EPF Recommendations for Council Common Position on Medical Devices

The European Patients' Forum (EPF) welcomed the results of the vote on 22 October in the European Parliament on the proposal for a Regulation of Medical Devices. The amendments adopted showed strong commitment towards more transparency on medical devices, and ensuring safety and quality of care for patients in the European Union.

EPF now calls on the Council to support key amendments of the European Parliament in its common position and address some remaining shortcomings to ensure European patients have access to safer devices across the European Union without delay.

1. Improving patient safety, quality of care, and patients' well-being as priorities within the new Regulation

EPF believes the Regulation should clearly commit to a stronger emphasis on patient safety and the protection of public health as core objectives. (*Amendment 1*).

The Regulation defines "benefit" of a medical device as the positive health impact of a medical device based on clinical and non-clinical data. However this definition may be too restrictive from our viewpoint, it would also need to encompass benefit for the quality of life of the patient. *Amendment 80* needs to be modified to ensure benefits for patients are fully considered.

2. Stronger conformity assessment

EPF welcomes the proposal from the Parliament to strengthen conformity assessment (*Amendment 38*).

Better scrutiny for high risk devices

We support the designation of special notified bodies[1] by the European Medicine's Agency to assess conformity of all high risk devices and implantable devices (*Amendments 136, 137, 138, 299, 360, 361, 363, 370, 371, and 373).* We also call on the Council to adopt *Amendment 314* that will ensure better assessment of clinical evaluation for class III devices[2] through pooling of expertise.

We welcome the setting up of the Assessment Committee for Medical Devices (ACMD), an independent committee composed mostly of medical experts that will be able to review the assessment of some high risk devices on a case-by-case basis. However, we believe the scope for scrutiny by the ACMD originally planned in the ENVI report should be restored: as it is, only class III implantable devices may be reviewed, which received particular political attention in the wake of the scandal over PIP breast implants. In our views, **all class III devices and implantable devices in class IIb which are considered to be potentially high-risk for patients need appropriate scrutiny**.

[1]Note: these notified bodies will have to fulfil additional requirements to be allowed to assess the conformity of Class III devices before they are placed on the market.

[2] Class II and III devices are the higher-risk categories for device, which are submitted to further control during the conformity assessment process compared to Class I devices.

This would also be more aligned on the first proposal by the Commission to have a scrutiny mechanism for all Class III devices. We call for adequate changes in *Amendments 364, 367, 374, 378.*

Clearer roles and responsibilities for all actors

Notified bodies have been flagged as the weak link in the current medical devices framework, therefore we welcome measures taken by the European Commission and reinforced by the European Parliament to better define their responsibilities and to improve oversight of their activities (*Amendments 141, 142, 143, 295, 310, 311*), transparency (*Amendments 140, 144, 294, 300, 301, 372*), and coordination *(Amendments 145, 146, 147*).

We particularly welcome provisions to ensure they have the right expertise to assess clinical data (Amendments 133, 134, 295, 296) and to set a transparent and fair system as regards the fees they levy to carry out assessments. This will ensure competition between them is not to the detriment of patient safety and quality of assessment of medical devices (*Amendments 53, 149*).

EPF also supports amendments that clarify the role and competences of **national authorities and Member States** (*Amendments 132, 220, 221*).

We welcome that **manufacturers** will need to have in-house a person responsible to ensure compliance with the law (*Amendments 22, 110*). EPF calls on the Council to adopt measures that will ensure patients' access to redress and compensation when harmed by medical devices (*Amendments 21, 103, 104, 105, and 106*). We also believe that taking measures to deter fraud by manufacturers is in the interest of patient safety and quality of care (*Amendment 51*).

In addition, the European Parliament proposed some rules as regard manufacturers' interactions with notified bodies: When a manufacturer apply to a notified body in another Member State he will have to notify the competent authority, as well as when they withdraw an application. We also welcome clearer rules for inspection by notified bodies of manufacturers' premises and notification to national authorities and other notified bodies when a manufacturer withdraws an application (*Amendment 160*).

3. The safe reuse of devices

EPF is concerned by the current absence of common rules as regards reprocessing of single use devices. Therefore we welcome efforts of the European Commission and the European Parliament to regulate this practice. But while there are steps in the right direction, the current proposal is still unsatisfactory from a patient safety perspective.

