EPF's feedback on the implementing act on joint clinical assessments of medical devices and in vitro diagnostic medical devices

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The European Patients' Forum (EPF) welcomes the publication of the draft Implementing Act on Joint Clinical Assessments (JCA) of medical devices and in vitro diagnostic medical devices, 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.

The Patient community is following closely innovation regarding in vitro and medical devices, which are vital for patients, significantly improving life expectancy and quality of life. **Patients are becoming increasingly well-informed and expert (in particular with regards to digital technologies, use of data, monitoring and AI, since many medical devices are digitally programmed or connected) and are actively calling for greater involvement in the development and approval of these technologies**, not only to address potential safety / side effect concerns (which aligns with our call to support continuous monitoring, especially in terms of post-market surveillance, as foreseen in the Medical Devices Regulation) but also to ensure that these innovations can meet their needs and answer to environmental preoccupations of the patient community in terms of maintenance, obsolescence and circularity.

Therefore, incorporating patient perspectives into JCAs for medical devices and in vitro diagnostic medical devices is essential as it provides evidence of patients' experiences of using / living with devices as well as assessing the potential impact on quality of life. While progress has been made, and following the first JCA done in 2025, patient involvement outlined in the Implementing Act must be further strengthened and refined to ensure predictability of involvement and representative and meaningful patient contributions.

- **The JCA sub-group must 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. Therefore, we recommend making use of the opportunity to involve patients, whose unique expertise and perspectives can significantly enhance the relevance and quality of the assessment scope.

- To ensure that patients can participate effectively in the process and contribute their insights and expertise in a timely manner, **they should be given sufficient time to provide input, with at least two weeks' notice, to allow experts to review documents prior to JCAs**.

- **Patients need also to have access to timely, clear and accessible information about the technology they are being asked to comment on**. In addition to the full JCA dossier submitted by the health technology developer, which must be accessible to the relevant patient experts and consulted patient organisations, plain-language summaries are useful not only for patients and patient organisations, but also for all contributors who may not have specific expertise in the condition or technology being assessed.

- For example, the current draft is mentioning for the consultation of stakeholder organisations during joint clinical assessments and the assessment scope proposal "*At specific steps and* timeframes". This is much too vague. We need clearer information to ensure that patient input can be me feasible.

- For example, the current draft lacks clarity regarding the term "individual expert," as we don't really know if this is meaning patient experts. It is unclear what specific information will be shared with them, how their participation will be operationalised (e.g. through interviews, written input, questionnaires, or meetings), and what support or guidance will be provided. Greater detail is needed to ensure transparency, predictability, and meaningful engagement of patient experts throughout the process.

- It would be also very important **that patients receive clear, concise, and understandable feedback on how their input has been used and what could be done in future stages of their involvement in JCAs** to ensure continuous improvement in the assessment process. This could involve guiding patients on how to provide more effective input or highlighting areas where their insights could be particularly valuable in upcoming assessments. The feedback should also be included in the final JCA report.

- It is also essential to take into consideration the need to involve a diverse, inclusive range of patient experts, as we know that medical devices may not be equally suitable for all, depending on factors such as age, gender, geographical location, ethnicity or race.

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 as patient organisations can play a pivotal role in ensuring smooth patient involvement in JCA. **Patient organisations should be given sufficient time to identify the appropriate patient experts, as this process can be time-consuming**. Indeed, this phase involves informing patient representatives about HTA and JCA procedures, explaining the relevant rules, and awaiting responses from the patients contacted. Extending the deadlines for identifying patient experts helps ensure the selection of individuals who can genuinely contribute value to the JCA process, **particularly in areas such as medicinal products and in vitro medical devices, where not all patients may have the necessary expertise. In particular, on this draft implemented act:**

- In the interest of transparency and effective stakeholder engagement, we recommend that the stakeholder network, including patient organisations, be informed alongside health technology developers when medical devices are identified for potential joint clinical assessment or not. Early notification would facilitate timely preparation and enable meaningful patient involvement in the procedure, ensuring that the assessment process reflects the real-world needs and experiences of patients.

Given the European scope of the JCA, the summary reports must be published in all official EU languages to ensure adequate access to information for all EU citizens, regardless of their language. The provision of translations is essential for promoting health equity, as it enables patients, carers and patient organisations across Europe to fully understand and engage with the assessment reports. The lack of translation of the summary report can exacerbate inequalities in access to healthcare and health information. Translations further support national health authorities and patient organisations

in their local dissemination efforts, facilitating more effective communication at the national level. It is also important that the organisations of the stakeholder network are invited to discuss the report.

Finally, we would like to take the opportunity of this consultation to remind the importance of adopting a constructive approach to conflict of interest. Indeed, a constructive approach to conflict of interest based on transparency should be taken, 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

The European Patients' Forum (EPF) is an independent non-profit, non-governmental umbrella organisation of patient organisations across Europe and across disease areas. Our 82 members include disease-specific patient groups active at EU level and national coalitions of patients. To read about our vision, mission, and strategy, visit: www.eu-patient.eu

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