Brussels, 8 June 2015

Re: European Patients' Forum's 3 priorities for the Regulation on Medical Devices

Dear Sir/Madam

I am writing on behalf of the European Patients' Forum to kindly remind you once again of the importance of the patients' perspective on Medical devices, ahead of the agreement due to be reached in Council this month on the proposal for a Regulation.

1. Patient Safety

EPF believes that improving patient safety and quality of care should be the core objectives of the Regulation. In our view this can be achieved through:

- Better scrutiny for devices: We believe that better scrutiny is needed through further control on high risk devices as proposed by the European Parliament, as well as clearer responsibilities for notified bodies.
- Better rules on clinical investigations and clinical evaluation are essential to guarantee the safety of patients in the EU.
- A safe framework for reprocessing: EPF believes that reprocessing should only be allowed when reprocessors (including healthcare institutions) have proven it is safe for the patients and with clear standards. Reprocessing may lead to device malfunction or healthcare-associated infection if not carried out properly.
- Improved vigilance as proposed by the European Parliament in their first reading position.

2. A strong commitment to improve transparency and information to patients

Implementing better transparency on clinical investigation, conformity assessment, and post market vigilance is paramount to restore trust and confidence, and ensure all actors have access to the information they need to play their part in the safety chain. Easy access to quality information can also empower patients and their healthcare professionals to make the best treatment choice.

3. Patient involvement

Patients with chronic and long term conditions have a specific expertise as users of devices and healthcare services. While patients are currently well involved at European level on governance for medicinal products, thanks to the model of involvement set up by the European Medicine Agency, this is not the case for medical devices. EPF strongly believe that patients need to be meaningfully involved in governance of medical devices and implementation of the Regulation.

Our full detailed recommendations on medical devices are accessible on our website.

We call on you to uphold these priorities when considering the Council position. EPF is committed to continue engaging in this debate with decision-makers to ensure patients have access to safe, high quality medical devices in the EU.

Yours Sincerely

Anders Olauson
EPF President

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 65 members, which are national coalitions of patients' organisations and disease specific patient organisations working at European level.

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.