EPF recommendations for the trilogue on the proposal for regulation on Medical Devices

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1. Introduction

This position statement was produced after the Council adopted its position on 5 October 2015 and aims at making final recommendations for the trilogue process, where the EU institutions will work on the final compromise for the medical devices Regulation.

These recommendations are based on our previous consultations on medical devices as well as a consultation of the EPF Policy Advisory group.[1] The main text of reference in this position is the Council's position adopted on 5 October 2015.[2] For EPF's position on the European Parliament's position or the European Commission's proposal, please see our previous statements.[3]

2. EPF recommendations for the trilogue

Medical devices 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.[4] For this reason, EPF has been engaged throughout the legislative process with the EU institutions to ensure EU patients have access to high quality safe devices that fit their needs. **While we have reached the final negotiation phase in the legislative process, we believe some key elements are still missing and need to be urgently addressed by the trilogue:**

1. **Gaps in patient safety and quality of care**
2. **Supporting meaningful transparency and information to patients**
3. **Good governance and patient involvement**

2.1 GAPS IN PATIENT SAFETY AND QUALITY OF CARE

EPF has advocated for patient safety and quality of care through the entire lifecycle of medical devices to be the main priority in the Regulation on medical devices, from clinical

[1] http://www.eu-patient.eu/About-EPF/structure/EPF-Policy-Advisory-Group/
[2] Medical devices: http://data.consilium.europa.eu/doc/document/ST-12040-2015-REV-1/en/pdf
[3] http://www.eu-patient.eu/whatwedo/Policy/Medical-Devices/
[4] One direct example of this comes from the area of Neurological conditions: "Neuromodulation devices can be of huge benefit to patients with neurological diseases, especially those with movement disorders, but are often not available for various reasons including re-imbursement issues and lack of neurologists. "

investigation through to post market surveillance. We believe some key changes are still necessary to make the Regulation fit for purpose for EU patients.

2.1.1 CLINICAL INVESTIGATIONS[5]

EPF welcomes several measures the Council has included in its position as regards clinical investigations, in particular:

- ✓ It requires the rules on clinical investigations to be in line with major international guidance including the most recent version of the World Medical Association's Declaration of Helsinki on Ethical Principles for Medical Research Involving Human Subjects (Recital 47).
- ✓ Article 50 point 3 makes it clear that clinical investigations should be subject to an ethics review.
- ✓ For class III devices it provides the possibility for manufacturers to voluntarily consult an expert panel on its clinical development strategy and on proposals for clinical investigations Article 49 point 1a. We welcome this possibility for early dialogue, which is a positive step for patient safety.
- ✓ An electronic system should be set up at EU level to ensure that every clinical investigation is recorded and reported in a publicly accessible database (Recital 38).
- ✓ There are provisions in Article 50c for protection of vulnerable subjects.

However there are several gaps in the Council proposal which we believe need to be addressed to ensure clinical investigations are conducted safely:

- ✘ While patient involvement in ethics committees is encouraged in the definition of ethics committee (Article 2, point 37l), we believe it should be made mandatory. The definition does not clearly recognise the specific expertise of patients as compared to that of a lay person. Patients are the ones who bear risks in investigations, they experience living with a condition every day, and they use devices. Therefore, their perspective on benefits and risk differ from that of other stakeholders.
- ✘ While the Parliament has proposed that the views of patients must be sought in the assessment of the application for a clinical investigation (Amendment 180)[6] there is no similar provision in the Council's position. It is an important provision in order to assess whether the investigation meets patients' needs, and to obtain an accurate risk-benefit assessment. Patients voluntarily provide data for research and ultimately

[5] Clinical investigations are the equivalent to clinical trials in medicines for medical devices
[6] http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+TA+P7-TA-2013-0428+0+DOC+XML+V0//EN

manage the risks involved. They have a right to be involved in the way research is developed, managed, and evaluated.

- ✘ The European Parliament requirement that the clinical investigation needs to be conducted in the target population (Amendment 83)[7] was not taken on board by the Council. We believe this is an essential provision to ensure devices meet the needs of their intended users, and we would recommend reinstating it in the trilogue.
- ✘ EPF is concerned 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). Joint assessments are a means to avoid unnecessary delays and duplication of procedures for clinical investigations conducted in more than one Member States and we could recommend making them mandatory. This could lead to undue delay in the conduct of clinical investigations and ultimately in the access to valuable innovation for patients.

