



## European Commission's proposal for a Regulation on Medical Devices (2012/0266 (COD))

### EPF Position Statement

April 2013

#### Introduction:

Medical devices include any apparatus, appliance, software, material or other article, which is used for the diagnosis, prevention, monitoring; treatment or alleviation of diseases, injury or disability. There are around 500,000 different types of devices on the market, covering a wide spectrum from simple bandage to x-ray machines or pacemakers.

They are of crucial, and often vital, importance for patients with chronic diseases: they can provide a major contribution to life expectancy and quality of life of patients.

In September 2012, the European Commission issued two proposals for Regulations, on medical devices, and *in vitro* diagnostic medical devices, as well as a "Communication on safe, effective and innovative medical devices and *in vitro* diagnostic medical devices for the benefit of patients, consumers and healthcare professionals" available [here](#).

EPF has been engaged in the process to review the medical devices from the very onset: We responded to a Commission's consultation in 2008 (our response is available [here](#)), and participated in the EU exploratory process on medical devices. We also participated regularly in the Medical Device Expert Group meetings.

In December 2012, we circulated a first draft position based on this previous work to our membership. Comments received were integrated into this position statement which was circulated again to our membership for approval. This position paper may be updated in the course of the legislative process, as necessary.

The European Patients' Forum (EPF) was founded in 2003 to become the collective patients' voice at EU level, manifesting the solidarity, power and unity of the EU patients' movement. EPF currently represents 59 member organisations, which are chronic disease-specific patient organisations working at European level, and national coalitions of patients' organisations. Collectively they reflect the voice of over 150 million patients living with various chronic diseases in the European Union. EPF's vision for the future is high quality, patient-centred, equitable healthcare throughout the European Union.

## Key recommendations

EPF is committed to uphold patient safety and quality of care as the main priorities throughout the legislative process on the proposal for a Regulation. While the debate focuses on the governance and whether a pre-market scrutiny or pre-market approval can achieve these goals, EPF would like to highlight that better safety can only be reached through establishing good governance principles for medical devices: transparency, objectivity, independence of expertise, fairness of procedures, and broad stakeholder participation from all relevant groups.

For this reason, EPF believes the cornerstones to build on a better framework for medical devices are:

**1/ Users' 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, 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. EPF strongly recommend transposing the model of patient involvement developed by the European Medicines Agency for medical devices and ensuring that this involvement is meaningful<sup>1</sup>.

**2/ Transparency throughout the system:** 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 their healthcare professionals to make the best treatment choice. EPF urges the EU institutions to set clearer and stronger provisions for transparency within the Regulation.

**3/ Patient safety as a priority throughout the medical device lifecycle:** In our view this can be achieved through enabling better clinical evaluation & investigation, a stronger conformity assessment process with tighter requirements for expertise within notified bodies, clearer responsibilities, and a strong EU cooperation in the area of post marketing vigilance.

In addition EPF would like to stress that the EU has taken key commitments to tackle health inequalities with the communication "Solidarity in health: reducing health inequalities in the EU" and the European Parliament resolution on health inequalities in the EU. In this context we believe the EU institutions should actively promote equitable access to high quality medical devices for all patients throughout the EU.

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<sup>1</sup> EPF has developed the concept of meaningful patient involvement as part of the project Value +: [http://www.eu-patient.eu/Documents/Projects/Valueplus/doc\\_epf\\_policyrec.pdf](http://www.eu-patient.eu/Documents/Projects/Valueplus/doc_epf_policyrec.pdf)

## 1. Scope and definitions (Chapter I)

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### 1.1. Scope (Article 1)

The Regulation covers all medical devices apart from *in vitro* diagnostic devices<sup>2</sup>. It merges the Council Directive 90/385/EEC on active implantable devices and Council Directive 93/42/EEC on medical devices. EPF welcomes the merging of the two directives. This merger should not mean applying lower standards for active implantable medical devices, however: when defective these devices can be the most harmful to patients, as various cases have shown in the past.

