Medical devices briefing for patients: Patient safety in the new Regulation

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1. Introduction

Patient safety is an important priority for the European Patients Forum, and it was also our main priority in our advocacy on the new Regulation for medical devices.[1]

From 2012, a new Regulation on medical devices was proposed by the European Commission and discussed in the European Parliament and by the Council of the European Union, to replace the EU directives adopted in the 1990s on medical devices.

Not sure what a medical device is in the first place? See our factsheet

You want to learn more about patient safety? See our factsheet

A final agreement was reached in June 2016, setting new rules to ensure the safety and quality of medical devices in the EU.[2] After a period of transition of 3 years after the official publication of the new rules, which should take place end of 2016, early 2017, the new Regulation will apply in all EU Member States (by 2020-2021). In the meantime, patients and their organisations can have a role in monitoring and contributing to implementation at national or European level in key areas of the legislation.

2. Why is the safety of medical devices regulated at EU level?

Under the treaty of Lisbon, the European Union has a competence to adopt harmonising measures setting high standards of quality and safety for medicinal products and medical devices (Article 168, paragraph 4).[3] As medical devices are produced and circulate all over the European Union, it is important to have common rules to ensure the devices on the European market are safe for EU citizens.

3. How is safety of medical devices currently ensured?

3.1 DIFFERENT RISK CATEGORIES

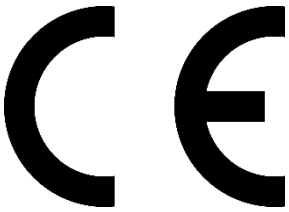
Medical devices encompass a large number of products; therefore, different rules apply according to their risk category. There are four classes: I, IIa, IIb and III, the latter containing

[1] See our position papers on medical devices here for more information: http://www.eu-patient.eu/whatwedo/Policy/Medical-Devices/
[2] http://data.consilium.europa.eu/doc/document/ST-9364-2016-REV-3/en/pdf
[3] http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=OJ:C:2008:115:TOC

the devices that would pose the most risk to the patient if they were to malfunction. A detailed set of rules to classify the devices is defined in Annex VII of the new Regulation.

3.2 BEFORE THE DEVICE IS PUT ON THE MARKET

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 while for lower risk devices manufacturers are only required to produce technical documentations required.



Notified bodies are independent bodies, accredited by authorities of Member States, to verify and certify the conformity of medical devices with the EU directives (or the new Regulation once it is in application). The authorities that accredit notified bodies are National Competent Authorities (also called competent authorities).[4]

In order to obtain the EU certification, all manufacturers must carry out a **clinical evaluation** to demonstrate the safety and the performance[5] of the device. How the clinical evaluation is carried out also varies according to the device's risk category. One method, usually for the higher risk category devices is **clinical investigations,** which are the equivalent of clinical trials for medical devices: they ensure the product is tested before being placed on the market.

3.3 AFTER THE DEVICE IS PUT ON THE MARKET

Once a device is on the market, there are still mechanisms to ensure patient safety.

Manufacturers undertake **post market surveillance activities** to monitor and report about the safety of their products and take corrective actions when needed.

National Competent Authorities also carry out **market surveillance activities** to ensure patient safety, such as the review of technical documentation or inspections.

Manufacturers (companies who develop the device and subsequently monitor its safety and quality), **notified bodies** (who assess and certify the device's safety and performance before it is placed on the market), and **national competent authorities** (who monitor safety of devices on the market and ensure notified bodies are complying with the law) are the key actors in the process to ensure devices provided to patients are safe.

[4] List of national authorities competent for medical devices: https://ec.europa.eu/growth/sectors/medical-devices/contacts

[5] Equivalent of efficacy

4. What are the key issues around patient safety addressed in the new Regulation?

4.1 CLINICAL INVESTIGATIONS

In the Regulation, as a rule, and with exceptions clearly defined in the legislation, manufacturers are required to carry out a clinical investigation for higher risk devices (class III and implantable devices).

For other devices, there are different methods to gather data for the clinical evaluation based on literature review and results of clinical investigations on devices that are similar for example. The manufacturer is the one who specifies the level of clinical evidence necessary to show compliance with the essential safety and performance requirements but this choice must be justified (article 49).

