Are We There Yet? Mapping Member State Readiness for Local Implementation of the EU Health Technology Assessment (HTA) Regulation

HTA40

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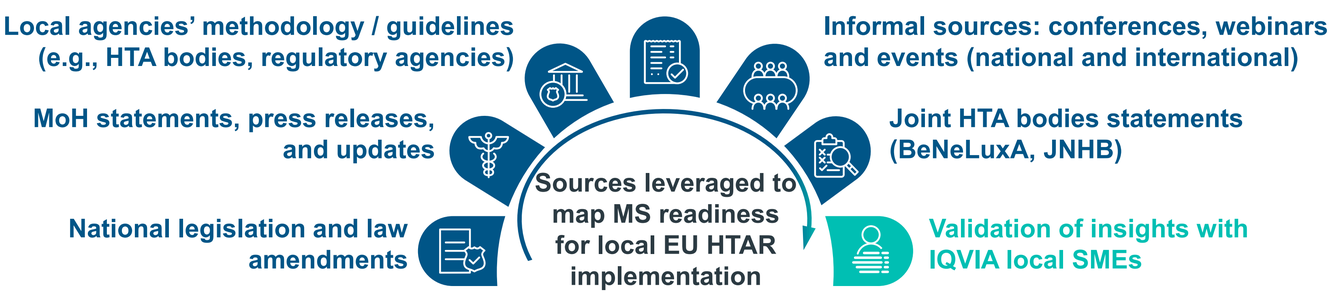
Introduction

- The European Union Health Technology Assessment Regulation (EU HTAR)[1] represents a **seismic shift in EU Market Access**, establishing a **unified evaluation framework** that **redefines how new technologies are assessed across Member States (MS)**
- Whilst **successful integration** of the Joint Clinical Assessment (JCA) into local Health Technology Assessment (HTA)/Pricing and Reimbursement (P&R) frameworks **is a key benchmark for the EU HTAR success**, the **reality is that few MS have articulated how this will be operationalised**, e.g., changes to national legislation, local dossier templates, etc. **This leaves significant uncertainty around local implementation of the EU HTAR**
- For Health Technology Developers (HTDs), understanding this patchwork is critical: **MS readiness for local EU HTAR implementation will directly impact launch timelines, evidence needs, and patient access**

Methods

- Formal and informal sources were reviewed (November 2024 – September 2025) to assess MS readiness for EU HTAR implementation and **insights subsequently validated by local subject matter experts** (SMEs) (**Figure 1**)
- **MS readiness** was then **mapped across European Economic Area (EEA) countries**, highlighting where adoption has been communicated and where gaps could disrupt EU-wide harmonization (**Table 1**)

Figure 1: Sources leveraged to map MS readiness for local EU HTAR implementation



Results

Table 1: MS readiness mapping for local implementation of EU HTAR across EEA countries[2]