EPF believes that for all devices, the review should address patient safety in a comprehensive way, from clinical data collection and evaluation to post-market follow-up. It is essential to ensure, with effective regulation, that the quality of medical devices authorized on the market is of high standard across all EU Member States. This applies equally to emerging new technologies as to those which are already on the market. We also welcome the extension of the scope to new categories of devices.

### 1.2. Definition of medical devices (Article 2) and borderline cases (Recital 8 and Article 3)

EPF agrees with the definition of Article 2 – and with the demarcation it sets between medical devices and medicinal products. We also welcome that combination products which are composed of substances and are intended to be ingested, inhaled or administered rectally or vaginally and that are absorbed or dispersed in the human body have to comply with requirements for high-risk medical devices and also with relevant requirements from the Medicinal products Directive 2001/83/EC.

We also welcome the possibility for the European Commission to adopt an implementing act to determine if a product or category of product is a medical device. However Recital 8 specifies that it should be the responsibility of the Member States to decide on a case-by-case basis whether or not a product falls within the scope of this Regulation. EPF believes it is important to have clarity and consistency: if a product is considered a medical device in one country, it should be considered a medical device across the EU, with no divergence.

#### EPF recommends:

1. To ensure relevant cooperation with the European Medicines Agency for borderline cases and combination products.
2. Users including patients should be involved in the working group which delivers an opinion on borderline cases.
3. The European Commission should issue EU wide decisions in case of divergence between Member States when deciding on what is considered a medical device

## 2. Making available of devices, obligations of economic operators, reprocessing, CE marking, free movement

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### 2.1. Placing a device on the EU market: general requirements

All medical devices have to go through a conformity assessment procedure, based on essential requirements, to receive the CE mark compulsory to place a device on the EU market. For higher-risk categories the procedure is carried out by notified bodies, a mix of state and commercial bodies

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<sup>2</sup> The proposal for a Regulation on *in vitro* diagnostic devices is available [here](#). EPF will publish a separate position statement.

appointed by National Competent Authorities (NCAs). Devices need to meet the general safety and performance<sup>3</sup> requirements listed in Annex I.

**EPF recommends:**

4. To include a provision in order for the patients' perspective to be taken into account when the general performance and safety requirements of Annex 1 are to be amended: Patients are the ones using the devices in their daily lives and have a different perspective on the risks they are willing to take, or not take, and on the risk benefit balance.

## **2.2. General requirements for information to patients**

Annex I, point 19 details elements that manufacturers must provide on the label of the devices and in the instructions for use.

Patients have a fundamental and legitimate right to access information on all aspects of their health and their treatments, including high-quality, non-promotional, unbiased, comparative and validated information on the safety, efficacy, clinical validity, utility, implications for daily life, clinical follow-up, HTA outcomes, product availability and costs of medical devices. We welcome that the Commission introduced a requirement for manufacturers to indicate circumstances where lay users should contact their healthcare professionals (Annex I, 19.3 (q)).

Appropriate patient-friendly information helps prevent the occurrence of users' errors that can cause medical device incidents and therefore improves patients' safety. Moreover, informed patients are more likely to report any issues they have with the devices and act correctly in case of defect. Information and health literacy is key for patients to become effective co-managers of their disease, and to empower them to contribute actively to their healthcare and to patient safety, and to the development of new innovative solutions.

**EPF recommends:**

5. Elements in the instructions for use for patients should be reviewed with the input of patient organisations to ensure they truly correspond to patients' needs and are understandable and accessible.
6. A similar practice should be introduced for medical devices as exist for medicinal products, where there is patient/lay review of the information supplied to them. For class IIa, IIb and III medical devices<sup>4</sup> (when the notified bodies are involved in the conformity assessment procedure), compulsory check of the information provided to patients should be foreseen and patients' involvement required.
7. We call for a comprehensive strategy at EU level to improve health literacy and patients' access to high quality information on medical devices and medicinal products alike.

## **2.3. Obligations of manufacturers (Article 8) and other actors**

EPF welcomes the requirement that each manufacturer should have a qualified person to ensure regulatory compliance. We believe this will ensure a better enforcement of this legislation.

