EFA response to the Health Technology Assessment (HTA) draft implementing Regulation on joint scientific consultations on medicinal products for human use at Union level

The European Federation of Allergy and Airways Diseases Patients' Associations (EFA) welcomes the opportunity to provide written feedback to the HTAR's fourth draft Implementing Regulation that covers the joint scientific consultation (JSC) on medicinal products and structures the selection and consultation of stakeholder organisations and patients, clinical experts and other relevant experts (individual experts).

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.[1] **EFA fully supports EPF's reply to the consultation on the proposal at hand on JSC on medicinal products.**

Barriers for individual patient involvement in EU JSC processes

EFA welcomes the draft Implementing Regulation's aim to improve individual experts' involvement in the JSC process, noting its intention to involve patients in the JSC process as early as possible. However, with the recent adoption of the Implementing Act on Conflict of Interest[2], the system proposed for JSC excludes current knowledge and capacity within the patient movement based on a highly restricting interpretation on what constitutes conflict. The approach to managing conflict of interest should be built on trust in a system that embraces civil society and pushes for the inclusion of the patient experience, from clinical trial design to pharmacovigilance.

At the same time, EFA notes the draft Implementing Regulation's aim to improve the process for involving individual experts in JSCs and recognises the role of the HTA secretariat. The proposal however does not fully embrace the volunteer nature of patient experts, who may face disproportionate challenges in complying with the administrative and procedural requirements in these processes, compared to the authorities, representatives and other individual experts involved.

As it currently stands, the proposal would generally require patients to register online for JSC, create an EMA account, create an application and submit a request for JSC, deal with the HTA secretariat, submit their response to the consultation and virtually join a multistakeholder meeting at a given time. All these stages require substantial digital office work methods from the patient, time availability during office hours, access to a mobile phone, a computer and a stable internet connection and requires the patient to work alone, to comply with confidentiality agreements. However, the proposal does not consider digital literacy nor a structure to provide briefing and support to enable digital participation. Worryingly, the proposal does not mention any health-related requirement patients' experts might have, ignoring patients are people living with unpredictable and debilitating diseases such as allergy, asthma and COPD. We therefore encourage the HTA Coordination Group and European Commission HTA Secretariat to define onboarding paths and appoint dedicated staff to

[1] 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 and on the HTA cooperation with EMA: https://bit.ly/48n9r4n

[2] Commission Implementing Regulation 2024/2745: https://bit.ly/3A8pBlF

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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 JSC procedures.

Finally, the draft Implementing Regulation does not outline if 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 Act and communicated at the launch of each selection of experts' procedure.

Recognition of the role of patients' organisations in JSC

EFA highly welcomes article 11 on consulting stakeholders and we encourage the Commission to explicitly recognise the role of patient organisations on it. 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.

Resulting JSC report and obligations of Member States

Improving patients' access to medicinal products relies on Member States having access to information on the implementation of JSCs. Unlike the Regulation, the Implementing Act currently omits the publication of anonymised, aggregated, non-confidential summary information on the joint scientific consultations in the annual reports of the Coordination Group. For a full understanding of the JSC process, we request that the HTA Secretariat make these reports available on the HTA IT platform, with translations in all EU languages. Publication of these reports would promote consistency in HTA standards across Member States, thereby promoting equal patient access to treatments. Member States could also benefit from referring to each other's reports as precedents.

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.[3,4]

[3] 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).
[4] 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

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