EPF calls on the trilogue to reconsider the provisions above in their discussions. The effectiveness of clinical investigation rules will ultimately impact patients' access to safe new devices.

2.1.2 ASSESSMENT AND SCRUTINY FOR MEDICAL DEVICES

- ✓ The Council proposes better monitoring of 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).
- ✓ The Council is also proposing several measures to clarify responsibilities of notified bodies[8] and national authorities responsible for notified bodies[9] and improve the monitoring and coordination of their work.
- ✘ We believe that notified bodies should have a stronger obligation to act upon the expert panel's opinion when clinical evidence is not sufficient (Article 81a).
- ✘ The Council is not foreseeing patient involvement in the expert panel, while the European Parliament was proposing to have several patients' representatives in its assessment committee for medical devices.
- ✘ EPF strongly agrees that the European Medicines Agency should designate special notified bodies for higher risk devices (Class III) as was proposed by the European Parliament. The Council has proposed no equivalent provisions. We believe this is an

[7] http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+TA+P7-TA-2013-0428+0+DOC+XML+V0//EN

[8] Notified bodies play a key role in assessing the conformity of medical devices with the specification of the EU legislation. More information http://ec.europa.eu/growth/tools-databases/nando/index.cfm

[9] Competent authorities at national level in each Member States that monitor the work of notified bodies

important measure to improve patient safety, as it has been reported that quality of the assessments delivered by notified bodies is unequal.[10]

EPF urges the trilogue to take a stronger stance on improving conformity assessment, notified bodies, and scrutiny of high risk devices in order to ensure the safety of EU patients and restore trust and confidence of the public in the safety of medical devices.

2.1.3 POST MARKET SURVEILLANCE AND VIGILANCE

The Council has taken on board many encouraging provisions in its position to monitor the safety of devices on the market:

- ✓ Patients and healthcare professionals will be encouraged to report incidents[11] to their competent authorities (Article 61). To this end, the Commission is allowed to adopt implementing acts to set the modalities for standard web based formats including minimum data sets for reporting by healthcare professionals and patients (Article 66).
- ✓ The position sets the ground for more cooperation at EU level on market surveillance to ensure the sharing of information between competent authorities on post market surveillance activities and on devices suspected to be in non-compliance with the Regulation (Article 67 to 71).
- ✓ It establishes clear measures to ensure the analysis of vigilance data (Article 63 and 65a) and set the obligation for manufacturers to take field safety corrective actions after a serious incident (article 61).

- ✘ We regret however that most measures would apply only to serious incidents, that is to say incidents that have provoked death, permanent disability, or had life-threatening consequences. The European Parliament has proposed a more comprehensive patient safety approach by ensuring all incidents are reported and monitored, which EPF strongly supports.
- ✘ The European Parliament had taken into account that patients may need different means of reporting. Crucially, they also require that reporting means are set up in consultation with stakeholders. This is essential to ensure reporting is user-friendly. Both these provisions are lacking in the Council Position. This provision was however included in the EU Pharmacovigilance of 2010 for medicinal products.
- ✘ The European Parliament also proposed that information should be collected about use errors, which we believe is key to improve safety and quality of devices, but the

[10] For example: http://www.bmj.com/press-releases/2012/10/23/joint-bmj-telegraph-investigation-exposes-flaws-regulation-medical-devices
[11] Adverse events

Council has not taken this proposal on board in its own position. Use errors are a major source of incidents with medical devices, according to the World Health Organisation[12]. Collecting information about these errors is crucial for prevention and improvement of information to users. This issue has already been recognised in the updated EU Pharmacovigilance legislation from 2010 where medication errors are in the scope of pharmacovigilance data being collected.

EPF calls on the trilogue to take on board the stronger approach of the European Parliament on vigilance measures for devices already on the market.

2.1.4 REPROCESSING[13] OF SINGLE USE DEVICES

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[14] 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 devices (for invasive procedures) poses particular risks.
- ✓ 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.
- ✘ There is no provision to trace reprocessed devices. Such provisions would be crucial to monitor the safety of these devices, whether they are reprocessed by healthcare institutions, third parties, or manufacturers.

We call on the trilogue to introduce traceability provisions in order to better monitor reprocessed devices.