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<sup>3</sup> Equivalent of efficacy

<sup>4</sup> Please refer to section 5 on classification for an explanation of the risk classes for medical devices.

## 2.4. Single use devices and reprocessing (Article 15)

Some medical devices are produced to be used only once. However, under current practice, they are sometimes reprocessed, that is to say prepared again for a second use. In this case the proposal states that the legal or natural person who reprocesses the device would be considered as the manufacturer of the reprocessed device and all obligations of the manufacturer apply to them.

We strongly believe the key priority should always be the safety of the patients over economic considerations. Reprocessing poses risks to patient safety and should be strongly advised against in the Regulation. We also believe the proposal should offer further protection for patients.

We support the provisions that allow Member States to ban reprocessing. We also warmly welcome that the information on which Member States have banned it will be made public by the Commission.

### EPF recommends:

7. 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.
8. Reprocessing of critical use devices should be prohibited, unless there is strong evidence that it is safe for a particular device: While there is little data on the risk, the SCENIHR indicated in [a study](#) that re-use may pose particular risks with this type of device.
9. To modify the definition for single use devices for critical use, which are devices “*intended to be used for surgically invasive medical procedures*”. This definition needs to be modified to take into account cases where the situation is critical due to the severity of the disease that is treated. One example given by our member the European Federation of Allergy and Airways Diseases Patient Associations is adrenaline injectors for patients with allergy, as the good functioning of these devices is critical and can save lives.
10. To ensure clarity in the legislation by introducing a definition for multiple use devices that would encompass the category of reprocessed devices.

## 2.5. Implant card (Article 16)

The Regulation introduces a new obligation that for all implantable devices, the manufacturer shall provide a card for the patient who has been implanted with the device.

### EPF welcomes this new requirement, but we recommend:

11. To refine the list of elements of information included in the card with the involvement of patients and users through their representative organisations.
12. The Regulation should state that this information must be supplied at the time of consent, before the device is implanted.

### **3. Identification and traceability of devices, registration of devices and of economic operators, summary of safety and clinical performance, European databank on medical devices**

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#### **3.1. Identification and Traceability**

EPF supports measures and requirements in Article 23 and 25 to improve identification of all devices. Traceability is essential for vigilance and post-market surveillance purposes, in cases where the product presents a risk and needs to be recalled, as well as in efforts to tackle counterfeiting more effectively. A solution also needs to be devised for the traceability of re-usable devices.

#### **3.2. Unique Device Identifier (Article 24)**

EPF supports the introduction of obligation for manufacturers to fit their devices with a Unique Device Identifier (UDI) which allows traceability.

##### **EPF recommends:**

13. While we welcome the gradual approach proposed by the Commission for the implementation of this measure, we believe that it should be clarified in this article that the long term aim is for all medical devices of Class III and II<sup>5</sup> to bear the UDI.
14. For the development of the unique device identifier, compatibility with the safety feature system being developed for medicines under the EU legislation on falsified medicines should be considered.

#### **3.3. Summary of safety and clinical performance (Article 26)**

For devices of Class III the draft Regulation introduces an obligation for manufacturers to prepare a summary of safety and clinical performance with key elements of the supporting clinical data, in a language which can be understood by the “intended users”. The Commission may set out the form and presentation of the data elements that need to be included in the summary.

EPF strongly welcomes this obligation. However, the article should also require explicitly that this summary will be made public. We also believe it should be clarified that the summary must be made understandable, always, for both categories of users: patients, and healthcare professionals, as they have different information needs.

##### **EPF recommends**

15. To ensure this summary of safety and clinical performance is made available to the public
16. To insert a provision to extend this obligation to other classes of device in the future
17. To task the Commission with setting clear standards to define what elements the summary needs to contain –These standards should be developed with the involvement of civil society, and in particular intended users including patient organisations.

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<sup>5</sup> 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. Class III encompasses active implantable medical devices. See section 5 for further details.

