FOR IMMEDIATE RELEASE

EU MEDICAL DEVICES REGULATION ADOPTED:

BRUSSELS, 28 June 2016 – The European Patients' Forum acknowledges the improved measures regarding some safety concerns. However, we deeply regret the lack of mandatory patients' involvement.

On 16 June the Medical Devices Regulation adopted by the European Parliament and the Council of the European Union has been published. EPF, which was involved in the consulting process since 2012, provides a patients' perspective on the resulting compromise.

No one can deny that compared to the current Directive, the new Regulation addresses many safety concerns. EPF welcomes the compulsory registration and ethical review of clinical investigations and recognises the clarifications regarding the conformity assessment, responsibilities of national competent authorities and notified bodies.

Reprocessing was singled out by EPF as a key safety topic. We therefore applaud the new provisions for reprocessors, and the rights of Member States to forbid or restrict reprocessing on their territory.

Another key milestone which has to be saluted is the possibility for Member States to enable the reporting by patients of suspected serious incidents. This will certainly improve reporting and increase safety and surveillance of devices on the market.

Better information to patients needs the involvement of patient organisations

The Regulation shows real progress in terms of information to patients, however an **important caveat** is the lack of **mandatory involvement of patient organisations** to ensure the information provided correspond to patient's needs. This is for us a crucial point, as patients and patient organisations have an incredible added-value and bring their unique expertise to define which information really matters for the patients.

We urge the European Commission and Member States to address this gap, as it is a condition to ensure accessible and quality information to patients.

Very little progress on patients' representations on medical devices expert groups

Whilst a provision requires expert panels to take into account information provided by patient organisations when preparing scientific opinions, this Regulation is a **missed opportunity** to ensure that the principles of patient involvement are put into practice. Article 78 point 8 merely evokes the possibility to invite patient organisations in the Medical Device Coordination Group "as observers" rather than experts.

This situation is in sharp contrast with the area of medicines, where the Patient and Consumer Working Party in the European Medicines' Agency offers an established channel for users to voice their perspective and concerns on medicines.

We exhort the European Commission to address this important inconsistency as regards users' representation. Involving patients meaningfully in the implementation of the Regulation, particularly on aspects such as vigilance and incidents reporting, information to patients and transparency is of paramount importance for EPF, and a central right for patients in Europe.

Finally, **we regret to see some safety provisions being dropped from the European Parliament position**:

- In the final text, **only serious incidents** with devices are addressed whereas **EPF** had **called for all incidents** including use errors to be monitored, ensuring better patient safety.
- The designation of **notified bodies will remain a national competence**, unlike the proposed system by the Parliament whereby notified bodies responsible for the assessment of high risk devices would be designated by the European Medicines Agency. EPF supported this proposal as the quality of the work carried out by notified bodies was pointed out as unequal in the past.
- Although the involvement of patients and patients' organisations in ethics committees is strongly encouraged, so far merely the **participation of a layperson is made compulsory**.

EPF Secretary General, Nicola Bedlington commented: "*The new Regulation clearly paves the way towards a safer and more robust system for medical devices. However, we deeply regret the lack of ambition and commitment towards the involvement of patients and patient organisations in the safety and surveillance processes*".

- END -

The **European Patients' Forum (EPF)** was founded in 2003 to ensure that the patients' community drives policies and programmes that affect patients' lives to bring changes empowering them to be equal citizens in the EU.

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.

www.eu-patient.eu

Contact persons:

Laurent Louette
Communications Officer

+32 (0)2 280 23 34
laurent.louette@eu-patient.eu

Patient Empowerment Campaign
Patients prescribe £ for Sustainable Health Systems

#PatientsprescribE

European Patients' Forum (EPF)

31 Rue du commerce, B- 1000 Brussels

t +32 (0)2 280 23 35 | laurent.louette@eu-patient.eu

www.eu-patient.eu | www.eu-patient.eu/blog | /europeanpatientsforum | @eupatients.eu | /eupatient

Act now for Patient Empowerment: Sign the pledge here!

Please consider the environment before printing this e-mail

This press release received funding under an operating grant from the European Union's Health Programme (2014-2020).