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S. Stengel, K. Ritz-Jansen, J. Barton, L. Ahrens, J. Leismann | Ecker + Ecker GmbH, Hamburg, Germany
D. Mari, A. Leary | regenold GmbH, Badenweiler, Germany

Navigating Joint Scientific Consultations under the EU HTA Regulation: strategic considerations for parallel versus HTA-only advice and alternative evidence alignment approaches

Background and objectives

The EU HTA Regulation introduces Joint Clinical Assessments (JCAs) for medicines, creating a need to anticipate EU-level HTA evidence requirements earlier in clinical development. Joint Scientific Consultations (JSCs) provide an opportunity to discuss clinical study design and evidence-generation plans with HTA bodies before evidence-generation decisions are fully locked. For medicinal products, developers may request either an HTA-only JSC or a parallel HTA/EMA JSC, allowing regulatory and HTA perspectives to be considered within the same development phase.

Which advice pathway provides the greatest strategic value for a given development programme? Which alternative advice pathways can support evidence generation when JSC access is not feasible?

Methods

A qualitative framework was developed to assess the strategic value of HTA-only versus parallel JSCs for evidence-generation planning under the EU HTA Regulation. The assessment drew on EU/EMA guidance documents, expert perspectives, early experience from various JSCs, and cross-functional input. Development scenarios and alternative evidence-alignment approaches were assessed across key dimensions of development and evidence-generation risk (Table 1). Each factor was qualitatively assessed for its potential to increase the strategic value of HTA-only versus parallel JSCs. Alternative evidence-alignment approaches were assessed against the same dimensions.

Table 1: *Assessment dimensions*

Development & evidence risk	Stakeholder alignment	Feasibility
Development complexity	Regulatory / HTA divergence	Resources
PICO uncertainty	PICO uncertainty	Procedural burden
Comparator uncertainty	Business / health impact	
Outcome novelty		

Results

Table 2: *Qualitative framework assessment*

	HTA-only JSC	Parallel JSC
Development complexity	Moderate fit	Strong fit
PICO / comparator uncertainty	Moderate fit	Strong fit
Outcome novelty	Moderate fit	Strong fit
Regulatory / HTA divergence	Moderate fit	Strong fit
Established regulatory pathway	Strong fit	Limited fit
Business / health impact	Moderate fit	Strong fit
Resources / procedural burden	Strong fit	Moderate fit

1 EMA scientific advice / protocol assistance	2 PICO & evidence gap assessment	3 HTA expert / advisory board	4 National HTA advice
When it may be useful:			
- When key uncertainties relate primarily to regulatory development, study design or clinical evidence requirements	- To proactively identify potential JCA evidence gaps and requirements - To identify and proactively manage evidence gaps where HTA-preferred study designs are not feasible	- To challenge the evidence strategy with former HTA assessors, payers and experts - To obtain early input on health economic evidence and cost-effectiveness modelling	- When country-specific HTA requirements or reimbursement considerations need to be explored - To obtain country-specific input on health economic evidence and cost-effectiveness modelling

Figure 1: *Beyond JSC – alternative routes to evidence alignment*

HTA-only JSC is particularly relevant when…

1. **Key uncertainties are predominantly HTA-related**
   Uncertainty around e.g. relevant patient population, appropriateness of the study design, study duration, timing and duration of outcome assessment, and the definition and relevance of minimal important differences
2. **Regulatory pathway is established**
   Regulatory expectations and key development requirements are relatively well defined
3. **Time and resources for consultation are limited**
   Focused discussion of HTA-specific questions without adding regulatory complexity
4. **Divergent Member State evidence requirements**
   Known differences in evidence expectations across Member States

Parallel JSC is particularly relevant when…

1. **Development is complex**
   Complex clinical programmes, innovative mechanisms, multiple indications or evolving evidence strategies
2. **PICO and trial-design uncertainty is high**
   Uncertainty around population, comparator, outcomes, study design, relevant subgroups
3. **High product impact**
   High expected patient, healthcare-system and/or business impact
4. **Early integrated evidence planning is needed**
   Bringing Clinical, Regulatory, Market Access/HTA and HEOR together early can strengthen internal evidence planning and alignment

Parallel JSC: what to weigh

Potential value

- Integrated Regulatory + HTA perspective
- Earlier identification of divergent expectations
- Earlier alignment on evidence requirements
- Potentially less duplication across advice processes
- Cross-functional alignment as an internal catalyst

Considerations

- Greater preparation effort (resources & EMA fees)
- Limited number and scope of questions
- More complex coordination across processes
- Regulatory and HTA discussions may not be equally relevant for all questions
- Regulatory and HTA perspectives can influence each other
- Timing and readiness of the development programme remain critical

Figure 2: *Different development scenarios call for different levels of Regulatory – HTA alignment*

Conclusion

- JSC strategy should be **tailored to each product** and development programme, based on its specific evidence risks, uncertainties and alignment needs
- Parallel JSCs may offer greatest strategic value when development complexity, PICO uncertainty and potential regulatory–HTA divergence are high. By bringing Regulatory and Market Access / HTA perspectives together earlier in development, **parallel JSCs can foster cross-functional evidence planning** and help embed HTA considerations earlier in the development process.
- HTA-only JSCs may be advantageous where the key uncertainties are clearly HTA-related and regulatory expectations are established, enabling a **more focused consultation** with potentially lower resource requirements.
- Where formal JSC access is not feasible, structured PICO analyses, evidence-gap assessments, external HTA expert input (e.g., advisory boards with former HTA assessors or payers/simulated consultation exercises), and national HTA advice can support JCA preparedness.

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Ecker + Ecker GmbH | Warburgstr. 50 | 20354 Hamburg | Germany
+49 (40) 41 330 81-0 | info@ecker-ecker.de | www.ecker-ecker.de

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