### 3.4. European Databank on medical devices (Article 27)

EPF welcomes the proposal to develop a European Databank for medical devices with integrated electronic systems on a European UDI, on registration of devices, on clinical investigations, on vigilance and on market surveillance and relevant economic operators and certificates issued by notified bodies.

One important step forward is that information to the public is clearly set as a new purpose for the database: the database must enable the public to be adequately informed about devices placed on the market. It must also enable the public to be adequately informed about investigations.

EPF believes that more transparency towards the public is necessary to empower patients and ensure public trust and confidence in the safety of medical devices. We would welcome the expansion of the role of the databank to become **a central point of information for patients** (and other stakeholders) **on medical devices**.

#### EPF recommends:

18. To design the database to be a central information point where patients can ask, seek and find information on medical devices.
19. The Commission should be required to establish a working group with relevant partners including patient organisations to ensure that users have access to information they need about medical devices, in a user-friendly format.
20. The database should contain clear information for the public on the quality criteria used to evaluate medical devices.
21. The results of all clinical investigations should be published on the database within one year in a format that includes all the relevant information, including a lay summary. The Commission should develop guidelines in consultation with stakeholders, including the research community and patient and consumers organisations, and to specify the exact content and format of the information that should be published.

## 4. Notified bodies

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EPF supports elements in the proposal that aim at improving the functioning of notified bodies – in particular the following provisions:

- Minimum requirements to be met by notified bodies set out in Annex VI are strengthened: notified bodies will now be required to have available personnel with clinical expertise.
- Any new designation and, in regular intervals, the monitoring of notified bodies are made subject to 'joint assessments' with experts from other Member States and the Commission. The Medical Devices Coordination Group will also be involved in the assessment of applications. Article 38 also provides for exchange of experiences between national authorities.
- The list of notified bodies will be publicly available.
- Article 37 gives power to the Commission to investigate when there are concerns regarding a notified body's compliance with the Regulation

EPF strongly welcomes that the roles and responsibilities of the competent authorities and notified bodies, as well as criteria for the selection of the latter, are defined more clearly in the Regulation. We believe this will make the conformity assessment procedure more reliable. EPF believe it is essential that the EU Regulation ensures notified bodies cannot compete on grounds that are detrimental to the quality of the conformity assessment procedure and cause risk to patient safety.

One of our key concerns which has not been fully addressed in the proposal for a Regulation is that competent authorities need to be required to verify that notified bodies have appropriate medical

and scientific expertise to be able to appraise carefully the clinical data and clinical evaluation. The requirement that notified bodies should have personnel with appropriate expertise is a step forward but as it is, it is not detailed enough.

**To this end, EPF recommends:**

22. The Regulation should foresee that the designation of all notified bodies should come under joint assessment – including established notified bodies. A report with the opinions of all Member states should be made publicly available by the European Commission after the assessment.
23. To further specify the conditions notified bodies should fulfil to comply with the requirement for appropriate medical expertise.
24. To ensure the Regulation contains strong provision for unannounced inspection of notified bodies.

## **5. Classification and conformity assessment**

Medical devices are classified into four risk categories (Article 41). The classification rules according to which manufacturers have to classify their devices are laid down in Annex VII and have been adapted to technical progress and experience gained from vigilance and market surveillance.

EPF agrees with the procedure to settle disputes on classification set in the proposal. In case of dispute between manufacturers and notified bodies on the class of the device, the competent authority will be referred to, and it must notify both the Commission and the Medical Device Coordination Group (Article 41(2)). We are also in favour of the provisions that allow the European Commission to decide through an implementing act how the classification rules apply to a device or group of devices and the possibility to update the criteria for classification in light of technical progress or new information gained through vigilance or market surveillance activities (Article 41(3)).

We support the setting up of the scrutiny mechanism for application for new high-risk medical devices (Article 44). It will empower the authorities to have a 'second look' at individual assessments, ensure they are aware of new high risk devices coming on the market, and give them opportunity to make their views heard before these devices are placed on the market. But we believe that it is essential to have representation of patients, and of healthcare professionals within the Medical Devices Coordination group.

