EURORDIS
European Organisation for Rare Diseases

EURORDIS - the European Organisation for Rare Diseases - represents 225 rare disease organisations from 24 countries, 16 of which are EU member states, and thereby reflects the voice of an estimated 30 million patients affected by rare diseases in the European Union.

In response to the Commission's open consultation on its proposal for a Directive amending Council Directive 93/42/EEC concerning medical devices, EURORDIS is pleased to send its contributions to the debate.

EURORDIS and its Members welcome the initiative of the Commission to amend Directive 93/42/EEC concerning medical devices, on the basis of the Report on the functioning of the Medical Devices Directive (June 2002) and the Commission's Communication on Medical Devices (July 2003).

Nevertheless, we would like to express some concerns and draw attention to the following four issues:

1. First of all, we would like to underline the importance of Medical Devices for rare disease patients and highlight the specifities of rare diseases in this context

Medical Devices are of crucial, and often vital, importance for patients living with a rare disease. In most cases, Medical Devices provide a major contribution to life expectancy and quality of life of our patients, both adults and children.

It is therefore fundamental to bear in mind the specific needs of rare disease patients in the current debate on Medical Devices: for most of them no therapeutic cure exists and the only way of alleviating their sufferings and helping them to live a life worthy of the name, is the long-term, and often life-long, use of very specialised Medical Devices.

Rare disease patients therefore need Medical Devices to be produced for a small number of patients: we acknowledge that the need for producing to the attention of single patients is covered by the Directive through the provisions on custom-made device and therefore that the problem doesn't relate to the PRODUCTION of specific devices. The problem for rare disease patients and their families is the COST of such specialised devices and the inappropriate system of reimbursement by national health schemes.

Decision-makers have to recognise that there is a public health need in terms of Medical Devices and that the debate should include a solidarity and public health dimension in addition to the economic need for free circulation of goods in the Single Market. This shift would also allow tackling the fundamental issue of true accessibility for all.

In this context we would like to propose the creation of the label "Humanitarian Medical Device" (HMD), as it is the case in the US, which would allow for fee waivers for the registration of designated devices. This label would appropriately represent for Medical Devices what the Orphan designation represents for medicinal products.

It is necessary that patients are involved in the procedure for granting the label in order to help appreciating the therapeutic added value of the device for which the HMD label is asked.

This proposal would help tackling the need for coordination at EU level of Medical Devices supplies to Centres of Reference. If relevant Medical Devices do benefit from the designation as "Humanitarian Medical Devices" (HMDs), the Commission could then fulfil its duty of ensuring a high level of human health protection by encouraging Member States to use this label in their decisions concerning reimbursement by the national health systems.

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2. Involvement of patients

- We believe it is a pity that patients have not been consulted in the course of the drafting of the Commission documents, neither in the past exercises (the Expert Report from 2002 and the Commission Communication from 2003) nor in the elaboration of the current proposal. Anyway, we now welcome the possibility to contribute to the debate on Medical Devices through the current consultation, bearing in mind that the sooner patients' viewpoint is taken into consideration, the best, as in the end Medical Devices are produced for the benefit of patients needing them.

- We deplore that patients are only mentioned with regards to "safety of patients" and that their role as interested parties is not explicitly recognised. We are concerned of the fact that already in the Commission Communication every time "stakeholders" or "interested parties" are mentioned, the list comprises Member States, national authorities, Notified Bodies and the industry, but never patients, as reflected in the Annex 4 of the Communication where the working groups involved in the implementation of the Medical Devices Directive does not include patients representatives. Currently, nothing specific regarding the role of patients is mentioned in the proposed amendments. We would therefore like to add "including patients" every time that the term "interested parties" do appear in the amended Directive on Medical Devices.

3. Transparency

- We deplore that the European Database for Medical Devices (EUDAMED) is not yet operational and we urge the Commission to take the necessary steps to set up EUDAMED without any further delay.

- We would like to underline that data stored in the European database shall not only be "accessible to the competent authorities" (article 14a), but also to the general public, including patients and their representatives.

- An important element of transparency is the need to inform adequately the patients: from our experience we can state that very little information is provided to patients on the device they are provided with, especially in the case of implantable devices implanted in the hospital. We consider that all information should be made available in the package leaflet, as for any other product.

- Transparency is also needed in areas such as national schemes for assessment of clinical investigations, designation and monitoring of Notified Bodies, recommendations and consensus views of the Notified Bodies, summary reports on market approval, etc. It comes as a disappointment that the need for more transparency on these specific issues is not clearly underlined among the proposed amendments.

4. Cooperation between Member States

- We welcome the new article 20b on cooperation. Nevertheless, we fear that its impact may be weakened by the lack of specific mechanisms of information and cooperation between authorities and with the Commission.

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- We welcome the amendment to article 15, par. 2 enhancing cooperation between Member States: “Such decisions (decisions not to commence clinical investigations based on considerations of public health or public policy) shall be communicated by the competent authority to the other Member States”.

- It comes as a disappointment that no reference is made to the creation of the High Level Group on Medical Devices, as mentioned in the 2003 Communication. When this HLG on Medical Devices would be set up, it is important for representatives of rare diseases to participate as experts in the discussions.