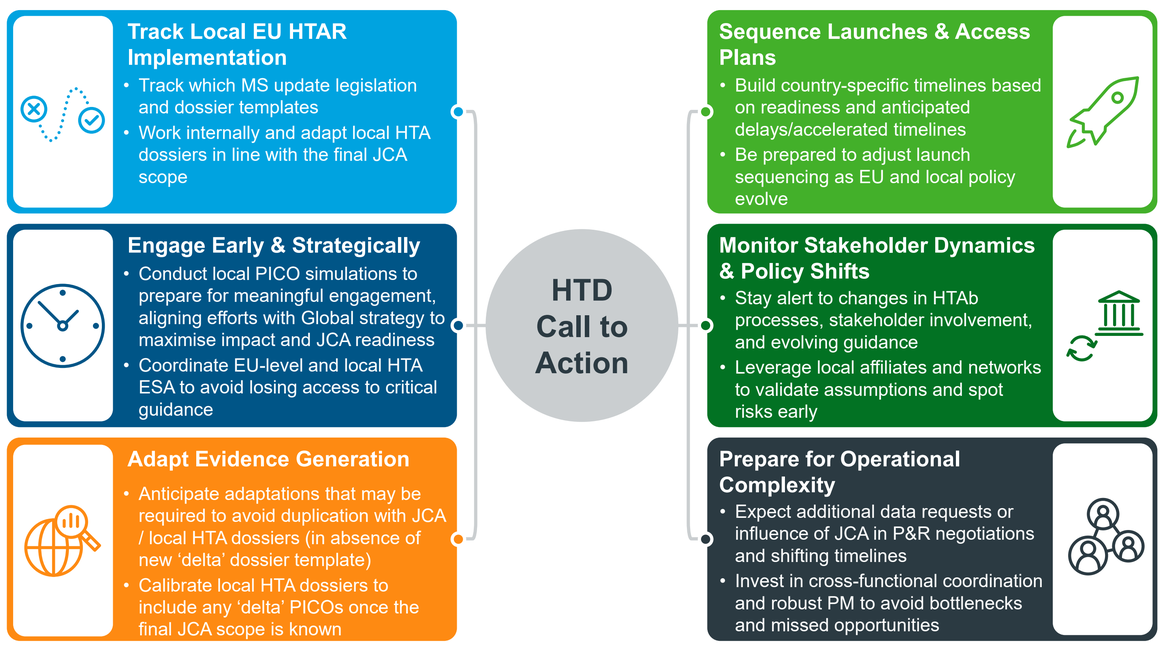
Member State	Established HTA process	MS readiness for local implementation of the EU HTAR				
	Is a HTAb/ HTA legal framework established?	Has the national legislation been adapted?	Has a new/amended dossier template been published?	How will the JCA report be used within national decision-making processes/ pricing & reimbursement/ health economic assessments?	Will the availability and/or relevance of the JCA report impact national HTA timelines/reimbursement procedures?	During the JCA scoping phase, will there be any possibility of interaction at local level between HTAb and HTDs?
Austria	Yes	In progress	No	Details on JCA report use not specified yet*	No change	Unclear
Belgium	Yes	Yes	In progress	JCA report to be referenced throughout	Possible delays	Yes
Bulgaria	Yes	In progress	No	JCA report to be attached and/or referenced in appendix	No change	Unclear
Croatia	Yes	In progress	No	JCA report to be attached and/or referenced in appendix	No change	Unclear
Cyprus	No	No	No	Details on JCA report use not specified yet*	Possible delays	Unclear
Czech Rep.	Yes	Yes	In progress	Details on JCA report use not specified yet*	No change	Unclear
Denmark	Yes	Yes	Yes	JCA report to be attached and/or referenced in appendix	Possible delays	Yes
Estonia	Yes	Yes	No	JCA report to replace clinical component of national submission (where appropriate)	Shorter timelines	Unclear
France	Yes	No	In progress	JCA report to be attached and/or referenced in appendix	No change	No
Finland	Yes	In progress	No	JCA report to be referenced throughout	Possible delays	Yes
Germany	Yes	Yes	Yes	DE dossier may reference JCA analyses**	No change	No
Greece	Yes	In progress	No	N/A (i.e. no identified communication)	No change	Unclear
Hungary	Yes	Yes	In progress	N/A (i.e. no identified communication)	Possible delays	Unclear
Ireland	Yes	Informal statements only	In progress	JCA report is expected to be integrated into the existing rapid review process^	Possible delays	Unclear
Italy	Yes	In progress	In progress	N/A (i.e. no identified communication)	No change	Unclear
Latvia	No	In progress	No	N/A (i.e. no identified communication)	No change	Unclear
Lithuania	Yes	In progress	No	N/A (i.e. no identified communication)	N/A (i.e. no identified communication)	Unclear
Luxembourg	No	No	No	N/A (i.e. no identified communication)	N/A (i.e. no identified communication)	Unclear
Malta	No	In progress	No	N/A (i.e. no identified communication)	N/A (i.e. no identified communication)	Unclear
Netherlands	Yes	Yes	Yes	JCA report to be referenced throughout	Possible delays	Unclear
Poland	Yes	In progress	No	JCA report to replace clinical component of national submission (where appropriate)	Shorter timelines	Yes
Portugal	Yes	Informal statements only	No	N/A (i.e. no identified communication)	No change	Unclear
Romania	Yes	No	No	N/A (i.e. no identified communication)	N/A (i.e. no identified communication)	Unclear
Slovakia	Yes	In progress	No	JCA report to be attached and/or referenced in appendix	No change	Unclear
Slovenia	Yes	In progress	No	N/A (i.e. no identified communication)	N/A (i.e. no identified communication)	Unclear
Spain	Yes	In progress	In progress	JCA report to be considered to avoid duplication, but complementary analyses may be needed#	Shorter timelines	Yes
Sweden	Yes	Yes	No	JCA report to be attached and/or referenced in appendix	Possible delays	Yes
Norway	Yes	Informal statements only	No	N/A (i.e. no identified communication)	No change	Yes
Iceland	No	Informal statements only	No	N/A (i.e. no identified communication)	No change	Unclear
Liechtenstein	No	No	No	N/A (i.e. no identified communication)	N/A (i.e. no identified communication)	Unclear