With the new Regulation, various key changes will be implemented as regards clinical investigations:

- All clinical investigations will be **registered a**nd receive a single identification number – Member States have a 10 days delay to notify to the manufacturer whether the application for the clinical investigation complies with the law (article 51)
- For investigations carried out in more than one Member State, **a voluntary single assessment procedure** was put in place in the Regulation. This means that manufacturers can make one single application for an investigation in several Member States, who will then do a joint assessment. After 6 years of application of this system, the European Commission will report on this experience and modify the provision if necessary (Article 58).
- For class III devices a manufacturer can consult, on a voluntary basis, an **expert panel** on its clinical development strategy and on proposals for clinical investigations. The panel will consist of advisors appointed by the Commission on the basis of up-to-date clinical, scientific or technical expertise in the field and with a geographical distribution that reflects the diversity of scientific and clinical approaches in the European Union (Article 49 1a and 81a). The manufacturer has to give due consideration to the views of the panel.
- An **electronic system on clinical investigation** will be put in place for the registration of investigations, to exchange information between member states, for the reporting of adverse events during the investigation and for notification by the sponsor of important changes to the investigation. The clinical investigation report and a

summary will also be provided on the system by the manufacturer after the clinical investigation (maximum one year). The system will be partially available to patients.[6]

EPF advocated for clearer provisions **on ethical review** of clinical investigations and **informed consent** of participants during the legislative process, and the new Regulation provides various positives changes in these respects:

- It states clearly that clinical investigations need to be subject to **an ethic review**, carried out by an ethic committee, in accordance with the laws of Member States, and at least one lay person needs to participate to the ethical review (article 50). The definition of the ethics committee further specifies that the views of laypersons in particular patients or patient organisations need to be taken into account (Article 2 (37l).
- It provides specific provisions on **informed consent** for participants to clinical investigations in article 50aa and for incapacitated subjects in article 50c to provide criteria to ensure patients are provided with information on their rights and the conduct of the investigation, in a comprehensive, concise, clear, relevant, and understandable way.

4.2 VIGILANCE AND POST MARKETING SURVEILLANCE

In the new Regulation, provisions around vigilance and marketing surveillance provide clear responsibility for manufacturers and competent authorities, and establish more cooperation and exchange of information across the European Union in this domain. EPF welcomes this, as we believe this will contribute to improved patient safety.

What is an **incident**?
It means that the device malfunctions or has an undesirable side effect (See Article 2 point 1 (43) for a formal definition)

An important innovation in the Regulation, from the patients' perspective, is that Member States must take appropriate measures to **raise awareness amongst professionals and patients to report incidents** and reporting of serious incidents by both groups should be enabled through harmonised forms. A standard structured form for both electronic and non-electronic reporting will be designed at EU level through an implementing act (Article 66).[7] EPF strongly welcomes this provision that enables patients to report incidents, as we believe that patients can play a key role in ensuring the safety of their devices, and

[6] To learn more about the summary please consult our other briefing on information to patients and transparency in the new Regulation
[7] Implementing acts are, in simple terms, a measure or text that will be adopted in order to ensure harmonised implementation of a provision on the legislation across the European Union

experience from the field of medicine has shown that reporting by patients can be as valuable as the report of adverse events by professionals.

The new Regulation requires manufacturers to have **a post market surveillance system** in place, as well as a system for risk management and a system for reporting of incidents and corrective actions they take as a result. They are required to cooperate with competent authorities and to actively gather information on experiences with their devices that are on the market.

The new Regulation also details further the role of national competent authorities in market surveillance, and establishes provisions for their cooperation in this area. Competent authorities will draw up an **annual market surveillance plan**, and will also provide yearly summaries of market surveillance activities to other competent authorities (Article 69). When devices pose an unacceptable risk for health or safety, they should communicate it to manufacturers, notified bodies, other competent authorities and the European Commission (Article 70).

An **electronic system on market surveillance** will also be put in place at EU level to ensure better exchange of information between Member States.