Since the onset of this debate, EPF advocated that **if reprocessing is to be allowed, it should be with clear, legally binding procedures, standards, and practical guidelines to define and explain in which conditions and how to reprocess safely, and after evaluating the potential risks for patients.**[3]

We also believe that clear definitions for single-use and multiple-use devices are needed. Therefore we welcome *Amendments 287 and 357*, and the first part of *Amendment 24* which clarify that if a device can be used more than once or reprocessed, it should not be called single use.

[3] http://www.eu-patient.eu/Documents/Policy/MedicalDevices/EPF-Statement_Medical-Devices_April13.pdf

We welcome the proposal from the Parliament to set **standards** for the safe reprocessing of devices (*Amendment 118*). We believe that hospitals should not be exempted from this, as it is crucial all reprocessors[4] comply with the standards in order to better prevent adverse events such as healthcare associated infections and device malfunctions.

While we welcome the possibility for a Member State to ban the practice of reprocessing (*Amendment 358*), we believe appropriate enforcement of the ban also needs to be addressed in the current proposal.

We are also concerned that hospitals, manufacturers and other types of reprocessors, which also include private for-profit companies, have no clear obligations to prove that devices can be reused safely or to do an analysis of the potential risks before being allowed to label a device as reusable. This is an important loophole in terms of patient safety in the Regulation. *Amendment 358* states that legal persons have to "provide scientific evidence that the device could be safely reprocessed" but sets no specific modalities. We urge the Council to specify requirements in an annex to ensure devices are only labelled as reusable when it is safe for patients. We also call on amending point 3 of this amendment, "Unless they are placed on the list of single-use devices referred to in Article 15b, medical devices shall be considered as suitable for reprocessing and reusable devices in accordance with the provisions laid down in Article 15c, and providing the highest level of patient safety is guaranteed." We are concerned this provision could lead to automatic labelling of devices as reusable when they are not on the single use list, without scientific evidence of the safety of reprocessing.

4. Improved clinical evaluation and investigation

The revision of the framework for medical devices is a crucial opportunity to improve the rules as regards the conduct of clinical investigations and the collection of clinical data for medical devices. We agree with the inclusion of a reference to the European Medicines' Agency policy on transparency as we support the process carried out by the Agency to reflect on a solution that serves science, patients and the public interest (*Amendment 32*). We also support the reference made to the principle of informed consent amongst the fundamental rights that the Regulation respects (*Amendment 56*). We strongly support *Amendment 347* that requires the sponsor to have a plan for the further treatment of the patient after the clinical investigation, to ensure continuity of care.

Application for a clinical investigation

EPF supports the obligation set for sponsors of a clinical investigation to submit an application to the Member State where it is to be conducted (European Commission's proposal). We strongly support the provision that **the view of patients must be sought in the assessment of the application**: it is crucial in order to assess the relevance of the investigation to patients' needs, and to obtain an accurate risk-benefit assessment *(Amendment 180*). Patients voluntarily provide data for research and ultimately manage the risks involved. They therefore have the right to be involved in the way research is developed, managed and evaluated.

[4] The reprocessing of devices encompasses various activities to ensure that a medical device can be safely reused, ranging from decontamination, sterilisation, cleaning, disassembly, repair, component replacement and packaging. Reprocessors designate companies or entities that reprocess devices.

Ethics review

We welcome the reference to the World Medical Association's Declaration of Helsinki including its article 15 which states clearly that an ethical assessment need to be carried out before a clinical study begins (*Amendment 40, 181).* We also support *Amendments 83* as it refers to well-controlled investigations in the target population. We believe it is important that investigations are carried out on the population that will later use the device with no restriction related to age, gender or disease*.* We also welcome the specification of the aim of clinical investigations in *Amendments 175 and 335,* as it clarifies that they should assess safety, efficacy, and benefits of the device for the patients.

Patient involvement in ethics committees

The scope of patient involvement was not clearly defined in the European Commission's proposal. EPF supports the new definition of "ethics committee" introduced by MEPs which includes at least one patient or patient representative (*Amendment 88*). However, EPF believes that qualifiers in the legal text ("well-experienced and knowledgeable") are contrary to the aims of patient involvement and could in practice lead to ethics committees excluding patients on the pretext that they cannot find suitably knowledgeable representatives. Instead, patient involvement should be supported through appropriate capacity-building initiatives and through identifying models for best practice, such as that of the European Medicines Agency. [5]

We also support the development of guidelines on best practice regarding patient involvement in ethics committees (*Amendment 181*). This approach clarifies the role of patients, and ensures that the patient perspective is included in ethical assessment.

