



EURORDIS contribution to the Public Consultation “Recast of the Medical Devices Directives”

EURORDIS - the European Organisation for Rare Diseases – represents 341 rare disease organisations from 38 different countries, 24 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.

EURORDIS is pleased to contribute to the current debate on Medical Devices (MDs) in the context of the Commission Public Consultation “Recast of the Medical Devices Directives”. This paper aims at expressing the main needs from the rare disease patients’ perspective in the field of Medical Devices and is based on EURORDIS response to the 2005 Commission’s consultation.

Main elements of EURORDIS response:

1. EURORDIS has not been reported by its members of any issue related to patient safety in the field of MDs.
2. EURORDIS does not support the proposed recast of the current legislative framework, including the proposal to create a MDs Committee within the EMEA.

On the contrary:

3. EURORDIS is in favour of the harmonisation at EU level of the designation and monitoring of the Notified Bodies.
4. EURORDIS is in favour of an improved post marketing vigilance/surveillance system, including reinforced cooperation between EU Member States.
5. EURORDIS is in favour of an improved reporting system by patients in order to evaluate the real patients’ needs in the field of MDs, including in terms of safety, quality and efficacy.
6. EURORDIS proposes the creation of the “Humanitarian Medical Device” label.

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1. General remarks on the Commission's proposal

Patient safety

From the Commission's consultation paper, it seems that the willingness to recast the EU legislative framework for MDs is based on the assumption that "experience indicates that the current system does not offer as high a level of protection of health as possible". Nevertheless, the Commission does not sustain this statement with any figures or statistics in the field. Furthermore, from the perspective of rare disease patients, EURORDIS has never been reported of any problems related to patients' safety from its membership, since its creation in 1997.

→ This is why EURORDIS believes that there is a need to further investigate the real concerns of patients in terms of MDs safety before reshuffling the current system.

Impact of the proposed recast

EURORDIS believes that the main immediate impact of the proposed recast as proposed in the Commission's document will be to notably delay - and increase the costs of - the placing on the market of MDs *without* adding any remarkable advantages for the patients in terms of safety, quality and efficacy.

In addition, it seems that the proposed system will mainly favour big industries at the expenses of SMEs in the MDs sector, while creating a globalised market in a field where the major contribution is currently produced by SMEs.

→ In order to address a hypothetical problem (patient safety concern) the Commission is proposing a system that will for sure create actual negative consequences for patients: increased costs and delayed placing on the market of MDs, and therefore reduced accessibility of MDs, some of which are life-saving for rare disease patients.

Timing

EURORDIS has serious reservations about the timing to launch such an exercise so shortly after the last revision of the MDs Directives, bearing in mind that the consolidated version of the MDs legislation was published on the OJ on 11 October 2007, not even one year ago.

→ It seems that this short period leaves little time to properly evaluate the effective impact of the legislation as lastly revised and to assess whether there is a real need to recast the whole system.



European and national levels

EURORDIS would also welcome a real weight up of the respective responsibilities of the national and European levels: wouldn't it be enough - in order to ensure patients' safety - that Member States designate and monitor the activities of the Notified Bodies on the basis of the same high quality criteria? If the national level does not ensure the correct implementation of the legislation coming from the European level, it is not the European legislation that has to be revised continuously. It is rather the national level's achievements and methods that have to be addressed.

→ This is why EURORDIS believes that it would be most useful to start by harmonising the designation and control criteria used by national Competent Authorities to nominate and monitor the Notified Bodies (NBs) in a way that would ensure an even level of competence of the NBs throughout the EU, and therefore an equivalent level of safety of MDs placed on the EU Market. This measure would help fighting the so-called "forum shopping" and would benefit both patients - ensured of the same level of safety, quality and efficacy - and industry – ensured to be treated equally.

2. Medical Devices and rare disease patients

HMDs

Medical Devices are of crucial, and often vital, importance for patients living with a rare disease. In many cases, Medical Devices provide a major contribution to life expectancy and quality of life of rare disease patients, both adults and children. For the vast majority of them no therapeutic cure exists and they need a long-term, often life-long, use of specialised Medical Devices.

Rare disease patients, by definition, need Medical Devices to be produced for a small number of patients: the need for producing Medical Devices to the attention of very small populations is already addressed by the current legislative framework through the combination of the provisions on "custom-made device" and on "compassionate use". Contrarily to the situation encountered for medicinal products, the problem for rare diseases patients concerning Medical Devices does not relate to the research, development and actual production of specific devices but rather to the cost of such specialised devices and the different reimbursement systems applied by national health schemes.

Therefore, EURORDIS is NOT in favour of the adoption of a specific Regulation on Orphan Medical Devices and of the proposed recast. As already expressed above, EURORDIS anticipates that this may lead to delayed and most expensive placing on the market of Medical Devices. EURORDIS believes that the solution resides in the recognition of the public health need in terms of Medical Devices for rare disease



patients: the debate should include a solidarity and public health dimension that would allow full reimbursement, and therefore true accessibility, of Medical Devices for all patients.

→ In this context, EURORDIS would like to propose, as in 2005, the creation at EU level 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 while taking into account the specificities of the two different products.

→ This proposal would also help addressing the need for coordination at EU level of Medical Devices supplies to the Centres of Expertise for Rare Diseases. 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.

→ EURORDIS also strongly advocates in favour of patients involvement 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.

Combined products

An issue of real concern that has been reported to EURORDIS is the issue of combined products, namely a product where a MD is associated to a Medicinal Product. In these cases, a drug is studied during the clinical trials in association with a given MD, but the Marketing Authorisation is granted only for the Medicinal Product and not for the MD with which the drug was combined and studied during the trials. Therefore, the patient will be prescribed the active substance in association with any similar MD, not necessarily the one that was studied together with the drug. This may result in a situation where the drug does not function on the patient in *exactly* the same way as it was studied during the clinical trials and the treatment may therefore not be *exactly* the same as the one needed: under-performing and under-dosage or over-performing and over dosage? In any case, this may lead to a different effect on the patient as the one aimed at. This situation is typically encountered with chemotherapy pumps, pumps releasing pain-killer drugs, or nebuliser devices for cystic fibrosis patients, and other cases where the link between the drug and the device is very tight.

→ EURORDIS wishes that a system is found to make more visible the MD combined to an active substance during the marketing authorisation procedure.



3. Other issues

Item 3:

Should MDs with non viable cells or tissues be included in the MDs legislation?

EURORDIS believes that the MDs consisting exclusively of non viable human cells and/or tissues and/or their derivatives and MDs incorporating such cells and/or tissues and/or their derivatives with an ancillary action to that of the MD should be included in the MDs legislation and evaluated by the Notified Bodies, as any other MD.

Item 4:

The issue of the “quasi medical devices”:

EURORDIS believes that any cosmetic implant should be subject to the same level of safety as any other medical device.

It is worth mentioning that for many rare diseases patients these kinds of “quasi medical devices” can notably improve their quality of life as they may help facilitating their social life (this is particularly true for disfiguring or mutilating diseases).