# CIRS Q2 2026 Newsletter

*Your quarterly update on CIRS meetings, global engagements, and research studies advancing medicine regulation and HTA.*

## CIRS Strategic Summit

In May we brought together multiple stakeholders in a strategic Summit to plan for our 2027-2029 Research Agenda.

Senior representatives from global regulators, industry, HTA/coverage bodies, academia and patient groups shared their perspectives on three cross-cutting themes:

- System co-design across the development–regulatory–HTA–access lifecycle
- Evidence evolution and decision making under uncertainty
- Post-HTA implementation and access to medicines.

We are reviewing all of the ideas proposed in preparation for our internal mid-year meeting in August, during which we will discuss and develop our research priorities for 2027-2029.




# Tracking Innovative Medicine Approvals in China and Beyond

We recently published an R&D briefing focused on **Class 1 innovative medicines approved in China between 2022-2024**, defined as products not previously approved in China or overseas at the time of submission to the National Medical Products Administration (NMPA).

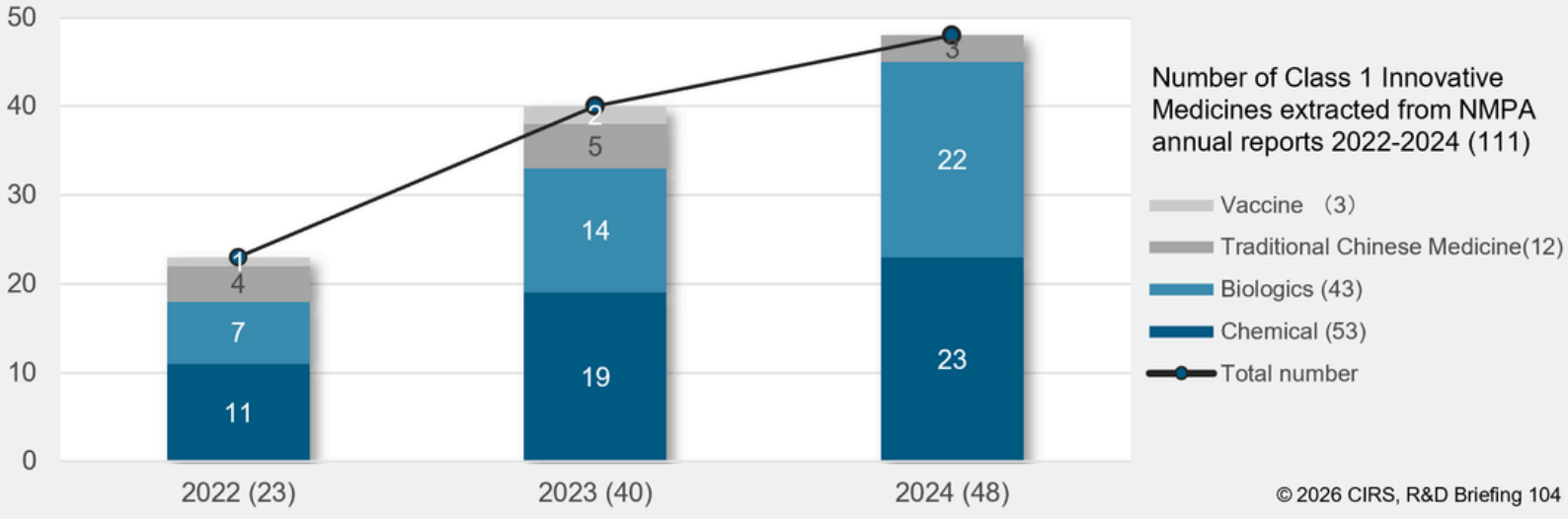
The research explored regulatory pathways, approval sequencing, and reimbursement outcomes, with comparisons to major global markets.

**Key insights include:**

- Class 1 innovative medicine approvals more than doubled from 2022 to 2024 (see below).
- Oncology was the leading therapeutic area, accounting for 46% of Class 1 approvals.
- Class 1 approvals were largely driven by domestic companies.
- USA was most often the first submission and approval jurisdiction for multi-national companies, with China typically included as an early, but not first, market (most NMPA submissions occurred within 31–180 days of the initial global filing).
- Use of expedited pathways increased over time, with priority review more common among multinational companies and conditional approval more frequently used by domestic companies.
- 66% of approved Class 1 medicines were included in China's National Reimbursement Drug List (NRDL), with a median time of 360 days from NMPA approval to reimbursement.

