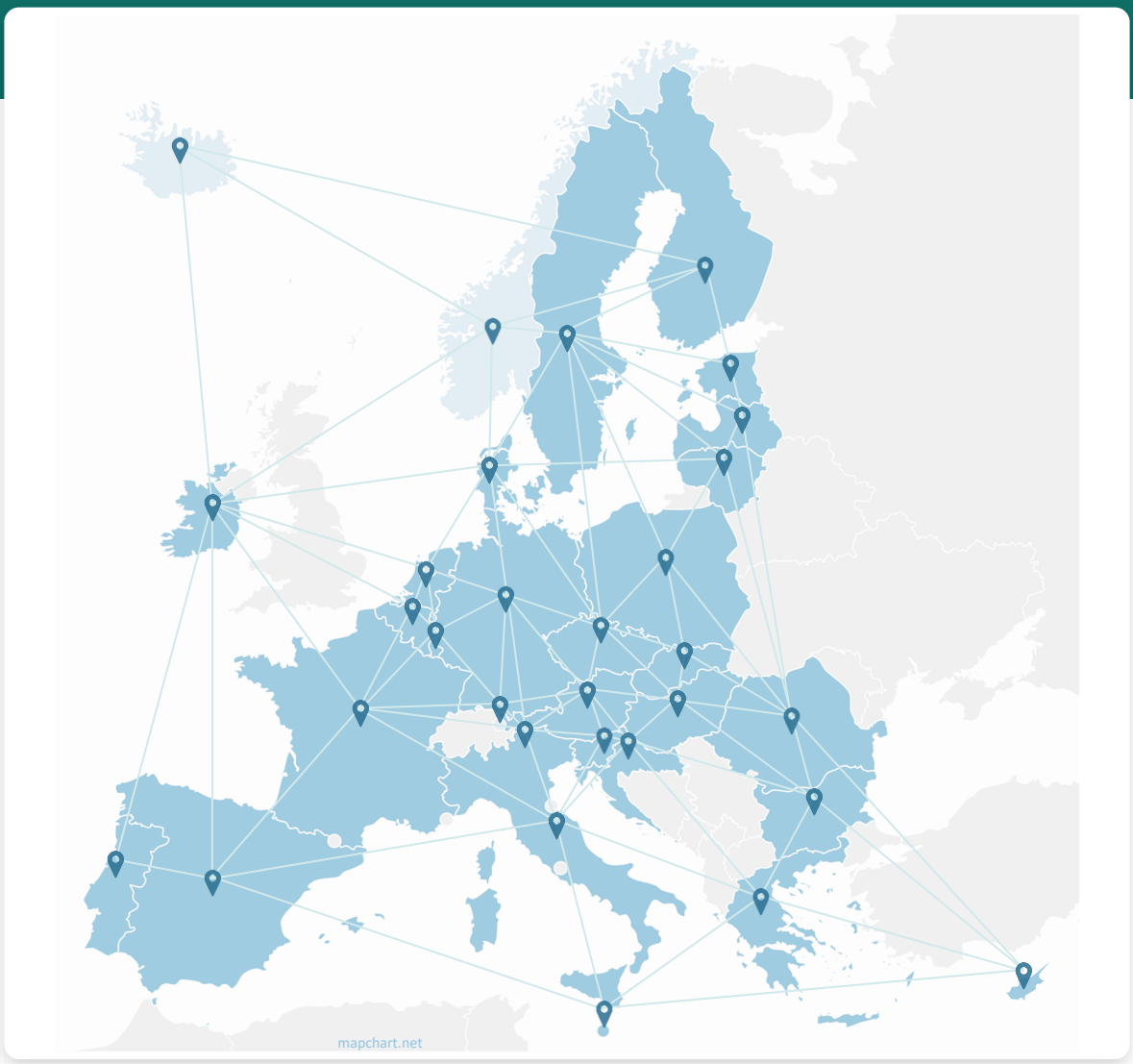
CIRS Centre for Innovation in Regulatory Science

The HTA Landscape under the EU HTA Regulation

Baseline Mapping of National HTA Authorities and Bodies across the EU and EEA Jurisdictions



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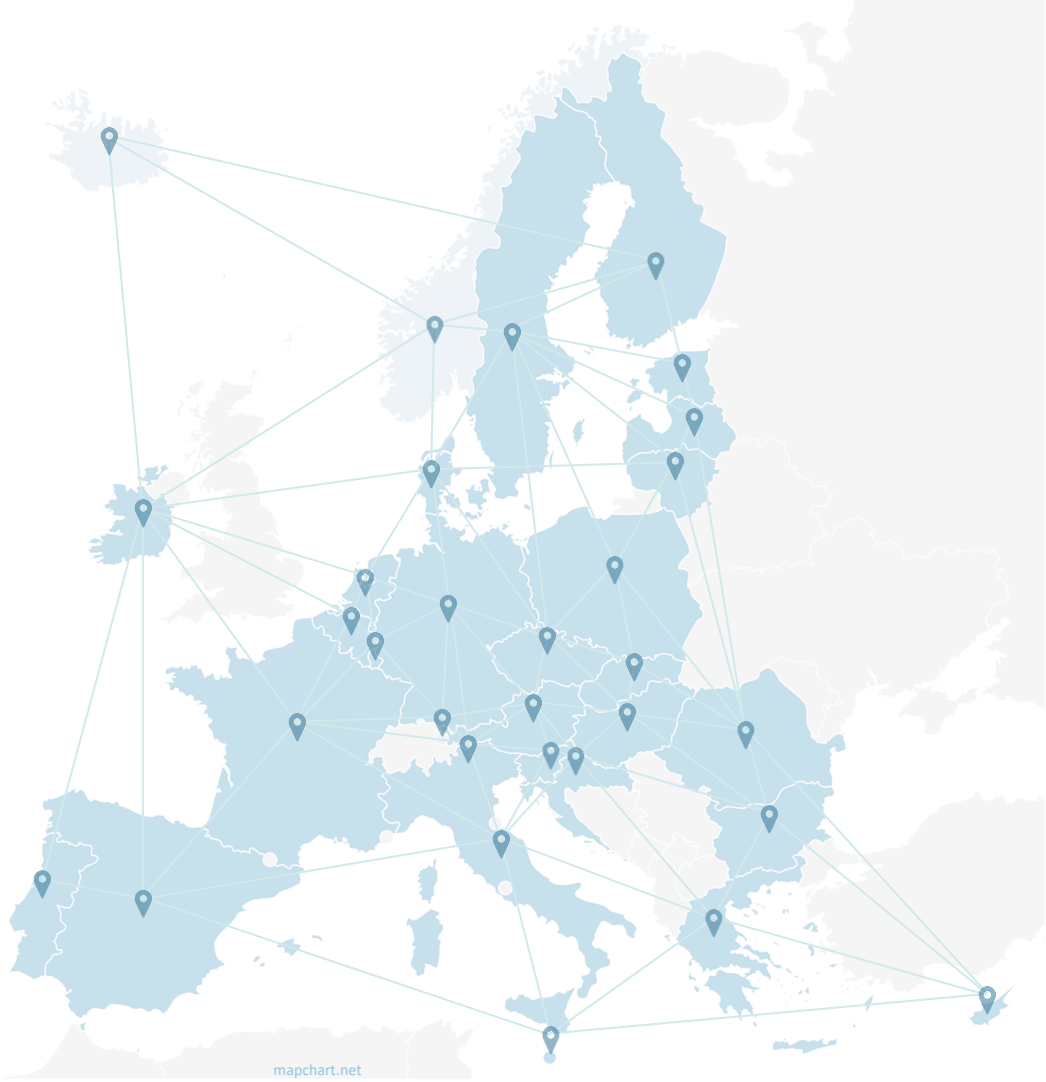

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Background

The implementation of the European Union (**EU) Health Technology Assessment Regulation** (HTAR) marks an important transition point for HTA in Europe. While the Regulation introduces a common EU level process for Joint Clinical Assessment (JCA), national HTA systems will continue to play a central role in appraisal, reimbursement, pricing and access decisions. Understanding the national stakeholder landscape therefore remains essential for interpreting how the Regulation may affect evidence requirements, decision processes and future alignment across countries.

