EFA Position on Medical Devices Regulation: final review, trialogue phase

The European Federation of Allergy and Airways Diseases Patients' Associations (EFA) is the umbrella organisation representing patients with asthma, allergy and chronic obstructive pulmonary disease (COPD) at the European level. Devices such as inhalers and adrenaline auto-injectors are essential for millions of patients living with allergies and respiratory diseases. Their daily use and carriage may increase life expectancy and quality of life and empower patients to better manage their diseases, contributing to patient-centred disease- and self- management. For these reasons, EFA considers the review of the medical devices legislation a high priority.

Previous EFA position papers on this file are available on EFA's website[1]. Now, in the framework of the ongoing trilogue between the European Parliament, the Council and the European Commission, EFA would like to emphasise that some key elements are still missing to ensure patients' safety and improve their quality of life, and therefore need to be addressed by the legislators.

Gaps in patients' safety and quality of care

To ensure that medical devices that enter the EU market are properly checked, and especially those devices that are particularly risky for patients, the European Parliament proposal that EMA should designate special notified bodies for higher risk devices should be followed. All incidents which occur with the devices should be reported and monitored, as well as the safety of reprocessed devices.

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 public confidence, and to ensure that all actors have access to the information they need to play their part in the safety chain. Patients can feel more empowered to manage their conditions through comprehensive informed consent, implant cards and wider access to lay meaningful information.

Good governance and patient involvement

Patients are the ones using medical devices in their daily lives. Their expertise and vision should be taken into account as they know better than others which kind of risks they are willing to take to have benefits in exchange. Therefore, patients' involvement in ethics committee should become mandatory and not only encouraged. Also, views of patients must be sought in the assessment of the application for a clinical investigation. Patients should be involved in the assessment of medical devices through participation in advisory committee, in the Medical Devices Coordination Group, Eudamed management and other groups discussing issues important to patients.

[1] http://www.efanet.org/medecines-and-clinical-trials