European Federation of Allergy and Airways Diseases Patients Associations

Brussels, 1st of December

Dear Sir/Madame,

As representatives of patients with asthma, allergy and chronic obstructive pulmonary disease (COPD), we are writing to you regarding the ongoing trilogue between the European Parliament, the Council and the European Commission on the proposed revision of the EU medical devices legislation. We consider this file a high priority: devices such as medical oxygen containers, inhalers or adrenaline auto-injectors are essential for millions of patients with allergies and respiratory diseases. Safety and efficacy of these devices, and future innovative ones, thus have to be guaranteed and enhanced, because they can increase life expectancy, improve quality of life and empower patients to better manage their disease.

To ensure that the new legislation serves the best for patients' needs, we would like to support the recommendations issued by the European Patients' Forum (EPF). As member of EPF and contributor to the recommendations, the European Federation of Allergy and Airways Diseases Patients' Associations (EFA), endorses these recommendations. Some key elements are still missing to ensure patients' safety and improve their quality of life, and therefore need to be addressed by the trilogue.

**(1) 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, EMA should designate special notified bodies for higher risk devices. All incidents should be reported and monitored, as well as the safety of reprocessed devices.

**(2) Supporting meaningful transparency and information to patients**

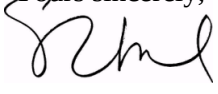
Implementing better transparency on clinical evidence, conformity assessment, and post market vigilance is paramount to restore trust and confidence to and to ensure all actors have access to the information they need to play their part in the safety chain. Patients can gain better empowerment through a comprehensive informed consent, implant cards and access to lay information.

**(3) 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. By empowering and involving patients, the regulation could help them better manage their disease and contribute to patient-centred disease management. 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.

For the detailed opinion on listed above and other issues, please read the recommendations here. We urge you to take the above-mentioned concerns into account in your position. We thank you in advance for your availability and support.

Yours sincerely,



Christine Rolland – EFA President

EFA European Federation of Allergy and Airways Diseases Patients' Associations
35 Rue du Congrès, 1000 Brussels, Belgium - Tel. +32 (0)2 227 2712 - Fax. +32 (0)2 218 3141 – Email info@efanet.org
www.efanet.org