CIRS
R&D BRIEFING 104

Class 1 Innovative Medicines Approved in China (2022–2024): An International Comparison

CIRS Centre for Innovation in Regulatory Science

INTRODUCTION

Pharmaceutical innovation has become increasingly global, with companies pursuing multi-jurisdictional approvals and timely patient access through evolving regulatory and reimbursement pathways.

In China, recent regulatory reforms have contributed to more efficient drug approval processes, alongside more dynamic approaches to reimbursement decision making. The introduction and wider use of expedited pathways, such as priority review, conditional approval, and breakthrough designation by NMPA have supported faster approval of medicines addressing unmet medical needs. At the same time, greater emphasis is being placed on evidence requirements and value assessment to inform reimbursement decisions, supported by an annual reimbursement cycle.

Since 2002, the Centre for Innovation in Regulatory Science (CIRS) has been tracking and publishing performance metrics to enable cross country comparisons of regulatory and HTA systems. Through its annual Regulatory and HTA benchmarking studies based on public domain information, CIRS provides insights into how regulatory and HTA policy and procedures are shaping patient access to innovative medicines. CIRS has also expanded the scope of its metrics to include additional jurisdictions, such as regulators in the Access Consortium and Project Orbis initiatives, as well as China.

Building on this context, this study focuses on **Class 1 innovative medicines approved in China between 2022 and 2024.** These medicines, defined as products not previously approved in China or overseas at the time of submission, represent an important indicator of innovation within the Chinese healthcare system. This briefing analyses the regulatory pathways and key approval milestones of these products in China and examines their reimbursement listing status. It also compares these products with six major global markets, placing China's innovative medicines approvals in an international context.

This briefing highlights China's evolving role in global pharmaceutical innovation, characterised by rapid growth in domestically driven innovation and increasingly early submissions for multi-national companies' innovative medicines, including examples of first-in-China submission. These developments are driven by convergence in regulatory science and harmonisation through the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), alongside domestic policy reforms from both regulatory and payer perspectives, which have delivered measurable impact.

CONTENTS

SUMMARY

This report examines **Class 1 innovative medicines** approved in China between 2022 and 2024, defined as products not previously approved in China or overseas at the time of submission. These medicines provide an important indicator of pharmaceutical innovation in China.

This research explores regulatory pathways, approval sequencing, and reimbursement outcomes, with comparisons to major global markets. Findings should be interpreted within this specific subset, reflecting strategic approaches to Class 1 approvals rather than overall company performance in China, and highlighting how regulatory and reimbursement processes shape patient access.

Number of China Class 1 innovative medicine approvals between 2022-2024

111	96	79	17
Total Class 1 approvals	In scope of the report (excl. Traditional Chinese Medicine & vaccines)	Domestic company approvals	Multinational companies (MNC) approvals

- Class 1 innovative medicine approvals showed a steady increase, more than doubling from 23 in 2022 to 48 in 2024.
- Oncology represents the largest therapeutic area (46% of approvals).Domestic approvals show a stronger focus on oncology (53% vs 23% for MNC), as well as broader range of other therapeutic area. This maybe attributed to a higher number of MNC approvals.

- Distinct regulatory strategies drive divergent global approval patterns: Domestic companies primarily pursue a China-focused strategy, with 90% of approvals remaining limited to the domestic market. In contrast, multinational companies (MNCs) adopt a global-first approach, with most products also approved in major markets such as the FDA, demonstrating broader international reach.
- Approval sequencing reflects these strategic differences: The FDA is the predominant first submission and approval jurisdiction for MNCs (12 of 16 products), supported by shorter review timelines. China is typically included as an early, but not first, market, with most NMPA submissions occurring within 31–180 days of the initial global filing. Consequently, NMPA approvals tend to occur later in the global sequence (2nd-4th).
- Use of expedited pathways differs by company type: MNCs more frequently utilise priority review and breakthrough pathways, whereas domestic companies make greater use of conditional approvals.

Note: Interpretation of MNC activity is influenced by the Class 1 definition. As Class 1 designation requires products to be unapproved globally at the time of China submission, many MNC products—typically first approved outside China—are excluded. These findings therefore reflect regulatory strategy rather than the overall level of MNC innovation or activity in China.

- From a reimbursement listing perspective, 66% of Class 1 innovative medicines were listed on the NRDL, with a further 6% included in the CHI list in 2025.
- For reimbursed products, the time from regulatory approval to reimbursement differed across jurisdictions. Germany and Japan had the shortest median timelines, at 50 days and 63 days, respectively. This reflects systems where reimbursement can happen soon after regulatory approval. Australia and France had longer median timelines, at 419 days and 410 days.
- In China, the median time from NMPA approval to NRDL/CHI listing was 360 days. This is partly because NHSA review follows an annual cycle rather than a rolling process. If a product misses the submission window, reimbursement may be delayed by another year.

METHODOLOGY

Step 1 — **Identification of Class 1 innovative medicines in China**

Class 1 innovative medicines approved between 2022 and 2024 were identified based on the National Medical Products Administration (NMPA) annual reports.
Class 1 innovative medicines are defined as products not previously approved in China or overseas at the time of New Drug Application (NDA) submission, representing first-in-class or globally novel therapies. These products are considered a key indicator of innovation within the Chinese pharmaceutical market.

Step 2 — **Assess the regulatory status in China**

For each product identified in Step 1, regulatory information was collected from the Center for Drug Evaluation (CDE) websites, including: review pathway (e.g. priority review, conditional approval, breakthrough designation) and key regulatory milestones (submission, approval timelines).

Class 1 traditional Chinese medicines (s) and vaccines were excluded to ensure consistency with international regulatory and HTA comparisons, focusing on comparable innovative therapeutic products.

Step 3 — **Assess the reimbursement status in China**

For each identified product identified in Step 1, reimbursement status were obtained from the National Healthcare Security Administration (NHSA) website, based on the National Reimbursement Drug List (NRDL) updates published between 2022 and 2025, and the newly introduced Commercial Health Insurance (CHI) list in 2025. The publication date of each annual NRDL list from 2022-2025 was also captured.

Step 4 — **Global metrics comparison**

For each identified product identified in Step 1, regulatory pathway and milestone data across six jurisdictions (Australia, Canada, EU, Japan, Switzerland, and US) were obtained from the CIRS Regulatory Review Timelines Database (RRTD) based on datasets tracked up to 31 December 2025.

HTA status for each product across Australia, Canada, England, France and Germany were derived from the CIRS HTADock database, based on public domain datasets tracked up to 31 December 2025. Additionally, the reimbursement status for Australia, England, France, Germany and Japan were collected from official HTA agencies and payers' website, tracked up to 31 March 2026.

Step 5 — **Analyse trends in Class 1 innovative medicines in China with global comparisons**

A trend analysis of Class 1 innovative medicines in China was conducted. This included breaking down by company type (see explanation below), assessment of regulatory submission sequences, approval timelines, use of expedited pathways, as well as HTA and reimbursement processes, timelines, and outcomes, in comparison with other jurisdictions in the study.

For the purpose of this report, Class 1 innovative medicines were analysed by the company type to reflect both imported innovative medicines and the contribution of medicines from Chinese developers.