**EPF recommends**

25. To set a provision in the Regulation for permanent patient representation in the Medical Devices Coordination Group: Patients have a different and unique perception of the risks and benefits of a device, therefore their direct views need to be taken into account in the assessment of new high-risk devices.
26. As regards ad hoc expertise for classification, meaningful and adequate patient involvement could be achieved through setting up a database of patient representatives to be able to identify patients from a relevant disease area when necessary. ( See also p.10)

## **6. Clinical evaluation and clinical investigation**

### **6.1. Clinical evaluation (Article 49)**

In order to obtain the EU certification, all manufacturers must carry out a clinical evaluation to demonstrate the safety and the performance of the device.



Robust clinical evaluation is paramount for patient safety and quality of care. Having reliable data proving the benefits of a device is also essential for healthcare technology assessment (HTA), and for pricing and reimbursement purposes, which ultimately affect patients' ability to access innovative devices. From our perspective, transparency on clinical evaluation is essential to ensure trust and confidence in the safety and quality of medical devices.

#### **EPF recommends**

27. The provisions which require manufacturers of class III devices to provide publicly available information on this as part of a summary of safety and clinical performances should also apply to other categories of devices.
28. Patients want access to all information that can be made public, notwithstanding genuinely confidential information. This should include information about clinical evaluation, and post-market follow-up plans and measures.
29. Manufacturers should be required, for devices belonging to a risk category above class I, to make publicly available a summary of the clinical evaluation report, justifying the methodology they have chosen for the clinical evaluation of the device, and to provide a summary of results of this evaluation accessible to patients and healthcare professionals.

## **6.2. Clinical investigations**

EPF welcomes the proposal to align rules for clinical investigations to the rules applicable for clinical trials as we believe this will strengthen the collection and analysis of data before the device is certified and placed on the market, and thus improve patient safety and quality of care. We support Article 50 which provides for protecting rights, safety and well-being of the subjects participating in a clinical investigation. We also welcome Recital 47 which states that rules of clinical investigation need to be in line with major international guidance in this field such as the Declaration of Helsinki on Ethical Principles for Medical Research Involving Human Subjects. For this section, we also refer you to our position on the proposal for a Regulation on Clinical Trials<sup>6</sup>.

### ***Electronic system on clinical investigations (Article 53)***

EPF is in favour of the requirement that every clinical investigation must be registered in a publicly accessible electronic system which the Commission will set up (Article 52). The electronic system on clinical investigations on medical devices should be interoperable with the future EU database to be set up in accordance with the future Regulation on clinical trials on medicinal products for human use.

#### **EPF recommends:**

30. To ensure the results of the clinical investigation are also made public through the electronic system.
31. To involve all user groups in defining an access policy for clinical investigation results and clinical evidence.
32. EPF welcomes the recent efforts of the European Medicines Agency to open discussion on how to publish data from clinical trials. We are committed to participating in this public debates in order to find a good solution that serves both science, patients and the public interest. We believe these efforts should be extended to a discussion on publication of results from clinical investigations for devices.

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<sup>6</sup> [http://www.eu-patient.eu/Documents/Policy/ClinicalTrials/EPF-position-statement\\_CTR\\_Feb-2013.pdf](http://www.eu-patient.eu/Documents/Policy/ClinicalTrials/EPF-position-statement_CTR_Feb-2013.pdf)

33. All relevant updates to the information concerning an investigation should be posted on the database, such as measures taken by Member States to terminate, suspend or modify an investigation, as well as updated information on the benefit-risk balance or any urgent safety measures taken.

### ***Application for clinical investigation (Articles 51, 56, 57, 58)***

#### *Obligation to submit an application*

EPF is in favour of the obligation set for sponsors of a clinical investigation to submit an application to the Member State where it is to be conducted set in the proposal. We strongly support the provision that the patients' views 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. Patients, who ultimately bear the personal risks of participation in research, have the right to be involved in assessing its risks compared to that of investigators or regulators. They may be more willing to take up higher risks for less or different benefits (such as quality of life), or a lesser guarantee of benefit.