What is a serious **incident**?
A serious incident is an incident that causes whether directly or indirectly the death, permanent disability, or temporary or permanent deterioration in patients' health, or is a public health threat.

Article 2 point 1 (44)

A caveat from EPF's perspective is that many measures on reporting and surveillance are required **only for serious incidents**. In our view it is important to collect and monitor information about all incidents in order to prevent them and ensure patient safety. However, the Regulation does include "use error due to ergonomic features" and inadequacy in the information provided in the definition of incidents, which EPF welcomes as we believe it is important to take corrective action to prevent such errors and rectify instructions if they are not clear.

4.3 TRACEABILITY

The new regulation establishes a **Unique Device Identification (UDI)** system for all devices except these that are custom made for the patient (Article 24). EPF strongly welcomes this provision as this can improve the monitoring of the safety of devices on the market, and can help fighting against falsified devices.

4.4 REPROCESSING

Some medical devices are produced to be used only once (they are called "single-use devices"). However, under current practice, they are sometimes reprocessed, that is to say prepared again for further use, either by private bodies (companies specialised in

reprocessing, manufacturers) or hospitals. This practice is not regulated evenly across Europe, potentially putting patients at risk.

The new Regulation clarifies the rules in this domain (Article 15). Reprocessing can only happen when the national law of the Member States allows it.

Only the reprocessing of single use devices that is considered **safe according to the latest scientific evidence** is authorised. This means that if the scientific literature or a scientific committee highlights a risk in reprocessing a device, it should not be possible to reprocess the device in question.

The reprocessor[8] has the same responsibilities in terms of ensuring the device responds to safety and performance requirements of the Regulation as manufacturers do. An exemption to this rule was provided for health institutions, but they still have to ensure the same level of security as the initial device, and to fulfil requirements such as having appropriate reporting mechanisms for serious incidents with the reprocessed devices.

Member States are required to encourage health institutions to provide information to the patients on the fact that the healthcare institutions are using reprocessed devices. They can even make this mandatory for healthcare institutions.

The European Commission will make a report on the provisions of reprocessing after 4 years of application, in order to review whether the rules are functioning.

4.5 NOTIFIED BODIES

Another crucial change in the Regulation concerns measures related to notified bodies. The quality of the work of notified bodies was reported to be unequal.[9]

Various improvements have been put in place to ensure the efficacy of notified bodies, which have a pivotal role in assessing and certifying the quality and performance of devices:

- Notified bodies need to have sufficient administrative technical and scientific personnel, and the necessary relevant **clinical expertise** (Article 29)
- For the designation of notified bodies, the regulation establishes a **joint assessment procedure** with experts from different Member States to ensure a more independent assessment process (Article 32)

[8] 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

[9] http://www.bmj.com/press-releases/2012/10/23/joint-bmj-telegraph-investigation-exposes-flaws-regulation-medical-devices

- The Commission and the Medical Device Coordination Group (which comprises all the national competent authorities) can investigate when it is brought to their attention that a notified body is not working according to the provisions in the law (Article 37)

4.6 SCRUTINY FOR HIGH RISK MEDICAL DEVICES

During the legislative process, an essential debate took place around ensuring additional scrutiny for the safety of medical devices that are in higher risk categories (class III and implantable devices), and notably to put in place further scrutiny to empower authorities to check the assessment work done by notified bodies on these devices when necessary.

The Regulation establishes a **Medical Devices Coordination Group** at EU level, with 2 members and 2 alternates respectively to give expertise on medical devices and in vitro medical devices nominated by each Member State (Article 78). This group will have various tasks, including monitoring designation of notified bodies, to contribute to the development of guidance to ensure harmonised application of the Regulation, to contribute to the development of device standards, and various aspects of vigilance and post market surveillance.

To advise the Medical Device Coordination Group and the European Commission on various aspects of the implementation of the Regulation, the Commission can nominate **expert panel and expert laboratories** for scientific advice (Chapter VIII).

Article 44 sets a mechanism for class III and class IIB devices whereby notified bodies must notify competent authorities when granting a certificate to these devices through the electronic system. Based on “reasonable concerns” the Medical Devices Coordination Group or Commission can request scientific advice of an expert panel regarding safety and performance of the device.