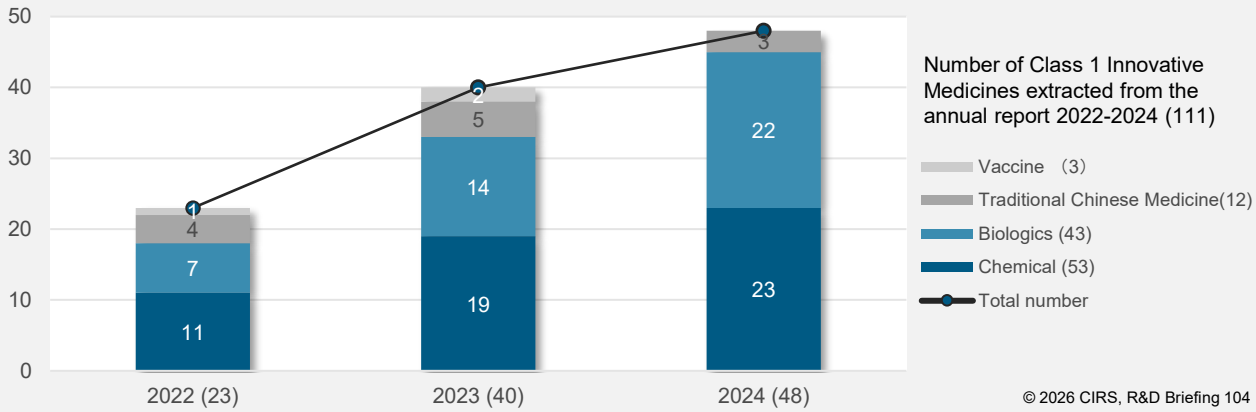
- **Domestic companies** were defined as companies headquartered in China with primary control over product discovery and development.
- **Multinational companies (MNC)** were defined as companies headquartered outside China, including cases where NMPA approval was granted to a China registered subsidiary of a multinational group (for example, locally incorporated manufacturing or commercial entities).

Overview: Class 1 Innovative Medicine Approvals

A total of 111 Class 1 innovative medicines were approved by NMPA 2022-2024.

China New Drug Application (NDA) approvals include chemical drugs in classes 1, 2 and 5.1, therapeutic biological products in classes 1, 2, 3.1 and 3.2, and traditional Chinese medicines (s) in classes 1, 2 and 3. Among these, **Class 1 innovative medicines** are defined as products not yet marketed in China or overseas at the time of their NDA submission. This report focuses exclusively on Class 1 innovative medicines approved between 2022 and 2024, representing an important indicator of innovation within the Chinese pharmaceutical system. Other categories of new drug approvals (for example, chemical class 5.1 and biologics class 3.1) were excluded from the analysis.

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

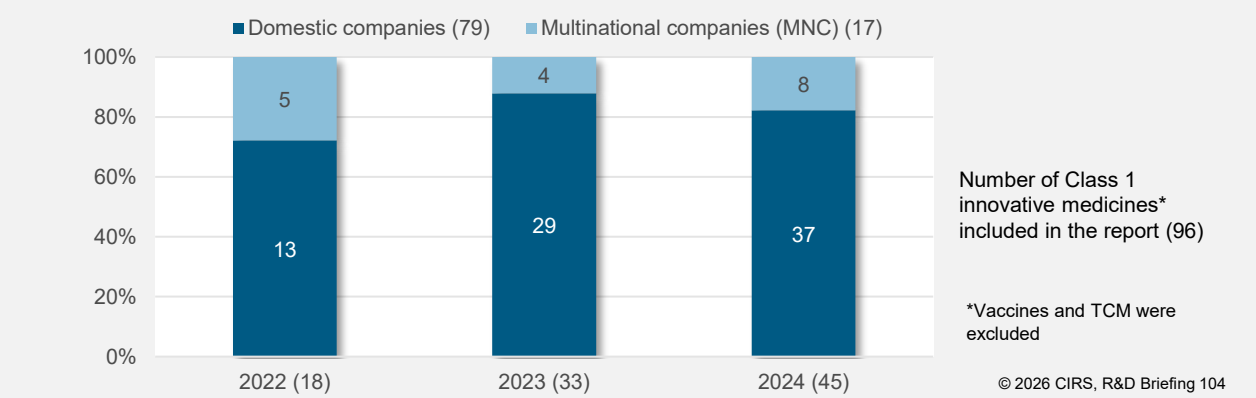


The number of Class 1 innovative medicines approved increased from 23 in 2022 to 40 in 2023 and 48 in 2024, with a total of 111 approvals overall (Fig 1). Excluding traditional Chinese medicines and vaccines, **a total of 96 medicines were included in this report.**

Approvals of Class 1 innovative medicines were largely attributed to domestic companies, with 79 approvals compared to 17 by MNC between 2022 and 2024.

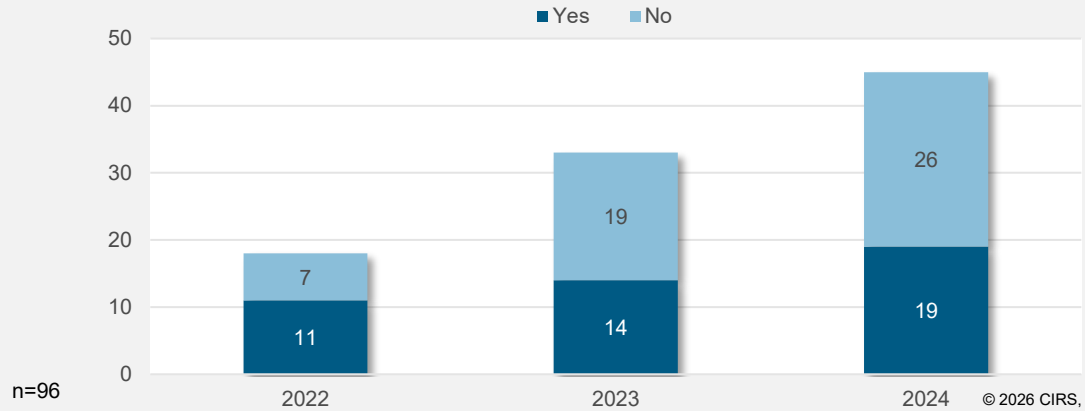
Domestic companies accounted for 13 out of 18 approvals in 2022 (72%), increasing to 88% in 2023, and 82% in 2024, contributing to the majority of the overall growth in approvals (Fig 2). Approvals from multinational companies (MNC) remained relatively low (17 in total from 2022-2024), however a slightly higher number of approvals (8) were observed in 2024. This may reflect the definition of Class 1 approval, which excludes products that have already received approval outside China (for example by the FDA) prior to submission in China. As such, caution should be taken when interpreting these data, as they do not represent the overall performance of MNC in China, but rather focus on a subset of Class 1 products only, reflecting their regulatory strategy to submit to China, prior to any approvals worldwide.

Figure 2. NMPA Approvals of Class 1 Innovative Medicines by Company Type (2022–2024)



Overview: Class 1 Innovative Medicine Approvals

Figure 3. Flexible Regulatory Pathways Used by the NMPA, by Approval Year (2022–2024)



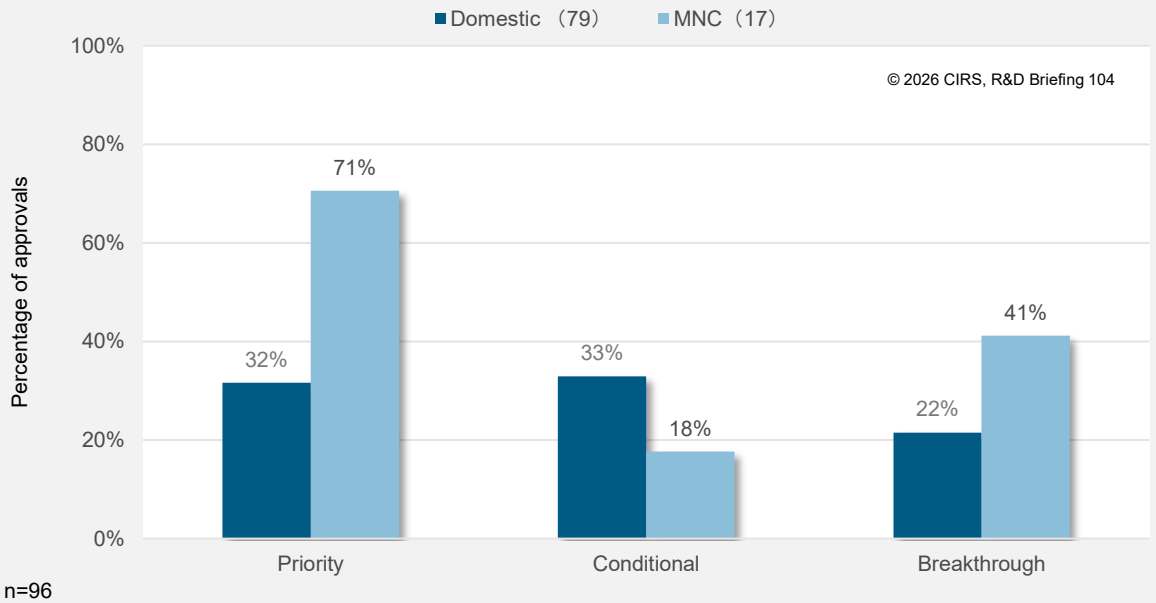
The use of flexible regulatory pathways increased over the period from 2022 to 2024.

