europeanpatients' forum

EPF's response to European Commission's public consultation on the Recast of the Medical Devices Directives

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The **European Patients Forum** (EPF) welcomes the Commission's initiative to invite stakeholders to comment on the recast of the Medical Devices Directives and is pleased to send its contribution. Medical devices are of crucial, and often vital, importance for patients with chronic diseases. In many cases, medical devices can provide a major contribution to life expectancy and quality of life of patients.

The European Patients' Forum (EPF) was founded in 2003 to become the collective patients' voice at EU level, manifesting the solidarity, power and unity of EU patients' movement. EPF currently represents 37 member organizations - which are chronic disease specific patients organizations operating at European level, and national coalitions of patients organizations. EPF reflects the voice of an estimated 150 million patients affected by various diseases in the European Union, and their families.
EPF facilitates exchange of good practice and challenging of bad practice on patients' rights, equitable access to treatment and care, and health-related quality of life between patient organizations at European level and at Member States level. EPF's vision for the future is patient-centred, equitable healthcare throughout the European Union.

Methodology around EPF's consultation with its membership in agreeing this response

An initial draft was prepared on the basis of EPF's core principles and values, position papers and our input to other consultations in recent months. This was then circulated to EPF's members for comments and input. This response deals explicitly with the **patients' rights perspective** and does not address certain specific issues like socio-economic or legal issues, which are not in EPF's remit.

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

EPF supports the legal simplification in one legal text only if the important issue of patient safety and equitable access to quality health care of is covered in the merged text in a prominent and comprehensive way.

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EPF believes that all patients have the right to be treated on an equal basis for access to quality health care. Therefore, it is essential to ensure, with mandatory and efficient regulation, that the quality of medical devices authorised on the market is of high standards across all Member States. This applies equally to emerging new technologies as to those which are already on the market.

Item 2*: Risk-based classification: In your opinion is such a risk-based classification system more desirable than the current European List system?*

Although EPF does not have a specific expertise on this issue, we believe that a risk-based classification system may 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 specificity of the risk.

EPF believes that all patients have the right to be adequately informed when highest risk category products are being used for their treatment. We consider that information about all medical devices, especially in the case of implantable medical devices implanted in the hospital, should be made available in the package leaflet, as for any other product.

EPF considers that it is important that patients are meaningfully involved and their view point and unique experience and expertise is taken into consideration when defining such a risk-based classification.

***Item 3*: To your knowledge, are these the only medical devices currently not regulated at an EU level?**

EPF does not have specific knowledge about medical devices currently not regulated at EU level. However, we would recommend the Commission to take into account the *World Health Organization* work on medical devices as a major subset of health technologies (the discussion of the Executive Board on the essential health technologies at its 120th session - the document EB119/2006-EB/120/2007/REC2 or the ongoing work on priority medical devices). This includes various definitions coming out from broad consultations with stakeholders and proposals to analyse and fill the gaps in preventive, diagnostic, therapeutic and assistive devices.

***Item 4*: In your opinion is it necessary to ensure full protection of public health to regulate these products as 'quasi medical devices'? (…)**

As a European umbrella organisation representing patients with chronic diseases, EPF does not focus on 'quasi medical devices'. Nevertheless, EPF is aware of the role of the legislator to ensure a high level of protection of EU citizens and urges for measures that contribute to ensuring safety for all patients.

***Item 5*: Which aspects of the revision of the New Approach do you consider of particular relevance to the medical devices sector, and why? (…)**

From EPF's perspective, it is essential that the reflection on the medical devices, within the so called "New Approach" umbrella legislative framework insists on providing a high quality, equitable and patient-centred healthcare.
Patients have a right to access safe, quality and appropriate information, services and treatments. The Commission's legislation should ensure that medical devices produced guarantee the quality of manufacturing process, security of the supply chain and high quality and understandable information to patients.

***Item 6*: Evaluation procedures - in your opinion what changes are needed to the essential requirements? (…)**

EPF calls for evaluation procedures to be strengthened so that injuries due to unsafe medical devices are reported. Reporting process should imply not only health professionals but also patients, in a no shame no blame culture.

Patients' right to information should be extended by allowing them to be involved in the evaluation process of the medical devices. As main users, they have a key role to play in partnership with their healthcare professionals to improve the treatment.