This briefing provides a high-level overview of HTA authorities and bodies (HTAb) involved in pharmaceutical assessment across the 27 EU and 3 European Economic Area (EEA) jurisdictions. The purpose is to establish a baseline understanding of the current HTA stakeholder landscape, including agency establishment and evolution, scope of activity, publicly available information (e.g., HTA reports, milestones), and participation in EU HTA activities. This baseline will support future monitoring of changes following implementation of HTAR, particularly in relation to institutional roles, information availability, and the interaction between EU level and national HTA processes.

This work builds on CIRS' wider programme of research on regulatory and HTA systems. CIRS has developed tools such as the **CIRS HTA Agency Benchmarking Methodology** and **Regulatory and Reimbursement Atlas** to map detailed national decision-making processes, evidence requirements and stakeholder roles across different jurisdictions. It complements CIRS' annual metrics **HTADock project**, which tracks regulatory and HTA timelines, decision pathways and system level trends over time. In this context, the present briefing is intended as a focused European baseline rather than a full assessment of national HTA performance.

The scope of this briefing is limited to pharmaceuticals, with medical devices and vaccines excluded. The selection of HTAb (see Annex) included in this report is based on the list of members of the subgroups for JCA and Joint Scientific Consultation (JSC) in the medicinal products configuration. This approach was used to maintain a clear and consistent analytical focus, recognising that different agencies may be involved in medicinal products JCA, wider national HTA processes, or other health technology areas. HTAb outside the pharmaceutical JCA and JSC scope are therefore not included.

This briefing serves as an initial policy baseline to support ongoing monitoring of changes across the European HTA ecosystem.

Methodology

Data collection was conducted through a structured review of publicly available information from official sources. These included HTA agency websites, national authority websites, official methodological or procedural documents, published assessment process descriptions, and information made available through the European Commission's HTA Coordination Group and its relevant subgroups. The HTAb included in this study were identified using the the European Commission's published lists of members of the subgroups for JCA and JSC, both in the medicinal products configuration (accessed in March 2026). As a result, other national or regional HTAb that may operate within a country that are not represented in these subgroups were excluded.

To support consistency across countries, information was extracted using a predefined data collection framework. Where information could not be identified from official or public sources, this was recorded as "Not identified". No blank cells were left in the tables to avoid ambiguity in interpretation.

The information reflects the status of HTAb at the time of study, up to April 2026. As this remains an evolving policy area, the analysis will be monitored and updated as needed.

The analysis focused on 4 analytical dimensions:

Institutional Characteristics

Information was collected on:

- year of establishment of HTA bodies
- scope of assessment activities, including whether agencies assessed outpatient medicines, inpatient medicines, or both
- regional collaboration across Europe.

The year of establishment was used to characterise the historical development of HTA systems across jurisdictions rather than to assess performance or institutional maturity.

Transparency Characteristics

The study evaluated the extent of information publicly available from HTA bodies, including:

- publication of HTA assessment reports
- disclosure of procedural milestones
- availability of detailed decision rationales.

Where available, milestones such as submission dates, recommendation dates, and final outcomes were recorded.

Adaptation to HTAR

The study explored early evidence of procedural adaptation to Regulation (EU) 2021/2282, including:

- whether national submission templates referenced Joint Clinical Assessments (JCA)
- whether national procedures had been updated to reflect EU HTA implementation
- whether national processes could begin prior to publication of the JCA report.

As implementation of the Regulation remains ongoing, findings represent an early snapshot of adaptation activities during the initial phase of implementation.

Participation in HTAR activities

Participation of national HTA bodies in EU level collaboration activities was mapped based on publicly available records of:

- Joint Clinical Assessment (JCA) assessors and co-assessors
- Joint Scientific Consultation (JSC) assessors and co-assessors
- Technical Support Instrument (TSI) participation.

The findings descriptively provide a baseline overview of the evolving European HTA landscape to support future longitudinal monitoring of changes associated with implementation of the EU HTAR.

HTAb ESTABLISHMENT YEAR RANGE

Figure 1. Establishment of HTAb (earliest per country) in the JCA and JSC subgroups, EU-27 and EEA-3