A number of flexible regulatory pathways (FRPs) can be utilised by NMPA to facilitate timely availability of medicines, including priority review, conditional approval, and breakthrough designation. A comparison between 2022 and 2024 shows that at least one FRP by NMPA was applied for innovative medicines, increasing from 11 approvals in 2022 to 19 approvals in 2024.

Further analysis examined the specific pathway applied, breaking down by the company type (Fig 4). Among MNC approvals, priority review was the most frequently applied FRP (71%), followed by breakthrough therapy designation (41%). On the other hand, conditional approval was more frequently used by domestic companies (33%) than by MNC (18%).

Overall, MNCs show a higher proportion of use of priority review pathways, while domestic companies show a higher proportion of use of conditional approval. Among domestic companies' approvals (79), 19 products underwent both priority review process with a conditional approval, benefiting from the use of multiple FRPs.

Figure 4. Use of Flexible Regulatory Pathways by Company Type (MNC vs Domestic), by Approval Year (2022–2024)



Overview: Class 1 Innovative Medicine Approvals

Product types of Class 1 approvals were similar across domestic companies and MNC, with chemical drugs accounting for 55% of approvals in total.

Looking at the specific type of products, for domestic companies, 43 out of 79 approvals (54%) were chemical drugs and 36 (46%) were biologics (Fig 5). While for MNC, 10 out of 17 approvals (59%) were chemical drugs and 7 (41%) were biologics. In general, chemical drugs accounted for a slightly higher proportion than biologics, with a comparable picture between domestic and MNC products.

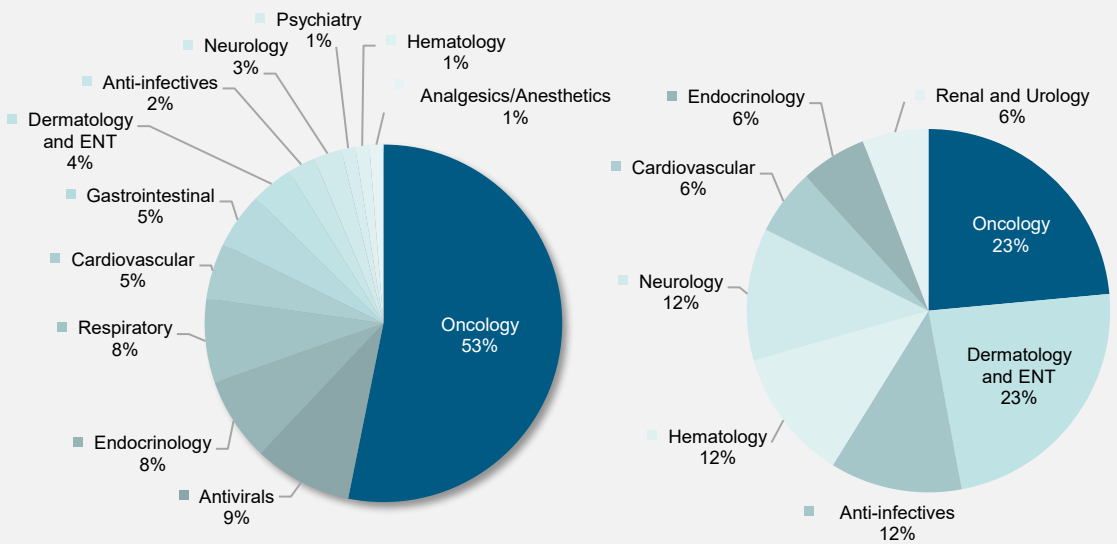
Figure 5. NMPA Approvals of Class 1 Innovative Medicines by Product Type and Company Type (2022–2024)

(n) =number of product

Oncology represents the largest therapeutic area of Class 1 Innovative Medicine approvals (46%).

Of the Class 1 innovative medicines included in this study, 17 approvals (18%) were from MNCs and 79 from domestic companies. MNC approvals were concentrated in oncology (23%) and dermatology/ENT disorders (23%), whereas domestic approvals were led by oncology (53%) with the remainder distributed across a broad range of non-oncology therapeutic areas.

Figure 6. Therapeutic Areas of Class 1 Innovative Medicines by Company Type (2022–2024)



Domestic (79)

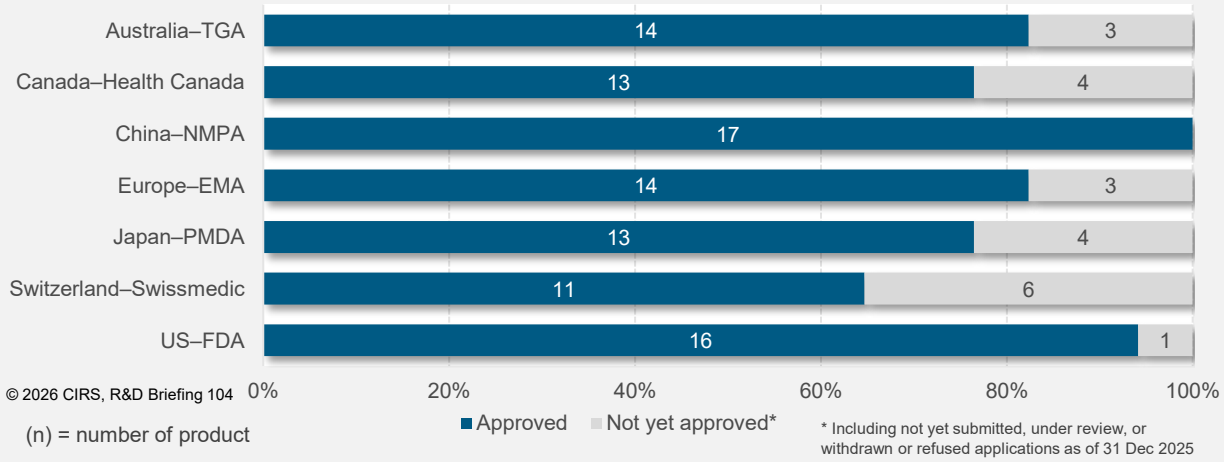
MNC (17)

Global Regulatory Comparison: MNC Approvals

Most Class 1 innovative medicines approved by NMPA from MNC were also approved by FDA and EMA.

The global regulatory approval status of Class 1 innovative medicines by MNC was assessed using CIRS datasets tracked up to 31 December 2025. By that time, most had been approved by the FDA (16), followed by the EMA and TGA (14), while Swissmedic had fewer approvals (11); cases without approval may reflect products not yet submitted, under review, withdrawn or refused, as specific reasons were not assessed in this study (Fig 7). Seven out of 17 MNC products were approved by all seven regulatory agencies.

