EU Joint Clinical Assessments On Health Technologies Is Approaching – Are We Prepared?

HTA205

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Introduction and objective

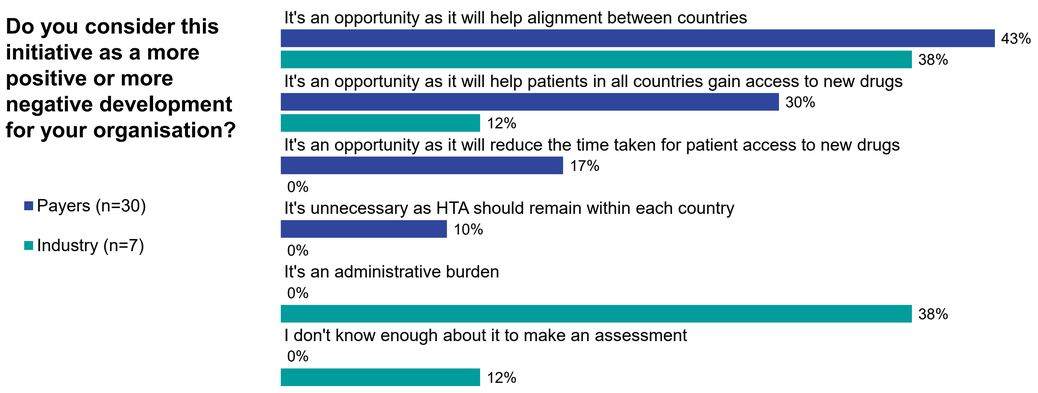
- In December 2021, the HTA regulation was adopted, which would see joint clinical assessments on health technologies across Europe. To ensure preparedness from all stakeholder sides, a transition period of 3 years has been set. Since the initial agreement in March 2021, EUnetHTA 21 joint consortium [1] and other joint initiatives [2] worked towards supporting implementation of the HTA regulation by developing templates, draft guidelines and supporting the preparation of national systems.
- This research explores how payer and industry views on opportunities and challenges of joint clinical assessment has changed from the Ipsos survey [3] conducted after the initial agreement in March 21, as the implementation date is approaching and guidance documents become available. In addition to the larger EU markets included in the previous research, this research also explores the views of smaller EU markets, and preparedness of the industry and health systems in Member States.

Methodology

- Ipsos fielded an online survey, in June 2023, with 30 payers from the Ipsos payer panel (Austria, Belgium, France, Germany, Greece, Italy, Poland, Portugal, Spain) and 7 representatives of multinational pharmaceutical companies with global/regional remit for market access.

Results

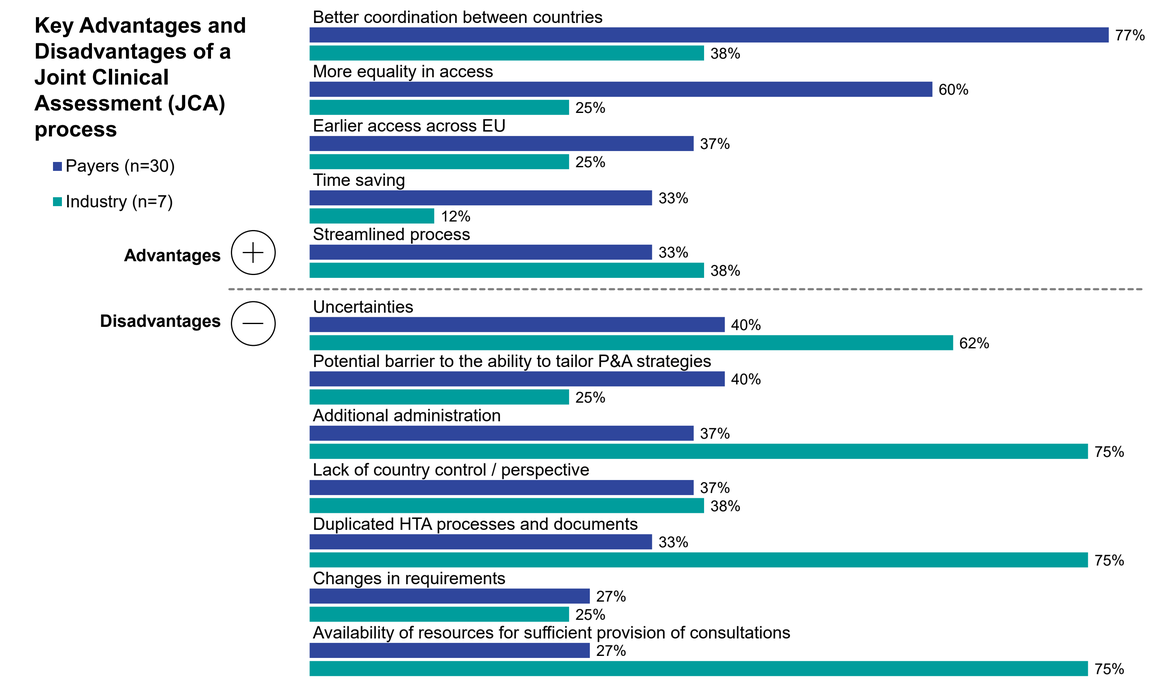
- Overall, we see that compared to 2021, Payers have become slightly less worried about the lack of country control or perspective compared to the results in 2021
- Respondents still see the initiative mostly positive, providing an opportunity for alignment between countries, and to potentially shorten the time it takes for patients to gain access to new drugs. Positive views are particularly true for payers from smaller EU Member States. German payers are an exception with 43% of respondents consider this initiative as unnecessary as HTA should remain within each country.
- Payers see more advantages than disadvantages, while industry remains more sceptical about the JCA. Payers consider the uncertainties and the potential obstacles in tailoring pricing and access strategies to each Member State as the main disadvantages Encouragingly, compared to 2021, a smaller number of respondents see extended time to approval as a disadvantage.
- For industry respondents additional administration, duplicated processes and the availability of resources to ensure sufficient provision of consultations with the manufacturers as were noted as key disadvantages
- Payers are generally more comfortable with proposed methodological guidelines for the JCA than the industry respondents, but both are concerned with comparators and believe that harmonisation of current methods must still be addressed for successful implementation of the JCA.
- Among payers, some concern remained about the representation of each country's values in the JCA, with half believing that ensuring consolidation of each member state's needs in the scoping process would be difficult.
- Most payers believe that it is going to be challenging to ensure that the national system is aligned with the changes introduced by JCA ahead of January 2025. According to industry respondents, half have not started preparations yet while other half have started trainings across EU affiliates, regional functions, EUnetHTA consultations or business risk assessments.
- Most industry representatives believe large leading markets will remain manufacturers' priority, whereas payers from EU4 and smaller EU Member States see the potential for earlier launch strategies in some of the smaller EU markets. Most respondents believe the changes will not impact Europe's position in the global launch sequence.

