

EFN would like to see the Commission to encourage further co-operation between Member States and to involve representatives of nurses, other healthcare staff and patients when devising relevant legislative initiatives and guidelines.

EFN believes that the Commission, ones we have it right for the EU, should then focus on promoting the European system for medical device regulation in other regions of the world that have less developed regulatory systems and would benefit from an existing proven model.

3. Evaluation Procedures

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

- a) in general? There is a huge range of medical technologies and the original essential requirements for medical devices appear to have been effective overall. But we can do better. Also, there has recently been a review of the Medical Devices Directive, and, as a result, some amendments have been made to the requirements. We do not see why the subject should be discussed again so soon after this exercise.
- b) for non viable tissues and/or cells and/or their derivatives? No changes appear necessary. The use of non-viable animal tissues in medical devices is established within the Medical Devices Directive.
- c) for 'quasi medical devices'? An appropriate regulatory vehicle should be developed rather than trying to fit these products within the medical device definition. The separate processes could be coordinated by the EMEA.
- d) to make medical devices more robust to technology change? The current essential requirements seem to have worked so far but minor changes were found to be necessary by the recent statutory review of the Medical Devices Directive. But minor changes can make a huge difference in patient safety.

What new essential requirements could be needed and why? The EFN believes that the evaluation procedures should be strengthened so that injuries due to unsafe medical devices are reported. Reporting process should imply the health professionals and patients in a no blame culture (see EuNetPas DG Sanco Project).

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'?

EFN is aware that some Member States have introduced additional requirements for registration of medical devices and also specific national labelling. We are not aware of the cost implications though.

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);

EFN would need further detail of the proposal before we can express an opinion.

Proposal 2

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

The Notified Bodies are clearly an important part of the regulatory framework for medical devices. Therefore, this proposal would seem to make sense. The EMEA can play an essential role in making progress as they are used in collaborating with different stakeholders.

Proposal 3

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

The Notified Bodies are clearly an important part of the regulatory framework for medical devices. Therefore, this proposal would seem to make sense.

Proposal 4

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

EFN understanding is that this possibility already exists but lacks implementation.

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;

EFN is familiar with this subject and therefore beliefs that safety criteria are essential to prevent shopping. EFN experience with DG Internal Market initiative "IMI" also prevents 'shopping' as all competent organisations have all the same information and alerting signals.

Proposal 6

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

EFN thought that this was already a possibility.

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.

Although this raises questions of subsidiarity as Notified Bodies competent for evaluating and authorizing high-risk medical devices are monitored and managed by Member States, more cooperation is needed at EU level between those authorities so that the information obtained by one of them could be spread easily and rapidly in the EU. This would lead to cost effectiveness in healthcare systems and prevent from avoidable injuries to patients and court cases.

An EU system should contain quality criteria ensuring manufacturers not to go for the easier way but for the safer way. Therefore, the initial information provided by Manufacturers should be made available not only for Authorities but for all stakeholders. Administrative and legal barriers should be reduced so that the link between main stakeholders could be direct.

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.

EFN would like to see first a definition of "highest risk category devices" and as EFN is already working closely with the EMEA, in which NGOs are involved, EFN sees the rationale for involving and expanding the terms of reference of the pharmaceuticals agency in the regulation of medical devices, ONLY on the condition that Health Professionals and Patients are involved in the process, as requested by the European Parliament.

EFN supports the creation of an experts' specific committee on medical devices within the EMEA, to assess, authorise and guarantee the quality of the products proposed by Manufacturers. It is essential that health professionals and patient representatives are present among those experts. The Regulation should ensure that the process timeline will not be excessive. The authorisation given by the EMEA on new medical devices, even of highest risk category devices, should not represent a barrier to the access to patients to new tools which are needed to their treatment.

It is fundamental that Notified Bodies collaborate on a transparent way with this structure to impact positively at EU level.

From the economic standpoint, EFN would suspect that such an approach will increase the overall costs as experts input can not be taken for granted. Next to travel and accommodation costs, an "intellectual" per diem needs to be given to NGO experts as it is already done within the Commission and other European institutions.

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?

EFN understands the argument for involving the EMEA in the evaluation of medical devices.

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;

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.

Any initiative should ensure that a transparent and efficient cooperation between the main stakeholders are included so that the information is complete when it arrives to the health care professions and patients. Providers, patients manufacturers, Notified Bodies and the EMEA are all parts of the process.

The administrative process is necessary to ensure high quality and safer products. EFN is aware of that this could slow down access to new devices in treatment. However, this is unavoidable to ensure highest protection of patients.

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?

EFN calls for transparency and provision of access to all evaluation reports.

4. Vigilance

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;

EFN support the obligation to report all adverse events in an accurate and timely fashion. It needs to be recognised that in high pressure health care environments the users of medical devices need simple and effective reporting systems, as time is at a premium.

EFN believes that health professionals and patients have a key role in the vigilance system. To facilitate that, clarity regarding reporting procedures and a variety of reporting options to enable them to react rapidly and with confidence should be ensured. EFN recommends the Commission in following the EuNetPas project, although mainly focussed on medication errors at this stage, the same methodology can be used in this field.

Proposal 2

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

This seems sensible, but EFN understood that this obligation was already existing.

Proposal 3

Mandate EMEA to coordinate vigilance reports and to detect signals;

Agree!

Proposal 4

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

Although the current system already provides relevant specialist expertise to evaluate the need for restrictive measures to be imposed, the EMEA committee could play an important role on the condition that Health care professionals and patients are involved.

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.

We believe that there is an exchange of information between agencies around the world. EFN supports the work of the Global Harmonisation Task Force, in helping ensure consistency around the world. Strengthening exchange of information on incidents and corrective measures at an international level would permit to spread information rapidly and consequently to react promptly. The database of shared information should be managed transparently in collaboration with European, national and local authorities.

5. Market Surveillance

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?

EFN supports a centralised registration system for medical devices.

As mentioned in the numerous previous responses to European Commission's consultations, EFN welcomes the recent policy developments regarding pharmacovigilance and the setting up, in the framework of EMEA, of EUDRAVIGILANCE database of adverse reaction reports to medicines licensed across the EU. This could be extended to medical devices surveillance. A platform for cooperation between main stakeholders will allow a better monitoring of the medical devices market and help to fight against counterfeiting. EFN believes that a stronger alert system will permit to respond promptly when new concerns come to light.

It is very important that the experiences of nurses and other users of medical devices are captured and positively utilised. We encourage the Commission to ensure that consistent and effective processes are in place in all Member States.

6. Borderline Cases

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?

7. GHTF

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?

EFN supports appropriate harmonisation of the medical devices regulations.

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?

EFN believes, although different specifications may be appropriate for different markets, that equal standards for the regulation and approval of medical devices should be applied whatever the supply source or market destination. Mandatory standard requirements should be created so that manufacturers do not produce for two separate markets: EU and non EU. This could be controlled by specific authorities, such as the EMEA.

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?

EFN agrees that counterfeiting is an issue that needs to be tackled. The International Council of Nurses, EFN sister organisation at global level, has done enormous work in this field and should be taken into account, leading to a safer health care for patients. Medical devices market is international. CE labelling does not prevent from counterfeiting products to enter the EU market from other non EU countries. An alignment at international level on regulatory principles would benefit the EU patients.

9. Simplification

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?

EFN suspects that this would be a complex and costly process, probably with some unexpected consequences. The justification would need to be very strong.