National Implementation of the EU HTA Regulation: Progress and Strategic Developments Across Member States

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HTA240

Introduction

- The European Union (EU) Health Technology Assessment (HTA) Regulation (EU 2021/2282) mandates Joint Clinical Assessments (JCAs) across all 27 EU Member States (MS), as well as the three European Free Trade Association (EFTA) countries (Norway, Iceland, and Liechtenstein), beginning in 2025 for new cancer medicines and advanced therapy medicinal products (1,2).
- This shift requires harmonisation of processes and poses both challenges and opportunities for MS and health technology developers (HTDs).

Objective & Methods

- This research aimed to assess the progress of EU MS and EFTA countries in preparing for JCA implementation under the EU HTA Regulation, while also examining strategic developments and potential implications for HTDs.
- A literature review was conducted covering the period January 2023 to September 2025, drawing on resources from all 30 participating countries. Sources included national HTA agency websites, press releases, PubMed, and grey literature. The analysis focused on four key areas: guideline and procedural updates; national timeline adaptations; HTD input to PICO scoping; and capacity building.

Results

- Countries with established HTA systems (e.g. France, Netherlands, Sweden, Finland) are proactively updating guidelines and processes and communicating more openly on JCA integration (3-10), while less mature systems (e.g. Estonia, Greece, Lithuania, Croatia) remain at early stages with draft guidelines or capacity building and limited public communication (11-17) **(Figure 1)**.
- National timeline adaptations follow different approaches **(Figure 1)**:
  - Some MS/EFTA countries are accelerating national access by shortening deadlines (Bulgaria) (18) or running tasks in parallel during the JCA (e.g. health economic assessment in Norway) (19).
  - Others wait until JCA reports are available before starting full national HTA dossier assessments (e.g. Netherlands, Sweden, Finland), with possible earlier preparatory steps (e.g. preliminary material submission) (4, 6-10).
  - France, Belgium and Germany proceed with national assessments even if JCA reports are not yet published (3, 20, 21).
- Approaches to manufacturer input to PICO scoping vary **(Figure 1)**:
  - The Netherlands, Belgium, and France provide no opportunity for HTD input. The Netherlands shares its national PICO with HTD only after JCA dossier submission (4), Belgium allows HTD access to national PICO only once EU PICO is established (22), and France does not plan to share national PICO (3).
  - Sweden and Finland enable voluntary contributions, with Finland allowing proactive PICO proposals under defined deadlines (7, 23).
  - Italy, Poland, and Bulgaria have expressed willingness to involve industry, but no structured pre-PICO consultation mechanisms have been published (24, 25).
- Several countries are expanding capacity through staff recruitment, funding, and training (e.g. Netherlands (4), Sweden (7), Italy (26, 27), Lithuania (16)), while others have not stated whether similar initiatives are underway **(Figure 1)**.
- As of September 2025, nine products are undergoing JCA. The distribution of assessor and co-assessor roles is relatively even, with Germany (assessor for 3 JCAs) and Ireland (assessor for 2 JCAs) taking the lead, while others, including smaller markets (e.g. Hungary, Slovenia), are contributing as co-assessors (28).

Figure 1. Country-level communication on key EU HTA implementation topics

✓ Action taken / planned ✘ No actions planned ∅ No published data

	Strong communication																			No identified communication/publication										
	France (3, 29, 30)	Netherlands (4,5)	Sweden (6-8)	Finland (9, 10, 23)	Italy (24, 26, 27, 31)	Belgium (22, 32)	Greece (14)	Lithuania (15, 16)	Poland (25)	Spain (33-35)	Austria (36, 37)	Bulgaria (18, 24)	Croatia (17)	Denmark (38-40)	Germany (20, 21)	Ireland (41, 42)	Norway (19)	Czechia (43)	Estonia (11-13)	Portugal (44)	Hungary	Romania	Slovenia	Latvia	Luxembourg	Slovakia	Cyprus	Malta	Iceland	Liechtenstein
Guideline and procedural updates	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	∅	✓	✓	✓	✓	✓	✓	✓	✓	∅	∅	∅	∅	∅	∅	∅	∅	∅	∅
Ongoing procedural updates				✓	✓		✓	✓	✓	✓	✓		✓					✓		✓										
Updated guidelines/dossier templates	✓	✓	✓			✓								✓	✓	✓	✓		✓											
National timeline adaptations	✘	✓	✓	✓	∅	✘	∅	∅	∅	✓	∅	✓	∅	✓	✘	∅	✓	∅	∅	∅	∅	∅	∅	∅	∅	∅	∅	∅	∅	∅
National dossier assessment starts once JCA report is available	✘	✓	✓	✓		✘				∅		∅		✓	✘		∅													
Timeline shortened	✘	∅	∅	∅		✘				✓		✓		∅	✘		✓													
Possibility for HTD input to PICO scoping	✘	✘	✓	✓	✓	✘	∅	∅	✓	∅	∅	✓	∅	∅	∅	∅	∅	∅	∅	∅	∅	∅	∅	∅	∅	∅	∅	∅	∅	∅
HTD may provide input			✓	✓	✓				✓			✓																		
HTD input not requested	✓	✓				✓																								
Capacity building	✓	✓	✓	∅	✓	∅	✓	✓	∅	∅	✓	∅	✘	∅	∅	✓	∅	∅	∅	∅	∅	∅	∅	∅	∅	∅	∅	∅	∅	∅
Additional workforce (taskforces, recruitment)		✓	✓		✓						✓					✓														
Allocating financial funds			✓										✘																	
Providing trainings	✓	✓	✓				✓	✓																						

Note: The analysis assessed the transparency of countries regarding their actions on EU HTA implementation. It focused on the four main topics: Guideline and procedural updates; National timeline adaptations; Possibility for HTD input to PICO scoping; and Capacity building.
References: 3-44

Discussion & Conclusion

- Our analysis shows that while many countries have started adapting guidelines, timelines, and processes for JCA integration, transparency of these actions varies widely.
- Given that our analysis relies on information published by national bodies, unreported adaptations may not be captured. However, even countries that have not publicly detailed their preparations (e.g. Hungary, Slovenia) are already contributing as co-assessors in JCAs. This highlights the importance of systematic monitoring to understand how JCA participation translates into national readiness and potential influence on national decision-making.
- For HTDs, the lack of harmonisation in PICO involvement, divergent timelines, and variable capacity building translate into uncertainty and additional planning needs. Early anticipation of comparators, proactive evidence generation, and alignment with both EU and national requirements are therefore critical.
- Continuous monitoring of early JCAs against national outcomes will be key to understanding their role in national decision-making, by identifying where alignment is strong, where additional evidence is required, and how trends evolve as the EU HTA framework moves toward full implementation by 2030.

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Abbreviations

EFTA, European Free Trade Association; EU, European Union; HTA, health technology assessment; HTD, health technology developer; JCA, joint clinical assessment; MS, member state; PICO, population, intervention, comparator, outcomes.

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