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National Implementation of the EU HTA Regulation: Progress and Approaches Across European Countries

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Background

+ Regulation (EU) 2021/2282 has applied since 12 January 2025, initially to new cancer medicines and advanced therapy medicinal products. It establishes Union-level Joint Clinical Assessments (JCAs) and corresponding obligations for the 27 EU Member States. The Regulation has also been incorporated into the European Economic Area (EEA) Agreement for the three EEA European Free Trade Association (EFTA) states: Iceland, Liechtenstein and Norway.
+ The Regulation establishes a framework for joint assessment of relative clinical effectiveness and safety, supporting national HTA processes.
+ JCA outcomes do not affect Member States' discretion to assess clinical added value in their national contexts or to make pricing and reimbursement decisions.
+ Implementation requires countries to adapt their national processes for considering JCA reports while retaining responsibility for context-specific health technology assessment conclusions and pricing and reimbursement decisions.
+ This study explored the extent to which the HTAR has been implemented at the national level.

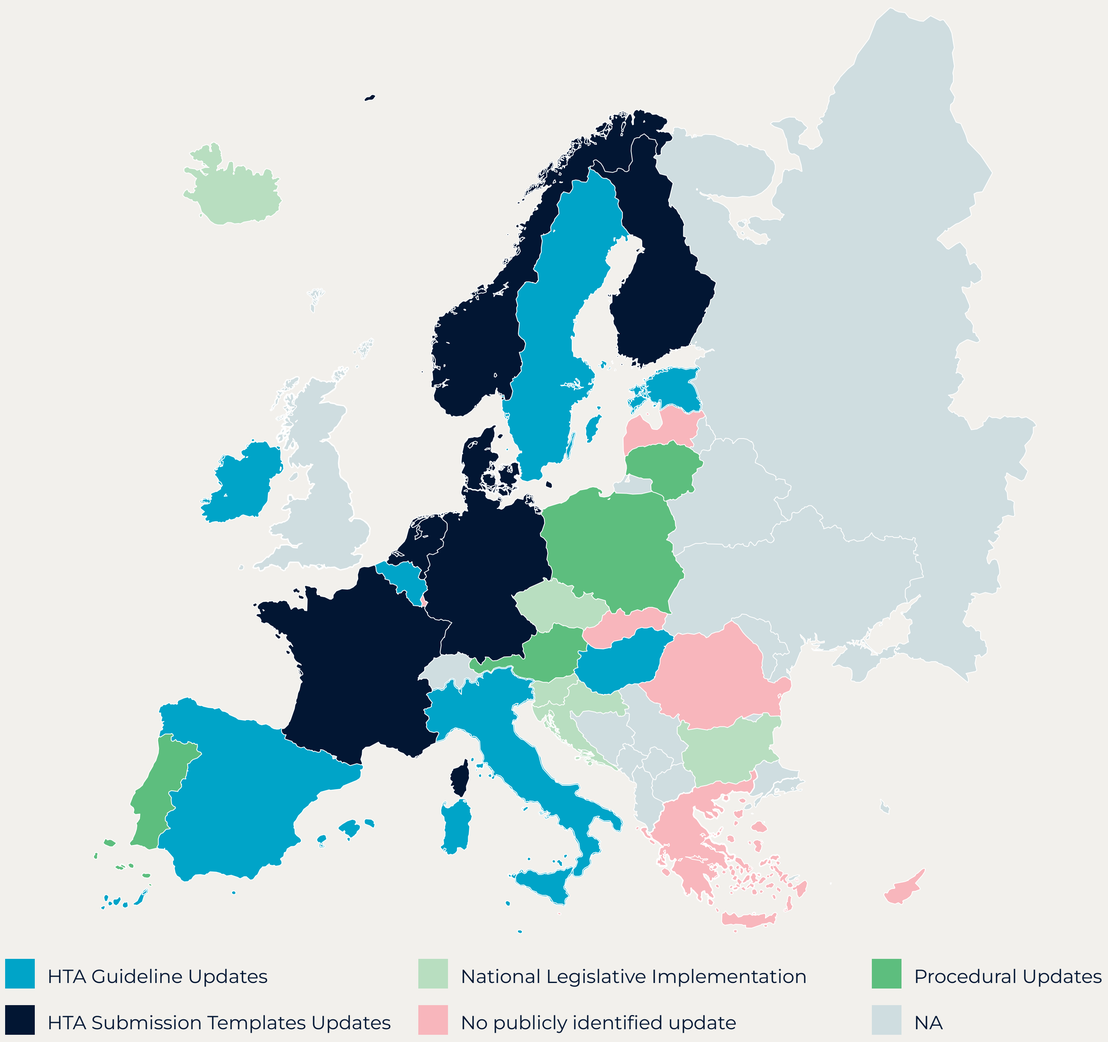
Methods

A targeted review of publicly available sources was undertaken across 27 EU and three EEA-EFTA countries, encompassing national legislation, procedural updates, HTA methodological guidelines, and submission templates. Data were extracted into a predefined framework and synthesised descriptively. For each country, data were extracted from sources available as of June 2026. Key sources included:

- National legislation and regulatory documents
- Procedural updates published on HTA agency websites
- National HTA methodological guidelines
- HTA submission templates and dossier requirements

Results

Figure 1. The European HTAR Implementation Map



+ Evidence from **30 European jurisdictions** indicated implementation activities following the entry into force of the HTAR, with **22 countries (73%)** introducing HTAR-related updates to their national processes:
+ Among these, **five countries (17%)** have formally designated a competent authority responsible for HTAR implementation, with roles and responsibilities defined at the legislative level (Bulgaria, Croatia, Czech Republic, Iceland, and Slovenia).
