Insights Guide

Joint Scientific Consultations

Getting the Most from Early Scientific Advice

Executive Summary

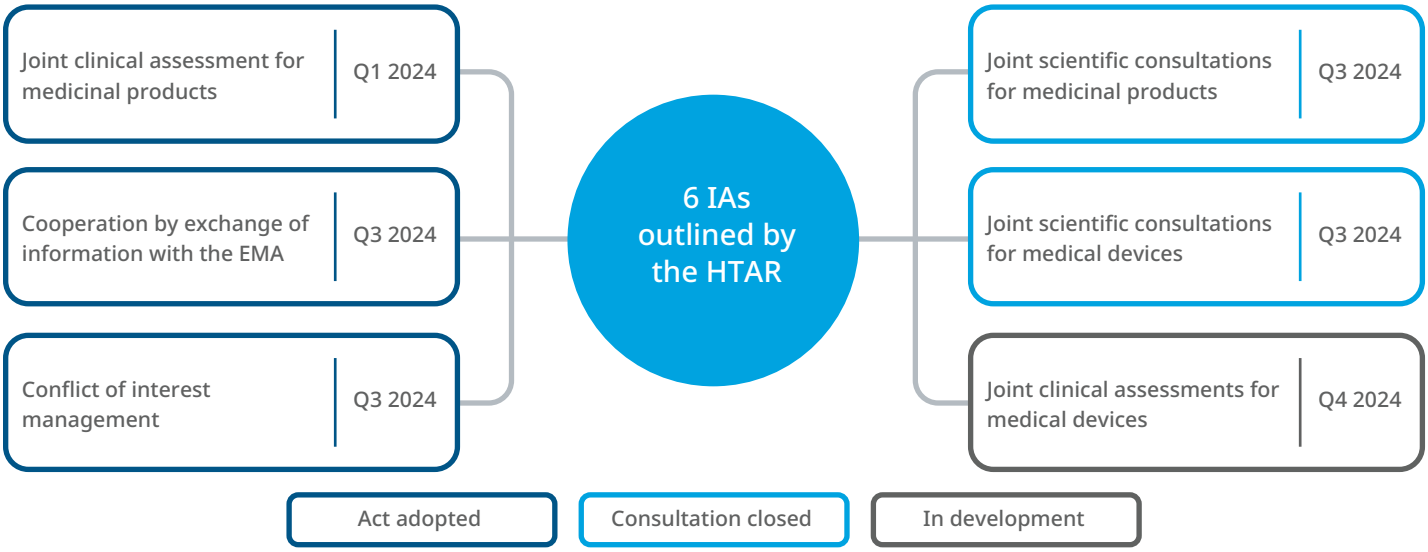
The European Union (EU) Health Technology Assessment Regulation (HTAR) will come into effect on 12th January 2025, with the aim of reducing duplication across member states and ensuring more rapid access to innovative treatments. In addition to introducing joint clinical assessments (JCAs) for new medicines and medical devices, the HTAR also provides a framework for joint scientific consultations (JSCs), allowing health technology developers (HTDs) to obtain early advice on the evidence packages required for future JCAs and national HTA submissions.

The European Commission (EC) committee on Health Technology Assessment (HTA) published the draft of the implementing act (IA) for the Joint Scientific Consultation (JSC) for medicinal products on 1st October 2024, and the JSC for medical devices and in-vitro diagnostic medical devices on 29th October 2024. The final IAs will be adopted before the end of Q4 2024 (Figure 1). The procedural guidance for JSC, guidance for selection of medicinal products for JSC and associated templates (i.e., JSC request, briefing document, outcome document) were published on 9th December 2024, providing greater clarity on the JSC process. The IA for the JCAs for medical devices are expected to follow shortly, which then concludes the 6 IAs outlined by the HTAR.

How will the JSC work?