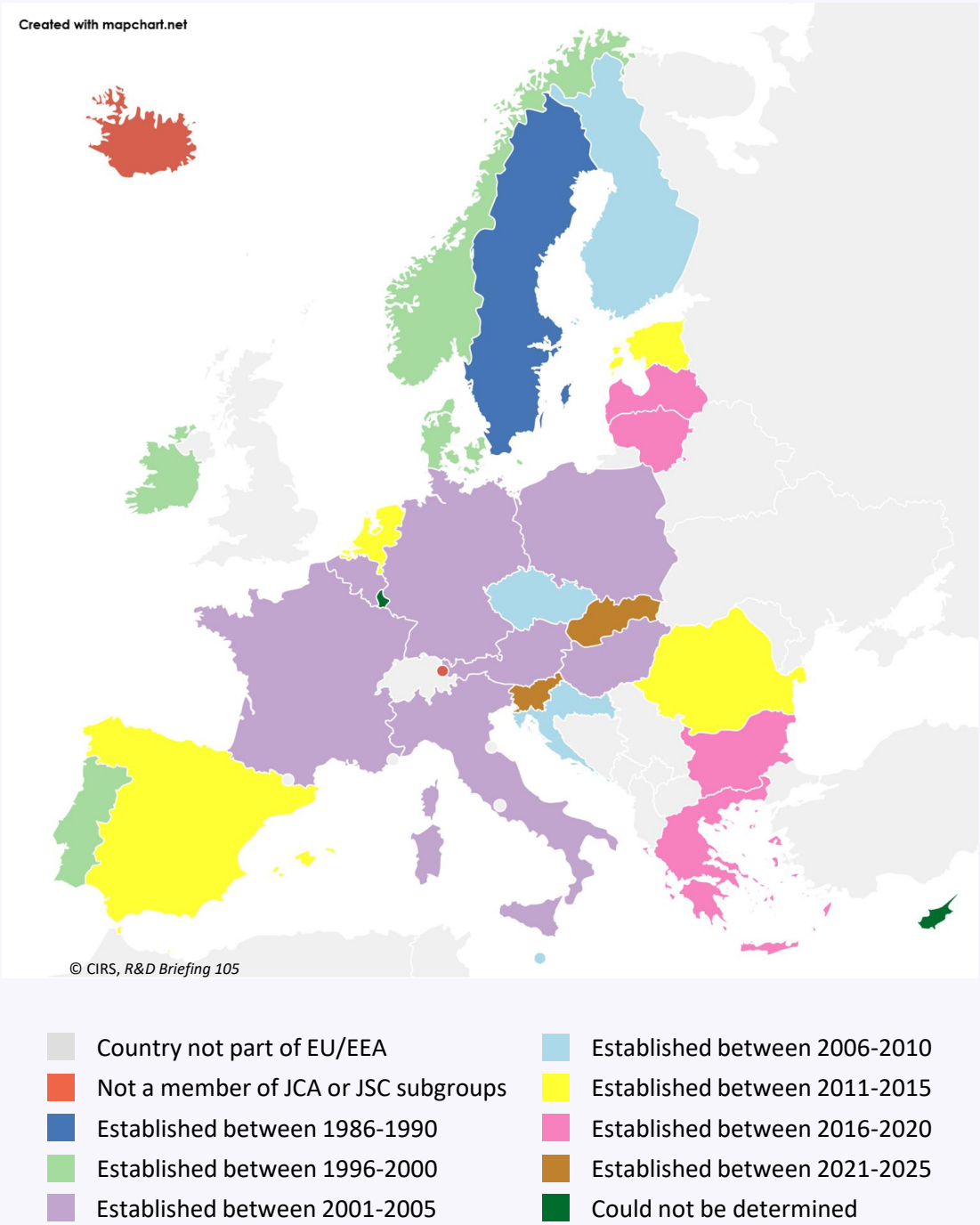
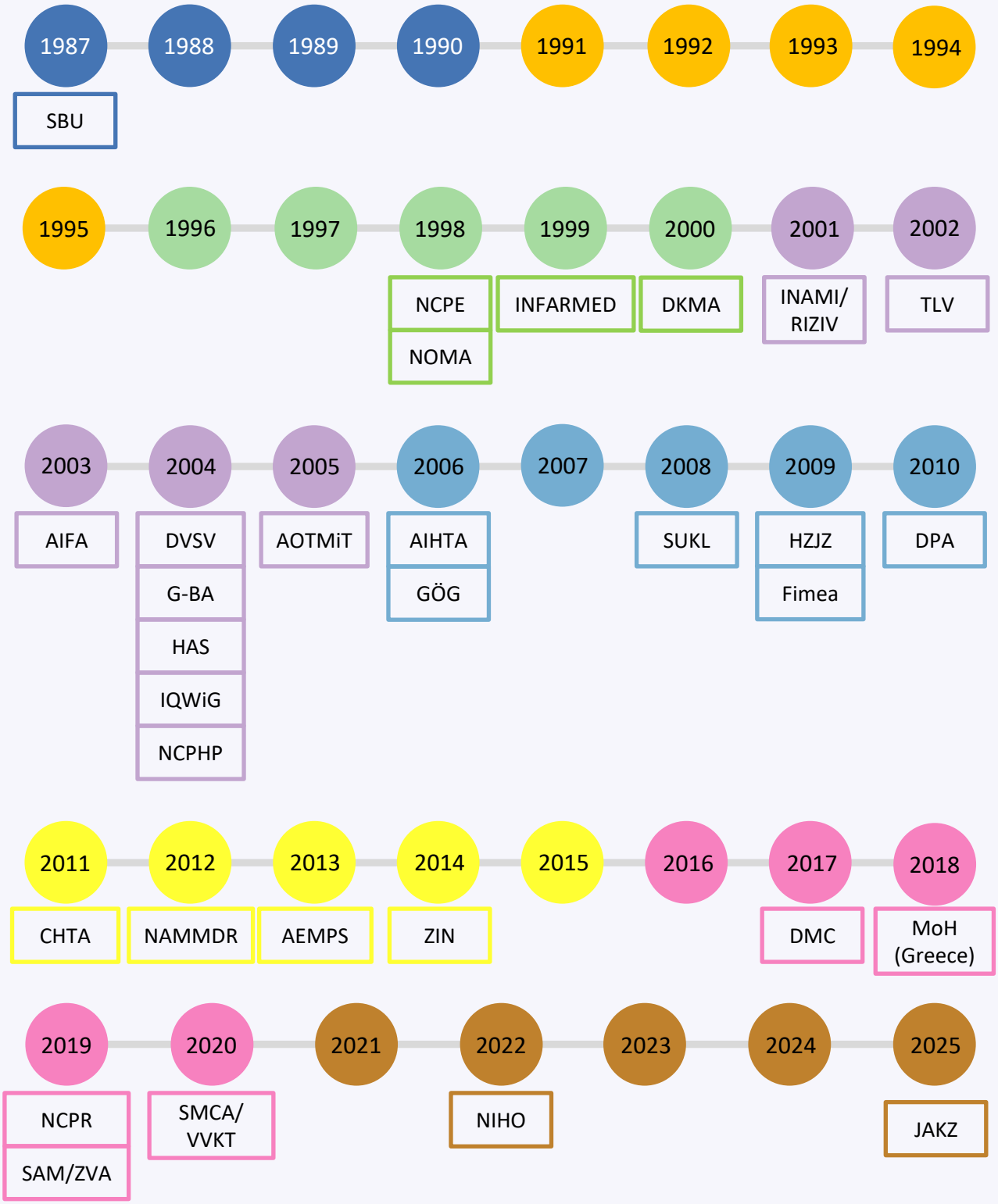


Figure 1 represents the year of establishment of HTAb that are members of the JCA and JSC subgroups. For countries represented by more than one HTAb, the earliest establishment year is reported. For instance, Sweden is represented by both SBU and TLV; the map therefore reflects the establishment year of SBU (1987), as it predates TLV (2002). Further detail on the establishment years of individual HTAb is provided in Figure 2 (see next page).

HTAb establishment year

Figure 2. Timeline of establishment of HTAb in 27 Member States and 3 EEA jurisdictions*



*Refer to Annex for full name of HTAb and corresponding country.