However, the wording of Article 51 – “at least one patient” is not sufficient in our view. The view of one patient is not enough, as it is difficult for one patient to represent the view of all patients in an investigation. In fairness and to give strength to the process, there must be at least two. Therefore, a support structure needs to be put in place.<sup>7</sup>

Involving patients requires that they are given appropriate support and educational opportunities both about research and ethics generally as well as the specific area to be researched, to help their participation in scientific discussions. Those working with patients and involving them also need training.

#### **EPF recommends:**

34. Guidelines are needed at EU level to define how patient involvement should be implemented, drawing upon existing good practice in this area and addressing the necessary capacity-building and the role of patient organisations.
35. An EU database of patient organisations, including organisations from different disease areas as well as national and EU wide platforms, would help sponsors and national authorities in identifying suitable patient experts for involving in specific studies. This should be set up and maintained by the Commission.
36. EPF calls for capacity building for bodies and individuals working with patients in clinical investigations based on the recommendations of the projects VALUE+<sup>7</sup> and PatientPartner<sup>8</sup>, to ensure that the benefits of this collaboration are fully realised.
37. As an existing model of good practice, we refer to the European Medicines Agency, which since its establishment in 1995 has successfully included patient representatives in its scientific committees and scientific advisory groups. EPF believes this model of meaningful patient involvement should be more widely disseminated among EU Institutions and national regulatory bodies as well as ethics committees. (See p.14)

#### *Single application for investigations conducted in several Member States*

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<sup>7</sup> <http://www.eu-patient.eu/Initatives-Policy/Policy/Clinical-Trials/>

EPF supports the principle of coordinated assessment. We are concerned however, that the provision of information to patients, and informed consent have been left completely up to Member States' discretion. In our view, the Regulation also needs to be clear that an ethical assessment must be carried out. It must also request appropriate patient involvement in the design and conduct of clinical investigations.

In EPF's view patient representatives should be systematically involved in the research and development process, including in ethics committees. Patients' specific experiential knowledge gives them a unique perspective on the impact of their condition, various treatments, and the risk-benefit balance, which can contribute to a more accurate risk assessment. Patient representatives can also ensure that informed consent forms and information to patients participating in clinical investigations are comprehensive and understandable. In line with the Council Conclusions on innovation in the medical sector this will enable to take better into consideration the needs of patients when designing medical devices, and can contribute to fostering public trust and confidence in these products. We refer to EPF's comments concerning clinical trials, available on our website.

**EPF recommends:**

38. The Regulation needs to be clear that an ethical assessment must be carried out
39. Appropriate patient involvement in the design and conduct of clinical investigations, including in ethic committees.

*Modification, termination of investigations*

**EPF recommends:**

40. EPF believes that patients and the public have a right to know why a given Member State would refuse to participate in a clinical investigation. Therefore, the reasons for opt-outs should be made public on the website by the European Commission.

## **7. Vigilance and market surveillance**

As for medicinal products<sup>8</sup>, having a robust vigilance system (i.e. a system for identifying and reporting of adverse incidents) is essential for medical devices, as clinical investigations are controlled environment and limited in time, complications and incidents may only become apparent once a device is on the market.

### ***Reporting of incidents by manufacturers***

To ensure a coordinated approach to vigilance across the EU, the Regulation introduces the obligation for manufacturers to report any serious incidents and corrective actions to a central EU electronic system, which will be part of Eudamed. For similar serious incidents occurring with the same device or device type, and for which the root cause has been identified or the field safety corrective action implemented, manufacturers may provide periodic summary reports instead of individual incident reports in agreement with national competent authorities.

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<sup>8</sup> EPF gave input into the legislation on post market surveillance for medicinal products, and produced recommendations for its implementation, which are useful in this context. Our work in this area is available at: <http://www.eu-patient.eu/Initatives-Policy/Policy/Pharmaceutical-Package/Pharmacovigilance/>

EPF welcomes the creation of this central EU electronic system which will collect information on incidents and corrective actions by the manufacturer.

