

EPF feedback on the implementing act on joint clinical assessments of medicinal products

April 2024

The European Patients' Forum (EPF) welcomes the **publication of the draft Implementing Act on Joint Clinical Assessments (JCA) of medicinal products**, which sets out the rules for patient involvement in the context of JCA and brings us a step closer to implementing the EU HTA Regulation.

Incorporating patient perspectives into JCAs is essential as it provides evidence of patients' experiences of living with a disease, navigating treatments and assessing the potential impact on quality of life.

We commend the **progress made in improving patient involvement**, recognising the contribution of both individual patients and patient organisations. We also welcome the various ways in which patients can provide input, either during the assessment scope process or in the JCA and summary reports.

While progress has been made, patient involvement outlined in the Implementing Act must be further strengthened and refined to ensure predictability of involvement and representative and meaningful patient contributions.

Patient input, whether from patient advocates, patient representatives, individual patients or carers, should be streamlined throughout the process. The JCA sub-group should proactively seek patient input and fully take advantage of patients' insights starting from the preparatory phases, not only when the assessment scope proposal and draft reports are finalised. Seeking patient input after document consolidation risks tokenistic patient involvement, as their insights, if at all incorporated, would be integrated too late in the process. The JCA and summary reports should reflect how patient input has been integrated, and summary reports in lay language should be publicly available in all relevant EU languages.

In addition, **JCAs should integrate patient experience data¹**, such as core outcome sets and patient preference studies² co-designed and co-developed with patients, to complement patient involvement. This approach facilitates the collection of robust evidence at earlier stages, thereby promoting a broader perspective, across disease severity, age, gender and nationality, and ensuring that the patient view is integrated even with time and resource constraints. Other relevant sources to complement patient involvement in JCAs could include EU protocol guidelines, especially when developed by clinicians in collaboration with patients.

The role of patient organisations in the implementation of JCAs needs to be further recognised. Although the Implementing Act acknowledges that the HTA secretariat may consult patient organisations when compiling a list of relevant patients, their role and capacity should be strengthened. Patient organisations can play a pivotal role in ensuring smooth patient involvement in JCA: 1. Through their networks and established governance and transparency mechanisms³, they can better identify appropriate profiles and coordinate the engagement. 2. They can provide support to identified patients who are not trained or have no previous experience of participating in JCAs, in return for compensation. In Germany, patient

¹ See [EMA workshop](#) on patient experience data in EU medicines development and regulatory decision-making workshop.

² See [IMI project PREFER article](#) on patients as research partners in preference studies.

³ See [EPF Transparency Guidelines](#).

organisations provide this support to the patient on behalf of the assessor. 3. Patient organisations will also play a key role in coordinating national and European contributions to the assessment scope proposal to ensure coherence between the two levels.

To ensure that patients can participate effectively in the process and contribute their insights and expertise in a timely manner, **they should receive sufficient time, translation services, and financial support.** Patients should be given sufficient time to provide input, with at least two weeks' notice, to allow experts to review documents prior to JCAs. Similarly, patient organisations should be given sufficient time to select experts and be informed of the JCA calendar as soon as it is available.

EPF further advises **the HTA Coordination Group and Member States to adopt a stepwise approach to patient involvement with short-, medium-, and long-term objectives.** EPF is aware of the reality of patient involvement practices in different Member States and recognises that not all of them can yet count on procedures, human and financial resources allocated to patient involvement. This leads to different levels of maturity of patient involvement practices and consequently to fragmented patient involvement outcomes at national level. We anticipate that this may jeopardise the contribution of national patient organisations in the scoping phase. A stepwise approach would allow Member States to equip themselves with the necessary resources and skills to fully embed patient involvement in JCAs.

Finally, the Implementing Act on JCA should **ensure consistency with the upcoming Implementing Act on conflict of interest (CoI).** Patients with expertise from a European or International perspective in the therapeutic area of the JCA will most likely be part of patient organisations. In this respect, the Implementing Act on CoI needs to define a clear and transparent framework that takes a constructive approach. A constructive approach implies limiting competing interests to the extent that they do not hinder patient involvement in JCAs and access to the best available expertise.

EPF will continue to work with the European Commission and Member States to ensure that the implementing rules for the joint HTA lead to meaningful patient involvement.

ABOUT EPF

EPF is an umbrella organisation of patient organisations across Europe and across disease areas. Our 79 members include disease-specific patient groups active at EU level and national coalitions of patients representing 19 countries and an estimated 150 million patients across Europe. www.eu-patient.eu

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