R&D BRIEFING 102

Tracking Availability in China of Medicines Approved in Six Key Global Markets

CIRS Centre for Innovation in Regulatory Science

INTRODUCTION

All approved medicines have been rigorously assessed by regulatory authorities to ensure their benefits outweigh the risks. Today, pharmaceutical companies are increasingly focused on integrated global drug development strategies, with the aim of achieving worldwide registration. This approach enables them to make their new active substances (NASs) available to patients globally in a timely manner.

Since 2002, CIRS has benchmarked regulatory agencies using a methodology developed in collaboration with agencies to enable like-for-like comparisons. Published annually since 2012, our briefings[1] review the performance of six major regulatory agencies: the U.S. 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). These briefings provide unique insights into regulatory performance, highlight areas for improvement, and support strategic planning by companies and agencies.

In recent years, there has been significant progress in reducing delays in new drug approvals in China. The introduction of expedited pathways in 2020, such as breakthrough, conditional, priority and special review pathways, has supported accelerated development and approval of drugs with significant clinical value or for urgent health needs[2].

This study expands on the CIRS regulatory benchmarking method, exploring NASs approved between 2019-2023 by six regulatory agencies in Australia, Canada, Europe, Japan, Switzerland and the US, and assessing their regulatory status in China by January 2025. 25 NASs approved by all seven regulators were classified as 'internationalised medicines'. This briefing focuses on the submission and approval trends of these internationalised medicines.

CONTENTS

References

1. Lara J, Kermad A, Bujar M & McAuslane N (2025) R&D Briefing 101: New drug approvals in six major authorities 2015–2024: Trends in an evolving regulatory landscape. Centre for Innovation in Regulatory Science, London, UK.

2. Sharpe J, Bujar M, Kermad A, Wang T & McAuslane N (2022) R&D Briefing 84 : China's evolving regulatory landscape: What are the opportunities and challenges? Centre for Innovation in Regulatory Science, London, UK.

METHODOLOGY

Step 1 — **Identify common approvals across all six agencies**

NASs approved between 2019-2023 by all six agencies in Australia, Canada, Europe, Japan, Switzerland, and the US were identified (38 in total).
The characteristics of the NASs were extracted, including the ATC code, regulatory review pathway, orphan designation, regulatory timelines (submission and approval date), and the size of the company.

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

For each of the NASs identified in step 1, the regulatory information was searched by the generic name on the official website of CDE (Center for Drug Evaluation) to determine the regulatory status. Regulatory status was recorded as: not submitted, submitted and under review, reviewed and approved. Rejections were not included.

Data Source:
国家药品监督管理局药品审评中心:信息公开:受理品种信息

Step 3 — **Collect regulatory information of NMPA approvals**

For the approved NASs identified in step 2, the assessment report was reviewed, and the relevant information extracted as below:

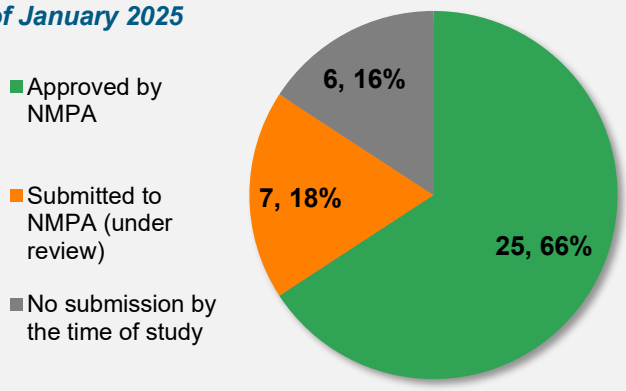
- Registration type: 注册分类
- Acceptance date: 承办日期
- Approval date: 发证日期
- Regulatory pathway: 附条件批准，优先审批，突破性治疗药

Data Source:
国家药品监督管理局药品审评中心-信息公开-上市药品信息

Step 4 — **Analyse trends for internationalised medicines**

Of the 38 NASs identified from Step 1, 25 were approved by NMPA, China, by Jan 2025 and 7 were under review (Figure 1)
These 25 NASs are defined as internationalised medicines. This briefing analysed the trend of the 25 internationalised NASs in terms of their approval characteristics, review timelines, pathways and submission pattern.