**EPF recommends:**

41. Information regarding incidents that are caused by user errors should also be collected, as they are a major source of incidents with medical devices. This information can contribute to improve the safety and knowledge of the device.

***Reporting by healthcare professionals and patients***

The draft Regulation enjoins Member States to take all appropriate measures to encourage healthcare professionals, users and patients to report to their competent authorities suspected serious incidents. They shall record such reports centrally at national level. EPF welcomes the provisions on direct reporting in the Regulation. But we believe further measures are necessary to make reporting work in practice. The proposal also provides for appropriate follow-up actions by competent authorities and manufacturers, who are required to update their technical documentation. We welcome that a statement will be included in the instructions for use (Annex I, 19.3 (t)), as it is now for medicinal products.

42. Clarity regarding reporting procedures, and a variety of reporting options (there are good practices in this area, for example the YellowCard Scheme in the UK) to enable patients to react rapidly and with confidence, should be ensured.
43. The reporting form for patients needs to be developed with the input of patient and consumer organisations to ensure its usability.
44. The Regulation should also provide for Member States to put in place at least one other non-electronic format of reporting to ensure that patients who do not have access to internet are able to report.
45. We recommend that information campaigns should be developed to inform patients on the importance of reporting.

***Electronic system on vigilance: information***

**EPF strongly recommends:**

46. Information on post-market surveillance of medical devices should be available through a public database to patients and consumers, to enable informed choice as regards treatments, and to enhance public trust in the regulatory framework for medical devices.
47. The Commission needs to develop an access policy for this database<sup>9</sup>, and should involve relevant stakeholders from civil society including patient, healthcare professionals' representatives, and academia to define further what the appropriate level access for each group is. It should be as user friendly as possible.

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<sup>9</sup> Such an access policy was developed by the EMA for Eudravigilance, with a working group in which patients, consumers and healthcare professionals were involved: <http://eudravigilance.ema.europa.eu/human/EudraVigilanceAccessPolicy.asp>

### ***Analysis of serious incidents and trend reporting (Article 53 and 54)***

Alongside with incentives to report incidents to tackle underreporting, ensuring the analysis of the reports effectively collected is essential to ensure that post-market surveillance of medical devices is effective in Europe. We welcome the provisions for coordinated response to serious incidents. But we believe that availability of transparent reports for the public on data collected after marketing is essential to ensure patient safety and quality of care. In our view patients should be involved by competent authorities in this area as the risk-benefit balance comes under assessment. Patient organisations also have a key expertise in communicating risk and benefits to the patient community that they know well.

#### **EPF recommends:**

48. To ensure patients' view is taken into account in the response to serious incidents and the communication around these.

## **8. Governance (Chapter VIII)**

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### **8.1. Coordination for medical devices**

EPF welcomes the choice to put in place a Medical Devices Coordination Group, provided the final Regulation sets clear and binding rules for increased transparency for the public, with an adequate level of patient involvement in governance. EPF is also in favour of a scrutiny mechanism or further cooperation to ensure the safety of medical devices of class III, but regulators should ensure this procedure does not result in unnecessary double checking and long delays for patients.

If the option of pre-market approval is chosen and the task to authorise high medical devices is provided to EMA, EPF recommends it should be with the condition “sine qua non” of sufficient additional resources and staff being allocated to cope with this new requirement.

### **8.2. Patient involvement in governance and implementation**

The draft Regulation provides for possibilities for patient involvement in the Medical Devices Coordination Group: However the role foreseen for patients remains advisory and the modalities are not specified in the legislation.

EPF believes patient involvement is a fundamental and legitimate right, and also highly beneficial, as patients have unique expertise resulting from living with a specific condition and their experience of navigating the healthcare system and services. Patients can contribute effectively towards safe, quality patient-centred, equitable healthcare.

As stressed by the conclusions of the medical devices exploratory process<sup>9</sup>, patient empowerment is necessary to optimise clinical decision-making, treatment adherence, self-care and self-management of chronic diseases. Involvement of patients throughout the research and development process can also contribute to improving communication and trust between all actors involved, including patients and consumers, healthcare professionals, the industry, and competent authorities.