Room for improvement: Transparency on results

EPF strongly supports rules to improve transparency on clinical investigations and their results. We believe this is essential to ensure trust and confidence in the safety and quality of devices, and to empower patients and healthcare professionals to make informed decisions.

We welcome the setting up of an electronic system on clinical investigations and the right for any member of the public to request information (*Amendment 185*). We also welcome that information on the methodology of the study will have to be on the electronic system (*Amendment 182)*

However one key area which lacks clarity is publication and access to results of clinical investigations. While we support the requirement for sponsors to publish results within one year from the end of the clinical performance study or from its early termination irrespective of the outcome of the investigation, and the requirement to publish a layperson summary (*Amendments 41, 183, 190*), we think several issues remain: The Regulation does not explicitly mention that the layperson summary needs to be accessible to the public on Eudamed for devices other than class III. In addition, for devices that are evaluated through non-clinical testing methods, there are no transparency requirements.

We believe that core elements of the summary need to be defined by the Commission with the participation of key stakeholders including patients and consumers, healthcare professionals and

[5] The EMA has since its establishment in 1995 successfully included patient representatives in its scientific committees and scientific advisory groups. For information see "Framework" document and subsequent assessment reports, available at http://www.ema.europa.eu/ema/index.jsp?curl=pages/partners_and_networks/document_listing/document_listing_000235.jsp&mid=WC0b01ac05800aa3cb

researchers to ensure these groups have access to the quality information they need (*Amendment 190*). We welcome the provision for the voluntary sharing of raw data, but we believe the Commission needs to consult with stakeholders when drawing up the guideline to ensure data are shared appropriately, with consideration for the privacy of study participants, and in a user friendly way. We also believe there is a need for a mechanism to facilitate access by researchers and healthcare professionals to the clinical investigation report.

5. Risk classification

The European Patients' Forum welcomes measures to ensure more coordination between Member States and more transparency on risk classification for devices (*Amendments 150, 151*).

6. Traceability

Implant card

EPF welcomes the setting up of implant cards that will aim at ensuring traceability of implantable devices and to provide information to patients on these devices. We welcome the expanded list of mandatory information proposed by the European Parliament, but we believe the list needs to be reviewed with the participation of users (including patient and consumers) to ensure information about implants meet their needs. One crucial element that is missing is the requirement to submit the information to the patient before the device is implanted. Since the information is in an electronic format it is also unclear how patients can access it. Not all patients have access to electronic health records across the European Union. We believe *Amendment 120* needs to be modified taking into account these points.

Unique Device Identifiers (UDI)

EPF welcomes that the UDI system that will be put in place to ensure better traceability of the devices needs to be compatible with the safety features for medicines and existing international systems (*Amendments 123, 127-128*). While we agree with the gradual approach proposed by the Commission for the implementation of this measure, we believe that there is a need to clarify which devices will need to bear UDI in the long term.

Medical devices registers

We welcome *Amendment 248* that requires the setting up of registers for all class III and IIb devices to better gather post market surveillance data.

7. Vigilance and post market surveillance

We believe that the European Commission and the European Parliament made considerable achievements in terms of ensuring better post market surveillance for medical devices, and we urge the Council to adopt the changes they proposed.

Key improvements EPF strongly supports are:

- Collection of information about **users' errors**. We believe this can improve the safety and knowledge of devices as users' errors are an important source of incidents with medical devices (*Amendment 195*).
- Ensuring that Member States take appropriate measures including **targeted information campaigns** to encourage users to report (*Amendment 46, 198*). We believe this is essential to ensure the vigilance system works effectively in practice.

- The setting up of several **means for reporting** including both electronic and non-electronic format, and ensuring they are developed in consultation with relevant stakeholders (*Amendment 196, 198*). These measures are important to enable all patients to report, and to ensure usability of the forms.
- Replacing the wording serious incidents by "**incidents**" in the vigilance chapter of the Regulation (Amendments *203, 204, 205, 206, 207 208, 210,212*). We welcome this as the definition for serious incidents is very narrow and would only encompass incidents that have provoked death, permanent disability, or had life-threatening consequences. In our view it is important to collect information on **all incidents** to ensure patient safety and to better prevent incidents with medical devices.
- New vigilance requirements for the manufacturers, including drawing up of a Periodic safety update reports (*Amendment 209*) and Post-Market Clinical Follow-up evaluation plan and reports (*Amendments 292, 330, 331, 332, and 333*).
- When there is an incident, Member States have to take action, taking into account the views of patients' and healthcare professionals' organisations (*Amendment 200).*
- Clarification of responsibilities of manufacturers and Member States to take appropriate action without delay, and to step up cooperation on vigilance (*Amendments 219, 223, 224, 225, 234,235, 228, 230, 231, 232, 233*).

