EFA response to the Health Technology Assessment (HTA) draft implementing Regulation on the procedural rules for assessing and managing conflicts of interest – June 2024

The European Federation of Allergy and Airways Diseases Patients' Associations (EFA) is the independent and democratic 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.

EFA welcomes the adoption of the Health Technology Assessment Regulation (EU) 2021/2282 (HTAR), which contributes to improving patients access to the health technologies they need to stay healthy and prevent disease progression or disease, such as medicines, vaccines, and certain medical devices. We highly welcome the opportunity to provide written feedback on behalf of our patients' community to this important consultation that is set to determine how patient participation, and therefore their needs, will be structured for EU joint HTA and beyond.

Enabling patients' organisations participation

Patient organisations are civil society groups representing vulnerable people with chronic diseases they live with every day. Federations like EFA operate under rigorous frameworks that roll out patient-led missions, with robust governance structures based on principles of transparency, independence, accountability and legitimacy, and closely manage integrity and reputation across their activities. Patient organisations like EFA operate with publicly available statutes[1], internal rules[2], and codes of conduct[3]. They operate thanks to unrestricted financial support from a variety of sources that enable their mere existence as nonprofit organisations: from membership fees, public and research grants and unrestricted financial support from companies active in different industrial sectors[4]. Our biggest asset is trust, and EFA is proud of ours. Our weakest asset is access to operational funding, especially for involvement in representing our patient community to inform EU decision-making affecting them.

While we welcome the possibility for the EU HTA Joint Clinical Assessment (JCA) Subgroup to be able to seek input from patient organisations active on the disease and therapeutic area[5], because of their pivotal role within the HTA ecosystem, EFA expresses concern with a *de facto* restriction on most, if not all, patient organisations to participate in EU HTA consultation processes. **The declaration of interest and its assessment based on the proposal at hand should serve as a basis *to manage***

[1] EFA Founding Statutes (1996, reviewed 2004), https://efanet.org/images/documents/EFAs_Statutes.pdf
[2] EFA Internal Rules (2004): https://efanet.org/images/documents/EFA_Internal_Rules.pdf
[3] EFA Code of Ethics and Conduct (2016), https://efanet.org/images/documents/EFA_Code_of_Ethics_and_Conduct.pdf
[4] EFA Framework for Sustainable Corporate Partnership (2016), available at https://efanet.org/images/documents/EFA_Sustainable_Corporate_Partnership_Framework.pdf
[5] Article 8 of Commission Implementing Regulation (EU) 2024/1381 of 23 May 2024 laying down, pursuant to Regulation (EU) 2021/2282 on health technology assessment, procedural rules for the interaction during, exchange of information on, and participation in, the preparation and update of joint clinical assessments of medicinal products for human use at Union level, as well as templates for those joint clinical assessments, https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ%3AL_202401381.

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potential risk of conflict of interest **rather than to apply** ***a zero risk of conflict criteria*** **that risks leading to automatic exclusion of patient representatives who are part of a patient organisation.** Patient organisations, independently of their funding, are key partners in health and care representing the genuine interests of the patients, and we have a track record to show.

The assessment on the risk of conflicts of interest should therefore not exclude the participation of patient organisations who receive unrestricted financial support from companies, irrespectively of the volume or the purpose of that income (i.e. public health advocacy, patient-evidence generation). Instead, the implementing regulation on the **management of conflict of interest should rather enable participation and build public trust on a system that embraces diversity, citizen's opinions and that trusts civil society organisations who operate with legitimacy, independence and transparency.**

EFA recommends the European Commission to **assess the risk of conflicts of interest among patient organisations in a structured and predictable manner**, **requiring a full declaration of income** (i.e. annual reports, quarterly income reports), **and with declaration of safeguard procedure by patients' organisations** (i.e. internal rules, code of conducts, partnership frameworks) to assess the potential risk of conflict of interest. We are accountable to our members in the first instance, but also to the public and policy makers due to our citizen-led role in society.

From applying exclusion to managing the risk balanced assessment on the involvement of individual experts

According to the proposed implementing regulation, patient experts who play a leading role in patient organisations, receiving funding from companies with products under assessment, will be automatically excluded from the EU HTA work. This criterion significantly restricts the pool of patient experts who can effectively contribute to the HTA process. In addition, and worse, it assumes that these patient representatives are naive. The proposal can have harmful collateral effects beyond HTA, as not only it excludes many patient experts with leading roles in patient organisations, but also, it can refrain them continuing doing it so if their executive function undermines their eligibility for public processes such as HTA. In other words, the proposal is counterproductive, based on assumptions on conflict, as it is offensive.

Therefore, EFA recommends that the assessment of the risk of conflict of interest remains balanced and reflects the reality of patients who are part of organisations of patients who receive corporate funding, as that link can in no way be attributed as to directly impacting the independence and impartiality of patient experts involved in medicines development and healthcare systems decisions. We embrace rigour and transparency in public involvement, and we are committed to legitimate, responsible and consistent patient input.

