European Commission

Joint Scientific Consultation for Medicinal Products

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Under the Health Technology Assessement Regulation (EU) 2021/2028 (HTAR), Joint Scientific Consultation (JSC) enables Health Technology Developers (HTDs) to exchange information on their development plans for a medicinal product or medical device and obtain guidance on the information, data, analyses and other evidence that are likely to be required from clinical studies for the Joint Clinical Assessment (JCA) of those products.

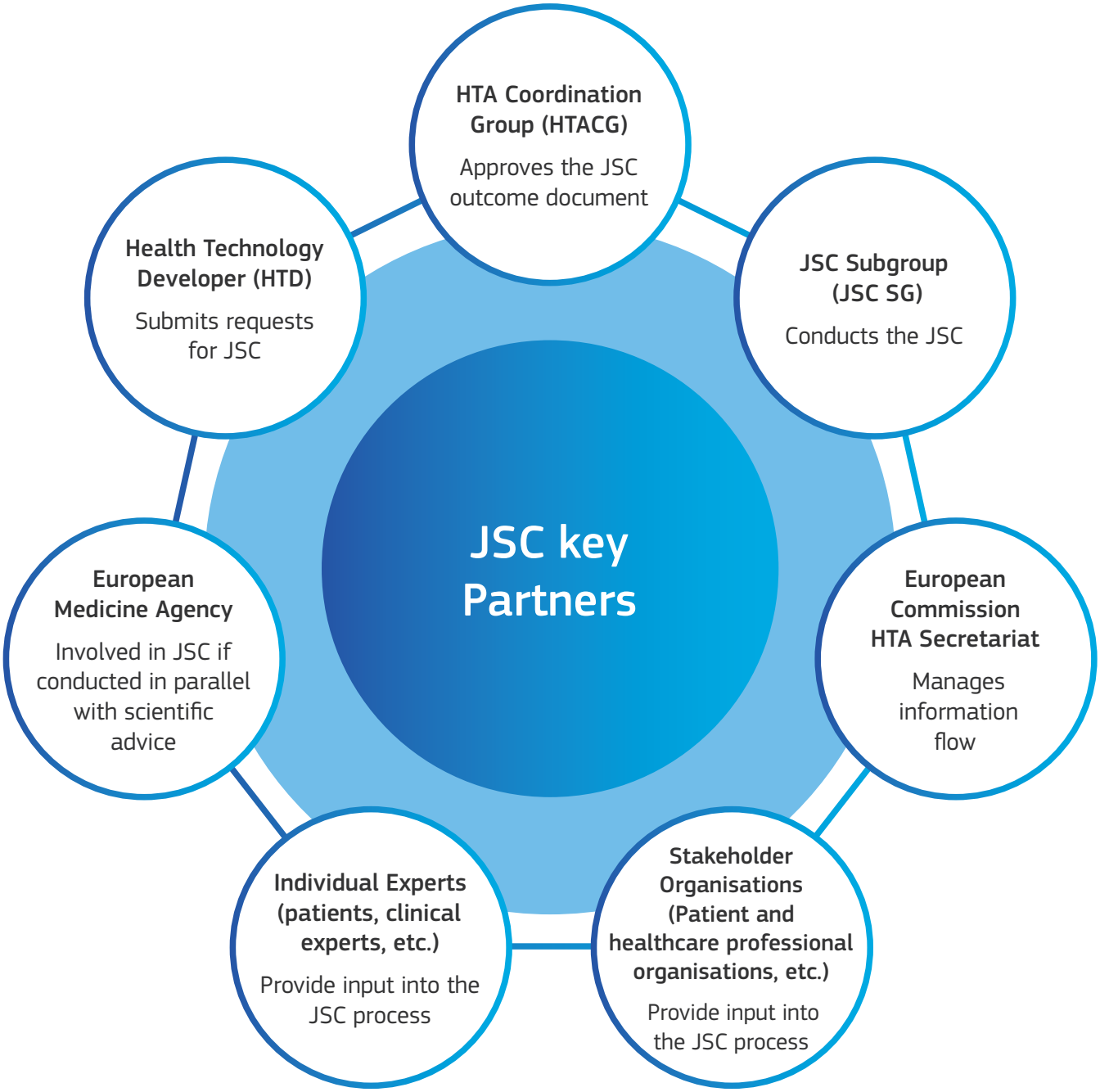
WHAT IS A JOINT SCIENTIFIC CONSULTATION?

