

## EPF Statement

### EPF urges the Council to prioritise discussions on the Medical Devices Regulation

Brussels, 8 November 2013 - The European Patients' Forum (EPF) welcomes the vote on 22 October of the European Parliament on Medical Devices. The adopted text maintains commitment towards more transparency and safer medical devices. However EPF urge the European Parliament and the Council to address the remaining shortcomings in the legislation and adopt it before the 2014 European elections to ensure that EU patients gain access to safer medical devices without delay.

*"We hope the EU institutions will send a strong signal to patients and citizens that the safety and quality of their care is still a priority on the EU agenda before the elections, with the Regulation on Medical Devices as a tangible result"* said Nicola Bedlington, EPF Director.

#### Improved assessment process but weaker scrutiny

EPF is supportive of the **improved conformity assessment process**. Special notified bodies designated by the European Medicines Agency will carry out the assessment of high-risk devices. In addition, an independent expert committee, the Assessment Committee for Medical Devices, will be able to review some devices on a case-by-case basis.

However, we are disappointed that **the scope for scrutiny has been considerably watered down** compared to the ENVI report. We believe all class III devices and implantable devices in class IIb which are considered to be potentially high-risk for patients, need appropriate scrutiny by this committee composed of medical experts – not only implantable class III devices, which received particular political attention in the wake of the scandal over PIP breast implants.

#### Progress on patient involvement

The European Parliament listened to our call for more patient involvement. Patient representatives will be involved in the Assessment Committee for Medical Devices and in another advisory committee with relevant stakeholders. Patient organisations will also be involved in ensuring information to the public is user-friendly.

It is vital that patients are involved in medical devices regulation as they are already in regulation for medicines through the Patients and Consumers' Working Party of the European Medicines Agency<sup>1</sup>. Patient involvement is a legitimate right, and beneficial for safety and quality of devices: patients can contribute their expertise at various stage of the process from clinical investigation to vigilance

EPF strongly believes that patient involvement will foster **better quality information** to the public and **more transparency** in the system. There is a strong commitment in the report to improve this, notably through opening parts of the Eudamed database to the public, and through giving better information on implants to patients. In addition, a summary of the safety and performance report for Class III high-risk devices will be accessible to the public.

#### Better clinical investigations but need for more clarity and transparency

<sup>1</sup>[http://www.ema.europa.eu/ema/index.jsp?curl=pages/partners\\_and\\_networks/general/general\\_content\\_000317.jsp&mid=WCOB01ac058003500c](http://www.ema.europa.eu/ema/index.jsp?curl=pages/partners_and_networks/general/general_content_000317.jsp&mid=WCOB01ac058003500c)

The report also improves the rules to conduct **clinical investigations**; an area previously pointed out as a weakness of the system. All investigations would be subject to an ethics review, and patients' views would be taken into account in assessing applications for clinical investigations on medical devices. Sponsors would have to plan for post-trial treatment of patients participating in investigations. The results of investigations, including a layperson summary, would have to be provided to member states within clear deadlines.

However, EPF would welcome more transparency towards the patients and the public on investigations, with clarity that the layperson summary of results will be available to the public on Eudamed.

### **A real achievement: the vigilance and post-market surveillance**

We call on the Council to maintain the text adopted by the European Parliament as regards **vigilance and post-market surveillance**. The report ensures patients have the possibility to report suspected safety incidents; the availability of key safety information in the EU database; awareness campaigns for patients and health professionals to encourage reporting; the obligation for manufacturers to report all incidents; and the collection of information about users' errors. We welcome these as major step forwards toward putting in place a real patient safety culture in medical devices.

### **Unclear provisions on re-use of devices**

We consider that the rules for **reprocessing of single-use devices** still need to be improved by legislators. This practice is currently unevenly regulated across the EU, and this is potentially dangerous for patients as reprocessing<sup>2</sup> may lead to device malfunction or healthcare-associated infection if not carried out properly.

We agree with the setting-up of clear definitions for single-use and re-usable devices, and that standards to ensure safe reprocessing will be established. However, the text does not currently require reprocessors and manufacturers to prove the safety of re-use before they are allowed to label a device as re-usable. We consider this an important gap in patient safety.

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.

For further information see EPF's position paper on medical devices, available on our [website](#).

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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 61 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.

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](http://www.eu-patient.eu)

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<sup>2</sup> Reprocessing means preparing a single use device for a second use (e.g. cleaning, disinfecting, refurbishing etc.)