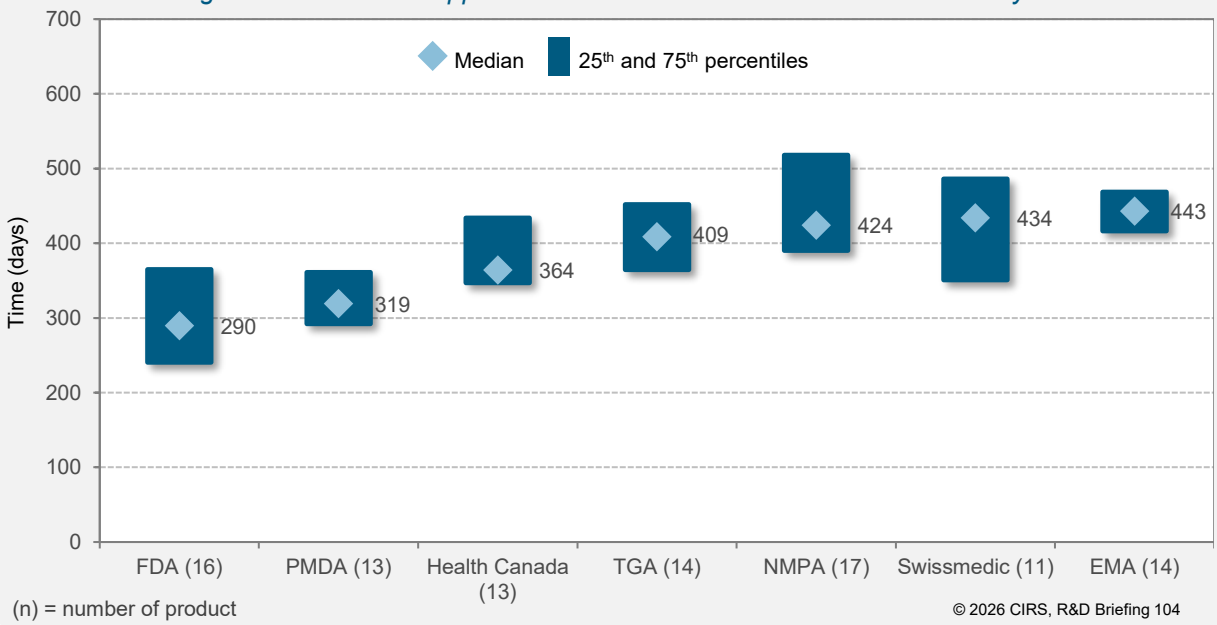
Figure 7. Regulatory Approval Status of Class 1 Innovative Medicines by MNC across 7 Regulators



For the same cohort of 17 NMPA approvals by MNC, the FDA had the shortest median approval time followed by PMDA.

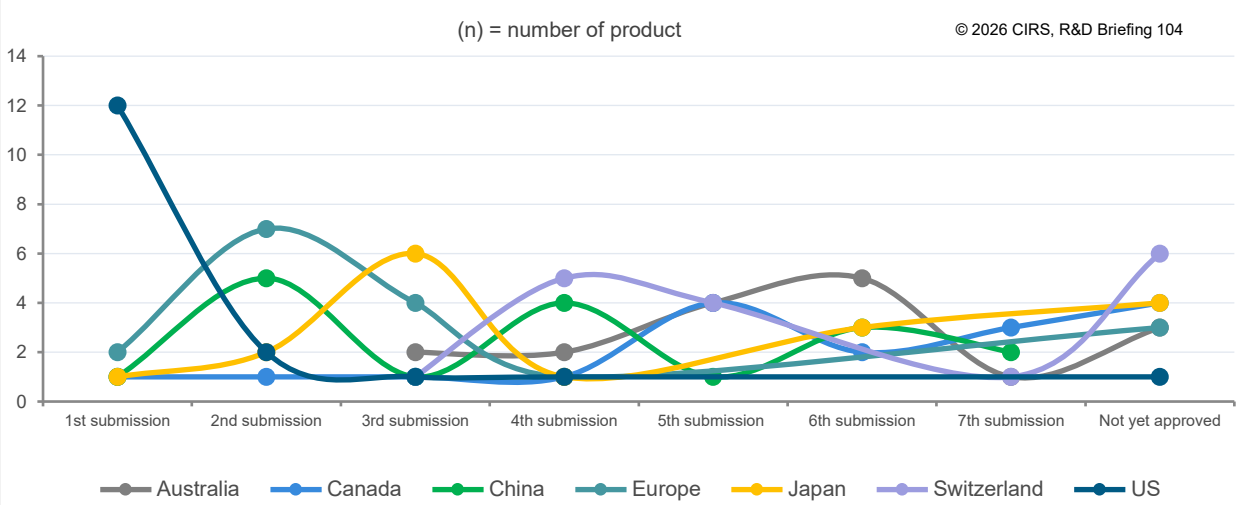
The approval timelines were assessed based on the time taken from submission to approval within each jurisdiction (Fig 8). FDA had the shortest median approval time at 290 days, while the EMA had the longest median approval time at 443 days. However, the EMA approval times were the most consistent, with an interquartile range (IQR) of 52 days. These differences in approval times are associated with the specific regulatory processes and review pathways utilised by each agency which was examined further in Fig 11.

Figure 8. Variation in Approval Time for Class 1 Innovative Medicines by MNC



Global Regulatory Comparison: MNC Approvals

Figure 9. Submission Order across Regulators for Class 1 Innovative Medicines Developed by MNC

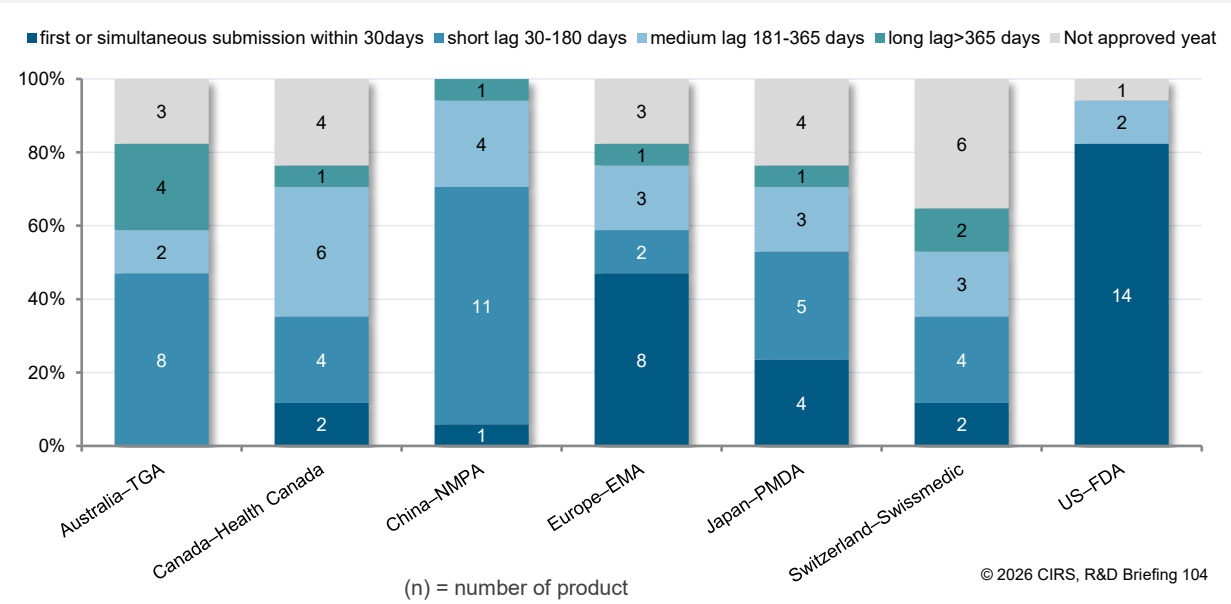


For the Class 1 NMPA approvals from MNCs, the FDA was the most frequent first submission agency.