EPF and its member organisations argue strongly that an informed patient will contribute significantly to the best and ultimately most cost-effective disease management in partnership with health professionals, by promoting health literacy, health democracy, treatment compliance and risk benefit analyses. And that this will impact positively on healthcare expenditure and national economies.

***Item 8*: the functioning and the activities of the Notified Bodies,**

From a patients' safety perspective, EPF strongly calls for more cooperation at EU level between Notified Bodies competent for evaluating and authorizing high-risk medical devices in Member States, so that the information obtained by one of them can be spread easily and rapidly in the EU. This would help preventing avoidable injuries to patients.

For this purpose, strict quality criteria should be set up at EU level to ensure that manufacturers do not go for having their products reviewed by the Notified Body considered most likely to provide favourable opinion.

EPF also calls for more transparency. The initial information provided by manufacturers should be made available not only for authorities, but also for the public, for the patients. We strongly believe that administrative and legal barriers should be reduced so that closer links between main stakeholders can be established and that patients can be involved in a knowledgeable way in their treatment.

Measures to assure the quality of the manufacturing process and the security of the supply chain should also be considered, in light of how they affect the level of accessibility for the patients and the final cost the patient has to bear. These measures should not end up raising barriers or additional costs for patients.

***Item 9*: What are the social and economic advantages and disadvantages of extending the role of EMEA in the medical devices legislative framework? (…)**

From EPF's experience, the system of Notified Bodies appears to work rather well for reasonable costs. Our initial suggestion (*EPF needs to go however through more extensive consultation with members on this topic*) would be to use first all available options to improve the existing system rather than extending EMEA's role and therefore increase the burden of its responsibility. Our patients' organisations experience in working with EMEA on the EUDRAPHARM database shows that there are not sufficient resources to deal with the current tasks in an optimal way.

Nevertheless, if the responsibility for authorizing medical devices will lie with EMEA, then this should apply only for devices belonging to the highest risk category and on condition "sine qua non" of sufficient additional funds being allocated to EMEA to cope with this new task. If this is the case, the Medical Device Committee of EMEA could indeed act also as final decision maker on "Borderline Cases" (item 15).

From EPF's perspective, if such an EMEA expert committee on medical devices is created, it would be essential that patient representatives are present among those experts.

Moreover, the Regulation should ensure that the process timeline will not be excessive. The authorisation given by the EMEA on new medical devices and event of the highest risk category devices should not represent a barrier to the patients' access to devices which are needed to their treatment.

***Item 11*: an expanded role of EMEA in the evaluation of the highest risk category medical devices**

EPF calls on the Commission to ensure that a transparent and efficient cooperation between the main stakeholders is taking place - manufacturers, Notified Bodies, EMEA, patients are all parts of the process - so that the information is complete when it arrives to the patients.

We also believe that the administrative process is necessary to ensure high quality and safer products. EPF is aware of that this could slow down access to new devices in the 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 (…?)**

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

***Item 13*: improve the vigilance system**

EPF strongly believes that patients have a key role in the vigilance system. To facilitate that, clarity regarding reporting procedures and a variety of reporting options to enable patients to react rapidly and with confidence, in a no blame culture, should be ensured.

Adequate information should be provided, in a transparent and accessible way, so that patients can become aware of the policy developed at EU level, especially quality criteria used to evaluate medical devices. This will allow them to recognize counterfeited, inadequate or unsafe devices and to act.

Strengthening the 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.

***Item 14*: reinforce market surveillance**

As mentioned in its previous response to European Commission's consultations[1] EPF 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, including patients, will allow a better monitoring of the medical devices market and help to fight against counterfeiting. EPF believes that a stronger alert system will permit to respond promptly when new concerns come to light.

***Item 17*: imports, exports and counterfeiting**

EPF believes that international cooperation could lead to providing a safer health care for patients. Medical devices market is international. CE labelling ensures that medical devices imported within the EU are safe. However it does not prevent from counterfeiting products to enter the EU market from other non EU countries. EPF believes that an alignment at international level on regulatory principles would benefit for EU patients.

[1] EPF's response to Commission's consultation on pharmacovigilance, 1 February 2008, http://www.eu-patient.eu/news/2008_02_19_EPF_response_to_ECs_consultation_on_legislative_proposals_on_pharmacovigilance.php