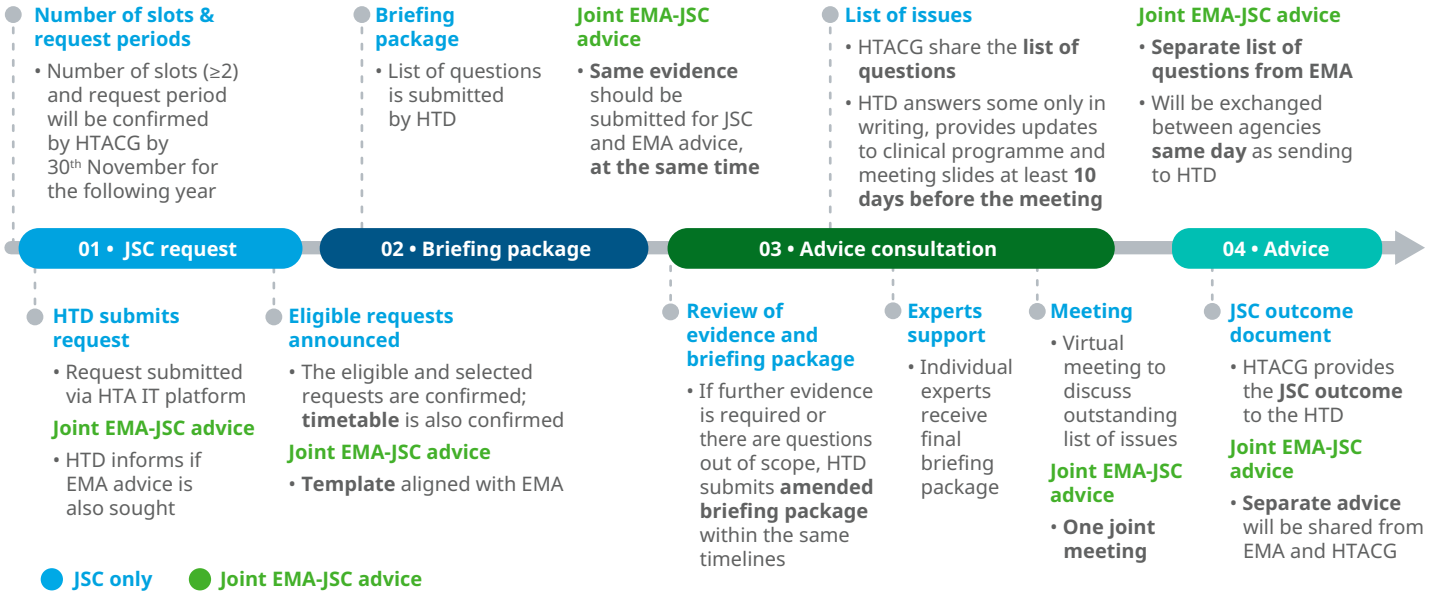
JSC facilitates a discussion between HTDs and EU HTA bodies (HTAb) on clinical development programmes before the pivotal trial protocol lock. JSCs may also be conducted in parallel with scientific advice from the European Medicines Agency (EMA), where the timing and submission of briefing package to both bodies will be synchronised. The overall aim is to streamline regulatory and HTA advice procedures, thus optimising opportunities for the generation of robust evidence fit for both marketing authorisation applications and JCAs, particularly where there is a high unmet need and substantial uncertainty.

Figure 1: Planned implementing acts under the EU HTAR



Source: Regulation (EU) 2021/2282 on health technology assessment.

Figure 2: JSC process overview



Source: Procedural guidance for Joint Scientific Consultations (JSC) on Medicinal Products (MP) (28th November 2024).

The Coordination Group on HTA (HTACG) will set the request periods (minimum two each year) by 30th November of each year, in line with the adoption of its annual work plan (Figure 2). The request periods for 2025 are (i) 3rd February to 3rd March 2024 for medicinal products only, and (ii) 2nd to 30th June 2025 for medicinal products and medical devices. The number of slots are anticipated to be limited in the first years whilst capacity builds up at a member state level, with a maximum of 10 slots available in 2025 (5 to 7 for medicinal products, 1 to 3 for medical devices).