Figure 1. The registration status in China of 38 NASs approved between 2019-2023 in Australia, Canada, US, Europe, Switzerland and Japan, as of January 2025



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Between 2019 and 2023, a total of 38 NASs were approved by all six major regulatory agencies. Of these 38 NASs, 25 (66%) were approved by NMPA by January 2025, with a further 7 NASs under review.

These 25 NASs, approved by all seven agencies, were defined as 'internationalised NASs' and form the basis of the analysis in this briefing.

Of the 25 NASs, 64% were chemical entities and 36% were biological/biotech. 15 NASs were anti-cancer and immunomodulating agents, and 12 NASs were designated as Breakthrough Therapies by FDA.

KEY FINDINGS

Overview of internationalised NASs

- 25 NASs were approved by all seven agencies (FDA, EMA, NMPA, PMDA, TGA, Health Canada, Swissmedic) and were defined as 'internationalised medicines' in the briefing.
- Drug types: 64% chemical drugs; 36% biologics. Therapeutic focus: 60% Antineoplastic and immunomodulating agents.
- Flexible regulatory pathways: 76% of NASs approved by FDA were through priority review, followed by 56% by PMDA and 48% by NMPA.

Submission Patterns and Global Rollout Timing

- FDA was usually the first agency to receive submissions (84% of the NASs), followed by EMA. Submission patterns to PMDA were variable, while Health Canada was typically 4th and TGA 6th in order of submission among all seven regulators.
- China had the longest median submission gap (822 days), making it often the last jurisdiction for submission. Despite the lag, there was notable variation (IQR 688 days) in when drugs were submitted to NMPA, suggesting differences in company strategy.
- Global coordinated filing is a key submission strategy for companies. 11/25 NASs were submitted to all seven agencies within two to three years, while six NASs achieved full global submission within one year.

Review Timelines and Expedited Approvals

- FDA had the shortest median approval time (244 days) among all agencies.
- Expedited review pathways were most frequently used by FDA, PMDA and NMPA. This contributed to NMPA's comparable review timelines (390 days median) with other regulators. However, a large submission gap to NMPA resulted in a longer rollout time.
- 12 of 25 NASs received NMPA priority review, of which two were also granted as breakthrough therapies and four were approved under conditional approval.

Internationalisation of NASs approval

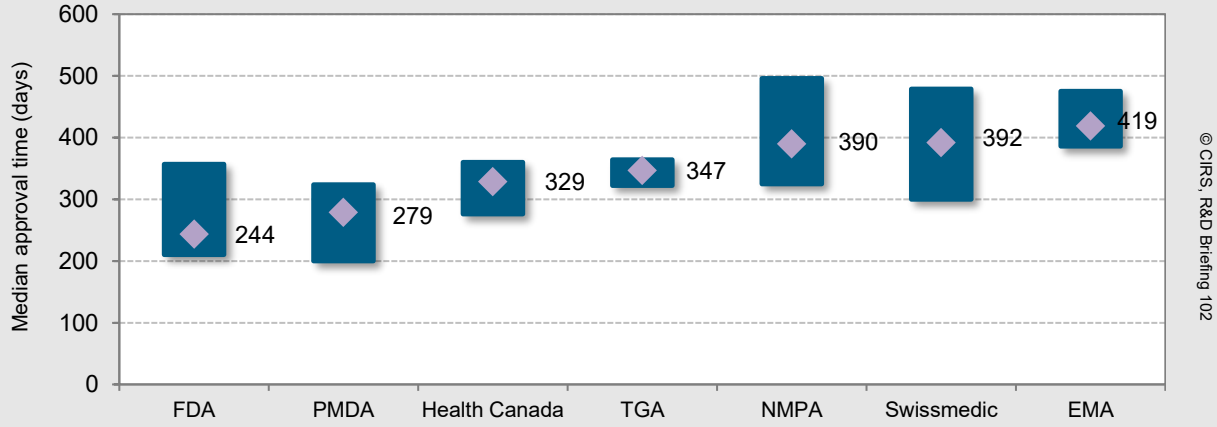
- Cumulative analysis showed that FDA approved 70% of internationalised NASs first or within a month of first worldwide approval. Approvals by the other agencies followed relatively quickly, except for NMPA, which showed a delay.
- The observed differences in overall rollout time reflect not only regulatory approval timelines, but also companies' global submission strategy.