Scope of HTAb (April 2026)

Figure 3. Scope of the HTAb (n=34)

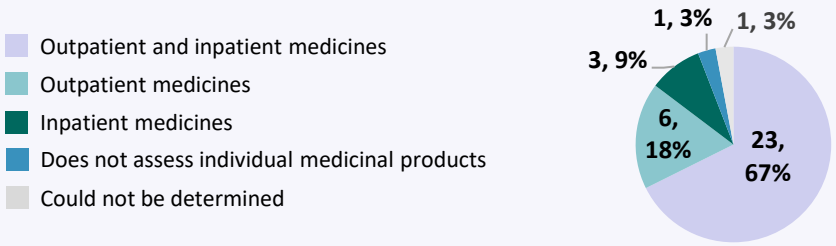


Table 1. List of HTAb and their scope

Country	HTAb (Abbreviation)	Outpatient medicinal products	Inpatient medicinal products
Austria	AIHTA	×	√
	DVSV	√	×
	GÖG	√	√
Belgium	INAMI-RIZIV	√	√
Bulgaria	NCPR	√	√
Croatia	HZJZ	Not identified	Not identified
Cyprus	DPS, MoH	√	√
Czech Republic	SUKL	√	√
Denmark	DKMA	√	×
	DMC	×	√
Estonia	CHTA	√	√
Finland	Fimea	×	√
	MSAH	√	√
France	HAS	√	√
Germany	G-BA	√	√
	IQWiG	√	√
Greece	MoH	√	√
Hungary	NCPHP	√	√
Ireland	NCPE	√	√
Italy	AIFA	√	√
Latvia	SAM/ZVA	√	×
Lithuania	SMCA/VVKT	√	√
Luxembourg	MoH	√	×
Malta	DPA	√	√
Netherlands	ZIN	√	√
Norway	NOMA	√	√
Poland	AOTMiT	√	√
Portugal	INFARMED	√	√
Romania	NAMMDR	√	√
Slovakia	NIHO	√	√
Slovenia	JAKZ	√	√
Spain	AEMPS	√	√
Sweden	SBU	×	×
	TLV	√	×*

*For inpatient products, TLV (Sweden) does not provide a recommendation as these fall outside of their remit, however, TLV still produces health economic assessment reports for these products to guide decision making at the regional level.

Availability of HTAb information (1)

Table 2. Information available in the public domain*

Country	HTAb (Abbreviation)	Publication of product-specific HTA assessment reports	Procedural milestones	Detailed decision rationale
Belgium	INAMI-RIZIV	√	√	√
Czech Republic	SUKL	√	√	√
Denmark	DKMA	√	√	√
	DMC	√	√	√
Estonia	CHTA	√	Not identified	Not identified
Finland	Fimea	√	√	Not identified
France	HAS	√	√	√
Germany	G-BA	√	√	√
	IQWiG	√	√	√
Ireland	NCPE	√	√	√
Latvia	SAM/ZVA	Not identified	√	Not identified
Netherlands	ZIN	√	√	√
Norway	NOMA	√	√	√
Poland	AOTMiT	√	√	√
Portugal	INFARMED	√	√	√
Romania	NAMMDR	√	√	√
Slovakia	NIHO	√	√	√
Spain	AEMPS	√	√	Not identified
Sweden	TLV	√	√	√

For each of the 34 HTAb, we systematically reviewed its official website to determine whether three key elements of the HTA process were publicly disclosed:

- Publication of single technology HTA assessment reports for specific medicinal products: Whether product-specific HTA documents are publicly available, including full assessment reports, appraisal reports, clinical reviews, recommendation documents or reimbursement summaries.
- Procedural milestones: Whether product-level process steps are publicly available, such as submission, assessment start, committee review, draft or final recommendation, reimbursement decision or publication date.
- Detailed decision rationale: Whether the HTA body explains the basis for its decision, including clinical benefit, comparative effectiveness, safety, unmet need, cost-effectiveness, budget impact, uncertainty or restrictions.

Italy (AIFA) is not included in the table, as HTA reports are published mainly for innovative medicines and products of particular interest, while reports for other medicinal products are not systematically published.

*Table includes only HTAb for which at least one of the specified transparency elements was publicly available. For the remaining HTAb, no evidence was found that they publish HTA reports for medicinal products in the public domain.

Availability of HTAb information (2)

Table 3. Types of milestones shared publicly by HTAb*

Country	HTAb (Abbreviation)	Submission date	Recommendation date	Outcome
Belgium	INAMI-RIZIV	Not identified	√	√
Czech Republic	SUKL	√	√	√
Denmark	DKMA	√	√	√
	DMC	√	√	√
Finland	Fimea	Not identified	√	Not identified
France	HAS	√	√	√
Germany	G-BA	√	√	√
	IQWiG	√	√	√
Ireland	NCPE	√	√	√
Latvia	SAM/ZVA	√	√	√
Netherlands	ZIN	√	√	√
Norway	NOMA	√	√	√
Poland	AOTMiT	√	√	√
Portugal	INFARMED	√	√	√
Romania	NAMMDR	√	√	√
Slovakia	NIHO	√	√	√
Spain	AEMPS	Not identified	√	√
Sweden	TLV	Not identified	√	√

Table 3 details which specific procedural milestones are publicly available for each of the HTAbs included, for which at least one of the procedural milestones are publicly available. It was assessed whether three milestones were published: the submission date (date on which the assessment request or dossier was submitted), the recommendation date (the date on which the HTAb issued its recommendation or decision), and the outcome (the final conclusion, recommendation or decision, produced after the health technology assessment).

*Table includes only HTAb for which at least one of the specified milestones is publicly available. For the remaining HTAb we could find no evidence that they publish procedural milestones for medicinal products in the public domain.

ADAPTATION TO HTAR

Figure 4. Has the HTAb submission template changed to incorporate JCA?

Changed template

8 HTAb

In progress

1 HTAb

HTAb that have adapted their template

- Italy – AIFA
- Denmark – DMC
- Finland – Fimea
- Germany – G-BA
- France – HAS
- Belgium – INAMI-RIZIV
- Norway – NOMA
- Netherland – ZIN

HTAb that are in the process of updating their template

- Bulgaria – NCPR*

*HTAb has confirmed an update of the submission template is in progress.

The submission templates of each HTA body were systematically reviewed on their official websites. Submission templates were only identified for 9/34 (26%) of the HTAb members of the JCA and JSC subgroups. When a template was identified it was classified as updated if it explicitly referred to HTAR or Joint Clinical Assessments. Templates without such references were classified as unchanged.

Figure 5. Can the national process occur before the JCA report is officially published?

- Belgium – INAMI-RIZIV
- Denmark – DMC
- Germany – G-BA
- Ireland – NCPE
- Italy – AIFA
- Netherland – ZIN
- Norway – NOMA

Across the 7 HTA bodies with confirmed responses, national HTA activities may begin before the JCA report is officially published, but the level of formal initiation varies. NCPE and ZIN, for example, allow preliminary dossier submission in advance, while the formal process starts only after JCA publication. G-BA differs, as its benefit assessment runs irrespective of JCA availability, with the JCA report incorporated later where feasible.

