EFA response to the Health Technology Assessment (HTA) draft implementing Regulation on joint scientific consultations on medicinal devices and *in vitro* diagnostic medical devices

The European Federation of Allergy and Airways Diseases Patients' Associations (EFA) welcomes the opportunity to provide written feedback to the European Commission's Health Technology Assessment Regulation[1] (HTAR) fifth draft implementing Regulation that structures the process for joint scientific consultations (JSC) on medical devices and *in vitro* diagnostic medical devices. The proposal lays out the selection and consultation of stakeholder organisations and patients, clinical experts and other relevant experts (individual experts) for the JSC process. The proposal takes into account the provisions laid out in the EU's Medical Device Regulations (MDR), which has recently been put under pressure to be reopened, to the dismay of the patient community and EU policymakers[2] [3].

Medical devices and *in vitro* diagnostic medical devices are essential for the allergy and chronic respiratory diseases patient community, as by using biological samples outside of the human body, they provide modern technologies for testing, monitoring and diagnosing diseases. Innovative and/or digital devices can significantly improve detection and disease management, significantly improve patients' lives and therefore their regulation must also take into account the patient perspective.

EFA is a full and founding member of the European Patients' Forum (EPF) and has contributed to EPF's responses to HTA implementing regulations' consultations.[4] This includes the latest draft implementing Regulation for JSCs on medicinal products for human use, which the given proposal follows closely in terms of structure and process. **EFA fully supports EPF's reply to the consultation on the proposal at hand on JSC on medical devices and *in vitro* diagnostic medical devices.**

The HTAR is set to apply in all Member States from 12 January 2025 onwards. By 31 March 2025, the European Medicine Agency's (EMA) Coordination Group will set at least one request period for JSC on medical devices for 2025.

Barriers for individual patient involvement in JSC processes on medical devices

EFA welcomes the draft implementing Regulation's aim to improve individual experts' involvement in the JSC process for medical devices and *in vitro* diagnostic medical devices, applauding the HTA Secretariat intention to involve individual patients in the JSC process as early as possible.

Health technology developers (companies) must be aware that many patients will need friendly information to interpret the data from the health technologies falling under this proposal. Patients will therefore need to access the information available to assess the medical device according to the

[1] European Parliament and Council Regulation on health technology assessment: https://bit.ly/3CzaMt0
[2] European Parliament and Council Regulation on medicinal devices: https://bit.ly/3UWusNH
[3] EPF warns against rushed revision of the EU Medical Devices Regulations (15.10.2024): https://bit.ly/3UVVepA
[4] EPF response to the stakeholder consultation on the proposed Health Technology Assessment (HTA) Implementing Regulation on Joint Clinical Assessment for Medicinal Products: https://bit.ly/46qkokH, on assessing and managing conflicts of interest: https://bit.ly/4frTm0y, the HTA cooperation with EMA: https://bit.ly/48n9r4n and on Joint Scientific Consultations for medicinal products for human use: https://bit.ly/4hRCzVO

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criteria of the MDR, while also being digitally literate to comment on the new developments that integrate digital aids and artificial intelligence (AI) to optimise patient treatment and monitoring

As with the previous proposal on JSCs for medicinal products, the current draft implementing Regulation does not fully embrace the volunteer nature of patient experts, who may face disproportionate challenges in complying with the administrative and procedural requirements in the process, compared to the authorities, representatives and other individual experts involved. Patient experts are a fundamentally different category of experts. We therefore encourage the HTA Coordination Group and the HTA Secretariat to define onboarding paths and to appoint dedicated staff to guide patients' experts in overcoming procedural and digital barriers, and to accommodate, when possible, their health needs throughout the cycle to ensure meaningful and smooth patients' participation in EU JSC procedures.

In an effort to assess conflicts of interest, recital 13 of the implementing Regulation requires the European Commission to assess the individual experts' declared interests before they can be involved in the JSC process. While EFA supports EMA's intention to ensure impartiality in the selection of individual experts involved in the JSC process for medical devices, EFA asks the proposal to further detail whether having an interest in a healthcare company, specifically a pharmaceutical company, would render individual experts ineligible for a medical device procedure and vice versa.

