FOR IMMEDIATE RELEASE

EUROPEAN PATIENTS' VERDICT ON THE COUNCIL POSITION ON MEDICAL DEVICES

"PROMISING ON TRANSPARENCY BUT NOTABLE GAPS IN PATIENT SAFETY AND GOOD GOVERNANCE"

Brussels, 23 June 2015– Medical devices are of crucial importance for patients with chronic diseases. They can provide a major contribution to life expectancy and quality of life of patients.

The European Patients' Forum (EPF) welcomes the fact that the Council has reached partial agreement on the medical devices regulation on 19 June. However some key shortcomings need to be addressed in the trilogue to ensure the final Regulation provides for safer medical devices in the EU.

A LUKEWARM STANCE ON PATIENT SAFETY

"Patients are expecting a stronger commitment to patient safety in the final Regulation", said Nicola Bedlington, EPF Secretary General. A new case of faulty implants fraud was unveiled in May in Spain, showing the need for a stronger focus on safety and urgent reform in the medical devices area.[1]

Expert panel vs. special notified body

The Council proposes to better monitor the **safety of high risk devices** with an expert panel. They would provide scientific opinion on whether clinical evaluation is appropriate and if notified bodies do not follow their opinion, they will have to justify why (Article 81a and Annex VIII, Chapter 1, point 6).

This approach is not as comprehensive as the one proposed by the European Parliament in its first reading position. They suggested having special notified bodies to carry out the assessment of high risk devices, and an expert committee (involving patient representatives) to review assessments of medical devices on a case by case basis.

We believe both approaches are needed – special notified bodies, as well as an expert panel with clear obligation for notified bodies to act upon negative opinions when clinical evidence are not sufficient.

Clinical evaluation and investigation

Though the Council takes on board some key proposals for clinical investigations (Chapter VI), for example the obligations to have an ethical review, some loopholes remain.

[1] http://elpais.com/elpais/2015/05/12/inenglish/1431447137_818629.html

EPF is very concerned for instance that the option for a **joint assessment** of a single application for a clinical investigation would be voluntary for member states, unlike for clinical trials (Article 58 para 1).

Regarding rules for **informed consent** and protection of subjects EPF considers they are not as well defined as in the Clinical Trials Regulation . The Council includes only a short definition of informed consentin Article 2 without establishing criteria. High-quality patient information is a fundamental right. We strongly recommend defining at EU level the core elements of informed consent by relevant stakeholders, including researchers and patient organisations.

Post-market surveillance and vigilance (Chapter VII)

We are pleased that the Council has introduced many encouraging provisions in its position to monitor safety of devices already on the market, including measures for direct patient reporting of incidents.

We regret however that most measures would apply only to serious incidents, which have a very limited definition, preferring the European Parliament proposal that it should apply to all incidents. The European Parliament had also proposed that information should also be collected about users' errors, which we believe is key to improve safety and quality of devices, but the Council has not taken this proposal on board in its own position.

The rules on **reprocessing of single use devices** proposed by the Council are a step forward compared to previous proposals (Article 15). Healthcare institutions would need to comply with common specifications for reprocessing and need to guarantee the reprocessed device is as safe as the original. Other reprocessors would need to conform to all the obligations of manufacturers, which include the establishment of a risk management system.

EPF considers the list of devices that can never be reprocessed to be established by the European Commission as important for patient safety as, for example, a scientific committee has established that reprocessing single use critical use devices (for invasive procedures) poses particular risks.[2] Member States would also be able to ban the practice of reprocessing. While we support this, we further recommend introducing measures to encourage member states to monitor implementation of this ban.

TRANSPARENCY: A KEY STEP FORWARD FOR PATIENTS AND THE PUBLIC

EPF appreciates that the Council has endorsed in its general approach key provisions to ensure more transparency towards the public and patients on medical devices:

- A **summary of safety and clinical performance** for high risk (class III) and implantable devices that will be available to the public in clear language for the intended user [3]including where relevant the patient (Article 26).

[2] http://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_o_027.pdf
[3] Users of medical devices include patients, consumers and healthcare professionals

- **Information to patients on implants (Article 16)**: EPF is encouraged that the Council agrees that some key information should be provided to the patients even if they have not adopted the proposal of an implant card. We nevertheless call on re-introducing the Parliament provisions on providing information to patients on potential adverse events, or the recording of information about the implant on patients' medical records in the final Regulation, as they are important for patient safety. Further, EPF emphasises the importance of information being provided *before* the device is implanted, which is not required at the moment.
- **Access to the Eudamed database (Article 27)**: The Council, like the Commission and the European Parliament, supports the new goal to give information to the public through the database on medical devices. It proposes that the database should inform patients on devices placed on the market, clinical investigations, vigilance, and market surveillance.
- **Results of clinical investigations (Article 56)**: The Council supports publication of the results within one year of the end of the investigation, along with a lay summary. EPF strongly supports this provision.

An important caveat, however, is the lack of patients and users' involvement foreseen in implementation of all these transparency measures. We believe that this is a barrier to real transparency as patient and other users' organisations have a key role to play in advising on accessible formats, ensuring information is user-friendly, and that the content correspond to the user's needs.

PATIENT INVOLVEMENT: THE COUNCIL PROPOSES A TOKEN ROLE AS "OBSERVERS" FOR DEVICES USERS

Member states did not commit clearly to any progress on **patients' involvement in governance**. Patients and other users such as consumers and healthcare professionals would be invited to join sub-groups of the Medical Device Coordination Group in the capacity as "observers", not as experts (Article 78 point 7).

In the area of medicines, patients are recognised as experts and are participating in many aspects of access, innovation, safety and transparency. This is thanks, in no small part, to the commitment to patient involvement of the European Medicines' Agency.

This change of mind-set needs to happen in medical devices. Patient involvement in health and social care is a fundamental right, and an operating principle of European healthcare systems. Patients currently do not have a channel to convey their concerns, opportunities, and views on medical devices, and a permanent structure such as a sub-group with representatives of patients and users of medical devices is essential to close this gap.

The Council encourages, but does not make mandatory, the **involvement of patients in ethics committees (Article 2 (37l))** - as in the clinical trials regulation – we consider this provision is too weak**.**

In particular it makes the assumption that patient and lay person involvement is equivalent, which is erroneous.[4] Patients have a unique experiential knowledge stemming from living with a chronic or long term condition. They also have unique insight on benefit and risks, as well as a key expertise to assess whether the information provided to participants is appropriate. We strongly encourage the EU institutions to make patient involvement in ethics reviews mandatory.

NEXT STEP: THE TRILOGUE

According to the MEP rapporteur Glenis Willmot (S&D, UK), a trilogue where the European Commission, the Council and the European Parliament will discuss the final text is likely to take place in the autumn.[5]

"*This is the last opportunity for decision-makers to set the right framework to ensure patients have access to safe, high quality medical devices in the EU. EPF is committed to share the patients' perspective on medical devices with decision makers during this process*" concluded EPF Secretary General.

- 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 65 members, which are national coalitions of patients organisations and disease-specific patient organisations working at European level, and. EPF reflects the interests 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 person:

Laurène Souchet
EPF Policy Officer
Phone: +32 (0)2 274 08 63
laurene.souchet@eu-patient.eu

[4] http://www.eu-patient.eu/globalassets/policy/clinicaltrials/epf-statement_ctr_jan2014.pdf
[5] http://www.gleniswillmott.eu/medical-devices-rapporteur-welcomes-council-decision/

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