Across the seven regulators, the FDA was most frequently the first submission regulator, accounting for initial filings of 12 products, while EMA was most often second submission choice for 7 products, followed by NMPA for 5 products (Fig 9). One product among the 17 approvals submitted to NMPA first, and NMPA commonly appeared in second to fourth submission positions.

When further assessing the time lag from first global submission to local regulator (Figure 10), the US was the dominant first submission jurisdiction, with the majority of products filed within 0–30 days. China followed as an early priority market, with 71% submissions occurring within 0–100 days after first global filing. Europe was also an early filing market for 10 of 14 approvals, while other jurisdictions showed more dispersed submission patterns.

Figure 10. Time from First Submission to Local Submission for Class 1 Innovative Medicines by MNC

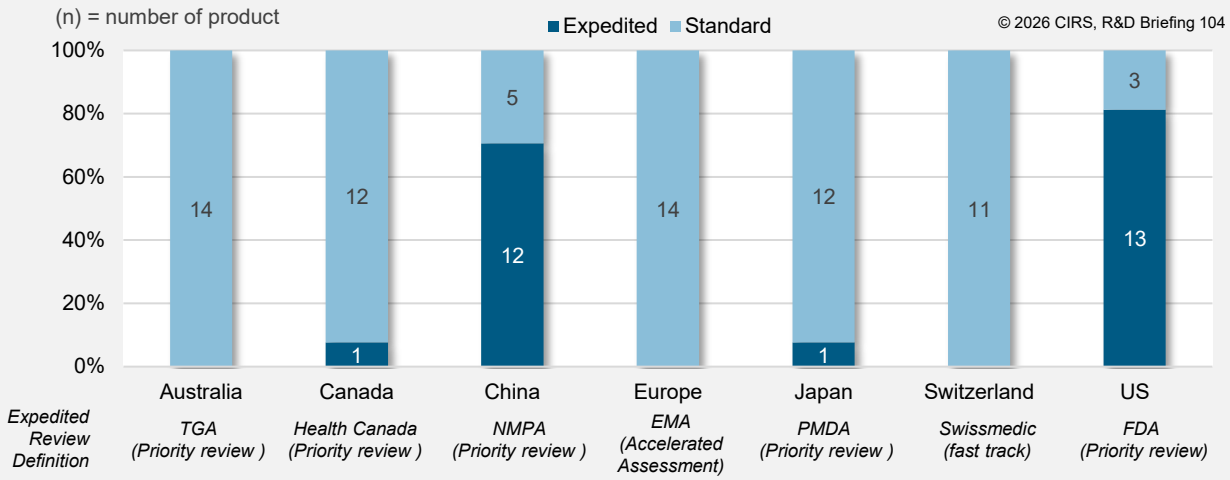


Global Regulatory Comparison: MNC Approvals

The use of expedited pathways differs across all seven regulators (Fig 11).

FDA and NMPA show the highest use of expedited pathways, with 13 and 12 products respectively, representing the majority of approvals in these jurisdictions. In contrast, EMA, TGA and Swissmedic approvals were entirely through standard pathways for these Class 1 innovative medicine, with no use of expedited routes observed.

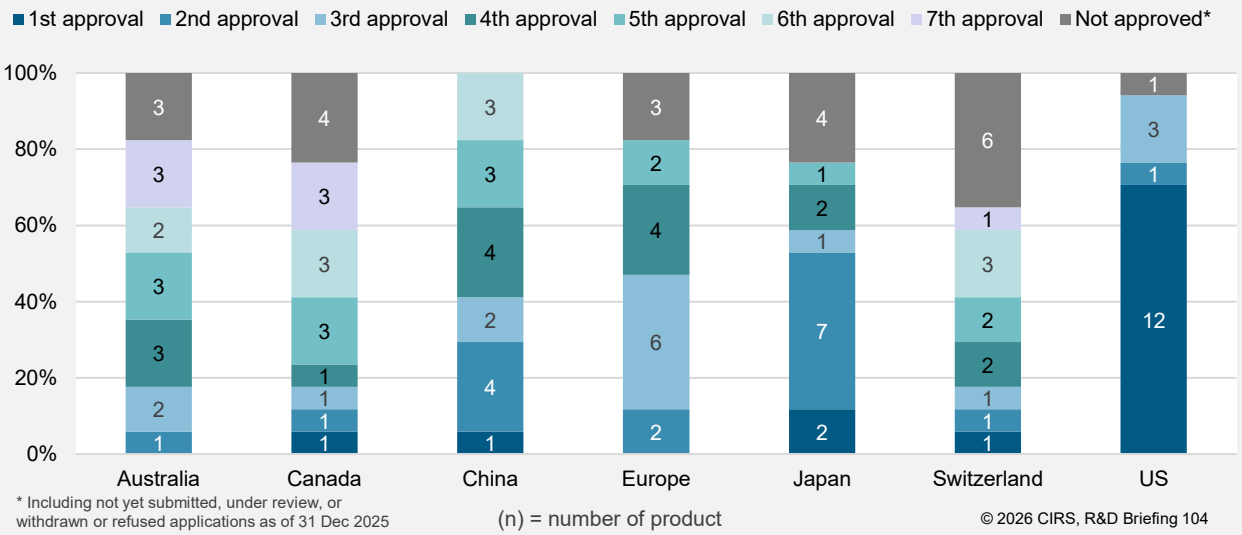
Figure 11. Number of Class 1 Innovative Medicines Approved through Expedited Pathways



The FDA was the most common first approval regulator, with 12 products receiving their first approval there.

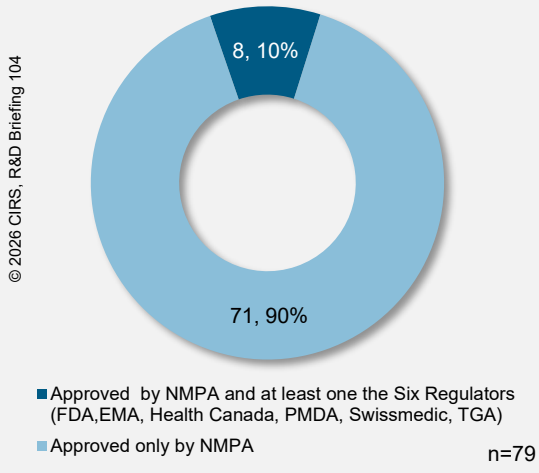
Submission sequence driven by company strategy, and together with regulatory timelines associated with the pathways used, leads to differences in approval order across jurisdictions (Fig 12). EMA approvals most commonly occurred as third approvals, while TGA and Health Canada were more frequently positioned at later stages, often as fifth to seventh approvals or not yet approved. PMDA showed a high proportion as the 2nd approval country, while Swissmedic had the highest number of non-approvals. While NMPA approvals were more widely distributed across later positions from second to sixth, it should be noted that this observation is based on the 17 Class 1 products from MNC and does not reflect overall MNC performance in China and the other studied jurisdictions.

Figure 12. Approval Order of Class 1 Innovative Medicines by MNC across 7 Regulators



Global Regulatory Comparison: Domestic Approvals

Figure 13. Regulatory Status Outside China for Class 1 Innovative Medicines By Domestic Companies



The majority of Class 1 innovative medicines developed by Chinese domestic companies (90%) were approved in China only.