Deep dive in China

- Class 1 NASs, defined as innovative new chemical drugs not yet approved anywhere globally, were submitted to NMPA a median of 151 days ahead of their first global approval, resulting in the shortest observed approval gap of 334 days between NMPA and the first worldwide approval.
- Submission gaps between NMPA and the six other regulators varied widely, with the shortest median gap observed with Japan's PMDA (347 days). There were cases where companies submitted to NMPA ahead of the other agencies, signalling early consideration of China in global regulatory strategies.

OVERVIEW

*Figure 2. Regulatory approval time comparison of 25 internationalised medicines**



Approval time = Time from the submission to approval at the local jurisdiction

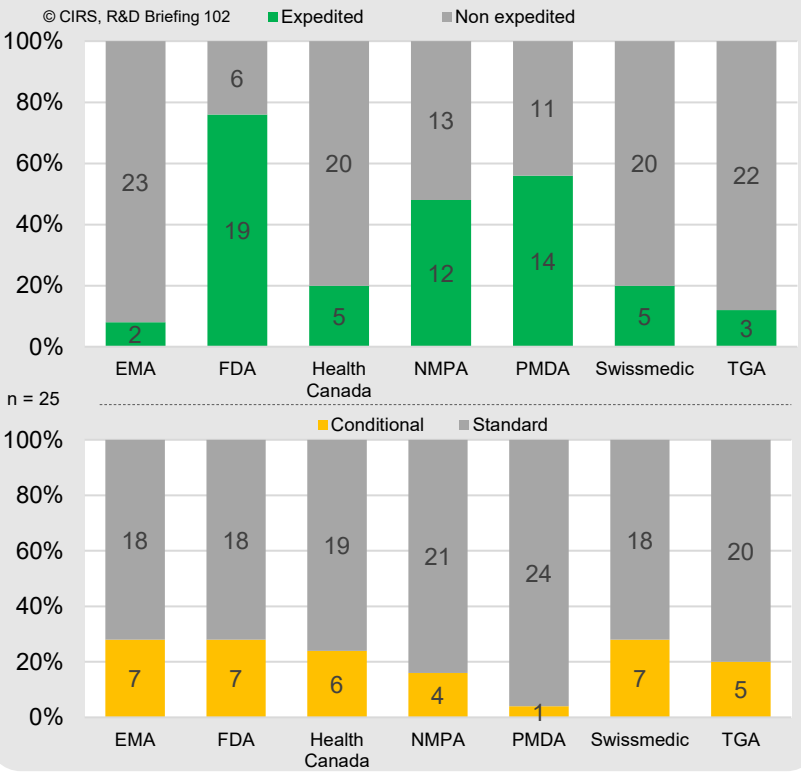
n = 25

** Products approved between 2019-2023 by all six regulator (FDA, EMA, PMDA, TGA, Health Canada, Swissmedic) and approved by NMPA in China by Jan 2025*

For the same cohort of 25 internationalised NASs, the FDA had the shortest median approval time with the highest proportion of priority reviews.

The approval timelines for the 25 internationalised NASs were assessed based on the time taken from submission to approval within each jurisdiction (Figure 2). FDA had the shortest median approval time at 244 days, while the EMA had the longest median approval time at 419 days. Approval times in TGA were the most consistent, with an interquartile range (IQR) of 42 days, whereas Swissmedic showed the greatest variability with IQRs of 179 days. These differences in approval times are associated with the specific regulatory processes and review pathways utilised by each agency.