EPF and its membership strongly believe that the model of patient involvement developed by the European Medicines Agency<sup>10</sup> is an example of good practice that should be transferred and adapted also to medical devices.

Key features of the EMA model include the following points:

- Patients' representatives are involved including in decision making bodies such as the management board, and in scientific committees.
- Patient and consumers also have a dedicated body which meets regularly and give input on issues that are essential for the patient perspective, including information for patients on products (e.g. summary of product characteristics, package leaflets) pharmacovigilance, transparency and dissemination of information. The Patient and Consumer Working Party is informed of the work of other working groups within the EMA and can be consulted by them.
- The involvement of patient representatives is planned and set within a clear framework
- The Agency has a plan for training and capacity-building for patient representatives

#### **EPF recommends**

49. To ensure the model of patient involvement that exists within the EMA is replicated for medical devices.

## **9. Equitable access to medical devices**

Because medical devices play a key role for prevention, diagnosis (including early diagnosis), disease management and treatment, EU legislation should also strive to ensure that patients have access to the devices they need, independently of their means, throughout Europe. Medical devices raise particular concern as this is a highly innovative sector: while it could help improve the long-term sustainability of healthcare systems, innovation tends to be costly. In addition, some important devices are no longer reimbursed as a result of budgetary restrictions. While Member States are responsible for pricing and reimbursement, the Commission could play a supporting role to improve access.

Another issue is that medical devices are not encompassed by the legislation on transparency of reimbursement and pricing decisions, therefore these decisions are not subject to clear timeframes, unlike medicinal products.

One concrete example of inequality that patients face in Europe is the treatment procedure by deep brain stimulation for patients with movement disorders including Parkinson's disease – it uses a neurostimulator device to deliver electrical stimulation to target areas of the brain – but DBS is not for example accessible in Ireland therefore the Irish Health Service refers patients to DBS centres abroad with some but not all of the cost covered, and increasingly asks patients who are applying for funding under the voluntary health insurance whether they have private health insurance. Responsibility for all logistical, financial and social arrangements relating to the treatments funded through the TAS lie with the patient and their family. These may include obtaining passports, travel booking and payment, transport and accommodation arrangements for the patient and a caregiver. Patients may need to fund up-front costs of up to €2,300, including flight costs for the patient and a

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<sup>10</sup> More information on patient involvement in the European Medicines Agency can be found at: [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)

caregiver, in the first year that DBS surgery is carried out. This creates a gap whereby some patients cannot access this treatment option.<sup>11</sup>

Another example is access to oxygen concentrator for patients with COPD. These devices are not reimbursed in Bulgaria: the average salary in Bulgaria is €400 while these devices cost around €1000. For this reason, some patients buy second-hand products for which quality cannot be guaranteed.<sup>12</sup>

#### **EPF recommends:**

50. To set an exchange and comparison of practices between Member states on best measures to ensure accessibility of medical devices, and take measures to encourage patient involvement in health technology assessment.
51. To use the HTA network created in the Directive on Cross Border Healthcare to encourage exchange of information on patient involvement by HTA bodies and authorities, and exchange of information on evaluation of medical devices.
52. A platform on access to medicines in the EU has been launched to enhance the collaboration among the Member States and relevant stakeholders in order to find common, non-regulatory approaches to timely and equitable access to medicines. We call on the EU institutions to launch a similar initiative for medical devices.

#### **Conclusions**

EPF is committed to work closely with the European Institutions and stakeholders in translating the vision and the core issues outlined in this statement into reality, to ensure that medical devices in the EU are safe, high quality, accessible and meet patients' needs.

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This draft position statement arises from the EPF 2013 Work Programme, which has received funding from the European Union, in the framework of the Health Programme.

Disclaimer: The content of this questionnaire reflects only the author's views and the Executive Agency is not responsible for any use that may be made of the information contained therein.

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<sup>11</sup> Source: European Parkinson's Disease Association

<sup>12</sup> Source: European Federation of Allergy and Airways Diseases Patients' Associations