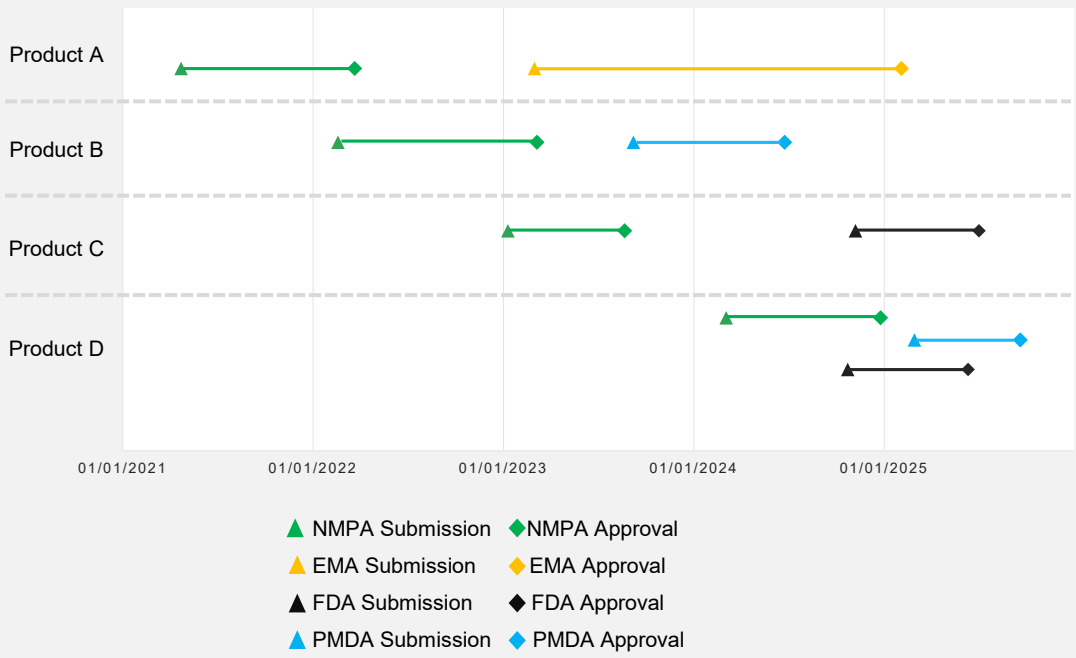
Among the 79 domestically developed Class 1 innovative medicines, 8 had received approval overseas by at least one of the regulators: FDA, EMA, Health Canada, PMDA, Swissmedic and TGA) (Fig 13).

Most products in the cohort, however, remained approved only in China at the time of the study. Several additional products were under review by other regulators, but these were not included because the approval process was still ongoing.

Figure 14 highlights 4 of the 8 domestically developed products that achieved overseas approval. These 4 products were selected because all had received both priority review and conditional approval in China. Their regulatory timelines were analysed and mapped to illustrate submission and approval sequences across the NMPA, FDA, EMA, and PMDA. Among them, 2 products also received priority review from the FDA.

The heterogeneity in both submission timing and approval duration across the four regulators may reflect different business models for internationalisation, for example, overseas subsidiary led submissions or license-out approaches, as well as different regulatory strategies that prioritise different markets.

Figure 14. Submission and Approval Timeline of 4 Priority/Conditionally approved Class 1 Innovative Medicines in China by Domestic companies, comparison with EMA, FDA and PMDA



China Reimbursement Status

In China, the National Reimbursement Drug List (NRDL) is the primary mechanism for public reimbursement, with annual updates determining inclusion and pricing through negotiation.

In 2025, the introduction of the Commercial Health Insurance (CHI) list provides an additional mechanism to support access, particularly for innovative medicines not yet included in the NRDL, reflecting a complementary approach to reimbursement.

Figure 15. Reimbursement Status of Class 1 Innovative Medicines Approved in China (2022-2024)

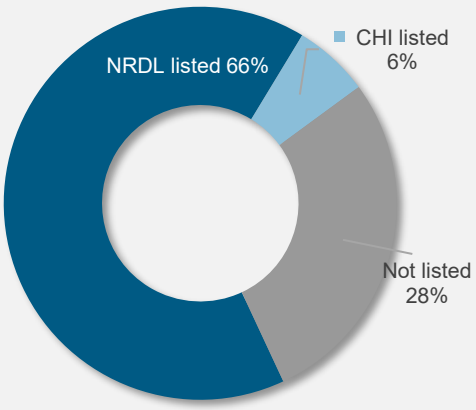


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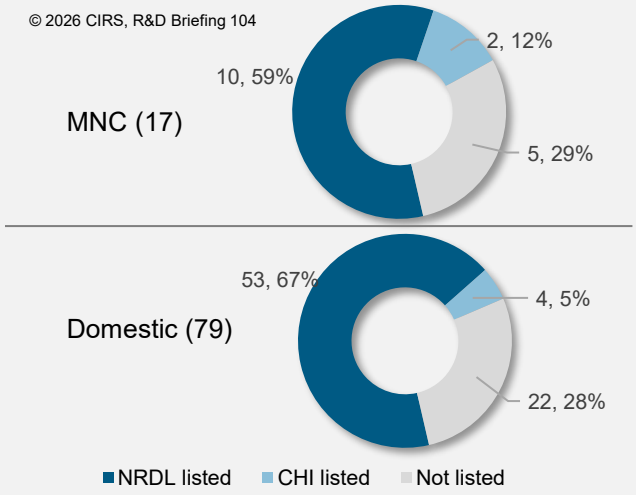
Figure 16. Reimbursement Status of Class 1 Innovative Medicines by Company Type

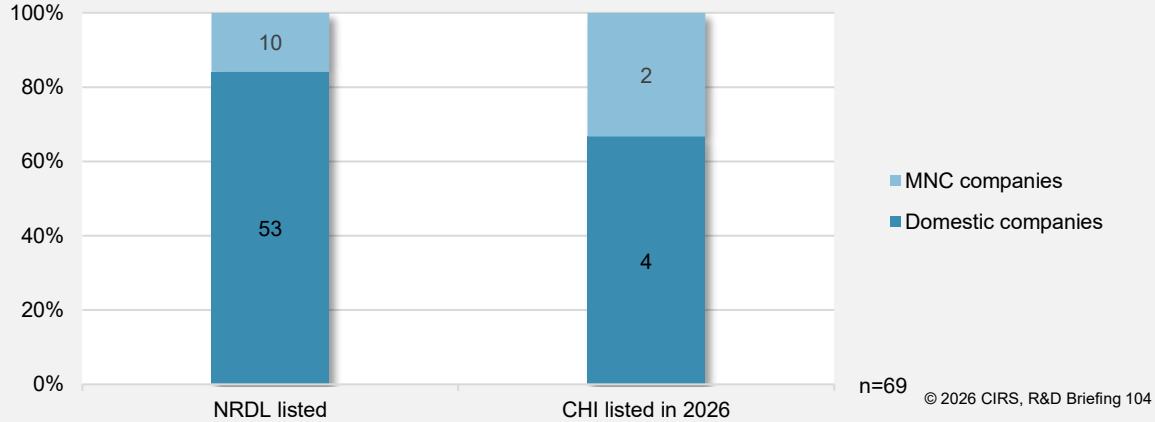


Among the 96 Class 1 innovative medicines approved between 2022-2024, 66% were listed on the NRDL, while 6 approvals were included in the CHI list (Fig 15).

59% of approved innovative medicines by MNC were included in the NRDL and 2 products were included in the CHI list (Fig 16). A slightly higher proportion of domestic approvals were listed in the NRDL, but there was a similar pattern for non-listed medicines across both MNC (29%) and domestic companies (28%). 27 of the Class 1 innovative medicine approvals were not listed for reimbursement. However, these medicines may still be accessed through individual private insurance plans or out of pocket payment.

Among reimbursed products, domestic companies accounted for the majority of NRDL listings (53 out of 63) and CHI listings (4 out of 6), reflecting the overall higher number of domestic approvals included in reimbursement schemes (Fig 17).

