How are national HTA bodies preparing for the implementation of the EU HTA regulation?

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Introduction

- The EU started preparing for the JCA under the new HTA regulation (HTAR) (1)
- Development of guidelines and implementing acts to facilitate the JCA process was delayed by 3 to 6 months, which has increased pressure on stakeholders preparing for these changes

Objective and methods

- This research aims to evaluate the readiness of various MS to align with the EU HTA framework, highlighting key challenges, progress, and national strategies employed to adapt to the EU HTAR
- A literature review was conducted, using publicly available resources from January 2023 to November 2024, including the EC website, PubMed, and grey literature

Results

MS/EEA willingness to adapt national processes for EU HTA transition

- Overall, MS show willingness to adapt or develop processes, despite organisational, resource, and timeline challenges **(Figure 1)**
  - **Countries with experience in HTA** (e.g., Germany, France) are expected to take the lead in JCA and may be the fastest adopters (2,3)
  - Most MS/EEA **countries with established HTA systems** declared their commitment to adaptation, while **countries lacking fully developed HTA systems** view the EU HTA as an opportunity for growth and development (5)
  - **Late access countries** (e.g., Slovakia) see the need for health technology developers to apply for reimbursement within a short period of time after obtaining marketing authorisation to ensure relevance of the JCA report (5)

Figure 1. Examples of MS/EEA willingness to adapt their national processes for the EU HTA transition

JCA leaders	Germany has been instrumental in shaping the EU HTA process, which is closely aligned with AMNOG (2) Minimal changes to national procedure are expected (5) A "delta" dossier will be requested if the EU HTA doesn't meet country needs, such as patient numbers, cost comparisons, or specific data for the AMNOG process (2)	France is ready to adapt to the JCA, with HAS engaged in the coordination group (3,5) For PICO, only consultations with experts or patient representatives are planned (4) No impact is anticipated on early access, national timelines, or the SMR/ASMR evaluation (3,4)
Established HTA systems	Italy's AIFA has merged 2 working groups into a new Scientific Economic Commission and plans to enhance transparency by publishing reports (5)	Sweden is mapping current processes, assessing potential changes and forming a new collaboration for HTA between TLV, Swedish Medicines Agency, and SBU (5,6)
	The Netherlands has prepared gap analyses and plans to engage stakeholders early in the PICO process (5)	Austria's AIHTA launched a pilot to adapt HTA methods using EUnetHTA guidelines, ensuring national readiness for EU HTA (5,7)
	Spain is adopting a 3-phase model to integrate JCA into national funding decisions. It aims to use reports with minimal changes (5,8)	Portugal's INFARMED plans to integrate the JCA report into their health system by adjusting the evidence and therapeutic value grading system to meet local needs (5)
Developing HTA systems	Bulgaria and Greece are reviewing their national criteria, which requires prior reimbursement in other countries (5)	Iceland and Cyprus, lacking formal HTA systems, are dedicated to establishing HTA structures implementing regulation (5)
	Luxembourg plans to adjust their national process to end reliance on Belgian HTA systems (5)	Croatia is enhancing their capacity for sustainable national HTA and active participation in joint HTAs (9)

National readiness for EU HTA transition

- Country representatives provided ratings on readiness at EC panel discussions (May 2023 to November 2024) **(Figure 2)** (5)
- The perception of readiness described by the ratings varies across MS and EEA countries. However, many express a cautious attitude to JCA, including those that were part of EUnetHTA21, and few have provided details of processes for incorporation of JCA into national HTA **(Figure 2)** (5)
- A representative from AOTMiT expressed reluctance to alter Poland's established HTA system (5). However, a draft amendment to the reimbursement act indicates a shift towards HTAR alignment. This amendment allows applicants to forgo clinical analyses if EU-level data for the same indication and population are available (10)

Figure 2. National readiness ratings based on EC panel discussions (May 2023–November 2024)[a]

[a]Twenty-seven MS, along with Iceland and Norway, participated in discussion panels conducted up to November 2024. The time point at which ratings were given varies depending on the date of EC panel discussion, which may affect the level of readiness described

Organisational challenges and extended expertise

- Implementing the EU HTAR presents various organisational challenges across MS, with a notable need to enhance expertise in areas such as indirect treatment comparisons, particularly in Spain and Italy. Engaging clinicians and patient representatives in discussions is also crucial in Bulgaria, Lithuania, and Hungary (5)
- Many countries (e.g., Cyprus, Iceland, Greece, Romania, Latvia, Estonia, Lithuania, Slovenia, Luxembourg, Malta, Portugal, Czechia) indicate that insufficient resources and/or lack of expertise will hinder the timely execution of HTA processes (5)
- Slovakia is also concerned about delays in reimbursement submission, which may result in outdated JCA data (5)

JCA integration into health economic framework

- Poland and Sweden are assessing how to best integrate JCA reports into their national economic assessments, which is essential for aligning with the EU HTA framework (5)

PICO and industry involvement

- Some smaller countries may face challenges in responding to the PICO survey, limiting their contribution and reducing JCA relevance (5)
- The adaptation of the PICO framework is contentious, such as in Italy and Bulgaria, where industry involvement is sought to streamline negotiations (5)
- France is not planning to involve industry in PICO scoping at the national level (4)

Potential role of existing joint HTA collaborations

- Collaborative initiatives such as **BeNeLuxA and the Nordic HTA bodies** (formerly FINOSE) are enhancing readiness for joint HTA by facilitating expertise sharing and maintaining established procedures following JCA (5)

Discussion and conclusion

- Most MS are committed to implementing JCA by preparing their national systems for the EU HTA transition
- Countries with less established HTA frameworks want to contribute to JCAs but recognise the need to build capacity, such as by raising awareness and building infrastructure for stakeholder engagement
- Publicly available information on how JCAs will be integrated into national assessments is limited, leading to several procedural challenges and uncertainties, including PICO scoping process; if national requirements are not well reflected in JCA, HTA bodies may require additional evidence from manufacturers
- Closely monitoring early JCAs and market engagement with industry during the PICO scoping process is crucial; adapting JCAs at the national level will be a learning process for all MS, regardless of their current HTA experience or methodological expertise

Abbreviations
AIHTA, Austrian Institute for Health Technology Assessment; AIFA, Italian Medicines Agency; AMNOG, pharmaceuticals market reorganisation act; AOTMiT, Polish Agency for Health Technology Assessment and Tariff System; ASMR, added clinical benefit; EEA, European economic area; EC, European Commission; EU, European Union; EUnetHTA, European Network for Health Technology Assessment; HAS, French national authority for health; HTA, health technology assessment; HTAR, health technology assessment regulation; INFARMED, National Authority For Medicines And Health Products; JCA, joint clinical assessment; MS, member states; PICO, patient/population, intervention, comparison and outcomes; SBU, Swedish Agency for Health Technology Assessment and Assessment of Social Services; SMR, clinical benefit; TLV, Swedish Dental and Pharmaceutical Benefits Agency

Key

Austria, Belgium, Bulgaria, Czechia, Denmark, Estonia, Hungary, Iceland, Ireland, Lithuania, Luxemburg, Malta, Poland, Portugal, Romania, Sweden, Spain, France, Cyprus, Greece, Latvia, Slovenia, Croatia, Finland, Italy, Netherlands, Slovakia, Germany, Norway

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