[12] http://apps.who.int/iris/bitstream/10665/44407/1/9789241564045_eng.pdf, p58
[13] 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
[14] Reprocessors designate companies or entities that reprocess devices

2.2 SUPPORTING MEANINGFUL TRANSPARENCY AND INFORMATION TO PATIENTS

Implementing better transparency on clinical evidence, conformity assessment, and post market vigilance is paramount to restore trust and confidence to 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. While we strongly welcome the intent in the Council position to improve transparency, we believe the trilogue still needs to fine-tune some of the provisions. Furthermore, a strong caveat is that the legislation does not involve patients' organisations and other users' representatives: we believe this is essential to tailor the information to the needs of patients.

In EPF's perspective, information for patients should be a priority: information is a right and well informed patients are also an asset to society, as they make more rational choices and use of treatment.

We recommend that the trilogue put in place the adequate structures and provisions to ensure the information that will become accessible will be meaningful for patients.

2.2.1 INFORMED CONSENT

Informed consent is a fundamental right for patients. Informed consent is still sometimes regarded as a sort of ritual, and not as a means by which patients are able to fully comprehend and evaluate the risks they will be taking in participating in a clinical trial or clinical investigations.

Informed consent should be provided in a language and format which is accessible and understandable for the patient and/or their representative. Unrealistic expectations need to be dealt with at this stage. Regrettably, there are still large disparities in informed consent across the EU, both in terms of quality and quantity of the information provided, and in the effectiveness of the process.

- ✓ The Council has defined informed consent in article 2 (37k) similarly to the definition on the Clinical Trials Regulation EU No 2014/536.
- ✗ In contrast to chapter 5 on protection of subjects and informed consent in the Clinical Trials Regulation, and in particular article 29 on informed consent, there is no established criteria for informed consent in the Regulation on Medical devices.[15] We recommend establishing similar rules in the Medical Devices Regulation.

[15] http://ec.europa.eu/health/files/eudralex/vol-1/reg_2014_536/reg_2014_536_en.pdf

We recommend that the Council applies a similar approach to informed consent in clinical investigations as in the Clinical Trials Regulation.

2.2.2 IMPLANT CARDS/INFORMATION TO PATIENTS

EPF welcomes that the Council specified that some key information should be provided to the patients even if they have not adopted the proposal of an implant card proposed by the European Parliament.

Whatever the means chosen by the trilogue, we believe however that the type of information to be provided to patients needs to be fine-tuned in the final Regulation, to ensure patients have access to the essential information they need on the implant they will live with.

- ✓ We welcome the Council's proposal to provide patients with information on identification of the device, expected lifetime of the device, and any necessary follow-up; as well as possible interferences. The Council also clarifies that providing this information is the responsibility of the healthcare institution where the device is implanted (Article 16).
- ✘ We 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 the safety of patients living with the implant.
- ✘ Our recommendation to provide information before the implant is implanted has not been taken on board. This is crucial in order for the patients to be fully informed about their treatment in a timely way and would also be in line with good clinical practice for informed consent before a clinical intervention.
- ✘ We would recommend further refining of the list of elements to be provided with the involvement of patients and users through their representative organisations to ensure patients are provided the information they need to manage their conditions and prevent incidents. They should also be consulted on the best format for the information to ensure it is accessible.

2.2.3 DATABASE

- ✓ The Council, like the European Parliament, has established provisions for public access to the Eudamed database on devices placed on the market, clinical investigations, vigilance, and market surveillance.
- ✘ The Council has not foreseen any patient involvement in making information accessible for lay users. We encourage the trilogue to put provisions for a future

access policy for the database, and to ensure patients and other users are involved in discussing the appropriate level of access to the database for different user groups, and also the format to ensure the information corresponds to patients' need and is in lay language.

2.2.4 SUMMARIES

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

A process of developing EU guidelines for lay summaries of clinical trials with patients' input is currently underway. We recommend to put in place a similar process in the Regulation in order to adapt the guidelines to clinical investigations.

2.3 GOOD GOVERNANCE AND PATIENT INVOLVEMENT

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.

In 2006 the Council adopted the Council Conclusions on common values and principles in European Union Health Systems, which declared that "all EU healthcare systems aim to be patient-centred" and committed to patient involvement as a common operating principle of all EU healthcare systems. The Conclusions also affirm that "All systems should also be publicly accountable and ensure good governance and transparency".

