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POINT OF VIEW

What is needed to successfully implement the EU HTA Regulation enabling broad patient access in Europe

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ABSTRACT

There has been a lot of discussion on the technical aspects of the soon to be implemented European Union's Health Technology Assessment (EU HTA) regulation. However, there has been limited discussion on the implementation aspects and the potential limitations from a policy perspective. In May 2024, a group of HTA experts with previous policy responsibilities met in Rome to propose some policy aspects to be considered.

As a result of the discussion, several proposals were made. Building mutual trust, improving collaboration and engaging all relevant stakeholders seems a must. Equally important are the communication aspects, and ensuring equal commitment by all parties, allocating the appropriate incentives at all levels. Finally, it is noted that the EU HTA regulation has to be seen from the perspective of a wider policy change within the large EU legal framework.

Keywords: EU HTA Regulation, HTA, Implementation policy

For patients in Europe, access to – and the availability of – innovative medicines vary widely across the different countries.

A longstanding issue across Europe, and the challenges related to access and affordability persist today. A recent report (1) from European Federation of Pharmaceutical Industries and Associations (EFPIA) shows that patients in one country can wait more than 6 times as long as patients in a neighboring country for medicines that received marketing authorization at the same time. Patients in Germany wait, on average, 126 days for a new product following marketing authorization. In Poland, the gap between authorization and availability balloons to 804 days – more than 2 years.

The European Union's Health Technology Assessment Regulation (2) (EU HTAR) regulation adopted in 2021 aims to improve the availability of innovative medicines across Europe. A key pillar of the HTA regulation is the Joint Clinical Assessment (JCA) process, which will introduce a new standardized, pan-EU framework that all member states will be asked to give "due consideration" to assess the clinical evidence and safety of newly submitted medicines or devices. The regulation, including the new framework, offers the potential to reduce redundant practices, increase the quality of the assessments, and bring innovative medicines faster to more patients across Europe. And with it, more equity, more Europe.

Earlier this year, we decided to organize a Think Tank to address this specific topic and discuss what is needed to successfully implement such a new HTA Regulation in Europe. The main objective of the meeting was to discuss the expected process, raise warning signals if needed and provide policy recommendations for a successful implementation of a plan that is otherwise a challenging revolution in the EU pharmaceutical space. Think Tank members, all with previous policy responsibilities in their own countries and across Europe, were gathered to create a stable discussion group and steer some debate about the EU HTAR challenges and opportunities.

Discussing this potential, it became clear that such a vast undertaking also presents significant complexities to overcome and will require ongoing collaboration and communication to successfully navigate the new processes. As we approach the implementation of the first phase of the JCA process in January 2025, which will include Advanced Therepies and Medicinal Products (ATMPs) and oncology products, it's important that the European Commission deploys a robust communications plan to clearly convey expectations and next steps to all healthcare system stakeholders. At the same time, this communication plan should drive awareness of how the JCA supports the Commission's overarching strategy to spur pharmaceutical innovation in Europe and expedite access to innovative medicines. Learnings from this first phase will help to manage the process when it goes live for orphan drugs in January 2028 and for all drugs registered with the EMA by January 2030.

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Improving Stakeholder Engagement & Connectivity

It is expected, that the new JCA framework should help to reduce the timeline between regulatory approval and the initiation of a country's national drug appraisal – an important step in the broader effort to expedite patient access to new therapies. A more consistent clinical evaluation process could also lead to an overall reduction in decision-making time.

The phased implementation and transition to the JCA offers tremendous opportunities for collaboration – including the sharing of best practices – among stakeholders to ensure readiness for the new framework and to explore opportunities to improve the system.

In order for the European Commission to achieve its objective of creating more equitable access to medicines across Europe, we want to make the following success-critical recommendations:

- **Execute a thorough communication strategy**: Consistent communication is critical to eliminate questions and uncertainty around implementation, particularly as member states will need to manage two systems until full implementation in 2030. The benefits and efforts should be made clear to all stakeholders, generating enough incentives (financial and non-financial) to attract member states to the common purpose and/or deterring them from using JCA as a convenience tool. Equally important is communicating how the JCA framework aligns with the Commission's overarching strategy and complements other pieces of legislation. Best practice sharing and identification of improvement areas are key to fully leveraging the first phase, as well as a transparent tracking system ensuring a constructive debate with similar conclusions across Europe.
- **Engage healthcare system stakeholders**: All stakeholders, including patients and clinical experts, should be engaged and involved throughout the process. A constant feedback loop from a broad range of healthcare system stakeholders – especially the HTA network – will help to establish new methods and guide important process improvements proposed and accepted by the Coordination Group. In 2028, the EC will collect feedback from different healthcare systems and ask them to make suggestions for improvement. This is a great opportunity to optimize the process in a transparent way and reach the overall objectives for this centralized procedure.
- **Secure commitment from 27 EU member states:** All countries need to be committed to collaborate in the JCA process, build the necessary capabilities and equip the HTA with needed resources. While at this moment, we see some leading countries driving the efforts and leading the development of this new process and its requirements, we also anticipate that smaller and mid-size countries struggle to prepare well for this EU HTAR. Not only are resources already constrained, but also many local systems don't seem to be ready for optimal support of the centralized EU procedure. We hope very much that member states will support each other, especially in the beginning, ensuring that manufacturers have clarity about local requirements and the potential impact of a JCA report.

Together with the recommendations for a successful JCA implementation, we would also suggest policymakers build a more reliable and attractive HTA ecosystem by

- **Considering the new regulation as a starting point**: As several pieces of legislation come together, the EU should also provide a wider perspective on collaboration via Centres of Excellence or capacity sharing. A fundamental part of this is the consolidation of the European Health Data Space (EHDS); therefore, advancing how this interplays with the EU HTAR seems paramount.
- **Building common trust**: Part of the policy process relies on the capacity of Member States and their technical bodies to establish trust in other Member States (especially with those with less capabilities or more reluctant to fully engage with a transparent HTA system), sharing knowledge and experience. Defining and communicating in an appropriate manner progress (or the lack of it) will also depend on the capacity of all stakeholders to define some concise albeit efficient metrics to monitor progress.

The goals of the HTA regulation offer tremendous promise for patients across Europe, which not only remains after the USA, the second largest market in the world for pharmaceuticals but also a prime breed for innovation. But it's important that the final framework doesn't stifle innovation or result in a more complex, duplicative process that could potentially delay access to the therapies being developed today. One concern countries, as well as manufacturers, have raised is the challenge of connecting the JCA outcome with the local pricing and reimbursement process (3).

As we move closer to 2025, it's imperative that all healthcare system stakeholders and all 27 EU member states be strong partners in supporting a transparent and efficient process.

As an EU HTA Think Tank, we are ready to follow the communication process and expand the discussion to a broader audience to support establishing a transparent and successful implementation of this new EU HTAR.

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