To further ensure the transparency of the process and increase trust in EU joint HTA, EFA recommends:

- Shifting the focus to enabling patient involvement rather than maximising restricting it;

- Introducing a scoring system to assess risk of conflict of interest among experts, as proposed by the European Patients Forum (EPF);
- Adopting mitigation measures similar to the 'expert witness' status used by the EMA, as proposed by EPF;
- Developing guidelines to mitigate conflict of interest among expert patients and clinicians, as proposed by EPF;
- Introducing an engagement report on the involvement of representatives and individual experts in the joint work, similar to the EMA biennial report on stakeholder engagement activities[6], which can further report and disclose the involvement of stakeholders in the joint work.

Deterred patient involvement in the HTA process

On top of having to fulfil general criteria such as having above-medium level of English skills and knowledge, as well as availability to travel and participate in a voluntary unpaid manner in regulatory processes, coupled with the lack of opportunities to public core funding both at European and national levels in most EU member states, the proposed criteria envisage patient experts to be further constrained from participating in HTA processes. For example, restrictions to participate in HTA process for patients who have received payment/reimbursements (above 1,000 EUR) for presentations, training courses, conferences/seminars/events where the therapeutic area cannot be identified (point 4.2 of Annex II) can result in patients limiting their participation in discussions affecting their health, such as patient-centred care meetings and unmet medical needs workshops. It would be unsustainable for patient experts, often volunteers in their advocacy, to participate in conferences, trainings and other relevant events at their own cost, and this should not be expected.

EFA recommends the European Commission to revise the proposal to follow EMA's guidance on handling the conflict of interests and, at the minimum, to consider the payments for or reimbursement of expenses incurred with the research work or reimbursement of reasonable expenses directly related to a conference/seminar/training attendance (i.e. accommodation and travel costs) not as financial interests[7], as it would lead to excluding individual patients from taking part in the joint work on health technologies.

Clarification on the criteria "intention to engage in activities with health technology developers"

While it is imperative that representatives and experts involved in the joint HTA declare any new interests which may be perceived as conflicting in accordance with the rules proposed in Article 8, EFA expresses concern in relation to assessing the risk of conflict of an 'intention of engagement in

[6] European Medicines Agency's biennial report on stakeholder engagement (2022-2023), https://www.ema.europa.eu/en/documents/report/stakeholder-engagement-report-2022-2023_en.pdf.
[7] European Medicines Agency policy on the handling of competing interests of scientific committees' members and experts, https://www.ema.europa.eu/en/documents/other/policy-44-european-medicines-agency-policy-handling-competing-interests-scientific-committees-members-and-experts_en.pdf.

activities' in Article 8(4) of the draft implementing Regulation, which must be clarified as to the means to determine it (e.g. would a written confirmation to participate in a training in an event in the future constitute a conflict of interest in this case), and the ambiguity related to the timeline of the engagement in such activities.

EFA asks for clarification of Article 8(4) on whether it includes activities with health technology developers that are planned to effectively start after the patient involvement in the HTA process has finalised, and the precise means in which an intention is demonstrated and assessed.

Background on EFA's work on HTA

Since 2016, EFA is engaged in the development of the EU HTA legislative framework, bringing our community patients' perspective to inform the setup of HTA cooperation at EU level. We are active elected members of the DG SANTE HTA Stakeholder Network[8], and we have joined and contributed to the series of stakeholder workshops organised by DG SANTE to scope approaches to the tertiary legislation foreseen by the regulation. EFA has stressed in repeated occasions the importance of patient involvement, notably on the draft implementing regulation on the Joint Clinical Assessment (JCAs) for medicinal products in which we sustain that patient participation must be done through individual patients and with patient organisations[9].

EFA is a full and founding member of the European Patients' Forum (EPF) and has contributed to the EPF's response to the consultation on the draft implementing regulation on the Joint Clinical Assessments (JCAs) for medicinal products[10], and the reply to the consultation on the proposal at hand on the procedural rules for assessing and managing conflicts of interest. Together with EPF, we highlight the importance of representative, structural and sustained patient involvement in joint EU HTA processes. Finally, EFA has contributed to and co-signed the recommendations from patient organisations on the JCA in June 2024.[11]

Patients, patient representatives and organisations do not exist in a vacuum. We contribute and provide experts to multitude of public and private stakeholders to embed patient perspective into the lifecycle of medicines and activities that can benefit the health and wellbeing of people with allergies, atopic eczema, asthma and COPD. This includes promoting prevention. This is what our community needs, and therefore their involvement becomes obligatory. We are proud to serve this purpose since 1996, as it is our role to advocate change for the people we represent.

[8] EFA is also member of the DG 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) since 2013.

[9] EFA response to the stakeholder consultation on the proposed Health Technology Assessment (HTA) Implementing Regulation on Joint Clinical Assessment for Medicinal Products, https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13708-Health-technology-assessment-joint-clinical-assessments-of-medicinal-products/F3461026_en.

[10] EPF response to the stakeholder consultation on the proposed Health Technology Assessment (HTA) Implementing Regulation on Joint Clinical Assessment for Medicinal Products: https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13708-Health-technology-assessment-joint-clinical-assessments-of-medicinal-products/F3460944_en

[11] 10 Key Recommendations from Patient Organisations on Joint Clinical Assessments under the EU HTA Regulation (June 2024), https://www.eu-patient.eu/contentassets/59fd1966940c4f2194644c8873e3cf2f/20240610-10-key-recomendations-from-patient-organisations-on-jcas---disclaimer.pdf.