FOR IMMEDIATE RELEASE

Patients voice their position on Medical Devices

Medical devices[1] are of crucial, and often vital, importance for patients with chronic diseases. They can provide a major contribution to their life expectancy and quality of life. EPF releases our position paper to ensure the EU hears the recommendations of patients while reviewing the framework on Medical Devices. EU patients are the users of medical devices, it is essential to ensure they have access to safe, high quality medical devices.

Brussels, 17 April 2013 – EPF takes a stand on the legislative proposal for a Regulation on medical devices. The European Commission has issued this proposal in September 2012 to modernise the existing EU regulatory framework adopted in the 1990s and overcome flaws and gaps identified in terms of patient safety.

EPF has been engaged in the review process from the very onset. We responded to a Commission consultation in 2008, and participated in the EU exploratory process on medical devices. EPF is committed to ensuring that patient safety and quality of care remain the primary objectives of this review.

"M*edical devices play a key role in patient empowerment and chronic disease self-management. Patients manage their condition in everyday life. Their experience and expertise can be a valuable contribution to the safety and quality of devices. Hearing the patients' voice in this debate is essential to ensure the Regulation brings concrete benefits for European patients,*" said Laurène Souchet, EPF Policy Officer.

We highlight that better safety can only be reached through establishing good governance principles for medical devices — transparency, objectivity, independence of expertise, fairness of procedures, and participation of users (patients, consumers and healthcare professionals).
Patients have a legitimate and fundamental right to be involved in all questions that relate to the safety and quality of their medical devices, from the innovation process and the clinical investigations, to post marketing vigilance. EPF strongly recommends transposing the model of

[1] Medical devices include any apparatus, appliance, software, material or other article which is used for the diagnosis, prevention, monitoring, treatment or alleviation of diseases, injury or disability. There are around 500,000 different types of devices on the market, covering a wide spectrum from simple bandage to x-ray machines or pacemakers.

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patient involvement developed by the European Medicines Agency in the field of medical devices and ensuring that this involvement is meaningful as defined by the Value+ model[2].

EPF calls on the EU institutions to set clearer and stronger provisions for transparency within the Regulation. Transparency guarantees all actors have access to the information they need to participate in the safety chain. It must be applied in clinical evaluation, conformity assessment, and post market vigilance. Access to information can also empower patients and their healthcare professionals to make the best treatment choice.

Our statement also provides recommendations to improve patient safety at all stages of the medical devices lifecycle. The key to this is better clinical evidence, tighter requirements for conformity assessments and for notified bodies, and clearer responsibilities. We also call for strengthening EU cooperation on vigilance, which is crucial to evaluate the benefit-risk balance of a device, to prevent incidents and react when they occur.

EPF calls on the EU institutions and Member States to fulfil their commitment to tackling health inequalities. We believe it is unacceptable that some patients still encounter difficulties in accessing the medical devices they need. We recommend the EU takes urgently incentives to establish cooperation at EU level to ensure equitable access for all patients in the EU to the medical technologies.

The Commission proposal will be discussed in the European Parliament and in the Council in 2013. It is expected to be adopted in 2014 and would then gradually come into effect from 2015 to 2019.

EPF is committed to working closely with the European Institutions and stakeholders in translating the vision and the core issues outlined in this statement into reality, to ensure that medical devices in the EU are safe, high quality, accessible and meet patients' needs.

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 the EU patients' movement. EPF currently represents 59 member organisations - which are chronic disease specific patient organisations working at European level, and national coalitions of patients organisations. EPF reflects the voice of an estimated 150 million patients affected by various diseases throughout Europe.

EPF's vision for the future is high quality, patient-centred, equitable healthcare throughout the European Union.

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[2] http://www.eu-patient.eu/Initatives-Policy/Projects/EPF-led-EU-Projects/ValuePlus/