+ A further **13 countries (43%)** have incorporated JCA-related adaptations into their HTA methodological guidelines (Belgium, Estonia, Hungary, Ireland, Italy, Spain, and Sweden) or updated their submission templates (Denmark, Finland, France, Germany, the Netherlands, and Norway).

Table 1. Progress in National HTAR Implementation (June 2026)

Increasing Level of HTAR Implementation

Extent of national HTAR implementation	Country	Summary on HTAR implementation	References
No publicly identified update	Cyprus; Greece; Latvia; Liechtenstein; Luxembourg; Malta; Romania; Slovak Republic	No publicly identified update on national HTAR implementation status	-
National Legislative Implementation	Bulgaria; Croatia; Czech Republic; Iceland; Slovenia	Competent Authority designated for HTAR implementation, with roles and responsibilities defined	1-5
Procedural Updates	Austria; Lithuania; Portugal; Poland	Contribution to defining the assessment scope regarding the PICO	6-9
HTA Guideline Updates	Belgium; Estonia; Hungary; Ireland; Italy; Spain; Sweden	Specification of how JCA reports can be used in national submissions, including: • the incorporation of local clinical context, • updated evidence based on later data cut-offs, • additional evidence not covered by the JCA	10-16
HTA Submission Templates Updates	Denmark; Finland; France; Germany; Norway; Netherlands		17-22

As this analysis is based on publicly available information from national authorities, some unreported or unpublished adaptations may not be captured.

+ For national dossier submissions, applicants were not required to resubmit clinical evidence already covered by the JCA. Instead, they were expected to demonstrate the relevance of the JCA to local clinical practice, including justification that its PICO framework was applicable as the basis for national clinical assessment.

Conclusions

+ National implementation of the HTAR is progressing across Europe. Countries with well-established HTA systems have integrated the JCA process through updates to procedures, methodological guidelines, or submission templates, while newer or less established HTA systems have primarily addressed HTAR implementation through high-level legislative measures.

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Abbreviations:

HTAR - Regulation on Health Technology Assessment;
JCA - Joint Clinical Assessments;
HTA - Health Technology Assessment;
PICO - Population(s), Intervention, Comparator(s), and Outcome(s);
EU - European Union;
EEA - European Economic Area.
EFTA - EEA European Free Trade Association

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