To: Health Attachés at Permanent Representations

Re: Council position on the proposal for a regulation on medical devices & perspective of patients with allergy and respiratory diseases

Brussels, the 30th of January 2013

Dear Health Attaché,

During this semester, you will be continuing the discussion on the proposal for a regulation on medical devices. As representatives of patients with asthma, allergy and chronic obstructive pulmonary disease (COPD), we consider this legislation 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 fully guaranteed and further enhanced, because they can increase life expectancy, improve quality of life and empower patients to better manage their disease.

We welcome the results of the European Parliament's plenary vote on the 22nd of October, as the amendments adopted showed strong commitment towards more transparency on medical devices, enhanced safety and quality of care for European citizens and increased involvement of patients. **We now call on the Council to support the key amendments introduced by the European Parliament and address some remaining open questions to ensure that European patients have access to safer devices across the European Union (EU) without delay and in a transparent way**.

Support enhanced patients' safety

Medical devices are fundamental for patients with chronic diseases as they may increase life expectancy and quality of life on daily basis or in emergency situations, and empower patients to better manage their diseases contributing to patient-centred disease- and self-management. Hence, the need to ensure patients' safety should always take precedence over any other consideration.

As we would like medical devices that enter the EU market to be properly checked, and especially those devices that are particularly risky for patients, we welcome the provisions that *harmonise the expertise of notified bodies* throughout Europe, introduce the designation of *special notified bodies* by the European Medicines Agency (EMA), as well as a *network* of these bodies coordinated and managed by EMA, and that involve the *Assessment Committee for Medical Devices*.

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We support that the Commission is defining a *list of single-use medical devices* for which reprocessing is not possible in consultation with the Medical Devices Advisory Committee. Indeed, we are particularly concerned about the possible reprocessing of adrenaline injectors, as lives of allergic people that use these devices are at stake, and often those of children.

Despite these positive measures, some provisions on patients' safety should be further improved. In particular, we believe that the scope for the Assessment Committee of Medical Devices' scrutiny originally planned in the report of the Environment, Public Health and Food Safety Committee should be restored. Indeed, as it is now, only class III implantable devices may be reviewed; while in our views, **all class III devices and implantable devices in class IIb need appropriate scrutiny as they are potentially high-risk for patients**. It is then essential that **EMA is granted adequate additional resources and expertise** to carry out the coordination role voted by the Parliament without creating undue delays for patients' access to effectively improved, necessary and innovative devices.

In addition, we deem that making all devices reusable by default would put patients at risk. **Medical devices should only be reprocessed, 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 requalified if the Commission listed them as single-use devices unsuitable for reprocessing. **Reprocessors of medical devices should then be subject to the same duties and have to respect the full requirements of the manufacturers.**

Support increased patients' 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.

We welcome the provisions that require patients' consultation when the *information to patients* and all *publicly accessible parts of Eudamed* are drafted and developed, as well as when the European Commission is deciding on the *formats for reporting of incidents* so that all these documents will be user-friendly and correspond to their needs.

We also strongly support the need for an *ethics review* in the assessment of the applications for clinical investigations and the requirement that the *view of patients must be sought* as these measures will ensure that clinical investigations are patient-centred.

The involvement of patients in the newly established *Medical Devices Advisory Committee* and the *Assessment Committee for Medical Devices* is also a positive step forward compared to the original Commission's proposal, where patients and their representatives could be invited, where appropriate, only in the capacity of observers in the Medical Device Coordination Group.

However, we believe that further patients' involvement should be fostered. For instance, **patients should be involved in deciding the set of information that have to be given in the implant cards** provided with implantable devices to ensure that they are tailored to patients' needs. With the same aim, **they should be consulted when deciding on the layout and form**

of the summary of the clinical investigation report that has to be made public for high-risk medical devices and **when drafting the access to Eudamed database policy**, consultation that resulted in a positive outcome in the case of the access policy for the Eudravigilance portal on pharmacovigilance.

The way the European Medicines Agency interacts with stakeholders should be a model followed in the framework of this legislation. In particular, EMA has a dedicated body for patients and consumers, the Patients and Consumers Working Party (PCWP), that meets regularly and gives input on all issues that are essential from the patient's perspective. In addition, the involvement of patients is planned and set within a clear framework and they are empowered to take an active role in every discussion as EMA has a plan for training and capacity-building for them.

Support greater transparency

Increased transparency in the clinical evaluation, the conformity assessment procedure and the post-market vigilance system helps restoring confidence in the medical devices' sector, paramount especially after the breast implants' scandal. Transparency ensures that all actors have access to the information they need to play their role in the safety chain, and empowers patients enabling them to make informed decisions. Appropriate patient-friendly information prevents the occurrence of users' errors that can cause medical device incidents and therefore improves patients' safety. Moreover, informed patients are more likely to report any issues they have with the devices and act correctly in case of defect.

First and foremost, the *opening of the Eudamed system* to the public is a fundamental step-forward towards this direction. The publication of the *summary of the clinical investigation report* for high-risk medical devices and of the *overview on vigilance information after six months* enhances trust in the safety of medical devices. The availability of the results of the clinical investigations they have taken part in makes patients more willing to participate in future investigations too.

We back the provision requesting *implant cards* to inform patients and enhance the traceability of implantable devices, as well as the measures *prohibiting misleading information* on a medical device and introducing the *right to obtain information upon "reasoned request"*.

Despite these huge improvements compared to the current legislation and to the original Commission's proposal, some measures still need to be clarified. In particular, **there is no clear guidance on what "reasoned request" means** and this may limit the positive results of the provision. In addition, **a simple mechanism should be put in place in the Eudamed database** to guarantee that the public may benefit as effectively as possible from the new requirement.

For additional information, please check EFA's briefing available in our website: http://www.efanet.org/wp-content/uploads/2013/04/Medical-devices-briefing.pdf. EFA is a member of the European Patients Forum (EPF), we share the same position on this important piece of legislation: having patients' safety considerations as the first priority, and therefore we also support their recommendations that can found in their website:

http://www.eu-patient.eu/Documents/Policy/MedicalDevices/20131217_MD_Recommendations.pdf.

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,

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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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