Finally, the draft implementing Regulation does not outline whether and how patients' experts will be compensated for their time invested to provide with quality input across each stage of the JSC process. The required time commitment, compensation and recognition administratively supporting patients to miss other obligations should be explicitly introduced in the implementing Regulation and communicated at the launch of each selection of experts' procedure. We therefore stress the need for a compensation scheme for individual experts that recognises the meaningful and active participation of patients in regulatory processes.

Selection of patients' organisations in JSC on medical devices

EFA welcomes the possibility for the JSC on medical devices process to take place in parallel with the 'expert panel' consultation, laid out in Regulation 2017/745. Article 106 of this Regulation provides that expert panels take into count information provided by patients' organisations when preparing their scientific opinions[5]. In addition, EFA requests EMA to clarify in article 8 which experts could be considered as a rapporteur or advisor on the expert panel.

EFA welcomes articles 6 and 12 which allow the HTA Secretariat to identify individual experts through the stakeholder networks set out in the HTAR, as well as the European reference networks for rare and complex diseases and other organisations. However, article 12 is not clear on how the JSC Subgroup may seek this input and EFA suggests to develop this further in the final text.

EFA highly welcomes article 12 allowing JSC Subgroup being able to consult stakeholder organisations at any time during the JSC. We encourage the legislators to provide organisations with sufficient time (minimum three weeks) to conduct internal consultations in order to reply to the request for input.

[5] European Parliament and Council Regulation on medicinal devices: https://bit.ly/3UWusNH

EFA encourages the Commission to explicitly recognise the role of patient organisations in the procedures. Patients' organisations play a crucial role in providing an aggregated perspective of the patient community and in providing evidence-based information that accurately reflects the burden of the disease and the value of treatment, especially in cases where symptoms and their impact vary widely. Therefore, we encourage the HTA Secretariat and the EMA to apply the same procedures as proposed in the section above, desk support, guidance, and compensation for stakeholders involved in JSC processes.

In the proposal, developers are allowed to submit the same briefing package to the HTA secretariat as to the expert panel in cases where the JSCs on medical devices and *in vitro* diagnostic medical devices are conducted in parallel with the expert panel consultation (article 8.6.c). Here, the Coordination Group may consult the EMA and the expert panel to align on the briefing template for the briefing package, allowing individual expert patients to provide input on the briefing package, which EFA celebrates. After receiving the briefing package from the HTA secretariat, individual expert patients can be invited to participate in an exchange of views with health technology developers to go over the medical condition and therapeutic area. EFA welcomes that patients are invited to these meetings, but as mentioned above, EMA should provide patients with additional training to be able to virtually participate in these meetings.

Protection and processing of patient data

EFA welcomes the proposal's approach to protecting personal data, which specifies that the European Commission and the EMA intend to implement suitable and specific measures to safeguard rights and freedoms of the patient. EFA agrees with article 13, whereby patients should not be obliged to disclose their identity to the companies. This should be complemented by clearly informing patients about how their personal data will be used, already from the call for patients for the JSC procedures.

Article 16 introduces measures on personal data processing, which EFA welcomes. Specifically, EFA supports the decision that the Coordination Group and JSC Subgroup only have access to the secure system of the HTA IT Platform relevant to their tasks.

Finally, while HTA is carried out by the national authorities of the Member States, there currently is no EU-level agency dedicated to assessing the implementation of the HTAR. EFA encourages the establishment of an EU agency dedicated to medical devices and *in vitro* medical devices.

About EFA

EFA is the voice of 200 million people living with allergy, asthma, and chronic obstructive pulmonary disease (COPD) in Europe. We bring together 45 national associations from 26 countries and channel their knowledge and demands to the EU institutions. Since 2016, EFA has been engaged in the development of the EU HTA legislative framework, bringing our patients' community perspective to inform the setup of HTA cooperation at EU level.[6,7]

[6] EFA is a member of the HTA Stakeholder Network, the HERA Civil Society Forum and the Critical Medicines Alliance, as well as member of the European Medicines Agency (EMA) Patients and Consumers Working Party (PCWP).
[7] EFA response to the stakeholder consultation on the proposed Health Technology Assessment (HTA) Implementing Regulation on Joint Clinical Assessment for Medicinal Products, https://bit.ly/3Ygo4TV, on Assessing and Managing Conflicts of Interest: https://bit.ly/4dfkJsQ, and on the HTA cooperation with EMA: https://bit.ly/4eXCJsO