This briefing highlights China's evolving role in global pharmaceutical innovation, including the growing contribution of domestic innovation and the increasing importance of China in global development strategies.

*Figure 1. Overview of NMPA Approvals of Class 1 Innovative Medicines (2022–2024)*




**Download the briefing**

# Sharing Insights From CIRS Research Globally

Members of the CIRS team presented insights from CIRS research and workshops at various conferences and meetings around the world (see below). These were great opportunities to connect with colleagues and partners, while contributing to discussions shaping the future of medicine regulation and HTA in different jurisdictions and regions.

Highlights included:

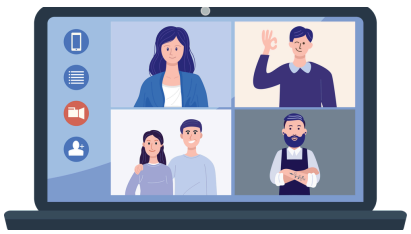
- **DIA Europe**, Rotterdam – Participation in a panel session on regulatory authority collaboration and in the China Town Hall.
- **ESIP-MEDEV Pharmaceutical Innovation Summit**, Brussels - Presented insights on developments in China and their potential implications for the European pharmaceutical landscape.
- **FIFARMA Annual Summit**, Brasilia – Presented key findings from a project developing a mechanism to monitor regulatory reliance globally.
- **DIA China**, Shanghai – Contributed to the pre-conference workshop and chaired the International HTA Townhall.
- **HTAi**, Istanbul – Participation in a panel session on HTA in China.
- **DIA Global**, Philadelphia – Prof Stuart Walker's PhD students presented posters sharing insights from CIRS regulatory strengthening research in Africa.




# Upcoming Webinar: Advancing Regulatory Reliance

**Innovative Approaches to Regulatory Reliance: Strengthening Regulatory Systems through Collaboration and Evidence | 30 June, 4pm UK**

This webinar, organised by FIFARMA, IFPMA, and EFPIA, will bring together international experts, regulatory authorities, and industry representatives to share evidence, practical experiences, and lessons learned on the implementation of reliance mechanisms.



CIRS will present on '*Why regulatory reliance matters: Global collaboration and insights from a new Latin American study*', including findings from a project on developing a mechanism to monitor regulatory reliance globally.

**Register here**

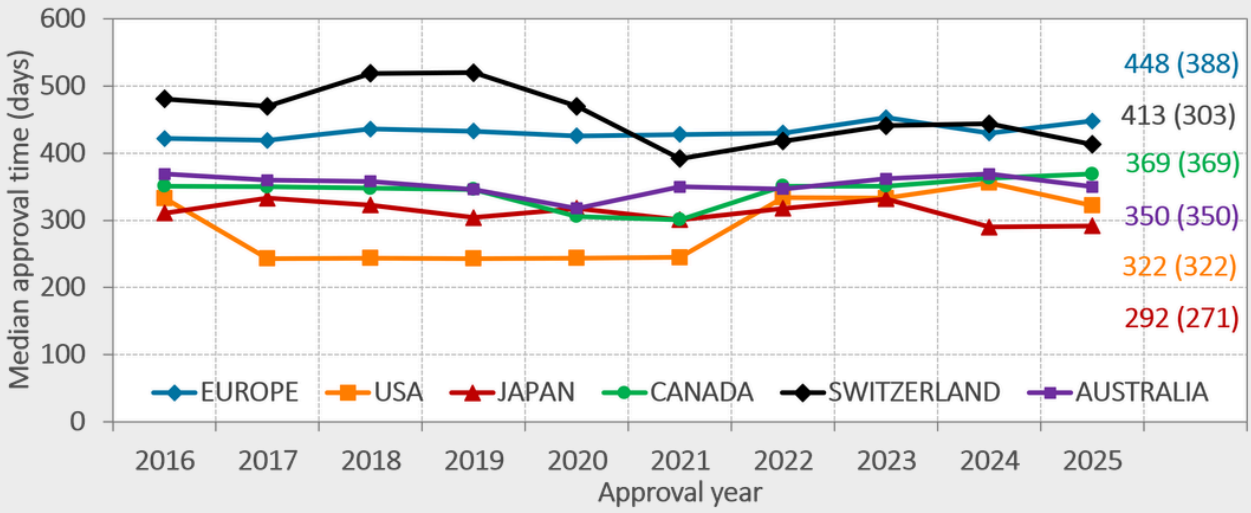
# Sneak Peek at our Next R&D Briefings

*Regulatory benchmarking briefing*

Every year we publish an R&D Briefing focused on the review performance of six major regulatory agencies: 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).

