

Briefing on the new *Medical Devices* Regulation: information to patients and transparency

20/12/2016



Contents

1. Introduction	3
2. Key measures for transparency and information to patients in the new Regulation.....	3
2.1 Provision against false claims.....	3
2.2 Instructions for use	4
2.3 Implant cards.....	4
2.4 The summary of safety and clinical performance.....	4
2.5 The Eudamed database.....	5
2.5.1 Notified bodies.....	5
2.5.2 Clinical investigations.....	6
2.5.3 Vigilance, post market surveillance and market surveillance	6
2.6 Informed consent for participation in clinical investigation	7
3. How can patient organisations get involved?	8
4. Conclusions.....	9
5. Glossary	9
6. Link to resources.....	10

1. Introduction

In our position on medical devices, transparency was a priority throughout the legislative process. EPF indicated in our first position paper on the legislation that implementing better transparency in clinical evaluation, conformity assessment, and vigilance activities to monitor the safety of devices on the market 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.

Through the new Regulation on Medical Devices on which an agreement was reached on 25 June 2016, decision makers have shown commitment to transparency and patient empowerment through providing access to various information about medical devices. As affirmed in the new Regulation *“Transparency and better adequate access to information, appropriately presented for the intended user, are essential in the public interest, to protect public health, to empower patients and healthcare professionals and to enable them to make informed decisions, to provide a sound basis for regulatory decision-making and to build confidence in the regulatory system.”* (Recital 35).¹ The new Regulation will enter into application in 2020.

This briefing further describes these measures. However, a caveat in the Regulation is that there is no provision to involve patients’ organisations to ensure the information provided to patients and level of access to the database correspond with patient’s needs. EPF believes that patients’ organisations involvement is a condition to ensure information to patients on medical devices is of high quality, easily understandable, and appropriately tailored. For this reason, this briefing also highlights areas where patients’ organisations can contribute, to ensure patients have appropriate access to quality information on medical devices.

2. Key measures for transparency and information to patients in the new Regulation

2.1 PROVISION AGAINST FALSE CLAIMS

The Regulation introduces a new provision with the aim to forbid false claims in the information provided to users of medical devices whether in the instructions or through advertising (article 5a). It is prohibited to attribute properties to the product that it does not

¹ <http://data.consilium.europa.eu/doc/document/ST-9364-2016-REV-3/en/pdf>

have, and to promote a different use than the one mentioned as the intended purpose of the device. This provision is important as it protects patients against misleading information.

2.2 INSTRUCTIONS FOR USE

The Regulation introduces a new provision to ensure clarity of labels and instruction for use accompanying the medical devices: *“The particulars on the label shall be indelible, easily legible, clearly comprehensible and indelible to the intended user or patient.” (Article 8)*

The full list of information that the instruction for use should contain is available in Annex I part I 19.3 of the Regulation. It should notably contain information for users or patients’ information that allows them to be informed of any warnings, precautions, contra - indications, measures to be taken and limitations of use regarding the device, to prevent use errors.

2.3 IMPLANT CARDS

A novelty in the Regulation, which EPF strongly supported, is that it requires to provide clear accessible information to patients who are implanted with a medical device.

Manufacturers will provide patients with an implant card, and healthcare institutions are also required to make the following information available to the patients:

- All necessary information to identify the device, and its manufacturer
- Warnings, precautions or measures to be taken by patients to avoid interference with the device from external influences
- Information about lifetime of the device and necessary follow-up which it requires
- Any other information for the safe use of the device

2.4 THE SUMMARY OF SAFETY AND CLINICAL PERFORMANCE

Another positive innovation in this Regulation is that, for high-risk class III medical devices and implantable devices, manufacturers will need to provide a publicly available summary of safety and clinical performance (Article 26).

Performance is the ability of the device to achieve its intended purpose which is defined by the manufacturer.

Intended purpose means the use for which the device is intended according to the data supplied by the manufacturer on the label, in the instructions for use or in promotional or sales materials or statements and in clinical evaluation.

The summary will need to be written in a language that is clear to the user, including where relevant to patients. The Regulation does not specify precisely however for which devices or categories it is considered relevant that the summary needs to be written in a patient-friendly way.

The summary will contain key information including a description of the device including information regarding previous generations of the same device and differences when relevant, a summary of the clinical evaluation of the device and information on the follow up in terms of safety once the device is on the market, therapeutic alternatives, and information on risks and precaution measures.