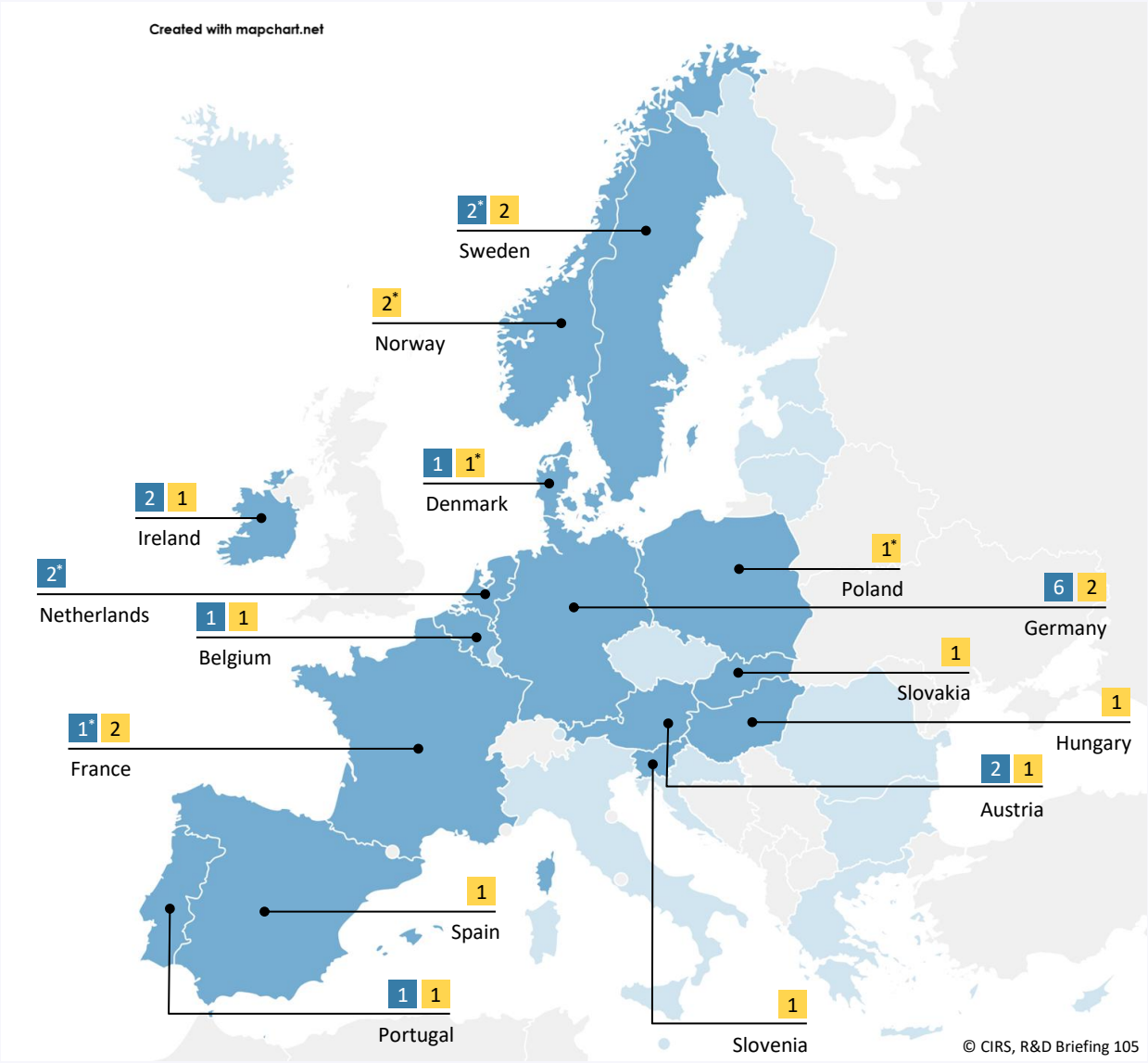
Figure 6. Has the national HTA/reimbursement process changed to adapt to HTAR?

The process has been adapted for the following HTAb (n=15):

- Spain – AEMPS
- Italy – AIFA
- Poland – AOTMiT
- Denmark – DMC
- Germany – G-BA
- France – HAS
- Belgium – INAMI-RIZIV
- Portugal – INFARMED
- Finland – MSAH
- Romania – NAMMDR
- Bulgaria – NCPR
- Norway – NOMA
- Slovenia – JAKZ
- Sweden – TLV
- Netherland – ZIN

JOINT CLINICAL ASSESSMENT ASSESSORS AND CO-ASSESSORS

Figure 7. Countries that have participated in JCA by June 2026 as assessors and/or co-assessors



Assessor Co-assessor

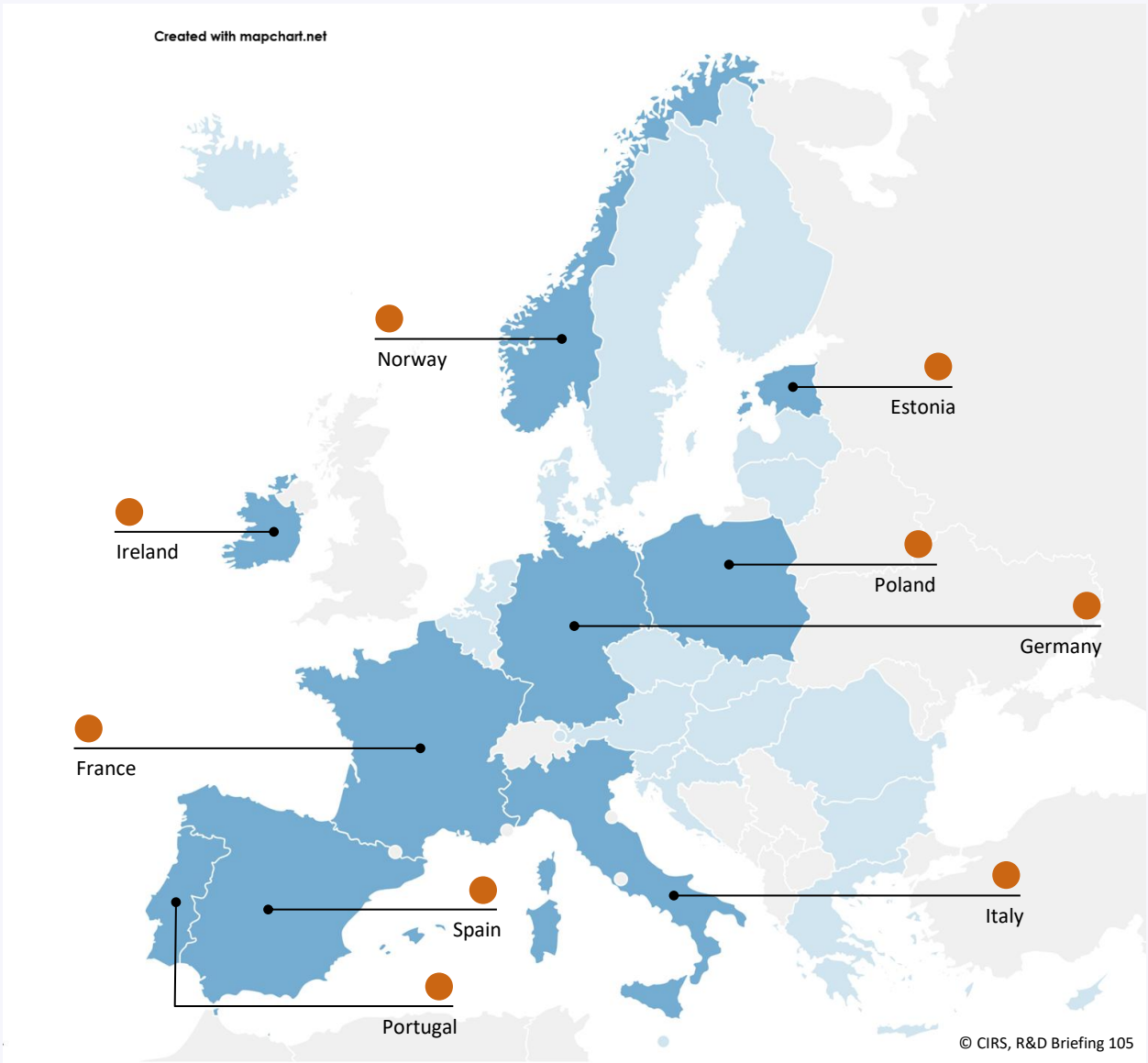
*Three JCAs were discontinued: one following a withdrawal by the health technology developer from the marketing authorisation application process and two due to failure to meet the requirements of the Regulation. These products had been assigned to the Netherlands, Sweden and France (assessors), with Denmark, Norway and Poland as co-assessors.

