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Navigating parallel Joint Scientific Consultations under EU HTA Regulation: Key Internal Considerations for Health Technology Developers

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BACKGROUND

- **The European Union's Health Technology Assessment Regulation** (HTAR), which applies since January 2025, marks a significant regulatory and market access shift, aiming to harmonize clinical evidence requirements across Member States and streamline patient access to innovative therapies.
- The HTAR **mandates Joint Clinical Assessments (JCAs) of new technologies**, requiring Health Technology Developers (HTDs) to submit a single clinical evidence dossier for EU-level review.
- To help inform the evidence generation package submitted as part of a JCA, the HTAR has introduced **parallel Joint Scientific Consultations** (pJSCs). These voluntary pJSCs **allow HTDs to obtain joint advice from the European Medicines Agency (EMA) and multiple national HTA bodies during early stages of product development to inform clinical trial design and evidence generation needs**.
- While pJSCs are designed to resolve potential evidence discrepancies and align requirements for JCA and Marketing Authorisation Applications (MAAs), successful engagement necessitates significant internal adaptation by HTDs.
- Navigating the complexities of multi-stakeholder advice and diverse national evidence needs demands a structured organizational approach to product selection, strategic alignment of timelines, and cross-functional decision-making.

OBJECTIVE and METHODS

Objective

This work outlines a framework and critical internal considerations for HTDs to achieve organizational readiness and successfully implement pJSC engagement, ensuring robust and efficient evidence generation.

Methods

This study utilized a conceptual analysis approach to synthesize the essential considerations necessary for HTDs to effectively engage with the new pJSC process under the EU HTAR framework.

Data Sources & Synthesis

- EU HTAR Framework & Guidance: Review and analysis of the official EU HTAR (EU 2021/2282) and subsequent published implementing acts and procedural guidance documents.
- Expert Consultation: Data was gathered through structured internal interviews with subject matter experts across regulatory, market access, and clinical development functions.
- Industry Intelligence: Synthesis of insights obtained from external industry discussions, workshops, and publications focused on HTAR implementation and HTA convergence strategies.

Analysis & Categorization

Key preparedness considerations derived from the data sources were analyzed and categorized across three critical dimensions:

- Organisational readiness, Procedural and Strategic Aspects, and Operational, Implementation Strategy.

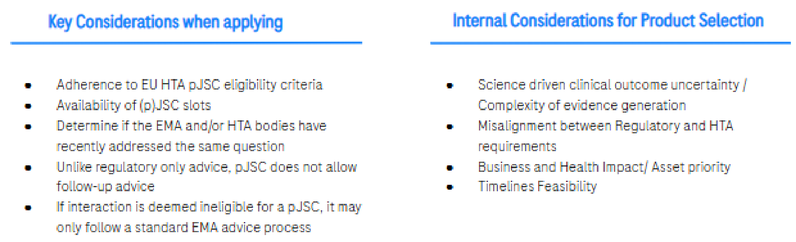
This analysis culminated in the development of a structured internal decision framework for selecting health technologies appropriate for pJSC engagement.

References: EU HTA Regulation (https://eur-lex.europa.eu/TodayOJ/) and Guidance for the selection of Medicinal Products (MP) for Joint Scientific Consultations (JSC) (https://health.ec.europa.eu/publications/guidance-selection-medicinal-products-mp-joint-scientific-consultations-jsc_en)

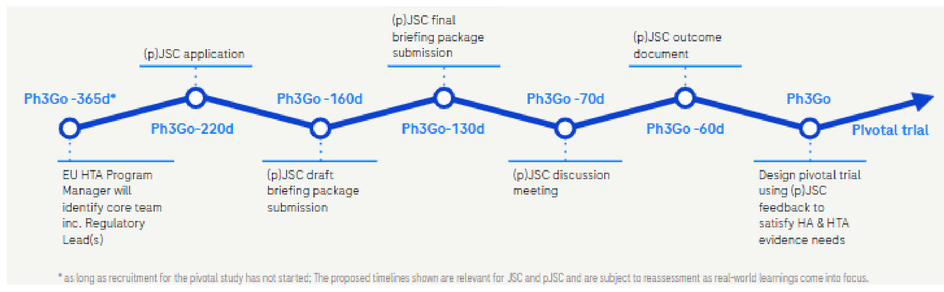
RESULTS

Successful pJSC engagement necessitates significant internal adaptations for HTDs:

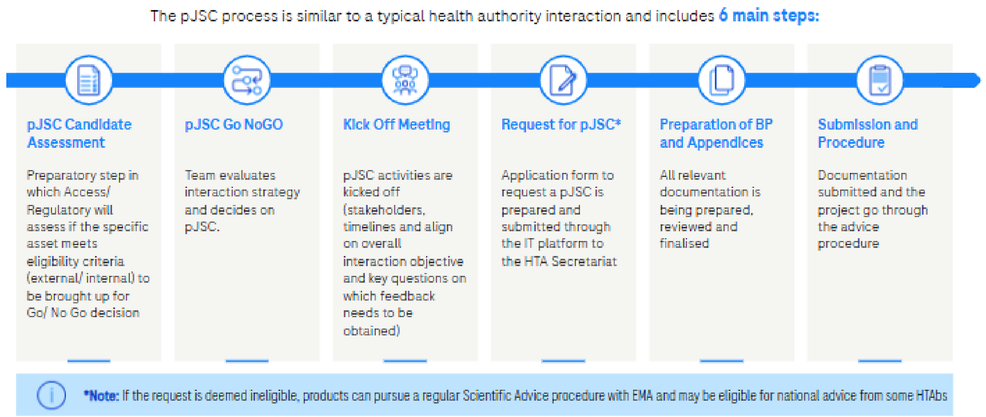
- **Organizational**: Defining internal governance, roles, and resource allocation, with a focus on establishing closer cross-functional alignment (Regulatory and Market Access) early in the development lifecycle. Creating clear frameworks for product selection, aligned with published pJSC eligibility and selection criteria, strategic considerations to support internal timelines and decision making for early evidence generation and briefing package (BP) preparation.



- **Strategic**: Aligning pJSC participation with product development timelines and commercial goals, including the development of joint capability-building programs and processes for external HTA policy engagement (e.g., commenting on Implementing Acts).



- **Operational**: Establishing robust procedures for data preparation, briefing package creation, timeline management, and utilizing centralized internal resource platforms to support joint processes.



DISCUSSION

- Successful engagement in pJSC relies fundamentally on HTDs organizational readiness, specifically **defining internal governance, roles, and ensuring co-leadership between Access and Regulatory teams**.
- However, even with robust internal preparation**, the current process faces limitations**. For instance, fixed, limited consultation slots create a capacity bottleneck that prevents alignment with critical internal milestones (e.g., post-Phase 2 data) and strategic timelines.
- **To fully leverage pJSC readiness and maximize its impact, the process requires optimization**. For example, introducing a rolling or flexible submission system with guaranteed response timelines to better match internal development milestones, and encouraging open, transparent communication among all stakeholders.

In conclusion, robust internal readiness must be paired with a flexible, predictable, and transparent pJSC mechanism to fully realize the strategic importance of the process and effectively accelerate patient access across the EU.