Figure 17. Reimbursed Class 1 Innovative Medicines by Company Type in China



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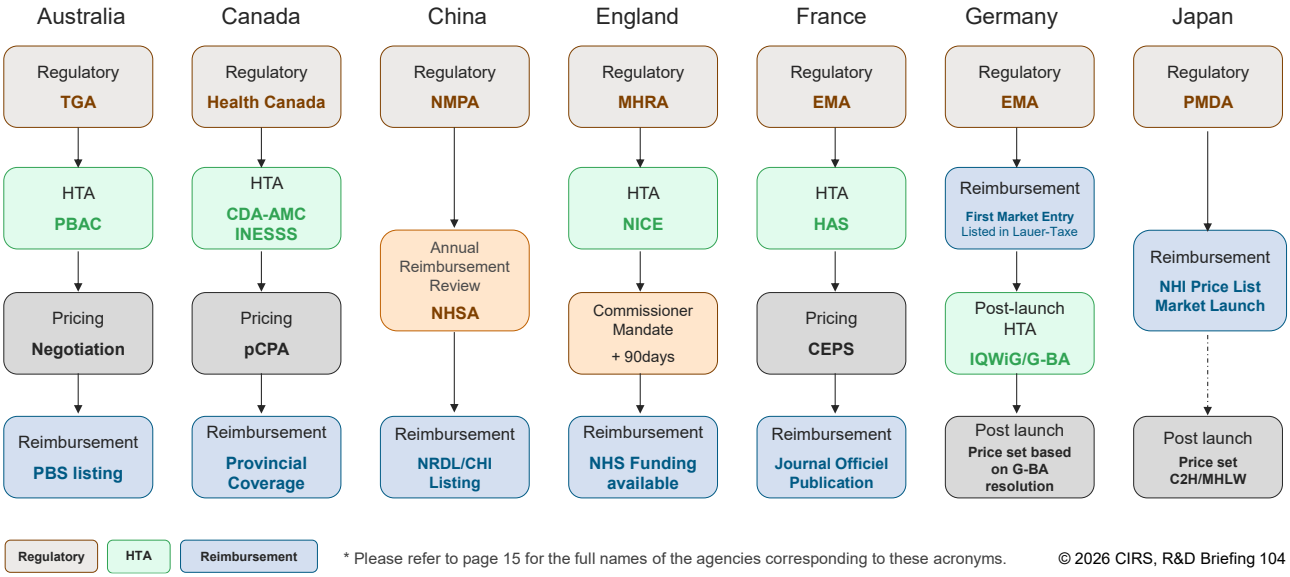
Global HTA and Reimbursement Comparison

HTA and reimbursement decision-making processes differ across jurisdictions, with variations in institutionalisation and role of HTA, and process among HTA assessment and pricing and reimbursement decisions, as illustrated on below*.



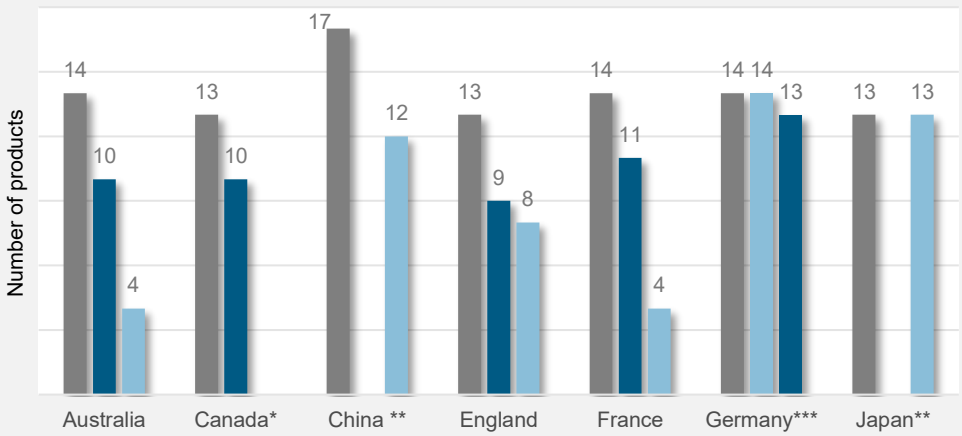
* Please refer to page 15 for the full names of the agencies corresponding to these acronyms.

For the 17 Class 1 innovative medicines developed by MNC, the HTA outcome and listing outcome were compared across studied jurisdictions (Fig 18).

Across jurisdictions, the process from regulatory approvals into reimbursement listings varies. For the cohort of products, the HTA status was tracked up until 31 December 2025 and reimbursement status until 31 March 2026 in the study jurisdictions. In Australia, the listed number of products is low considering its total approvals (4 of 14). In Canada, the number of HTA assessments is relatively high; however, listing decisions are made at the provincial level, as access depends on pCPA pricing negotiation and subsequent provincial funding decisions. In China, although no formal HTA agency exists, HTA principles are applied within the annual reimbursement cycle, with 12 out of 17 approved products listed. In Germany, products are launched immediately upon approval with free pricing, followed by a G-BA early benefit assessment that informs subsequent price negotiations for market access. In France, following HAS evaluation (SMR/ASMR), fewer products progress to listing at the time of study, indicating time taken for additional steps such as CEPS pricing negotiation after HAS assessment. In Japan, where no formal HTA agency exists for access decisions, all 13 approvals were listed through the NHI pricing, enabling market access. The official C2H/MHLW framework maybe used to adjust prices after listing.

Figure 18. Comparison of HTA Assessment and Reimbursement Status for Class 1 Innovative Medicines by MNC

(n) =number of product



*Canada HTA agency refers to CDA-AMC,the reimbursement decision is provincial and not included in the study

**No formal HTA agencies in the reimbursement decision making in China and Japan

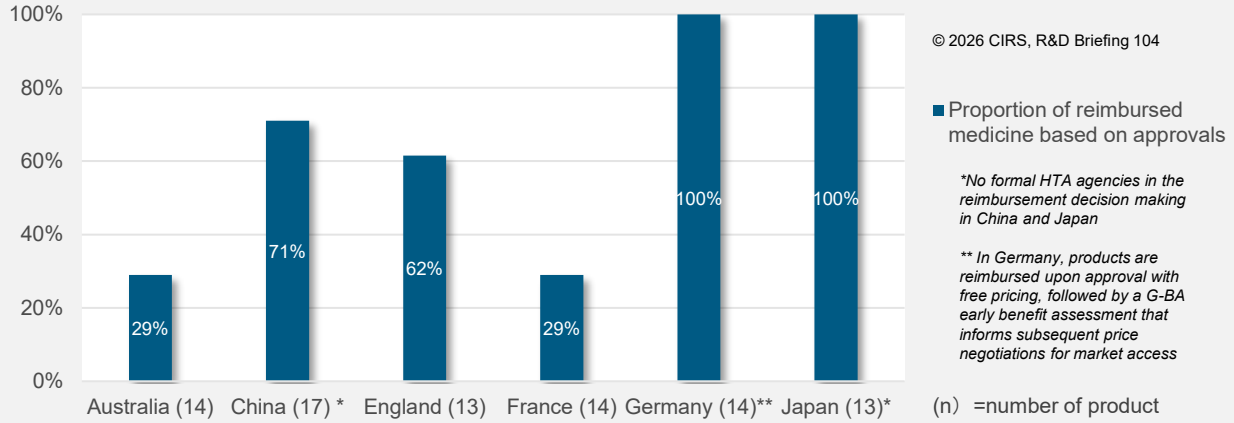
*** In Germany, products are reimbursed upon approval with free pricing, followed by a G-BA early benefit assessment that informs subsequent price negotiations for market access

Global Reimbursement Comparison

The proportion of approved products that were reimbursed varies across jurisdictions.

The highest rate of reimbursement was observed in Japan and Germany (100%), where market launch is available shortly after regulatory approval, followed by China (71%). In contrast, lower listing proportions were observed in Australia and France (29%). The variation in listing proportions across jurisdictions reflects differences in the healthcare system, HTA's role, and the processes required to achieve listing following a positive HTA recommendation.

