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Joint Scientific Consultation (JSC) and Joint Clinical Assessment (JCA) - a Better Road to Access?

Background & Objective

- In January 2022 the new EU HTA Regulation (2021/2282) came into force.
- From 2025 Joint Scientific Consultation (JSC) will be in place and innovative treatments will be subject to Joint Clinical Assessment (JCA) for the first time in Europe.
- Oncology products and advanced therapy medicinal products (ATMP) will be called upon for JCA followed by orphan drugs (2028) and all other medicines (2030).
- At present the EU HTA methodology and procedural rules are being developed and tested in pilot projects.
- The regulation may either enhance market access due to early alignment on study requirements (JSC) and timely assessment (JCA) or impose additional efforts as national submissions will still be required and final appraisal and decision-making will fall under the authorities of the member states (MS) as is the case now.
- The planned implementation is being assessed from an access perspective.

Methods

- Draft/final process and guidance documents (such as Guidance for Parallel EMA/EUnetHTA 21 Joint Scientific Consultation, Practical Guideline on Scoping Process, etc.) available from EUnetHTA21[1] by September 2022 have been reviewed.
- Central points of the proposed methodologies for JCA and JSC are being highlighted and discussed in view of current standard requirements for reimbursement submissions and decision making in Europe.
- Potential challenges and implications on market access are being addressed.

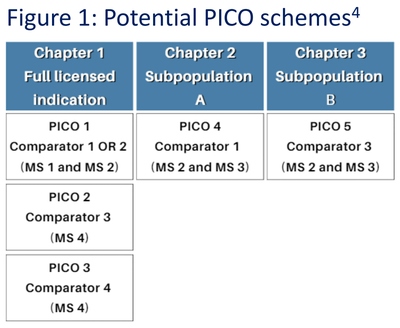
Results

Joint Clinical Assessment

Table 1: EU JCA Aspects[1,4]

Theme	Planned Process	Critical Evaluation
Scoping process	• Input of EU patients and HCPs in PICO survey as well as input from national externals possible • Final consolidated PICOs of MS as result • Manufacturer not involved, receives result of scoping process	• Early involvement of patients and experts is promising • Procedure to respect all PICOs requested by MS but might still be a challenge • Lack of communication with manufacturer in scoping process is a drawback
PICO	• Based on intended label • Input from all MS • PICOs for full licensed indication and subpopulations (Figure 1) • Comparators could be approved or not (off-label) in the EU	• PICO may need revisions after regulatory approval requiring more time and effort • Several PICOS for one population along with detailed workup and comparisons require substantial effort and resources, other than for national HTAs • Inclusion of off-label comparators may complicate national appraisal
Timing	• Aligned with regulatory timeline • Manufacturer (MF) submission latest 45 days before CHMP opinion • Plan to publish JCA report around EPAR	• Timeline of scoping process not detailed • Unspecified timing of PICOs communication creates uncertainty for MF in preparation of submission and launch • Substantial organisational effort for MF
National HTA process	• Complimentary to EU JCA (Figure 2) • Clinical analysis and non-clinical assessments required to amend submitted data • Appraisal considering all criteria concluding on added value according to national system	• Submission following national guidelines still required imposing an additional effort • Uncertainty on extent of JCA acceptance • Appraisal outcome of JCA by national HTAbs may differ between countries • Potential delay of national processes (e.g., in case of different label than planned)

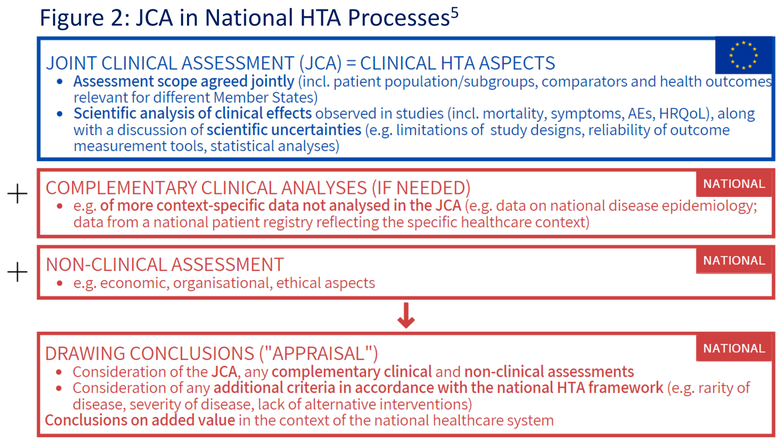
Figure 1: Potential PICO schemes[4]



Source: Compressed scheme, developed from practical-guideline-on-scoping-process-v1.0[4]

PICO=Population, Intervention, Comparators, Outcomes; HTAb=HTA body; HRQoL=Health Related Quality of Life; AE=Adverse Event

Figure 2: JCA in National HTA Processes[5]

