CIRS Centre for Innovation in Regulatory Science

CIRS Newsletter - September 2025

Approval trends in six major markets

In August, we published our annual six agency R&D Briefing, which presents a comprehensive analysis of new active substance (NAS) approvals by the US Food and Drug Administration (FDA), European Medicines Agency (EMA), Japan Pharmaceuticals and Medical Devices Agency (PMDA), Health Canada, Swissmedic, and Australian Therapeutic Goods Administration (TGA), focusing on 2024, while also examining trends from 2015 to 2024.

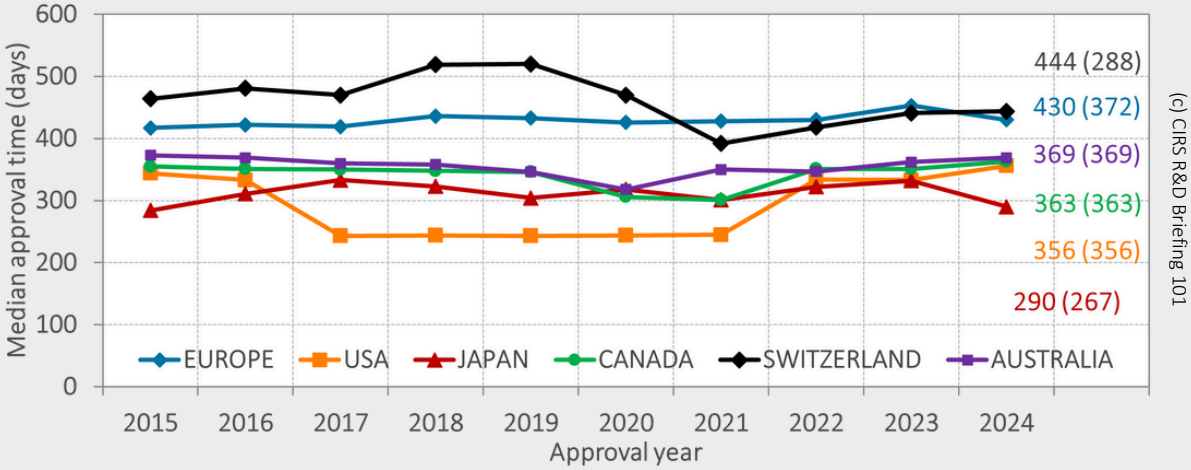
Key insights include:

- **Approval timelines** vary across the authorities (see below), however, differences narrowed when focusing on scientific assessment time.
- **Expedited pathways** continue to play a critical role in accelerating access to medicines, with expedited reviews consistently achieving faster approval times than standard reviews.
- **Therapeutic area trends** show that anti-cancer and immunomodulatory therapies accounted for the largest share of NAS approvals, while anti-infectives had the shortest median approval time.
- **Orphan-designated NASs** were generally approved faster than non-orphans, reflecting efforts to address unmet medical needs.
- **Submission strategies influence timelines**, with companies outside the top 20 in R&D having longer submission gaps.

PMDA and Swissmedic have cited data from this briefing in their own communications, demonstrating the trust in CIRS methodology and neutrality.

Download the briefing

Median approval timelines for NASs across six regulatory authorities (2025-2024)



N1 = median approval time for products approved in 2024; (N2) = median time from submission to end of scientific assessment for products approved in 2024.

Establishing a pre-JCA baseline for oncology product rollout in Europe

As part of our HTADock project, we published an R&D Briefing reviewing EMA oncology approvals from 2018 to 2023 and their first HTA outcomes and timelines across seven key EU jurisdictions.