Data were collected from the list of Joint Clinical Assessments published on the European Commission website[1]. The list was last updated on 9 June 2026.

[1]European Commission. Joint Clinical Assessments (JCA) – list of assessments [Excel dataset], last updated 9 June 2026. Available at: https://health.ec.europa.eu/health-technology-assessment/implementation-regulation-health-technology-assessment/joint-clinical-assessments_en

JOINT SCIENTIFIC CONSULTATION ASSESSORS AND CO-ASSESSORS

Figure 8. Countries that have participated in JSC as assessors and/or co-assessors



Countries involved in at least one JSC by 31 December 2025

Source: Adapted from European Commission (2025), HTA Coordination Group Annual Report 2025[1].

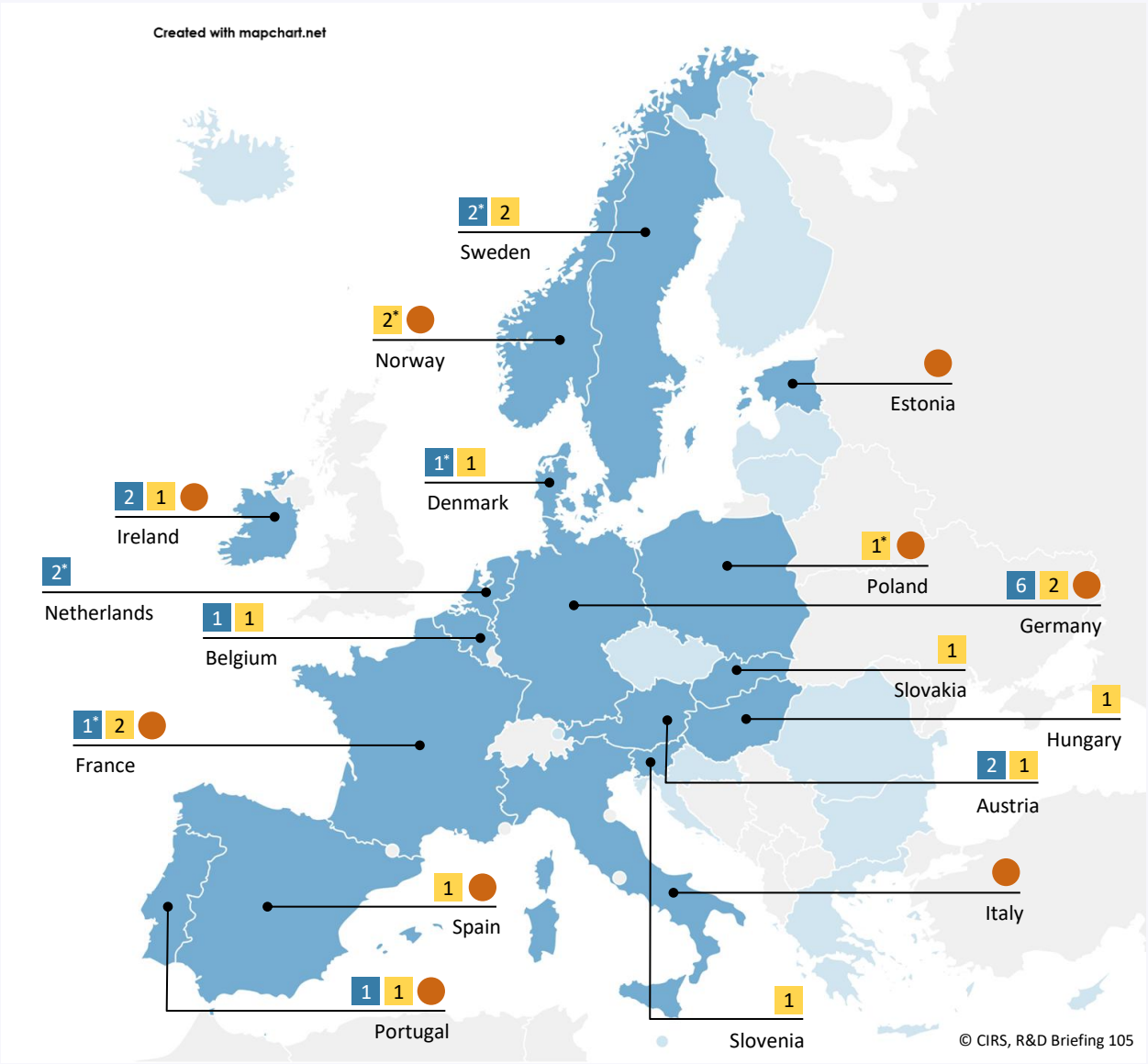
Data on which countries acted as assessors versus co-assessors were not available.

Publicly available data show that 17 JSC requests were received in 2025. Of these, 7 JSCs were selected and 4 of the selected JSCs were parallel between the HTA Coordination Group and EMA.

[1]European Commission. (2025). HTA Coordination Group Annual Report 2025 (Figure 6, p17). Available at: https://health.ec.europa.eu/document/download/45e9328b-f9f4-4d5b-9f5c-385671560785_en

OVERVIEW OF PARTICIPATION IN JCA/JSC

Figure 9. Countries that have participated in JCA and JSC



*Three JCAs were discontinued: one following a withdrawal by the health technology developer from the marketing authorisation application process and two due to failure to meet the requirements of the Regulation. These products had been assigned to the Netherlands, Sweden and France (assessors), with Denmark, Norway and Poland as co-assessors.