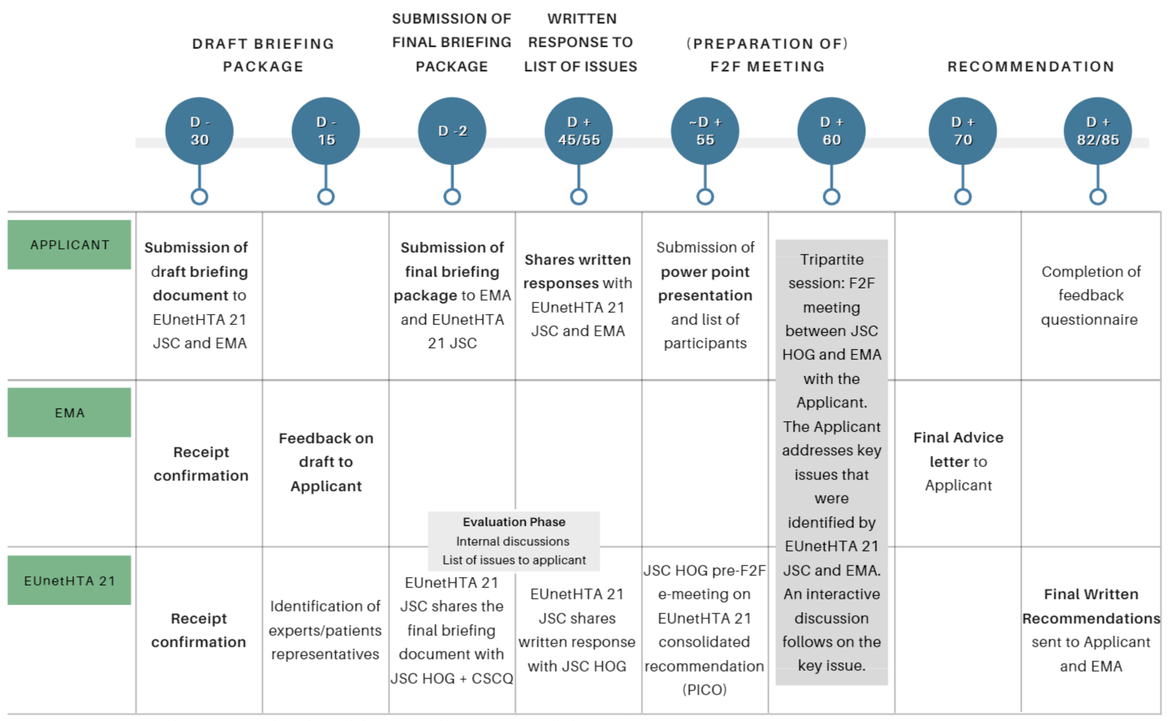


Source: Contents abbreviated, developed from EUnetHTA21 Stakeholder meeting 2022[5]

Results (ctd)

Joint Scientific Consultation

Figure 3: Timeline Joint Scientific Consultation[2]



Source: Compressed overview, developed from Guidance on parallel EMA/EUnetHTA 21 JSC[2]

JSC HOG=JSC Hands-on Group (involved in specific JSC); CSCQ=Committee for Scientific Consistency and Quality (11 natl. HTAbs)

Table 2: EMA/EUnetHTA JSC Process[2,3]

Theme	Planned Process	Critical Evaluation
Eligibility	• JSC candidates must meet essential criteria: high unmet medical need, first in class, major EU-wide added value and research priorities, impact on patients, public health or healthcare systems, and significant cross-border dimension	• Selection criteria limit access to JSC but will be developed further until full implementation
Timing	• Overall, about 4 months, from application to final recommendation (Figure 3)	• In line with national HTA advice (usually 3-5 months) with only 11 dates/year[3] imposing further limitations
Involvement of Externals	• Externals, patients, and HCPs, to be involved • Expert network is being built up • Potential participation in F2F meeting	• Approaches to involve experts (EMA and EUnetHTA) are promising. Identification and recruitment will be initiated early on national and European level. Timely availability may be a challenge
Questions/ Scope	• Questions to Regulators or HTAbs alone, or to both • Detailed information on choice of PRO and post-launch evidence generation plans	• Broad spectrum including preclinical (EMA) and economic (HTAb) questions possible
Recommen-dations	• Will follow the PICO approach • Provided separately by EMA and HTAbs	• Report with consolidated shared positions and individual HTAbs' answers where no consensus is obtained along with EMA reports might entail a dilemma for the manufacturer that need to be balanced

HCP=Health Care Provider; HTAb=HTA body; PRO=Patient Reported Outcomes

Conclusions

- Both, JSC and JCA, are a step towards a more unified assessment and hence might lead to faster and more aligned reimbursement decisions for new medicinal products in the European Union.
- JSC for new medicinal products is encouraged by authorities which seems to be beneficial in terms of trial design planning and expectations being set in advance. With advice provided separately by regulatory and national HTAbs, future will prove how aligned they will be.
- JCA represents an assessment of clinical aspects addressing MS requests as best as possible. Ideally this should be followed by joint conclusions (appraisal) similarly to the regulatory approval process. Taking into account country-specific requirements and national aspects, appraisals may still lead to diverse results though.
- Post-implementation process review and continuous refinements will be crucial going forward to make both a successful endeavor.

References:
1) https://www.eunethta.eu/about-eunethta/
2) Guidance for Parallel EMA/EUnetHTA 21 Joint Scientific Consultation EMA/410962/2017 Rev.5
3) 2022 SAWP meetings dates and submission deadlines (europa.eu)
4) EUnetHTA-21-D4.2-practical-guideline-on-scoping-process-v1.0
5) EUnetHTA21 Stakeholder meeting, July 13, 2022

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