JSC offers recommendations to HTDs on their development plans for a medicinal product or medical device, ensuring that evidence meets requirements for a subsequent JCA. This guidance can streamline preparation for JCA and enhance the quality of clinical studies.

HOW DOES THE JOINT SCIENTIFIC CONSULTATION WORK?

The JSC is conducted by the JSC subgroup (JSC SG) within the Health Technology Assessment Coordination Group (HTACG), which appoints an assessor and coassessor from different Member States to oversee the process. HTDs can request JSC for new medicinal products or existing ones with new indications. The JSC can also be conducted in parallel with scientific advice from the European Medicines Agency. Criteria for selection are listed in the HTA regulation and the selection process is detailed in the Guidance for the selection of Medicinal Products for JSC at https://health.ec.europa.eu/publications/procedural-guidance-joint-scientific-consultations-jsc-medicinal-products-mp_en.

JOINT SCIENTIFIC CONSULTATION KEY PARTNERS



CONDUCTING THE JOINT SCIENTIFIC CONSULTATION

Preparation for JSC

1. HTACG proposes dates for request periods and planned number of JSCs for the subsequent calendar year. These are published on the HTA IT platform.
2. HTD submits JSC request via the HTA IT Platform within the request period and indicates if they are also requesting a parallel process with EMA scientific advice.

Start of JSC Process

3. The JSC SG selects the requests which will be subject to a JSC. The HTA Secretariat then informs HTD of the decision within 15 days after the end of the request period.
4. The JSC SG appoints assessors and co-assessors for each JSC.
5. The HTA Secretariat identifies individual experts which are subsequently checked for Conflict of Interests by the HTA Secretariat and later selected by the JSC SG.

Submission of Briefing Package

6. HTD submits a briefing package for JSC in digital format via the HTA IT Platform and adherence to templates is checked by the HTA Secretariat. JSC SG requests further specifications or clarification if applicable.
7. HTD submits amended briefing package in digital format via the HTA IT Platform and adherence to templates is checked by the HTA Secretariat. Individual experts receive briefing package within 30 days of submission.

List of Issues and Meeting with HTD

8. The assessors and co-assessors draft List of Issues (LoI) for JSC SG to provide their comments, which the HTA Secretariat shares with HTD via the HTA IT Platform, with the possibility to provide a response at the latest 10 days before the meeting.
9. A virtual meeting with HTD, JSC SG, assessors, individual experts and, if in parallel, EMA is held to discuss LoI and the proposed development plan.

JSC Outcome Document and Approval by the HTACG

10. The assessors and co-assessors prepare the draft outcome document and finalise it after comments provided by JSC SG. The JSC outcome document is then submitted to HTACG for approval.
11. HTACG approves the JSC outcome document and HTA Secretariat sends it to HTD within the deadline.

PARALLEL CONSULTATIONS WITH EMA

If an HTD requests EMA scientific advice, the JSC can be conducted in parallel and the following takes place:

- JSC and EMA´s timelines have synchronised timing.
- HTD submits an identical briefing package to both the JSC SG and EMA at the same time.
- The JSC SG and EMA exchange information throughout the process. LoI documents are shared with HTD with the possibility to provide a response at the latest 10 days before the meeting.
- A single joint virtual meeting is held with HTD, JSC SG, assessors, external experts, and EMA to discuss LoI and the proposed development plan overall.
- HTACG and the EMA issue their outcome documents and scientific advice letters within the set deadline.

MORE INFORMATION

Implementation of the EU Regulation on Health Technology Assessment

https://health.ec.europa.eu/health-technology-assessment

Heath Technology Assessment Regulation

https://eur-lex.europa.eu/eli/reg/2021/2282/oj

Joint Scientific Consultation Implementation Regulation

https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32024R3169

Guidance Documents

https://health.ec.europa.eu/health-technology-assessment/key-documents_en?f%5B0%5D=topic_topic%3A236

LIST OF ACRONYMS

HTA	Health Technology Assessment
HTAR	Health Technology Assessment Regulation
HTACG	Health Technology Assessment Coordination Group
HTDs	Health Technology Developers
JCA	Joint Clinical Assessment
JSC	Joint Scientific Consultation
JSC SG	Subgroup Joint Scientific Consultations
EMA	European Medicine Agency
LoI	List of Issues
COI	Conflict of Interests

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