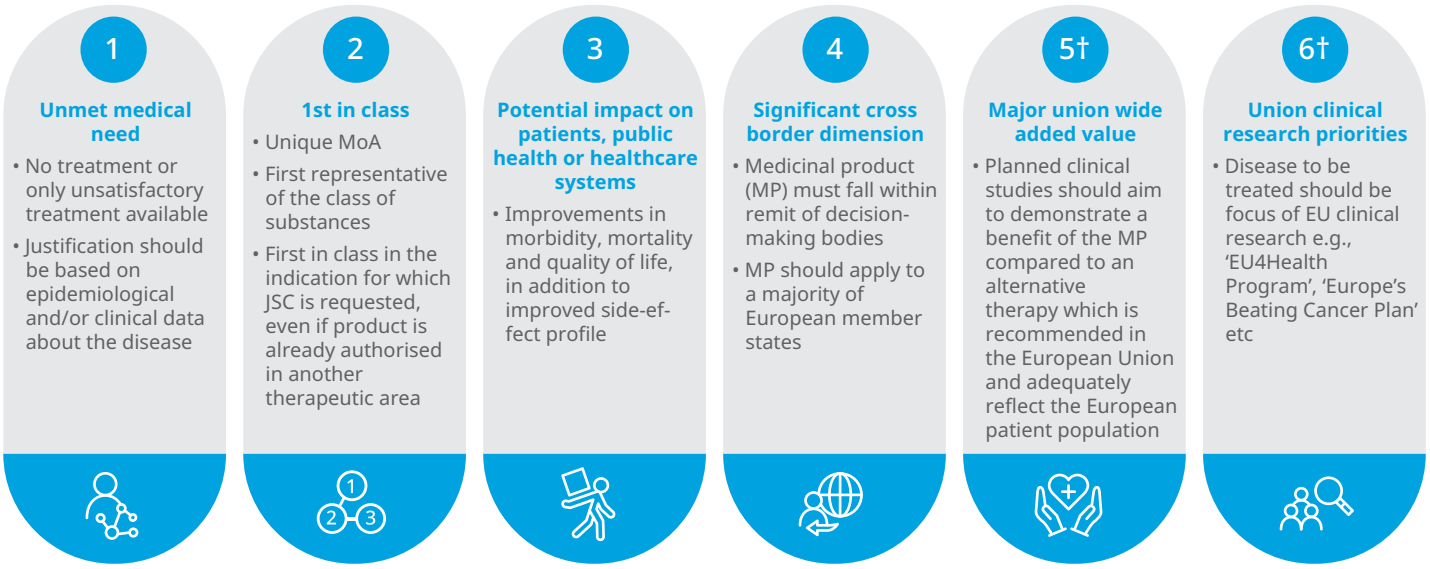
A medicinal product must fulfil two conditions to be eligible for JSC — (i) being likely to be subject to JCA, and (ii) the pivotal study(ies) are still in the planning stages.
If the number of eligible requests exceeds the number of planned JSCs in the request period, Member States (MS) will select medicinal products for JSC based on the selection criteria outlined in Figure 3. While it is not clear how the MS will assess and prioritise the medicinal products, HTDs should endeavour to demonstrate that all of the selection criteria are met (i.e., criteria 1 to 4 and 5 or 6 in Figure 3) to maximise likelihood of being selected for JSC.

HTDs of medical devices/ in-vitro diagnostic medical devices may request a meeting with the assessor and co-assessor and members of the HTA secretariat to seek assistance with the development of the briefing package. No such provision is formally available for HTDs of medicinal products. Following submission of the briefing package, the HTACG will share the 'list of issues' to be addressed either in writing before the meeting with HTAb or in the virtual meeting itself. Written response and any materials/ presentations to be used by the HTD in the meeting need to be submitted 10 days prior to the meeting.

JSC meetings will give HTDs the opportunity to discuss key concerns with a broad range of stakeholders, including JSC assessors, clinical and patient experts, as well as experts in the relevant disease or therapeutic area. If a JSC is held in parallel with EMA scientific advice, EMA representatives from the scientific advice working party will also participate in the discussions. Any updates on the development plan by the HTD can be reflected in the JSC advice if shared at least 10 days before the meeting.

The JSC process is anticipated to take approximately 4.5 months from the receipt of the draft briefing package. This is consistent with the current interim EMA/ HTAb parallel procedure that is being coordinated by Germany's Federal Joint Committee (G-BA). Factoring in the need for alignment and development of the

Figure 3: Selection criteria for JSC when eligible* requests exceed planned number of requests



Source: Guidance for the selection of Medicinal Products (MP) for Joint Scientific Consultations (JSC). (28th November 2024).