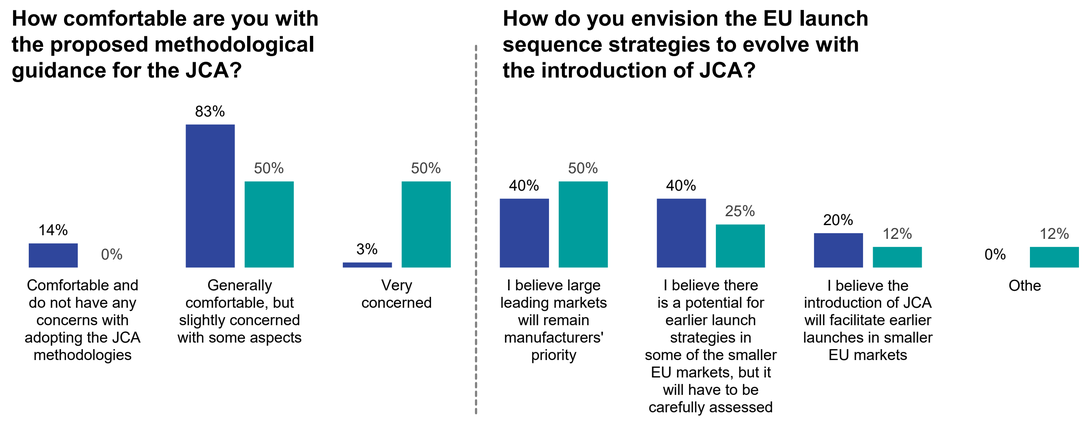


Conclusions

- Positive views from most of Member States indicate the HTA Regulation may potentially improve alignment between countries and reduce the time taken for patients to access new drugs.
- Better understanding of the JCA and increased clarity on what it entails have lessened certain concerns. However, there are still some areas of concern that persist, including those related to the proposed methodological guidance, especially when it comes to comparators.
- From the industry perspective, provision of consultations is crucial to align on evidence requirements as soon as possible. Therefore, it is not surprising that the industry respondents are concerned about whether the resources necessary for this to occur will be available.
- The implementation of the JCA may not be simple and will take time for the processes to develop and become more flexible. It is clear that more effort is necessary to align the current methods to support the successful implementation of the JCA.

Results continued...





Discussion

- Since 2021, industries and payers' views on opportunities and challenges of joint HTA have evolved. While most still see the JCA as an opportunity to help alignment between countries, there are some remaining concerns from both payer and industry sides.
- It is evident that it will take time for the national systems to align with the changes beyond the implementation of the JCA. While some Member States see these changes in a positive light and think that the national processes should adapt to the changes to support coordination with other countries and reduce repetitive evaluation of clinical evidence, others, like Germany, are more inclined to maintain their national procedures and consider JCA reports as an additional factor.
- Some payers think that changes in the national HTA procedures will be implemented slowly, and they will hold off on taking any action until the JCA becomes more established.
- It would be interesting to see how different Member States would use the JCA data and adapt their national level HTA processes.

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