This year's briefing will be published and shared with the CIRS mailing list on **Friday 3rd July**. In the meantime, here's a sneak preview of median approval times for new active substances (NASs) across the six agencies:

**Median approval timelines for NASs across six regulatory authorities (2016-2025)**




(c) CIRS R&D Briefing 106

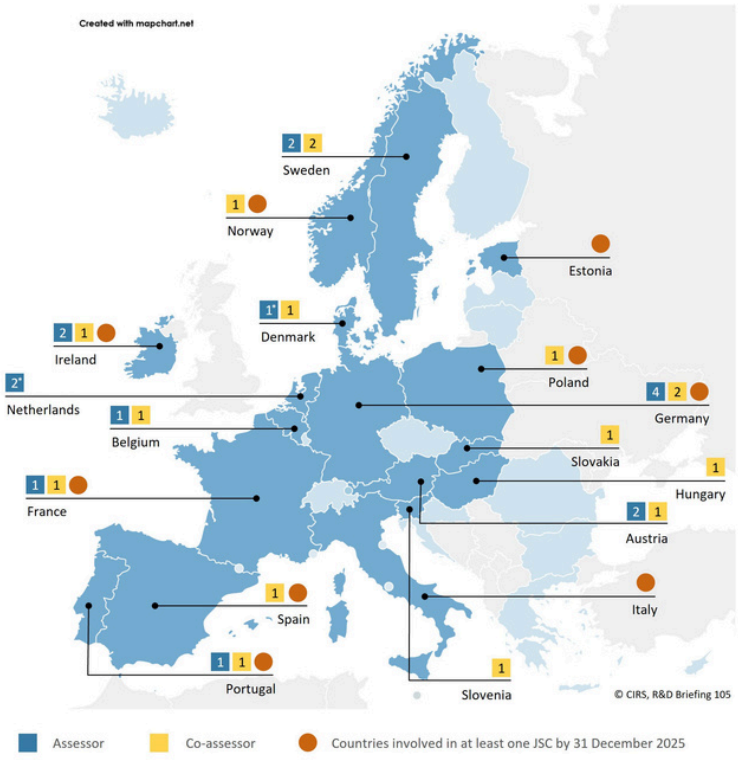
*N1 = median approval time for products approved in 2025; (N2) = median time from submission to end of scientific assessment for products approved in 2025.*

*EU HTA briefing*

In July we will publish a briefing on the evolving EU HTA landscape under the HTA Regulation. It examines HTA agencies across the EU-27 and EEA-3 jurisdictions, including their scope, publicly available information, and participation in EU HTA activities such as Joint Scientific Consultation (JSC) and Joint Clinical Assessment (JCA).

The briefing provides a baseline to support ongoing monitoring of changes across the EU HTA ecosystem.

**Countries that have participated in JCA and/or JSC**




# Latest Publications

**Briefings & Reports**

- CIRS R&D Briefing 104 – Class 1 innovative medicines approved in China (2022-2024): An international comparison
- CIRS 2026 Workshop Synopsis – Building capacity for patient involvement in regulatory and HTA decision making in the Asia-Pacific: Focus on rare diseases and precision medicine
- CIRS 2025 Workshop Report – Navigating national decision making post Joint Clinical Assessment (JCA): Enablers, barriers and the path forward

**Journal Articles**

- Dai Z, Cheung EKY, Wang T, et al. Comparative review of selected health technology assessment agencies: Features and insights for health technology assessment development and improvement, Pharmacoeconomics and Policy (2026).
- Chisha CS, Siyanga M, Leigh S et al. Evaluation of the Quality Decision-Making Practices Utilized by the Zambia Medicines Regulatory Authority Technical Committees. Pharm Med 40, 235–248 (2026).
- Sola-Barrado B, Wang T, McAuslane N. HTA submission strategies and their associations with rollout times and type of HTA recommendation in Australia and Canada. International Journal of Technology Assessment in Health Care. 2026;42(1):e20.

**Conference Posters**

- The African Medicines Agency (AMA): Historical perspectives of its origins, evolution, institutional structure and future prospects
- Assessment of Good Review Practices at the Zambia Medicines Regulatory Authority as it strives to achieve the WHO Maturity Level 3 status

**CIRS Commentary Pieces**

- What the MHRA-NICE aligned pathway could mean for development and access in England

**READ MORE**

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