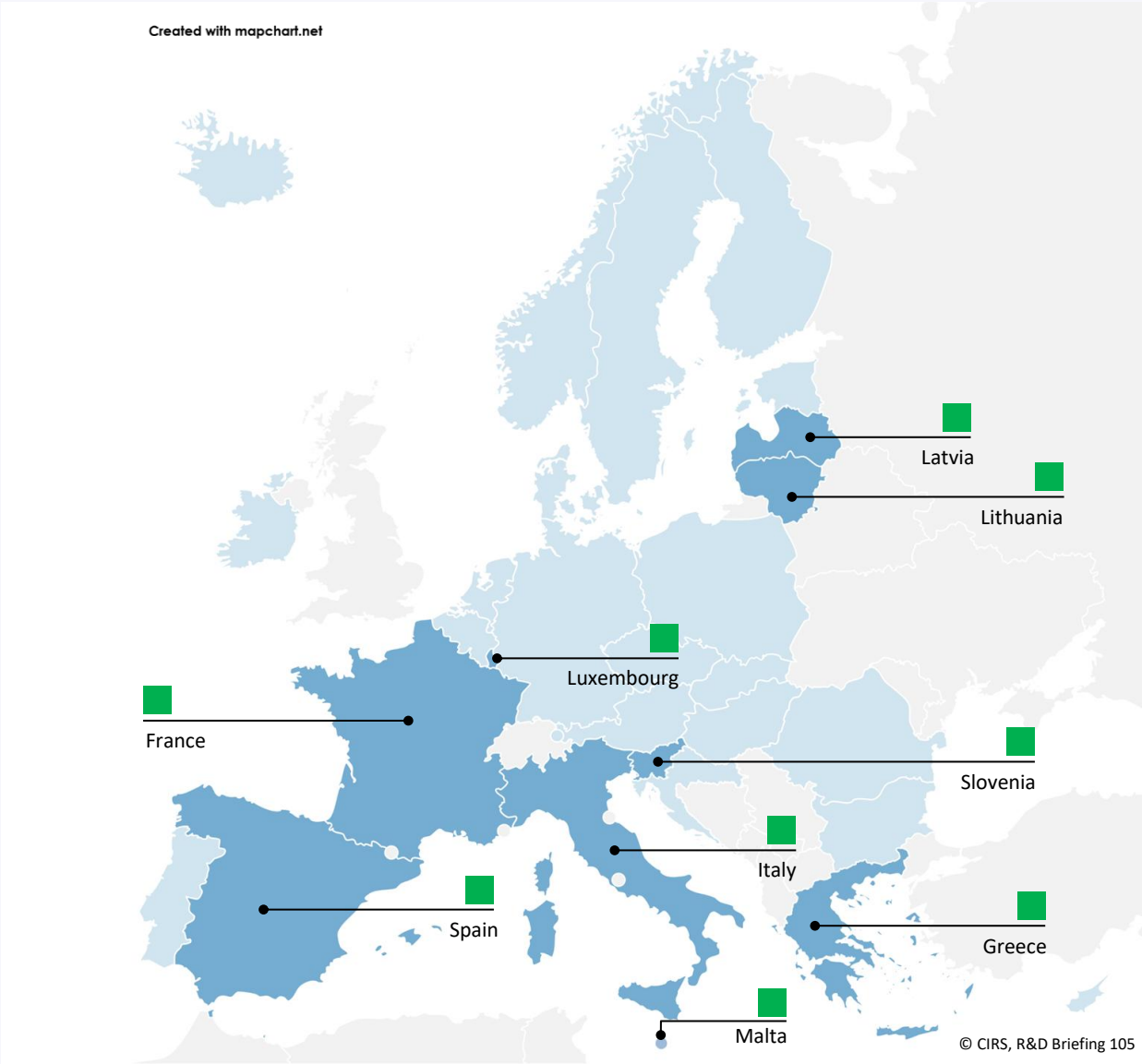
This figure combines the information from Figures 7[1] and 8[2].

[1]European Commission. Joint Clinical Assessments (JCA) – list of assessments [Excel dataset], last updated 9 June 2026. Available at: https://health.ec.europa.eu/health-technology-assessment/implementation-regulation-health-technology-assessment/joint-clinical-assessments_en

[2]European Commission. (2025). HTA Coordination Group Annual Report 2025. Available at: https://health.ec.europa.eu/document/download/45e9328b-f9f4-4d5b-9f5c-385671560785_en

Technical Support Instrument (TSI) for HTAR

Figure 10. Countries that have received technical support under the TSI

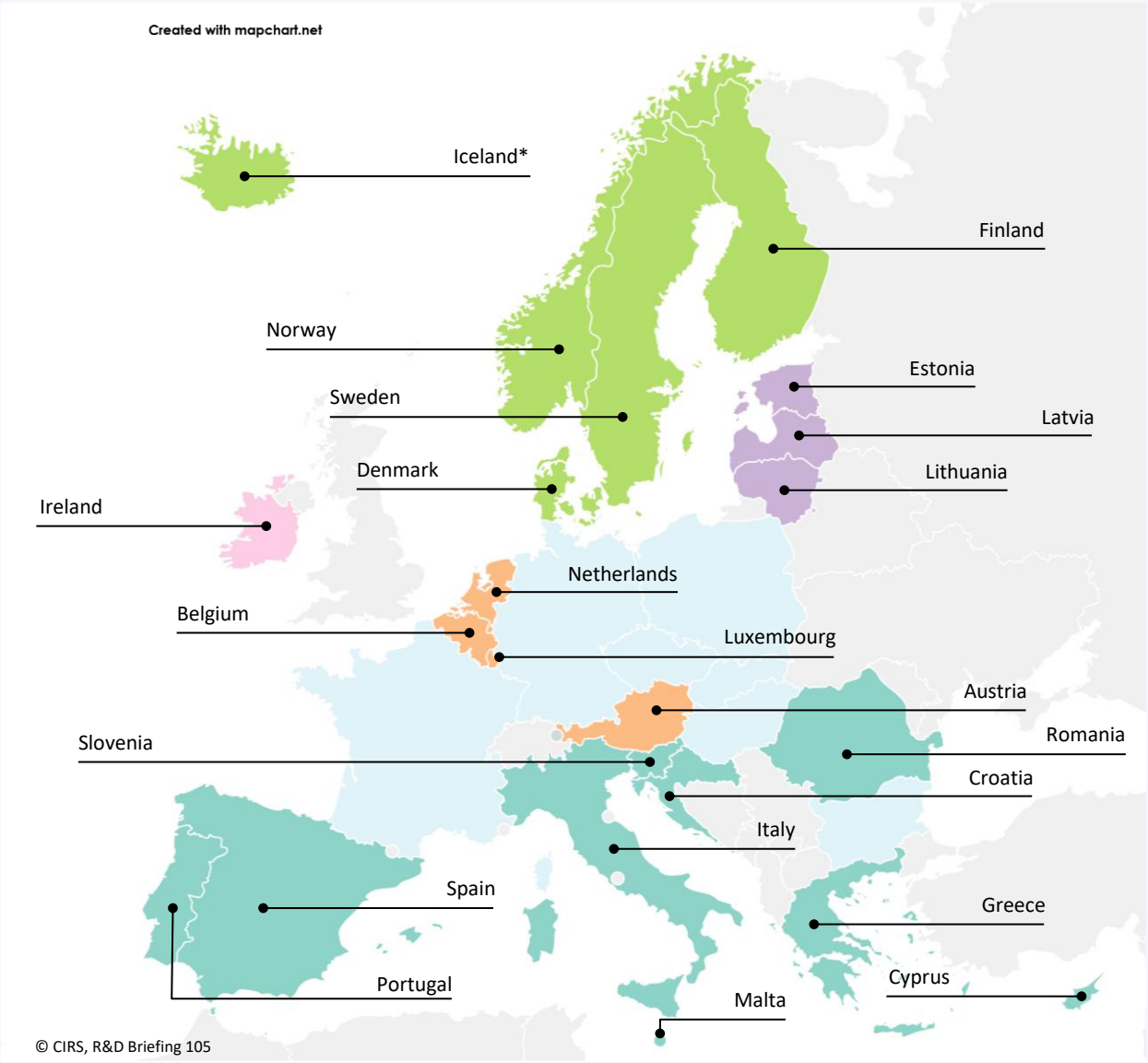


Countries that participated in the TSI programme for support with HTAR

The Technical Support Instrument (TSI) is a programme by the European Union that provides technical expertise to Member States to support the design and implementation of economics and social reforms. The Member States highlighted in the graph have requested support under the TSI to implement HTAR at the national level.

