FOR IMMEDIATE RELEASE

DEAL REACHED ON EU MEDICAL DEVICES REGULATION:

BRUSSELS, 26 May 2016 – BRUSSELS, 26 May 2016 – The European Patients' Forum welcomes the deal reached yesterday between the Council and the European Parliament on medical devices. However, more information on reprocessing and patient involvement is required.

Medical devices are of crucial, and often vital, importance for patients with chronic diseases: they can provide a major contribution to life expectancy and quality of life of patients. For this reason, the European Patients' Forum (EPF) has been engaged throughout the legislative process with the EU institutions to ensure EU patients have access to high quality safe devices that fit their needs.

In the late hours of 25th of May, the Netherlands presidency of the Council and the European Parliament reached a political agreement on new rules for Medical Devices and In-Vitro Medical Devices.

The deal paves the way for **stricter provisions** on pre-market assessment and post-market surveillance, putting the emphasis on the **safety of devices**. EPF **welcomes** these new measures as we believe a **safety approach through the device's lifecycle** is key to ensuring a better and more integrated patient safety.

EPF also **applauds** the approach towards **more transparency**, with the setting up of a central database containing information on devices, available to patients and healthcare professionals. Improving transparency and information to patients is a key priority for EPF as it empowers patients and healthcare professionals to make better treatment choices.

However, we **regret** the **uncertainty about the important question of reprocessing of devices**. The press release from the Council does not mention this crucial topic for patient safety. We hope details will be made available soon, alleviating any doubts from the patient community.

We **also miss details** on one of EPF's key demands: the **involvement of patients**. We call on the establishment of provisions to involve patients as experts in subgroups where their expertise can make a difference, such as patient safety, surveillance, clinical investigations and information to patient.

EPF Secretary General, Nicola Bedlington commented on the agreement: "*We can only welcome this agreement, as it clearly paves the way towards a safer and more robust system for medical devices. However, to fully assess its impact on patient safety and quality of care, more details are needed on the crucial topics of reprocessing and patient involvement*".

We will provide a fuller analysis once the agreement is published and we are committed to continue to engage on medical devices with EU institutions and stakeholders to ensure that medical devices in the EU are safe, high quality, accessible and meet patients' needs.

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EPF currently represents 67 members, which are national coalitions of patient' organisations and disease-specific patient organisations working at European level, and. EPF reflects the voice of an estimated 150 million patients affected by various chronic diseases throughout Europe.
EPF's vision for the future is that all patients with chronic and/or lifelong conditions in the EU have access to high quality, patient-centred equitable health and social care.

The EPF strategic goals focus on areas such as health literacy, healthcare design and delivery, patient involvement, patient empowerment, sustainable patients' organisations and non-discrimination.

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