This summary will be publicly available on the database mentioned below.

2.5 THE EUDAMED DATABASE

There is already an existing medical devices database at EU level, but the new Regulation defines new goals for the database and increases the amount of information that has to be reported in it (Article 27). In particular, it now has an objective to increase transparency including through better access to information of the public and healthcare professionals on medical devices (Recital 36).

The Commission is in charge of ensuring that public parts of Eudamed are presented in a user-friendly and easily-searchable format (Article 27).

The database will contain information on various aspects of medical devices, including clinical investigation, registration of devices, notified bodies, vigilance and market surveillance. The Commission is in charge of ensuring that the information for the public is in “a user friendly and easily searchable format”. While the information will be fully available to the Member States and to the Commission, it will only be partially available to the public. Below we describe which information will be made public on important topics of interest for patients.

2.5.1 NOTIFIED BODIES

Information on notified bodies which will be public on the database includes an up to date list of notified bodies, and a summary of the report made by Member States at least once a year for the European Commission and the Medical Device Coordination Group² on

² The Medical Devices Coordination Group is a group at EU level, comprising 2 members and 2 alternates respectively to give expertise on medical devices and in vitro medical devices nominated by each member states (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 devices standard, and various aspects of vigilance and post market surveillance.

monitoring and surveillance of notified bodies (Article 45a). The certificate for conformity that they issue after verifying the conformity of the devices with the requirements in the Regulation will also be accessible on the database.

2.5.2 CLINICAL INVESTIGATIONS

Like in the recent discussions on clinical trials for medicines, transparency in clinical investigation became an important topic in the debate on the legislative proposal, and the new Regulation contains several measures to improve transparency and information to patients in this context.

The database will comprise the following information on clinical investigation (Article 53):

- Information regarding the identification number of clinical investigations and submission of application
- modification by the sponsor with substantial impact on safety, right of subjects or, robustness or reliability of the clinical data
- reporting reports on serious adverse events and device deficiencies (as part of clinical investigation)

In addition, within one year from the end of the clinical investigation or within three months from the early termination or halt, the sponsor will need to submit to Member States a clinical investigation report (via the database), which will be accompanied by a summary presented in terms that are easily understandable to the intended user (including patients). Both will be publicly available. The Commission will be in charge of issuing guidelines on the structure of clinical investigation reports, and on how to voluntarily share raw data (Article 57). Identifiable personal data will not be made publicly available.

However, a caveat introduced into the Regulation is that the information mentioned above will not be made public if justified under one of these 3 circumstances: for reasons of compliance with protection of personal data, protection of commercially confidential information, or because confidentiality is needed for effective supervision of the clinical investigation by Member States (Article 53). It will be important to monitor the use of these exceptions once the Regulation is implemented.

2.5.3 VIGILANCE, POST MARKET SURVEILLANCE AND MARKET SURVEILLANCE

The database will also contain information about vigilance and post market surveillance activities of the manufacturers to monitor the safety of devices once on the market and take corrective measures when incidents happen (Article 66a). It will also contain information about Member States' competent authorities' activities to monitor safety and quality of devices (market surveillance).

However, the level of access to this information is not specifically defined in the Regulation, but there is a provision which notes that the Commission has to ensure appropriate level of access for the public and healthcare professionals in these areas (article 66a paragraph 3).

Therefore, publicly accessible information on vigilance and post market surveillance remains to be defined in the implementation of the Medical Devices Regulation.

2.6 INFORMED CONSENT FOR PARTICIPATION IN CLINICAL INVESTIGATION

The new Medical Devices Regulation also put in place measures to set criteria for informed consent for participants of clinical investigations. EPF strongly encouraged the inclusion of similar provisions as in the Regulation on clinical trials³ and this call was successful.

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.

With the new provisions in Article 50aa:

- Consent must be provided in written, or if not possible recorded, and it has to be given by the participant (subject) or if they are incapacitated by their legal representative
- Adequate time has to be given to give the subject enough time to decide about their participation to the clinical investigation
- It has to be provided by an appropriately qualified member of the team carrying out the clinical investigation in a prior interview with the participant.

