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Heading into the unknown: how will JCA implementation affect global launch strategies?

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Introduction

Joint clinical assessments (JCA) are a collaborative initiative among EU member states to streamline the clinical assessment of health technologies, and have become a key topic in market access over the last year as implementation draws closer. JCA will be mandatory for oncology drugs and advanced therapeutic medicinal products (ATMPs) from January 2025, and will be fully implemented for all other drugs by 2030.[1]

Whilst primarily affecting European launch strategies, JCA will also inevitably impact on strategy at a global level. It is therefore essential that manufacturers understand and evaluate the potential consequences of JCA as part of their early pipeline planning.

Objectives

To understand the potential implications of JCA implementation for global launch strategies.

Methods

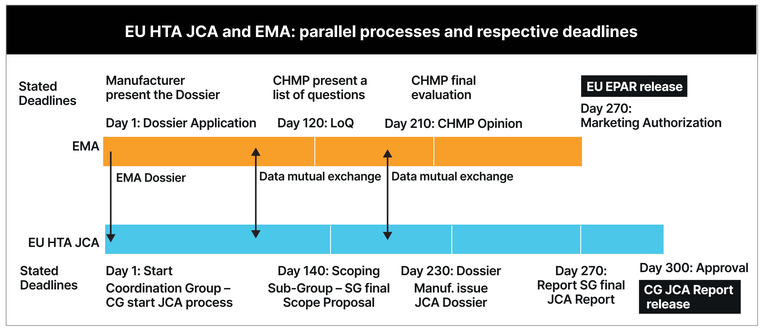
A targeted search of relevant gray literature published between January 2023 and March 2024 was conducted to investigate the implementation of JCA and identify the factors that should be considered by manufacturers to aid planning ahead of its start date.

Results

Four key potential impacts of JCA implementation were identified.

1. Shortened time frame between regulatory and reimbursement processes

Figure 1: Time frame of JCA



Current provisional timelines state that manufacturers will have 90 days from finalization of the stakeholders and research question (PICO: population, intervention, comparators, outcomes) until JCA dossier submission, which is also the date when the Committee for Medicinal Products for Human Use publishes its opinion.[2] Manufacturers have expressed concern that a longer time frame—at least 135 days—is required for a high-quality dossier to be developed.[3,4] There are also only approximately 40 days between the date of submission and publication of the JCA final report, leaving little time for manufacturers to submit any additional required data.[2] This may lead to increased pressure and resourcing concerns for manufacturers, as well as concerns around the quality of the submission. There is also a risk that the short timelines may result in more negative reimbursement decisions by shifting decision-making to an earlier point, potentially before long-term data are available.

2. Considering Europe as a single market

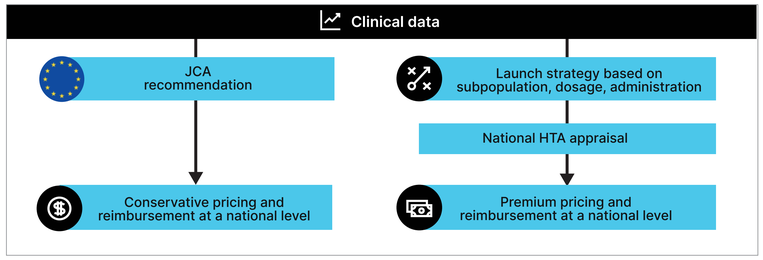
The JCA report will allow resource-constrained smaller EU markets to accelerate their health technology assessment (HTA) processes; however, manufacturers will need to consider Europe as a single market requiring a single launch, rather than staggering launches across Europe in waves.

Proposed changes to EU General Pharmaceutical Legislation (GPL) include incentivizing launch and supply in all 27 member states by offering manufacturers who do this longer exclusivity periods.[5] Taken together with JCA, this indicates a policy shift aimed at reducing disparities in access across the member states of the EU.

Manufacturers will need to be prepared to launch in all member states within a two-year period to fully benefit from both JCA and the GPL revisions. This is likely to require additional footprint in Europe and a greater reliance on regional affiliates. It may also entail greater complexity in launch planning for smaller manufacturers, who may not have affiliates in all markets and thus may need to partner with third parties to enable launch across all 27 member states.

3. Lack of flexibility with launch strategy

Figure 2: Lack of tailored pricing strategy per market due to JCA implementation



In the current system, manufacturers can optimize launch strategy by launching only in certain countries, or only targeting certain subpopulations in some markets to preserve value. JCA may jeopardize this approach, with payers flagging potential obstacles in tailoring pricing and access strategies to each member state as a main disadvantage of JCA.[6]

While JCA focuses solely on clinical assessment and does not include recommendations on a product's value or reimbursement, the choice of comparators and endpoints made at an EU level will significantly impact price negotiations. Additionally, with 26 of the 27 EU member states currently using some form of international price referencing (IPR), JCA will impact the ability of manufacturers to optimize price with tailored launch sequencing.[7] It is currently unclear how JCA will impact IPR and publication of list prices across the EU, but this lack of flexibility is likely to make Europe less attractive, especially for high-cost products such as ATMPs, and manufacturers may need to consider whether it is beneficial even to seek regulatory approval in the EU.

4. Potential delays and duplication of work

In theory, the JCA will save manufacturers time, costs, and resources by consolidating multiple HTA submissions to a single dossier, and eliminating the need for countries to review the same clinical data in multiple national appraisals.[8] However, there are concerns that the JCA process may lead to delays to market access.

For example, as the JCA focuses on clinical assessment, markets that base decision-making on cost-effectiveness may require additional data submission after the JCA opinion. Additionally, national HTA agencies will likely still need to request additional local data, including on clinical practice and relevant comparators, thereby delaying market access. Furthermore, as the JCA process runs alongside assessment by the European Medicines Agency, there are questions concerning what would happen if the label were to change during this time frame, which falls at a point when JCA has already begun.

While in many smaller, resource-constrained markets, launch is likely to be earlier than under the current system, potential delays in access in larger markets with more established HTA processes could result in Europe being deprioritized as a launch market, especially as markets such as China and Brazil ascend in the hierarchy.

Discussion

JCA implementation has the potential to harmonize the clinical assessment of drugs and medical devices across EU member states, but many uncertainties and concerns remain among both payers and manufacturers.

To prepare for such uncertainties, manufacturers should start incorporating stakeholder advice into their early pipeline planning, either through joint scientific consultations or specialized advisory boards. This will allow cross-functional teams to gauge potential requirements and plan JCA strategy. Manufacturers will also need to re-evaluate the working practices of cross-functional teams, and plan resource allocation earlier in clinical development to ensure organizational readiness within a rapidly evolving landscape.

Limitations of this research

Due to the provisional state of the current guidelines, many unanswered questions regarding JCA remain. It is not possible to determine how exactly each concern discussed above will impact JCA at the time of implementation. Additionally, more questions arise when JCA is discussed in the context of rare diseases and ATMPs, which are beyond the scope of this research.

Conclusions

JCA could result in an evolution in traditional global launch sequences, and so it will be even more important for manufacturers to follow a joined-up cross-functional approach, ensuring that the European perspective is included early on in clinical development.

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