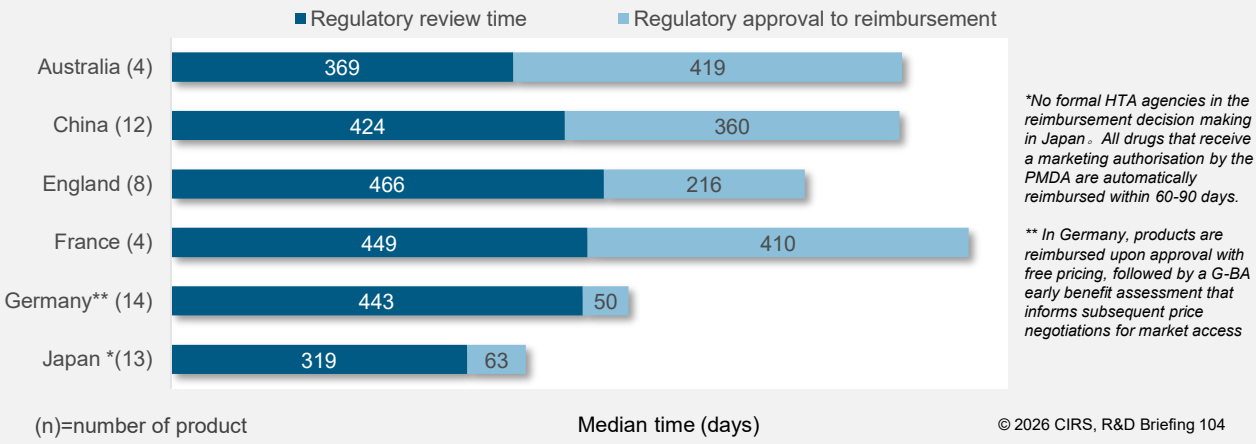
Figure 19. Proportion of approved Class 1 innovative medicines that were reimbursed, by MNC



For reimbursed products, the time from regulatory approval to reimbursement varied across jurisdictions (Fig 20). In Germany and Japan, where reimbursement is possible shortly after regulatory approval, relatively short median times of 50 days and 63 days were observed, respectively. By contrast, longer timelines were seen in systems with formal HTA processes that influence pricing and reimbursement decisions, including Australia (419 days) and France (410 days), while a shorter timeline was observed in England (216 days). In China, where NHSA review is conducted on an annual cycle rather than on a rolling basis, the median time from approval to reimbursement for this cohort was 360 days. This annual process means that products not submitted in time for a given cycle may experience an additional year of delay.

It is also important to note that differences in reimbursement processes across jurisdictions contribute substantially to time to listing. In Germany, the IQWiG/G-BA outcome does not determine whether a product is reimbursed, but rather affects pricing, unless a company chooses to withdraw the product from the market following an unfavourable pricing outcome. In Japan, HTA principles can be applied after listing for price adjustment rather than as a prerequisite for access, and products are typically listed through the NHI pricing system shortly after regulatory approval, resulting in shorter timelines to market launch.

Figure 20. Median time from Regulatory Submission to Reimbursement for Class 1 Innovative Medicines Developed by MNC



DEFINITIONS

Approval time
Time calculated from the date of submission to the date of approval by the agency. This time includes agency and company time.

Biological
A substance isolated from animal tissues or product produced by recombinant DNA or hybridoma technology and expressed in cell lines, transgenic animals or transgenic plants for therapeutic, prophylactic or in vivo diagnostic use in humans.

Chemical entity
An entity produced by chemical synthesis.

Class 1 innovative medicines
Products not previously approved in China or overseas at the time of NDA submission, representing first-in-class or globally novel therapies.

Applications that are excluded from the study:

- Vaccines
- Traditional Chinese medicines

Company type:
Domestic companies were defined as companies headquartered in China with primary control over product discovery and development.
Multinational companies (MNC) were defined as companies headquartered outside China, including cases where NMPA approval was granted to a China registered subsidiary of a multinational group (for example, locally incorporated manufacturing or commercial entities).

Expedited review
Refers to EMA 'Accelerated Assessment', FDA/PMDA/Health Canada/NMPA/TGA 'Priority Review' and Swissmedic 'Fast-track'.

Facilitated regulatory pathway
Regulatory pathway designed to facilitate availability, review and/or approval of medicines where there is an unmet medical need by providing alternatives to standard regulatory review routes.

NMPA Approval Classification
Chemical drugs
Class 1: Innovative drugs that have not been marketed in China or overseas. They refer to drugs that contain new compounds with clear structures and pharmacological effects and have clinical values.
5.1 Original drugs and modified drugs that have been marketed overseas and are under application for being marketed in China.

Therapeutic biological products
Class 1: Innovative therapeutic biological products that have not been granted marketing authorisation in or outside China
Class 3.1: Biological products that are manufactured outside China, having marketing authorisation outside China, and applying for marketing authorisation in China.

Reimbursement
Defined as the inclusion of an approved medicine on a country's public reimbursement list, or its eligibility for reimbursement under a country's public health insurance system.

Country specific interpretation depends on the structure of the healthcare system, the existence and role of HTA agencies, and the sequence of pricing and reimbursement processes, including the role of HTA.
(Continued on the next page)

Jurisdiction	Regulator	HTA	Reimbursement	Reimbursement Date Defined in This Study	Process Notes
Australia	TGA	PBAC	PBS listing	Date of PBS listing	Centralised HTA and reimbursement. Positive PBAC recommendation followed by pricing negotiation, then PBS listing marks access.
Canada	Health Canada	CDA-AMC / INESSS	Provincial listing decisions (post pCPA)	Date of provincial formulary listing (not assessed in this study)	HTA recommendation is advisory. Access depends on pCPA negotiation and separate provincial decisions, leading to individual provisional uptake.
China	NMPA	No formal HTA for listing	NRDL / CHI inclusion	NRDL / CHI List publication date	Centralised negotiation led by NHSA. Annual updates. Listing linked to price negotiation and inclusion in reimbursement list.
England	MHRA	NICE	NHS Mandatory funding obligation	NICE recommendation date + ~3 months	Legally mandated funding within 3 months of NICE guidance (extensions possible). Actual uptake may vary across NHS trusts.
France	EMA	HAS	Publication in Official Journal	Official Journal publication date	HAS assesses clinical value (SMR/ASMR), followed by CEPS price negotiation. Listing occurs upon publication in Official Journal.
Germany	EMA	IQWiG / G-BA	Market Entry	First Market Entry date	Early benefit assessment followed by price negotiation. Free pricing at launch; negotiated price applies after AMNOG process.
Japan	PMDA	No formal HTA for listing	NHI price listing and market launch	NHI listing / Market Launch date	Pricing determined centrally. HTA (cost-effectiveness) may be applied selectively post-listing for price adjustment rather than access decision.

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LIST OF ABBREVIATIONS

CDA-AMC – Canada's Drug Agency

CEPS – Comité Économique des Produits de Santé

CHI – Commercial Health Insurance

C2H - Center for Outcomes Research and Economic Evaluation for Health

EMA – European Medicines Agency

FDA – Food and Drug Administration

G-BA – Gemeinsamer Bundesausschuss

HAS – Haute Autorité de Santé

INESSS – Institut national d'excellence en santé et en services sociaux

IQWiG – Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen

MHRA – Medicines and Healthcare products Regulatory Agency

NHSA – National Healthcare Security Administration

NHS – National Health Service

NHI – National Health Insurance

NICE – National Institute for Health and Care Excellence

NMPA – National Medical Products Administration

NRDL – National Reimbursement Drug List

PBAC – Pharmaceutical Benefits Advisory Committee

PBS – Pharmaceutical Benefits Scheme

PMDA – Pharmaceuticals and Medical Devices Agency

pCPA – pan-Canadian Pharmaceutical Alliance

Swissmedic – Swiss Agency for Therapeutic Products

TGA – Therapeutic Goods Administration

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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.

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