# EU HTA R – Early Insights and Ideas for the 2027/28 Revision – Patient Perspective

**Solène Jouan**

Policy Officer, European Patient Forum (EPF)

solene.jouan@eu-patient.eu

*Strengthening patient involvement in the EU HTA Regulation: From implementation to evaluation and revision*

One year after the start of the implementation of the EU HTAR, it is already clear that this marks both an important milestone and a significant learning process for all involved. At the European Patients' Forum (EPF), we are proud to be part of this process and, through our daily work alongside other patient organisations, to help ensure that the HTAR delivers on its promise: greater harmonisation of HTA across the EU and real progress towards health equity, including better access to treatments for all patients in Europe.

One important lesson from this first year is that we are still in a learning phase. As with any new governance framework, practical issues have emerged that were not fully anticipated during the legislative negotiations, such as short deadlines for patient organisations to identify patient representatives and limited information provided to unsuccessful applicants. While not all of these issues have yet been resolved, some improvements have been made thanks to constructive dialogue with the EU HTA Secretariat.

This first year has also highlighted important lessons for the future and identified several elements that should be considered in the upcoming evaluation of the Regulation and in the future revision. As the first Joint Clinical Assessment reports are expected to be published soon, it will be crucial to assess how patient involvement is taking place in practice and how patient input is reflected in the drafting of those reports. Meaningful patient involvement cannot be reduced to consultation alone. It requires that patients' contributions, perspectives and lived experiences are genuinely taken into account in the assessment process and have a visible impact on outcomes. If the evaluation shows that this is not the case, a revision of the framework should be absolutely considered in order to address these shortcomings and provide more effective solutions.

In particular, we would need to know exactly:

- How patients are effectively involved at the different stages of the HTA process, including the clarity of their role and the timing of their contributions;
- How patient input is considered and integrated into the final reports, and whether this contribution is visible and transparent in the outcomes of the assessments;
- How diversity among patients is ensured, particularly in light of the current English-language requirements and the large volume of technical documentation patients are asked to review. EPF has long advocated for accessible materials in lay language, shared sufficiently in advance, as this would greatly support meaningful participation and ensure broader representation of patient perspectives across Europe;
- The role of patient organisations throughout the process. While the legislation allows for the participation of patient organisations, this potential has not yet been fully realised in practice. Further reflection is needed on how this role can be strengthened and better embedded in the HTA framework;
- How Joint Clinical Assessment reports are used at national level, and whether they contribute to faster and more efficient decision-making processes. While it may be too early during the 2027–2028 evaluation to fully assess whether the Regulation improves access to treatments,

analysing how these reports are used by national authorities will be essential;

- How the EU HTA Regulation is influencing national HTA processes. At EPF, we have begun exploring this question through the first EPF Barometer on Patient Involvement. This Barometer, which will be published in June 2026, analyses patient participation across various national policies and regulatory processes, including HTA, using data collected from EPF's national coalitions. Our findings already suggest some improvements in countries where patients were previously not involved in HTA processes, but improvements are not enough. National reforms taking place in the context of the HTAR provide a unique opportunity to embed best practices from the outset, ensuring that meaningful patient engagement becomes a core and permanent feature of all national HTA processes.

Another important point that should form part of any future revision is the recognition of the added value of patient organisations and the need to secure their sustainability. Their contribution to implementation should be explicitly recognized and publicly funded by the European Union, particularly at a time when many patient organisations face growing financial pressure (with the absence of operating grants under the 2025 EU4Health Programme, and the possibility that these may also be lacking in 2026) and when public resources for training and capacity-building in HTA remain limited or absent. Without such support, meaningful patient involvement in these processes will remain difficult to sustain. Expecting patient organisations to take on growing responsibilities, to train their patients and members, without the necessary resources is neither credible nor sustainable.

Patient organisations are not involved in the implementation of the HTA Regulation simply because this is a "nice to have". We are engaged because we firmly believe that greater harmonisation of HTA practices, combined with meaningful patient involvement, can lead to better access to treatments across Europe, and stronger public health outcomes. At a time when the value of European cooperation in health, and in other policy areas, is being questioned, the HTAR has the potential to demonstrate the concrete benefits of working together at EU level and of strengthening cooperation and harmonisation across Member States. Ensuring that this Regulation succeeds will therefore be essential and this can be achieved if patients remain genuinely at the centre of the process.