Life science industry concerns over the workability of EU HTA: Europe cannot miss out on the opportunity to speed up access to innovative medicines for European patients

ARM, EFPIA, EUCOPE, EuropaBio, Vaccines Europe

The draft Implementing Act (IA) on Joint Clinical Assessment (JCA) of medicinal products, prepared by Member States' "Comitology" Committee on Health Technology Assessment (HTA) with the support of the European Commission, has recently been published for public consultation and feedback. The draft IA will establish the detailed procedural steps and timelines of the new EU HTA procedure.

We welcome the Regulation (EU) 2021/2282 on health technology assessment which aims to provide a transparent and inclusive framework for quality HTA across the Union, to reduce duplication for national HTA authorities and industry and to facilitate business predictability and ultimately, to accelerate access of medicines to EU patients. For these aims to be achieved however, companies require sufficient information up front to prepare for JCAs, and there needs to be sufficient time for companies to gather, analyse and submit requested information to the assessors. **We believe that the draft rules in their current format will create an unworkable framework for JCAs and consequently lead to duplication of work.**

As industry association members of the HTA Stakeholder Network, representing the innovative European life science sector, **we share serious concerns over the lack of workability of the procedures in the draft IA on JCA of medicinal products. The proposed draft procedures risk the aim of joint EU HTA of ensuring better access for patients to innovative health technologies.**

While the IA aims to "…ensure that assessments are conducted in good time and that the relevant experts are involved or consulted", **the described procedures do not involve the companies whose products are subject to JCA, except in exceptional cases. Further, the timelines are unworkable and too short to allow companies to provide quality input regarding evidence, analysis and comments that is required of them throughout the JCA.**

Companies require sufficient information up front from the selected assessors to prepare for JCAs, and there needs to be sufficient time for companies to gather, analyse and submit requested information to the assessors. **If the JCA procedure, which ultimately is the measure of success of joint EU HTA does not provide transparency, predictability and workability for companies, joint EU HTA will fail to deliver on its aim of ensuring better access for patients to innovative health technologies.**

We see the successful implementation and conduct of JCAs as a shared responsibility between stakeholders, as it will require a significant investment in terms of resources, knowledge and time from all parties involved, from national HTA authorities to companies. However, these draft rules, due to lack of involvement and clarity at the scoping stage of the assessment, leave companies with the high risk of producing a JCA dossier which will not serve its purpose and be a clear waste of resources.

- The overall time of the JCA procedure is split in such a way that Member States will have four and a half months (140 days) solely to develop the scope of the assessment - that is the questions (PICOs) that they want companies to answer in their submission. During this time, there is no visibility for companies on the draft questions, and no opportunity for companies to engage with the assessors. It is only after this initial time period that companies will finally be informed of the scope, or the questions (PICOs) of the assessment, and are then given less than three months (90 days) to respond to these questions by putting together and submitting their submission dossier. Moreover, the proposed timelines may place companies in the impossible position of delaying regulatory procedural steps (e.g. clock stops) to satisfy JCA process needs.
- Without the possibility for early interactions with the assessors, especially small to mid-sized companies that are less resourced are put under a serious threat of being unable to adequately deliver on their submission and contributing to a JCA that can fulfil the aim of the Regulation.

- The JCA process would also be better served by allowing the opportunity for companies to contribute all relevant information, evidence, and knowledge as a key input into the definition of the assessment scope at the time of the application for the marketing authorisation.
- Earlier involvement of all companies via a scoping meeting, as is guaranteed in many national HTA procedures, and also the previous EUnetHTA Joint Actions, increases the efficiency of this scoping phase since companies can provide relevant information needed for the scope based on their own substantial research into the disease area and the condition.
- Furthermore, this allows companies to anticipate the different PICO scenarios, allowing for earlier preparation and thus increasing the quality of the submission dossier and ultimately the JCA report.
- Additionally, companies could confirm the intention to file for a Marketing Authorisation ahead of time, allowing HTA authorities to start their preparations in advance, rather than only at the time of the EMA filing.

We urge the Member States' representatives to take into account these serious concerns from the innovative life science industry, and to consider our proposed solutions in the finalisation of the Implementing Act on JCA of Medicinal Products, to ensure that the EU HTA procedure can deliver on its intended aims, starting with the first JCAs, from 12 January 2025.

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