

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

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Four years after the finalisation of the EU HTA Regulation, we are rapidly approaching the publication of the first JCA report, with several more to follow this year. Although there will be much to learn in the future, now is the right time to reflect on what has been achieved whilst keeping focussed on how we can all improve the process looking forward.

Currently we have a working system, but is it working for all in an effective way to make it a success? The IT platform is operational, methods and process guidance for assessors are published, and HTDs have made submissions based on the published template. The Coordination Group has been supported by many years of voluntary cooperation under EUnetHTA, although some positive learnings do not seem to have been incorporated into the JCA process. New HTA bodies have been established, and national processes are slowly adapting. But the current system is not an optimal system that works for all stakeholders, nor a system that makes Europe an attractive place for innovative technologies. We must therefore all continue to learn and adapt.

From a HTD perspective we are sharing insights and learnings. This not only helps us to ensure we are supporting each other on delivering the needs of the JCA but also identify common challenges and areas for potential improvement. We have seen increasing standardisation and information at the start of the procedure which is greatly welcomed. We also value the Q&A documents provided by the Coordination Group and Commission responding to emerging themes and ongoing dialogues regarding the process. However, the next critical stage of a JCA is the confirmation

check of the dossier, and this has begun to identify where the system may require adjustment. We recognise the challenge of timelines that the assessors have to deliver the JCA report, but those challenges are also relevant for the HTDs who have a greater burden given the volume of analyses requested and tight timelines to deliver “missing” requests. In fact, the time to undertake the confirmation check is longer than the time HTDs are given to deliver the additional requests.

Our joint learning has revealed confusion whether the confirmation check is a “pre assessment” or a confirmation that the HTD has completed the dossier in full. These two need to remain separate, as envisaged by the Regulation. We also observe that many “missing” requests refer to the template and guidance documents - and that assessors and HTDs may have a different interpretation of what is being required. We should recognise that the dossier template and accompanying guidance were released without consultation and engagement from HTDs who will need to deliver on it. With no opportunity for a proper dialogue between the assessors and the HTD, which could resolve divergences and ensure the submission meets expectations, the current process is denying the Regulation a significant opportunity to succeed. We must therefore be careful not to blame HTDs when issues may be subjective and caused by differences in interpretation, requiring further clarity from the Coordination Group. Talk of penalties is premature and fails to acknowledge there may be other underlying causes that are not HTD related; they would, ultimately, make the European region less competitive to invest in.

Every one of us is learning – from HTDs that have never launched in Europe to those with considerable experience, as well as the individuals at HTDs and national HTA bodies working on different JCAs. This is going to take several years. As noted, many issues could be resolved with dossier preparation meetings and dialogue beyond exchange of letters on an IT platform that introduce delay - something industry has called for during the last few years and is a feature of many established HTA processes.

Let's make a system that works for all and involves all – we have joint responsibility and therefore together we are part of the solution. JCA is a considerable investment to HTDs that has a real opportunity cost; if there are no demonstrable improvements in patient access, JCA becomes an additional

hurdle in Europe. This will mean the ambition of the Regulation will have failed. Unpredictability to HTDs and increasing requests for more data with no obvious benefit to downstream decision-making makes Europe less attractive as a region. We must keep focussed on the objectives of this Member State driven Regulation – facilitating patient access across the EU, reducing duplication, improving business predictability and supporting high quality, transparent decision-making. These must remain centre stage for the 2028 review and beyond - focussing purely on measurable process metrics at an EU level will undermine the potential of what the Regulation can achieve for European patients.