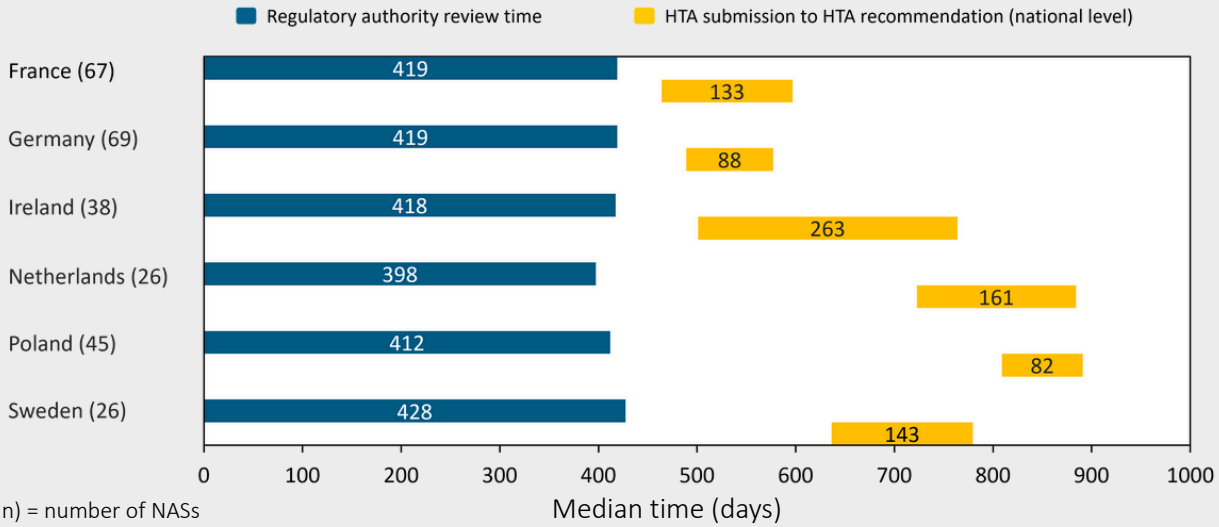
This briefing aims to provide a baseline understanding of oncology product rollout in Europe. Given that oncology products are among the first to undergo Joint Clinical Assessment (JCA), this briefing focuses exclusively on EMA oncology approvals and their corresponding HTA decisions across Europe — helping to enable comparisons and support iterative improvement as JCA is implemented.

Key insights include:

- **HTA outcomes:** France and Germany assessed the highest number of oncology NASs, while Portugal issued the highest proportion of positive HTA recommendations without restrictions.
- **Facilitated regulatory pathways (FRPs):** 53% of oncology NASs followed at least one FRP, with conditional approvals being the most commonly used. Products approved via accelerated pathways generally had shorter rollout times.
- **Submission strategies:** Poland showed the longest submission gap and rollout time, despite having the fastest HTA review time. Top R&D-spending companies tended to have shorter submission gaps than non-top companies.
- **ATMPs:** All oncology ATMPs assessed received a PRIME designation. France provided positive HTA recommendations for all of these ATMPs, and rollout times varied significantly across jurisdictions.
- **Orphan products:** In January 2028, the EU HTA Regulation (HTAR) will also extend to cover orphan products. Nearly half of the oncology orphan NASs were approved via the conditional pathway.

Download the briefing

Timing from EMA submission to first HTA recommendation
(oncology EMA approvals between 2018-2023 with an HTA recommendation)



Portugal is excluded due to the unavailability of HTA submission dates in the public domain.
For Ireland, both rapid and full reviews are included in this analysis. HTA review time for Ireland is calculated as (Rapid review completed - Rapid review commissioned) + (NCPE assessment completed - Full submission received from applicant)

Sharing insights and making connections at DIA Singapore and DIA Asia

Anna Somuyiwa, our Executive Director, and Dr Neil McAuslane, our Scientific Director (pictured), attended the DIA Singapore and Asia meetings in Singapore in July, which focused on the evolving healthcare landscape and trends in Asia. Key topics included the role of AI and digital tools in clinical trials, regulatory affairs, and pharmacovigilance.

Neil contributed valuable insights from CIRS research and workshops to the discussions through his presentation on 'Advancing regulatory practices and processes globally: Insights, new ways of working and impact'. He also participated in the ASEAN Townhall along with representatives from regulators and industry in the region.

In addition, visits to discuss CIRS research with senior leadership at Singapore's Agency of Care Effectiveness (ACE) and Health Sciences Authority (HSA) have further deepened our relationships with these key stakeholders. We look forward to continuing those important conversations and collaborations!

New agency brochure

We've launched a new brochure outlining the different options for regulatory and HTA agencies to be involved and collaborate with CIRS research. The brochure is available to download in English, Spanish, Chinese and Japanese.