The subject participating to the investigation has to be able to understand the following:

- The nature, objectives, benefits, implications, risks and inconveniences of the clinical investigation, as well as the conditions of participation (e.g. the duration)
- Their rights and guarantees as to their protection, including the right to withdraw from the investigation at any time
- Treatment alternatives including the follow-up measures if the participation of the subject in the clinical investigation is discontinued

Additionally, informed consent has to *“be kept comprehensive, concise, clear, relevant, and understandable to the intended user”*.

³ <http://www.eu-patient.eu/whatwedo/Policy/Clinical-Trials/>

3. How can patient organisations get involved?

In the Regulation, there is no specific provisions as regards involving patients’ organisations in ensuring information to patients is tailored to patients’ needs. There is also no provision that would allow patients to contribute views on the appropriate level of access for patients of the Eudamed database, unlike what was previously done with some other European database such as Eudravigilance.⁴ Therefore, all the steps that patients can take in this domain are voluntary.

In particular, we would recommend to look at the following issues:

Topic	What actions?	For which patient organisations?
Implant card	Ensuring implant card provides information that corresponds to the needs of patients	Relevant for organisations representing diseases where patients need implanted devices (e.g. cardiovascular diseases)
Access to the Eudamed database	Advocate for patient involvement in discussing the level of access to the Eudamed database and to help implement the requirement for the Commission to ensure public parts of the database are in a user friendly format	EU level patient organisations
Summary of safety and performance	Advocate for patient involvement in the decision to define which device summaries should be written accessibly for patients, and to fulfil the requirement	European level organisations
Transparency on clinical investigations results	Advocate for patient involvement in the guidelines that will be drafted by the European Commission for clinical investigation reports and the summaries	European level organisations
Vigilance and post market surveillance	Provide the patients’ perspective on appropriate level of access to data about serious incidents with devices and other vigilance information since it is not defined	All

⁴ http://www.ema.europa.eu/docs/en_GB/document_library/Other/2015/12/WC500199048.pdf

	specifically in the Regulation Call for an access policy defined with appropriate involvement of patients, consumers and healthcare professionals	
Informed consent	Monitor implementation of the new provisions and feedback	Patient organisations at national level

4. Conclusions

The European Patients’ Forum remains committed to ensure that patients have access to quality information on medical devices that corresponds to their needs. EPF will continue to provide input for the implementation of important measures such as the medical devices database, and will monitor implementation once the legislation enters into application.

For more information on EPF’s work in the field of medical devices, please contact:

Katie Gallagher,
EPF Policy Adviser
Katie.gallagher@eu-patient.eu

5. Glossary

Clinical evaluation: “clinical evaluation” means the assessment and analysis of a systematic and planned process to continuously generate, collect, analyse and assess the clinical data pertaining to a device in order to verify the safety and performance, including clinical benefits, of the device when used as intended by the manufacturer” (Article 2 paragraph 1 point 32)

Clinical Investigation is the equivalent of clinical trials for medical devices, i.e. an investigation in one or more human subjects in order to assess safety and performance of the medical device (Article 2 paragraph 1 point 33)

Conformity Assessment: A process by which all medical devices must go through before being placed on the market and receiving a CE Mark for conformity, to demonstrate they fulfil the requirements of the regulation (Article 2 paragraph 1 point 28. It is based on essential requirements. For higher-risk categories the procedure is carried out by notified bodies while for lower risk devices manufacturers are only required to produce technical documentation required by the Regulation.

Notified bodies: These are independent conformity assessment 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).

Market Surveillance: “the activities carried out and measures taken by public authorities to check and ensure that devices comply with the requirements set out in the relevant Union harmonisation legislation and do not endanger health, safety or any other aspect of public interest protection” (Article 2 paragraph 1 point 40b).

Post-market surveillance: activities carried out by the manufacturers to proactively collect and review experience gained from their devices on the market to identify any need to immediately apply any necessary corrective or preventive actions (Article 2 paragraph 1 point 40a).

Users: Any professional or lay person (e.g. patients or consumers) who uses a device (Article 2 paragraph 1 point 25).

6. 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/>



This briefing on information to patients and transparency in the new medical devices Regulation received funding under an operating grant from the European Union’s Health Programme (2014-2020).

The content of this briefing on transparency and information to patients in the new medical devices Regulation represents the views of the author only and is his/her sole responsibility; it cannot be considered to reflect the views of the European Commission and/or the Consumers, Health and Food Executive Agency or any other body of the European Union. The European Commission and the Agency do not accept any responsibility for use that may be made of the information it contains