To: Members of the European Parliament

Re: plenary vote on the draft European Parliament legislative resolution on the Medical Devices Regulation & perspective of patients with allergy and respiratory diseases

Brussels, the 18th of October 2013

Dear Member of the European Parliament,

Next week, you will be voting on the draft European Parliament legislative resolution on the proposal for a regulation on medical devices – 2012/0266(COD) – *Rapporteur* Mrs. Roth-Behrendt MEP.

As a representative of patients with asthma, allergy and chronic obstructive pulmonary disease (COPD), EFA considers the regulation of medical devices 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**. Studies show that both patients with asthma and COPD feel that their inhaler device is an indispensable item that makes their lives significantly better. **Safety and efficacy of these devices, and future innovative devices thus have to be fully guaranteed and further enhanced, because they can increase life expectancy, improve quality of life and empower patients to better manage their disease.**

EFA believes that **the changing role of patients and the need for patients' empowerment to take active role in their care** should be one of the key justifications underpinning the proposal. Particularly, we would like to draw your attention to three fundamental parts of the text that are crucial for patients with allergies and respiratory diseases and that should be further improved: **patients' safety**, **patients' involvement** and **transparency**. With this letter we would like to ask for your support on these topics that would significantly strengthen and streamline the document and help guarantee the best possible outcomes for patients in the European Union.

Support enhanced patients' safety

The need to ensure patients' safety should always take precedence over any other consideration. The safety of medical devices has to be guaranteed and patients have to be informed to be able to assess the risk and benefits of using them. Moreover, the same level of protection of EU citizens and performance of a device should be applied everywhere in the European Union. Hence, classification of medical devices should be clear and consistent across all EU Member States and the specific characteristics of borderline products should be defined by the Commission in order to avoid competence disputes.

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Re-use of medical devices: although to reprocess medical devices, manufacturers have to respect the same requirements as for the manufacturing of a new product, EFA believes that making all devices reusable by default would put patients at risk. **Medical devices should only be re-processed, and with clear standards and guidelines developed by the Commission, if there is sufficient evidence that it is safe for patients. They should never be re-qualified if the Commission listed them as single-use devices unsuitable for reprocessing.** EFA is particularly concerned because of adrenaline injectors. Lives of allergic people that use these devices are at stake, and often those of children.

Special notified bodies: in order to improve patients' safety, EFA would like medical devices that enter the EU market to be properly checked, and especially those devices that are particularly risky for patients. Authorities need to be empowered to have a deeper look at individual assessments. For this reason, **EFA is satisfied with the designation of special notified bodies by the European Medicines Agency (EMA).** European cooperation regarding highly specialised medical technologies is needed and therefore EFA welcomes the provision introducing a network of special notified bodies coordinated and managed by EMA. It is however essential that EMA is granted adequate additional resources and expertise to carry out this task without creating undue delays for patients' access to effectively improved, necessary and innovative devices.

Support increased patients' involvement

Patients are the ones using medical devices in their daily lives and taking risks. Therefore, they should be involved in decision-making, and their expertise and vision should be taken into account as they know better than others what it means and which kind of risks they are willing to take to have benefits in exchange. In particular, patients should be involved every time an important issue that threatens their safety is detected or suspected, when the information to patients and all publicly accessible parts of Eudamed are drafted and developed, when deciding on the formats for reporting provided by the national authorities, when the application for the clinical investigation of a medical device is assessed. By empowering and involving patients, the regulation could help them better manage their diseases and contribute to patient-centred disease management.

Medical Device Advisory Committee (MDAC): EFA welcomes the establishment of the Medical Device Advisory Committee as a support for the Medical Device Coordination Group (MDCG) and the EU and national authorities involved in all decisions regarding the regulation of medical devices. **As the involvement of patients and patients' representatives in the MDCG was originally very limited in the Commission's proposal as they could be invited, where appropriate, only in the capacity of observers to take part in standing or temporary sub-groups, the introduction of the MDAC improves the situation and goes in the direction of increased involvement.** Key features of the European Medicines Agency's (EMA) involvement with stakeholders could however be further developed in the framework of this legislation.

Ethics committees: EFA welcomes the provision that clarifies that **an ethics review is necessary in the assessment of the clinical investigations as it increases patients' protection. Patients should be represented in these committees.**

Support transparency

Transparency and access to quality information are essential to empower patients and to enable them to make informed decisions. Opening larger parts of the Eudamed system to the public, and implementing better transparency in clinical evaluation, assessment and surveillance, as well as in all the steps undertaken by notified bodies, are therefore paramount.

For additional information, please check EFA's briefing available on our website: http://www.efanet.org/wp-content/uploads/2013/04/Medical-devices-briefing.pdf.

We urge you to take the above-mentioned concerns into account for your vote. We thank you in advance for your availability and support.

Yours sincerely,

Breda Flood
EFA President

Roberta Savli
EU Policy Officer

The European Federation of Allergy and Airways Diseases Patients' Associations (EFA) is a non-profit network of allergy, asthma and COPD patients organisations, representing 35 national associations in 22 countries and over 400,000 patients. EFA is dedicated to making Europe a place where people with allergies, asthma and COPD have the right to best quality of care and safe environment, live uncompromised lives and are actively involved in all decisions influencing their health. www.efanet.org

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