* Eligibility criteria: The medicinal product must fulfil two conditions to be eligible for JSC – (i) being likely to be subject to JCA, and (ii) the clinical studies and clinical investigations are still in the planning stage.

† MP only needs to fulfil either criterion.

application at the start and alignment post-receipt of the final recommendations, this means that the decision to proceed with JSC needs to be taken at least 10 months prior to pivotal trial protocol lock.

Considerations before applying for JSC

There are numerous asset- and company specific factors that need to be evaluated before making the strategic decision to apply for JSC. A risk-benefit assessment should be conducted to evaluate the pros and cons of seeking JSC or scientific advice in general. A 'decision framework' should involve cross-functional teams (e.g. market access, commercial, regulatory, medical, statistics, external engagement) factoring in all potential routes of advice (JSC, national advice procedures, advisory boards) and analyses of the specific objectives for seeking advice. Timing, eligibility, objectives of advice, likelihood of selection, and budget are key factors to consider including in the decision framework (Figure 4).

Confidentiality is another key factor to account for when considering advice options. Whilst not legally binding, HTDs will need to include the outcome of previous JSCs in JCA submissions, including justifications for deviations from the advice given. There may be some instances where it may not be practical or feasible to implement advice, which may be viewed unfavourably in local HTA procedures. The objectives of the advice and the specific questions included in the briefing package therefore need to be carefully considered. If it is anticipated that adaptations to the existing protocol cannot be made, JSC may not be the most attractive option.

A high bar for selection

As outlined previously, the selection criteria for JSC are focused on assets where there is a high unmet need and uncertainty (innovative products, with no or unsatisfactory standard of care) (Figure 3). When applying for JSC, HTDs are therefore expected to clearly demonstrate how the product fulfils all (not some) of the stipulated criteria. Therefore, early phase work should focus on generating evidence that demonstrates fulfilment of these criteria to maximise chances of being selected for JSC. Given the anticipated high demand and limited number of requests, the bar will be set high for those seeking out the coveted requests.

Figure 4: Scientific advice strategic considerations

Areas of uncertainty/objectives
Clinical vs economic, scientific or commercial, etc

Timelines and budget
Timing of protocol lock relative to the advice, internal budget constraints

Selection criteria
Likelihood of selection, given strength of evidence base / asset considerations

Confidentiality
Inclusion of outcomes and deviations in future JCAs vs fully confidential

Parallel advice procedures
With local HTA bodies, regulators and/or advisory boards

Readiness
Availability of documentation, draft protocols, internal dedicated cross-functional resource

Preparation is key to get the most out of the JSC meeting

HTDs are expected to drive the JSC meeting, focusing on the list of issues shared by the HTACG/ EMA. Depending on the number of issues identified, HTDs may not have sufficient time to discuss all of the issues. For this reason it is important for HTDs to carefully consider the questions to be included in the briefing package to keep the discussion topics and recommendations manageable.

Attendees in the meeting will be limited; HTDs need to ensure that each participant they select has the necessary domain expertise to actively participate, summarising the issue(s), present the HTD's position and address any feedback from the stakeholders.

A mock meeting with all key stakeholders, to rehearse timing, presentation flow and anticipate potential questions from stakeholders are helpful to maximise the output of the meeting and ultimately, the final written advice.

Advice outcome – what's next?

HTDs will receive the formal written advice separately from the JSC assessors and EMA approximately two weeks after the JSC meeting. HTDs should carefully review the advice and align cross-functionally on the modifications to the clinical trial design and evidence generation plans. As JSC advice given needs to be disclosed in the JCA dossier, HTDs will need to consider the likely impact of deviations from the JCA recommendations and clearly justify rationale for not implementing advice to minimise risk. Similarly, any recommendations implemented based on the JSC advice should be documented and updated periodically as the pivotal trial progresses.

Moving forward

There is now greater clarity on the JSC process with the availability of the procedural guidance, guidance on selection, templates and workplan. Our experience with the JSC pilot shows that companies who carefully consider the need for JSC and meticulously plan for scientific advice will be able to better meet JCA requirements and thereby accelerate EU patient access.

Please contact us to discuss your specific questions: EUHTASolutions@iqvia.com

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