MS readiness legend: Final position confirmed | In progress or informal statements only | No identified communication/unclear

**JCA will be adopted as proposed and will inform HTAb decision-making for carrying out national HTAs for which JCA reports have been published or for which a JCA has been initiated; however, there are no details at the time of writing on how the JCA report will be leveraged locally; **The DE dossier may reference analyses in the JCA dossier, provided that JCA was not discontinued; If the JCA report is not yet published when the AMNOG process begins, the HTD must submit a version of their JCA submission dossier to the G-BA within 3 days. This interim version is temporarily published on the G-BA website and later replaced with a link to the official JCA report once available - this ensures no delays to AMNOG procedure due to JCA delays; ^Unofficially, it is expected that the JCA report can be integrated into the existing rapid review process, enabling NCPE to concentrate on CE evaluation of new therapies; #JCA report will be considered locally to avoid duplication of the assessment; however complementary clinical analyses will be conducted if the JCA scope does not fully reflect the ES context*

Conclusions and implications

- **Local implementation of EU HTAR is still highly uncertain, with limited clarity on how it will be operationalised in practice:** Only 8 MS have adapted legislation and just 3 MS (DK, DE, and NL) updated HTA dossier templates. **This presents a challenge for HTDs that have started to prepare local submissions in parallel to JCA**
- **JCA integration remains inconsistent:** Fewer than half of MS clarified how the JCA report will be used in national HTA; approaches range from full replacement of the clinical section to referencing or appendix attachment. **This makes local P&R preparations very challenging**
- **Timelines are unpredictable:** 6 MS confirmed no impact to national HTA timelines, 5 expect delays, 5 anticipate shorter timelines, and for most, impact remains unknown. **Launch sequencing and market access planning must be flexible and country-specific**
- **HTD involvement in JCA scoping locally is limited but presents real opportunities:** While formal engagement at EU level is minimal, several MS (BE, DK, ES, FI, PL, NO, SE) offer some possibility for local input or interaction during the JCA PICO survey process. **HTDs should actively leverage these opportunities, moving beyond the traditional focus of DE and FR to engage locally in EU wherever feasible**
- **JSC may impact local scientific advice:** In FR, products that have undergone or plan to undergo JSC are not eligible for ESA with HAS[3]; impact in other MS is currently unknown. **HTDs must align EU-level and local ESA strategies to avoid losing critical guidance**



References: 1 – Regulation (EU) 2021/2282 on Health Technology Assessment; EUR-Lex; Regulation (EU) 2021/2282 of the European Parliament and of the Council of 15 December 2021; 2 – IQVIA Local SMEs; 3 – HAS EU HTA Webinar (16 October 2024); **Abbreviations:** AMNOG – Pharmaceuticals Market Reorganisation Act (German: Arzneimittelmarkt-Neuordnungsgesetz); ATMP – Advanced Therapy Medicinal Product; BeNeLuxA – Beneluxa Initiative on Pharmaceutical Policy; CE – Cost Effectiveness; DE – Germany; DK – Denmark; EEA – European Economic Area; ES – Spain; ESA – Early Scientific Advice; EU – European Union; FI – Finland; FR – France; G-BA – Federal Joint Committee (Germany); HAS – National Authority for Health (France); HTA(b) – Health Technology Assessment (Body); HTAR – Health Technology Assessment Regulation; HTD – Health Technology Developer; ISPOR – International Society for Pharmacoeconomics and Outcomes Research; JCA – Joint Clinical Assessment; JNHB – Joint Nordic HTA-Bodies; JSC – Joint Scientific Consultation; MS – Member States; N/A – Not Applicable; NCPE – National Centre for Pharmacoeconomics (Ireland); NO – Norway; PICO – Population, Intervention, Comparator, Outcome; PL – Poland; PM – Project Management; SE – Sweden; SMEs – Subject Matter Experts; **Disclaimer:** The authors declare no conflicts of interest. This research received no external funding.