Regional collaboration in Europe

Figure 11. Countries that are part of a regional collaboration



Countries part of the Joint Nordic HTA-Bodies collaboration and the Nordic Pharmaceutical Forum

Countries part of the Baltic procurement Initiative

Countries part of the BeNeLuxA collaboration

Countries part of the Valletta Declaration

Countries part of the BeNeLuxA collaboration and the Valletta Declaration

*Iceland is part of the Joint Nordic HTA bodies and the Nordic Pharmaceutical Forum; however, no HTAb was designated by the country to be a member of the JCA subgroup.

Figure 10 maps regional initiatives across Europe that aim to strengthen cross-country collaboration. The scope of activities varies across initiatives but may include horizon scanning, joint assessment, joint negotiation and/or information sharing.

Detailed information in Annex 2.

ANNEX 1: HTA AUTHORITIES AND BODIES WITHIN THE STUDY SCOPE

Country	HTAb (Abbreviation)	HTAb (Full Name)
Austria	AIHTA	Austrian Institute for Health Technology Assessment
	DVSV*	Dachverband der Sozialversicherungsträger
	GÖG	Gesundheit Österreich GmbH/Austrian National Public Health Institute
Belgium	INAMI-RIZIV*	Institut national d'assurance maladie-invalidité/ Rijksinstituut voor ziekte- en invaliditeitsverzekering
Bulgaria	NCPR*	National Council on Prices and Reimbursement of Medicinal Products
Croatia	HZJZ	Hrvatski Zavod Za Javno Zdravstvo / Croatian Institute of Public Health
Cyprus	DPS, MoH	Department of Pharmaceutical Services, Ministry of Health
Czech Republic	SUKL	Státní ústav pro kontrolu léčiv/State Institute for Drug Control
Denmark	DKMA*	Danish Medicines Agency
	DMC*	The Danish Medicines Council
Estonia	CHTA	Center for Health Technology Assessment, University of Tartu
Finland	Fimea	Finish Medicines Agency
	MSAH	The Ministry of Social Affairs and Health
France	HAS*	Haute Autorité de Santé
Germany	G-BA	The Federal Joint Committee
	IQWiG*	Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen
Greece	MoH*	Ministry of Health
Hungary	NCPHP	National Center for Public Health and Pharmacy
Iceland	-	Not listed as a member of the JCA or JSC subgroup**
Ireland	NCPE	National Centre for Pharmacoeconomics
Italy	AIFA*	Agenzia Italiana del Farmaco
Latvia	SAM/ZVA	State Agency of Medicines of the Republic of Latvia/ Zāļu valsts aģentūra
Liechtenstein	-	Not listed as a member of the JCA or JSC subgroup**
Lithuania	SMCA/VVKT	State Medicines Control Agency/Valstybinė vaistų kontrolės tarnyba
Luxembourg	MoH	Minstère de la Santé – Santé Digitale
Malta	DPA	Directorate for Pharmaceutical Affairs
Netherland	ZIN*	Zorginstituut Nederland
Norway	NOMA*	Norwegian Medical Products Agency
Poland	AOTMiT*	Agencja Oceny Technologii Medycznych i Taryfikacji
Portugal	INFARMED*	Autoridade Nacional do Medicamento e Produtos de Saúde, I. P.
Romania	NAMMDR	National Agency for Medicines and Medical Devices of Romania
Slovakia	NIHO*	Národný inštitút pre hodnotu a technológie v zdravotníctve/National Institute for Value and Technologies in Healthcare
Slovenia	JAKZ*	Slovenian Quality Health Care Agency
Spain	AEMPS*	Agencia Española de Medicamentos y Productos Sanitarios
Sweden	SBU	Swedish Agency for Health Technology Assessment and Assessment of Social Services/Statens beredning för medicinsk och social utvärdering
	TLV*	The Dental and Pharmaceutical Benefits Agency

*Agencies that reviewed and provided feedback on the information included in this report.
**Not members of the JCA or JSC subgroups; however, Iceland and Liechtenstein are members of the HTA Coordination Group in the medicinal products configuration.

HTA authorities and bodies included in this study were identified from the list of members of the Subgroup for JCA and JSC in the medicinal products configuration, available on the European Commission website at the time of data collection.

Annex 2: Regional collaboration for HTA and/or Pricing/Reimbursement

Regional collaboration	Notes
Joint Nordic HTA-Bodies	The aim is to increase efficiency and produce high quality assessment reports. The Nordic collaboration offers efficient and transparent joint health technology assessments of medicinal products in the five Nordic countries. The collaborating HTA bodies are DMC, Fimea, Landspitali- University Hospital of Iceland, NOMA and TLV. The JNHB collaboration is not aiming for joint decisions on reimbursement or recommendations.
Nordic Pharmaceutical Forum	The aim is to ensure timely access to the right pharmaceuticals to the right price for patients in the five Nordic countries – Finland, Iceland, Norway, Sweden and Denmark. The forum's ambition in 2025 is to be: «Recognized Nordic collaboration, developing and delivering sustainable solutions to supply medicines to the public sector».
Baltic Procurement Initiative	The aim is to streamline the procurement procedure. The Baltic Procurement Initiative is a voluntary collaboration jointly undertaken by at least two of the three member countries (Estonia, Latvia, and Lithuania) for vaccines included in their national immunisation schedules.
BeNeLuxA	The aim is to ensure sustainable access to, and appropriate use of, medicines in the participating countries. The cooperation areas are horizon scanning, information sharing and policy exchange, health technology assessment and pricing and reimbursement.
Valletta Declaration	The aim is to establish multi-member state negotiation and procurement practices that improve citizens' access to new and emerging medicines and lead to increased sustainability of national healthcare systems. Participating Member States presently include Croatia, Cyprus, Greece, Ireland, Italy, Malta, Portugal, Romania, Slovenia, Spain, which covers over 160 million citizens (31% of the EU population)

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We are most grateful to the HTA authorities and bodies (page 17) for validating the information on this report.

About CIRS

The Centre for Innovation in Regulatory Science (CIRS) is a neutral, independent UK-based subsidiary of Clarivate plc. Its mission is to identify and apply scientific principles for the purpose of advancing regulatory and health technology assessment (HTA) policies and processes in developing and facilitating access to pharmaceutical products.

CIRS provides an international forum for industry, regulators, HTA and other healthcare stakeholders to meet, debate and develop regulatory and reimbursement policy through the innovative application of regulatory science and to facilitate access to pharmaceutical products. It is governed and operated by Clarivate for the sole support of its members' activities. The organisation has its own dedicated management and advisory boards, and its funding is derived from membership dues, related activities, special projects and grants.

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