8. Information to patients and transparency

The European Patients' Forum strongly welcomes the stance of the European Parliament to encourage better information to patients and transparency to the public on medical devices, as acknowledged in *Amendments 25, 28, 29, and 30.* Implementing better transparency in clinical evaluation, 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. Access to information can also empower patients and healthcare professionals to make the best treatment choice.

Key measures proposed by the European Parliament that we call on the Council to endorse include:

- **Clearer labelling**: All devices should bear the mention that this is a medical device, the fact that it is single-use where applicable, and the intended purpose when this is not obvious (*Amendments 285, 286*).
- **Prohibition of misleading information** (*Amendment 98*)
- Better **information on vigilance** through an overview for the public and healthcare professionals every 6 months, available through Eudamed (*Amendment 30, 217*).
- The **instructions for use** shall be lay-friendly and reviewed by representatives of relevant stakeholders, including patient and healthcare professionals' organisations. (*Amendment* 290)
- We welcome the right for an individual to obtain information without undue delay when they make a **reasoned request** (Amendment *30, 185, 199, 217, 249, 289, and 294*). However we believe a simple mechanism should be put in place on Eudamed to ensure members of the public can benefit from this provision effectively, alongside with clear guidance on what "reasoned" means.
- A **summary of safety and clinical performance** for class III devices, updated annually and publicly available through Eudamed (Amendments 130, 173) that would provide key information collected during clinical investigations for high risk devices to the public. While we welcome this provision, we believe the Commission should involve users in the drawing up of the format to ensure it corresponds to their needs.

Patients should have access to information on registered devices, economic operators, clinical investigations, vigilance data and market-surveillance activities through Eudamed. (*Amendment 30, 131*) While we welcome the European Parliament's proposal to consult healthcare professionals' and patients' organisations to ensure the information on the database is **robust and user friendly**, we believe they should be further involved to draw up an access policy for Eudamed, similarly to the Eudravigilance access policy to ensure members of the public have access to the information they need.[6]

9. Patient involvement

Patient involvement is a fundamental and legitimate right, and also highly beneficial. As users who also have expertise as a result of managing chronic conditions in everyday life, patients have a key role to play in contributing to safety and quality of devices, starting from the innovation process and the clinical evaluation, to post marketing vigilance. Their involvement is also key for the development of high quality information and to ensure real transparency about medical devices.

This is why EPF strongly recommends transposing the model of patient involvement developed by the European Medicines Agency[7] for medical devices and ensuring that this involvement is meaningful. The European Parliament made key changes in order to ensure the patients' perspective is better taken into account from clinical investigations to vigilance.

We strongly welcome that relevant stakeholders will be involved in the **Medical Devices Advisory Committee** that will provide support, advice and expertise on technical, scientific, social and economic aspects of regulating medical devices (*Amendments 8, 240*). However we would suggest that **creating a subgroup** for medical devices similar to the Patient and Consumer Working Party of the EMA is essential to capture the patients' expertise. This would allow for progress in areas of key interest for patients such as clinical investigations, vigilance, transparency, and for the good implementation of provisions involving patients in the Regulation once adopted.

We also support patients' participation in the **Assessment Committee for Medical Devices**. Patients are involved in key decision making bodies and scientific boards when it comes to medicines, but this is not currently the case for medical devices. However medical devices are also of crucial importance to patients as they can contribute to health, quality of life, and life expectancy of people with chronic conditions. Patient representatives in this committee will be able to bring the patients' specific perspective on risk and safety of medical devices, and may have experience in using or living with the device in everyday life. The number of representatives within the committee is unclear: we strongly believe 3 representatives are needed to ensure this involvement is meaningful. Therefore we call on modifying *Amendment 364* and adopting *Amendment 367*.

EPF is committed to working closely with the European Institutions and stakeholders to ensure that medical devices in the EU are safe, high quality, accessible and meet patients' needs.

[6] http://eudravigilance.ema.europa.eu/human/EudraVigilanceAccessPolicy.asp
[7] See *supra* note 5

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, 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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