2.3.1 THE COUNCIL POSITION

- ✗ The Council did not take on board the Parliament's proposal to involve stakeholders, including patients, in an advisory committee that would have provided support, advice, and expertise on technical, scientific, social, and economic aspects of regulating medical devices.
- ✗ The Council only foresees limited patient involvement in the Medical Devices Coordination Group: patient representatives could be invited (on an ad hoc basis) as observers rather than experts (Article 78 point 7). This does not correspond to a meaningful form of involvement whereby patients are considered as equals and experts in their own right, and are provided with support to take an active role in

activities or decisions that will have consequences for the patient community, because of their specific knowledge and relevant experience as patients.[16]

- ✘ Patients are not involved in discussing accessibility of Eudamed, contrary to what was done for other databases like Eudravigilance and the clinical trials database. Patient involvement is essential to ensure relevant information is accessible and patient friendly.
- ✘ The Council encourages, but does not make mandatory, the involvement of patients in ethics committees (Article 2 (37l)). Furthermore it makes the assumption that patient and lay person expertise are equivalent, while the two are very distinct. As patients bear the risk of clinical investigations, their participation in evaluating and managing risk is a right. In contrast, the European Parliament is proposing to include at least one patient or patient representative in ethics committees and the development of guidelines on best practices for patients' involvement in ethics committees.

2.3.2 BENEFITS OF PATIENT INVOLVEMENT

Patients are often said to be the most under-utilised resource in healthcare. They manage their chronic conditions every day, and as a result have a unique expertise on healthcare systems. As they use medical devices and are more frequently in contact with healthcare institutions, they have experienced both the gaps and good practices in healthcare. They also have a different perspective on risks and benefits compared to other actors.

Medical devices are not goods like any other; they can make a crucial contribution to patients' health, life expectancy, and quality of life. Conversely, medical devices that are lacking in safety or of substandard quality can also cause very serious and even fatal incidents for patients as end users of the devices. Patients could contribute in many ways to ensure better transparency and improve the safety and quality of medical devices.

More transparency towards the public is necessary to empower patients and ensure public trust and confidence in the safety of medical devices. Patients' organisations have a key role to play in identifying the information needs of patients, and in ensuring that the information provided is high quality, understandable, patient-centred, and accessible to patients. They can for example contribute to an access policy for a database

Patients can also contribute to the safety of devices by reporting incidents. Patient organisations can support this process by raising awareness of this right and ensuring the process to report is user friendly

[16] See the Value + Policy Recommendations for Meaningful Patient Involvement http://www.eu-patient.eu/globalassets/projects/valueplus/doc_epf_policyrec.pdf

The benefits of patient involvement have already been recognised by various initiatives at EU level: one example is the 'Healthy Brain Healthy Europe' conference led by the Irish Presidency in 2013, which recommended the promotion of "the role of patients in all stages of research and evidence-based healthcare… Patients need to be actively involved in the planning of research approaches, the execution of services and the maintenance of standards of healthcare practice". Research, health service delivery, and healthcare policy are intertwined and patient involvement in all three can become a virtuous circle. Involving patients in improving medical devices can result in those improvements being taken up at national level, eventually becoming standard and supported by policy. Similarly, patients' experience with healthcare services can help research be more relevant and credible, and make it more likely to succeed by fitting in with the reality of healthcare provision on the ground.

2.3.3 RECOMMENDATIONS

EPF recommends the establishment of provisions to involve patients as experts in subgroups that discuss issues important to patients and in areas where they could make a contribution such as: patient safety, vigilance, clinical investigations, information to patients, and the Eudamed database.

Furthermore, EPF recommends that decision makers should establish, through the Medical Devices Regulation, a group equivalent to the EMA Patient and Consumer Working Party for medical devices in order to advise on the implementation of the Regulation, and particularly on key issues relevant to patients such as patient safety, transparency and information to patients, and vigilance.

We also recommend making patient involvement in ethics committee mandatory.

3. Conclusions

While the position of the Council is a step forward compared to the current Directive, EPF calls upon the trilogue to take a stronger stance on patient safety and to improve the governance of medical devices at EU level by involving patients in areas that are important and relevant to patients such as patient safety, vigilance, and transparency

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