Therefore, the new Regulation does give the opportunity to further verify the safety of high risk devices when needed.

5. What role can patients’ organisations play to improve the safety of medical devices?

5.1 FORMAL ROLE OF PATIENT ORGANISATIONS UNDER THE REGULATION

The new Regulation contains some provisions to build upon to encourage patient involvement:

Involvement in which area?	What does the Regulation say?	EPF's assessment of the provision
In coordination at EU level and in monitoring implementation of the Regulation	Article 78 point 8 of the agreement provides the possibility for the Medical Devices to invite stakeholders including industry, patients, healthcare professionals, and other stakeholders in a capacity of observers in sub groups.	While EPF advocated for meaningful patient involvement and a dedicated subgroup like the patient and consumer working party, we strongly believe the compromise in the legislation can be built upon to ensure patients' organisations are consulted on issues of importance to patients, such as access for the public to information on medical devices through Eudamed and patient reporting.
In the context of vigilance/ market surveillance activities	Recital 54 affirms that "The competent authorities should take into account, where appropriate, the information provided by and views of relevant stakeholders, including patient and healthcare professionals' organisations and manufacturers' associations."	This provision enables patient organisations to raise concerns regarding the safety of a device with their National Competent Authorities.
Expert panels (who will advise manufacturers for clinical investigations, and who will advise the Commission and Medical Devices Coordination Group on various safety matters)	Article 81 requires Expert panels to "take into account relevant information provided by stakeholders including patients' organisations and healthcare professionals when preparing their scientific opinions."	This is another important channel for patients' organisations to have their safety concerns about a device taken into account.

5.2 WHAT ELSE CAN ORGANISATIONS DO, PROACTIVELY?

Which organisation	What action can you take
National	You can contact your national competent authority to advocate on the following topics: • Advocate for patient representatives to be involved in **ethic committees**, and raise awareness of the difference of expertise between a lay person and a patient. As patients bear the risk of clinical investigations, their participation in evaluating and managing risk is a right.

	• Advocate for your member states to provide patients with clear information on their policy regarding **reprocessing of single use devices.** For member states that ban the use of reprocessing, call for measures to monitor implementation of the ban within health institutions. For Member States that allow reprocessing, call for appropriate monitoring and reporting to the public on the safety of reprocessed devices. You can contact your national competent authority and offer to advise based on your expertise in the following areas: • Putting in place **effective information and awareness campaigns** to encourage the reporting of incidents • Providing patients with **understandable and appropriate information** on safety of medical devices Once the legislation is formally in place (from 2020), you can monitor and report on implementations of key provisions for patient safety listed in this briefing in your Member State and report back on major issues to your competent authority, or/and provide this feedback to the European Patients' Forum.
European	• Provide feedback on the **forms for the reporting of incidents** by patients (implementing act) to ensure they are user friendly. • Call for **meaningful patient involvement** and the recognition of the role of patients as experts by the European Commission and the Medical Device Coordination Group particularly on key issues of interest to patients like: patient safety, vigilance, clinical investigations, and information to patients. • Advocate for an **appropriate level of access to safety information** for patients and their organisations, in particular in relation to the clinical investigation and market surveillance databases, to ensure transparency on safety (see our briefing on transparency and information to patients in medical devices).

6. Conclusion

The European Patients' Forum will continue to inform its members and monitor implementation of the Regulation on Medical Devices, in order to ensure patients have access to safe, high quality medical devices.

7. Link to resources

The Regulation on Medical Devices (agreement of June 2016 –official publication foreseen in 2017): http://data.consilium.europa.eu/doc/document/ST-9364-2016-REV-3/en/pdf

European Commission (DG Growth) webpage on medical devices: https://ec.europa.eu/growth/sectors/medical-devices_en

EPF factsheet on medical devices: http://www.eu-patient.eu/globalassets/library/factsheets/epf_medical_devices_factsheet_2016.pdf

EPF webpage on medical devices (with links to all our position statements and history of EPF involvement in this area): http://www.eu-patient.eu/whatwedo/Policy/Medical-Devices/

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