Dear Health Minister,

**Re: Call for your commitment to patient-centred care within the new Medical Devices Regulation**

I’m writing to you on behalf of (name of organisation) and the European Patients’ Forum regarding an important concern arising from the current debate at EU level on Medical devices (Proposal 2012/0266 COD). Medical devices play an important role in the management of chronic conditions, and can have a major impact on patients’ health outcomes and quality of life. Currently patients’ involvement in the regulatory framework on medical devices is not structured or supported by EU legislation.

Patient involvement is an operating principles of European healthcare systems (Council Conclusions 2006/C 146/01). Patients manage chronic conditions every day, use medical devices directly and are frequently in contact with healthcare providers. We have a different perspective on risks and benefits compared to other actors, and expertise on gaps and good practices. Patient organisations can channel this collective experience to decision makers, to improve the safety and quality of devices, and ensure optimal communication with the patient community.

In the field of medicinal products, patients’ representatives are recognised partners in the EU regulatory framework, and have their own dedicated body, the Patient and Consumer Working Party, to advise the European Medicine’s Agency. Patients are actively involved in the implementation of EU legislation on pharmacovigilance, falsified medicine and clinical trials, driving advances in safety and quality. The current review of the Medical Devices framework will bring substantial changes that will have an impact on European patients; yet at this stage if the position of the Council of September 2015 were adopted without amendments, there would be no advisory body for patients to provide input into the implementation of the Regulation.

Furthermore, the new Clinical Trials Regulation explicitly encourages the involvement of patients in ethics committees (Regulation EU No 536/2014, Article 2 paragraph 11). This is a recognition of the moral right of patients to be heard on ethics aspects, because of their specific expertise and position as they participate in trials, bear the risk and contribute to advances in therapies. We call on you to support the same recognition in the Medical Devices’ provisions on ethics committees, as proposed by the European Parliament in its first reading position (amendment 88).

In the ongoing trilogue between Council and Parliament, you are in a position to be forward looking and ensure that the EU medical devices Regulation reflects the commitment of the Council in 2006 that “all healthcare systems in the European Union aim to be patient centred”. As patients we can contribute to ensuring a good implementation of the new Regulation in areas such as patient safety, vigilance, transparency measures, and the opening of the medical devices database to the public.

We urge you to support appropriate measures for the meaningful involvement patients’ organisations in an advisory role to any expert bodies on medical devices, including through setting up an expert group of users.

We thank you for your support and consideration.

Yours Sincerely

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| Insert name here | Anders Olauson,  EPF President |