

# EU HTA Regulation – Early Insights and Ideas for 2027/28 Revision

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



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A STRONG  
PATIENTS'  
VOICE  
TO DRIVE  
BETTER  
HEALTH  
IN EUROPE

# One year after the start of the implementation of the EU HTAR ...

**Significant learning experience**

As with any new governance framework, **practical issues in terms of patient involvement have emerged that were not fully anticipated during the legislative negotiations !**

**Important lessons for the future**

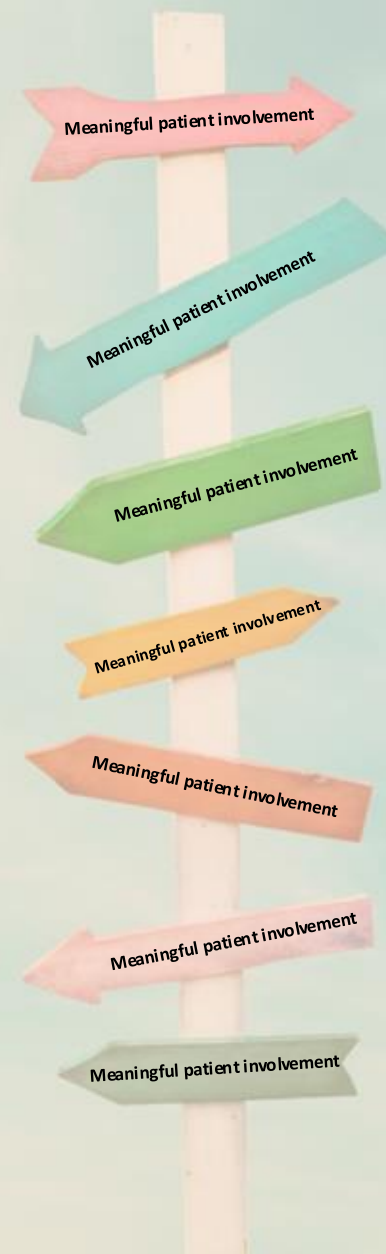
As the first JCA reports are expected to be published soon, it will be crucial to assess **how patient involvement is taking place in practice and how patient input is reflected in the drafting of those reports !**

**Meaningful patient involvement ?**

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.**



# What we would need to know...

1. **Patient involvement in HTA stages:** clarity of roles and timing of contributions ?
2. **Use of patient input:** integration into reports and transparency of impact ?
3. **Ensuring diversity:** particularly in light of the current English-language requirements ?
4. **Accessible materials:** in lay language, and timely sharing ?
5. **Role of patient organisations:** strengthening and embedding participation ?
6. **Use of JCA reports nationally:** Contribution to faster and more efficient decision-making processes ?
7. **Influence on national HTA systems:** stronger patient engagement ?



**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.**



# BUT the recognition of the added value of patient organisations must be part of any future revision

- 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 recognised 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 in the future MFF) 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.**

**EPF's call:** *"Our work **is valuable**, and the success of this Regulation depends on keeping patients and patient organisations genuinely at the centre, **with full recognition of their contributions to this success.**"*



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