You can find this brochure, along with our FAQs and Company Membership brochure, in the new 'Get Involved' section of our website.

We hope these resources will help companies and agencies join us in our mission to advance regulatory and HTA policies and processes.

Download the agency brochure

Download the company brochure

2024 Annual Report

The CIRS 2024 Annual Report showcases a year of impactful research and global collaboration, highlighting our workshops, projects, publications, and other activities. It also includes a case study illustrating our long-term role in assessing the landscape and impact of regulatory and HTA collaborations.

Key insights include:

- **Advancing rare disease policy:** We contributed to key international initiatives on rare diseases, including a National Academies of Science, Engineering and Medicines study providing recommendations to strengthen FDA's approaches and mechanisms to support development and registration of treatments for rare disease.
- **Shaping the future of HTA:** Through a multi-stakeholder workshop and the expansion of the HTADock database, we helped the HTA community prepare for the implementation of JCA.
- **Global regulatory engagement:** Insight meetings with EMA, FDA, and other regulators across five continents helped share our research findings and explore collaborative opportunities.
- **Evidence-based impact:** Our benchmarking data were cited in high-profile reports, including the Draghi Report on EU Competitiveness and Australia's HTA Policy Review.
- **Stakeholder input:** A comprehensive stakeholder feedback study was conducted, providing valuable insights to inform our future direction. Thank you to everyone who contributed!

Download the Annual Report

2024 in numbers

10
Briefings & journal articles

6
Workshops & fora

19
Conference presentations

20
Insight meetings with agencies

Latest publications

- CIRS R&D Briefing 102 – Tracking availability in China of medicines approved in six key global markets
- CIRS R&D Briefing 101 – New drug approvals by six major authorities 2015-2024
- CIRS R&D Briefing 99 – Tracking the journey: First HTA outcomes and timelines for oncology medicines approved by EMA 2018-2023
- Owusu-Asante M et al. Evaluation of good review practices at the Food and Drugs Authority of Ghana as it strives to become a World Health Organization-listed agency. *Regul. Toxicol. Pharmacol.* 2025; 163:105932.
- Wang T & McAuslane N. Enhancing Development Strategies Through Early Scientific Advice from HTA Agencies–Experiences, Expectations and Best Practices from Health Technology Developers. *Ther Innov Regul Sci* (2025).
- Mohd Sani N et al. Assessing the Malaysian Regulatory Process for Medicinal Product Approval: An OpERA Methodology and Standardized Reporting Approach. *Ther Innov Regul Sci* (2025).
- Owusu-Asante M et al. Comparison of the review models and regulatory timelines of seven countries participating in the ECOWAS-MRH initiative: identifying opportunities for improvement. *Front Med* (Lausanne). 2025;12:1587761.
- Danks L et al. The value of a structured, systematic approach to benefit-risk assessment of medicines: A South African regulator case study. *Regul Toxicol Pharmacol.* 2025;162:105893.
- CIRS workshop report – Regulatory agency collaboration and system strengthening: How is this enabling national, regional and continental models and improving medicines availability for patients?
- CIRS 2024 Annual Report

Where to meet us

- **DIA Latin America Annual Meeting**, 29th September – 1st October, Buenos Aires, Argentina
  - Dr Magda Bujar will be presenting in a session on 'Navigating Regulatory Reliance: Practical Insights and Applications Beyond Initial Marketing Authorization Application'.
- **ISPOR Europe**, 9-12th November, Glasgow, UK
  - Dr Neil McAuslane will be presenting in a session on 'A New Era for EU HTA: What Can the EU HTAR Learn from the EMA's Path to Harmonization?'
  - Dr Belen Sola will present a poster on 'Canadian HTA Decisions (2020-2023): Comparing CDA-AMC and INESSS Recommendations on Drug Reimbursement'.
  - Penelope Cervelo will present posters on 'The HTA Landscape of Orphan Products in the UK between 2019 and 2024' and 'HTA Submission Trends for EMA-Approved Oncology NASs Prior to the EU HTA Regulation (2018-2023)'.
- **7th Biennial Scientific Conference on Medical Products Regulation in Africa** (SCoMRA VII), 11 – 13th November, Mombasa, Kenya
- **International Genomic Medicine Symposium**, 17th November, Hong Kong

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