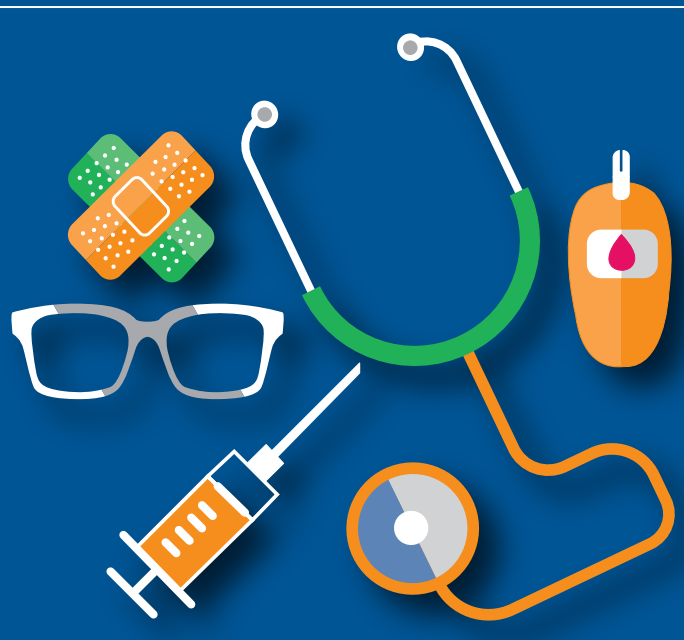
MEDICAL DEVICES



WHAT IS A MEDICAL DEVICE?

An article, instrument, apparatus or machine that is used in the prevention, diagnosis or treatment of illness or disease, or for detecting, measuring, restoring, correcting or modifying the structure or function of the body for some health purpose.

World Health Organisation

This category encompasses many different devices: from common consumer products like bandages or glasses, to medical equipment used by healthcare professionals and in hospitals. Patients with chronic conditions use medical devices in their daily life to support them with the management of their conditions, sometimes in combination with medicines.

There are also active implanted devices like stents, pacemakers or hip replacement. Some medical devices are also used for telemedicine, to enable remote monitoring or communication with the patients.

WHY DOES IT MATTER TO PATIENTS?

Medical devices play a key role in diagnosis and treatment of chronic conditions, and in supporting patients to remain independent.

They contribute to patients' life expectancy and quality of life.

Access to medical devices and to related quality information remains crucial for patients with chronic and long term conditions.

WHAT ROLE DOES THE EU PLAY IN THIS AREA?

The EU legislation aims at ensuring medical devices are safe. Medical devices have to undergo a conformity assessment to ensure they meet standards for safety and performance. If they do, they receive a CE mark before they are placed on the European market.

Given the diversity of devices, different rules apply according to the risk they can pose to patients.

2016

In 2016, The EU adopted **two Regulations**, on medical devices and in vitro diagnostics, which will be applied 3 years. The new legislation will bring important changes for patients:

1. Better **information to patients** through an EU database on medical devices, EUDAMED, accessible to the public and through information leaflet for implanted patients.

2. The **right for patients** to directly report incidents that happen with their medical devices allowing better prevention related to future risks.

3. **Stronger safety requirements** to improve the assessment and management of risks with devices. Expert panels will give scientific advice for the assessment of high risk devices. These expert panels are required to take into account the views of patient organisations when drafting their opinions.

WHAT IS EPF ADVOCATING FOR?

PATIENT SAFETY AS A PRIORITY THROUGHOUT THE LIFECYCLE OF THE DEVICE

EPF is advocating for high quality, safe devices. There are three stages which are crucial for patient safety: clinical investigation when the device is tested, conformity assessment when the safety and performance of the device is assessed, and vigilance which is the constant monitoring of risks and incidents once the device is on the market. In our view patients have a key role to play in each of these steps, to ensure devices meet their needs and in reporting safety and quality issues.

TRANSPARENCY AND INFORMATION TO PATIENTS

EPF is calling for patients' access to transparent, reliable information tailored to patients' needs on medical devices, to empower patients and their healthcare professionals to make informed choices in the management of their conditions.

PATIENT INVOLVEMENT

EPF is advocating for the fundamental right of patients and their organisations to be meaningfully involved in key aspects of medical devices including safety and quality, transparency and information, and vigilance. Patients have a unique expertise as users of medical devices, which needs to be better harnessed to ensure that medical devices in the EU are safe, high quality, accessible and meet patients' needs.

ACCESS

Because medical devices play a key role in prevention, diagnosis, disease management and treatment, we call on the EU to take actions to encourage equitable access to quality medical devices for patients according to their needs, not their means.

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