Figure 3. Proportion of 25 internationalised NASs approved through a flexible regulatory pathway

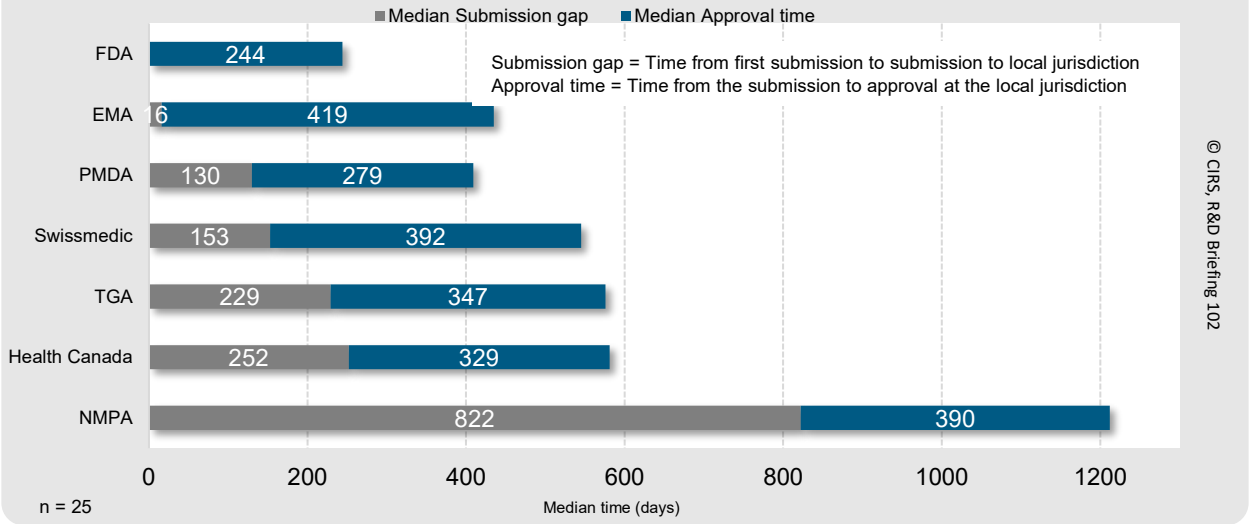


The FDA had the highest proportion of internationalised NASs approved through an expedited review pathway (FDA priority review), followed by PMDA and NMPA. The use of expedited review pathways could contribute to faster review times comparing to standard reviews (Figure 3).

Conditional approvals were utilised when the available evidence was insufficient for full marketing authorisation but justified making the product accessible to patients sooner, under the condition that additional data will be provided later. Among the internationalised NASs, the FDA, EMA, and Swissmedic granted the highest number of conditional approvals.

INTERNATIONAL APPROVAL

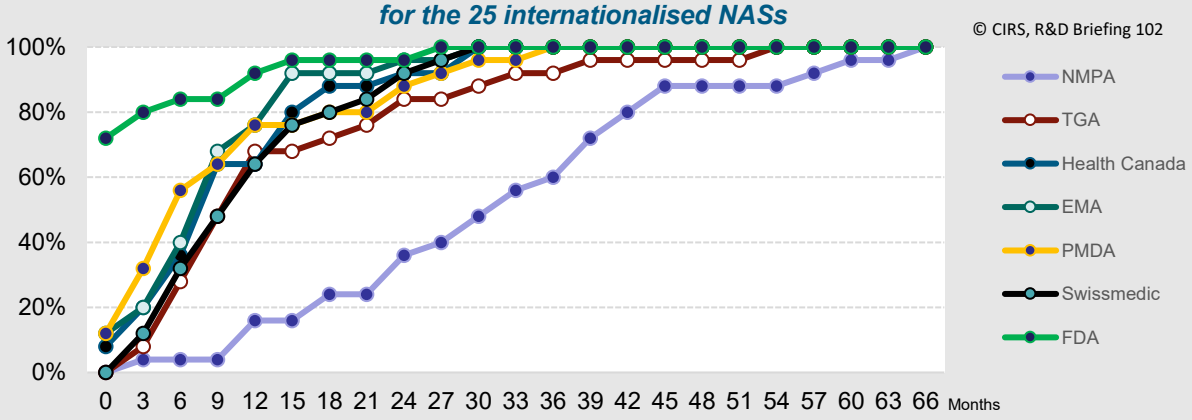
Figure 4. Internationalised medicine rollout time comparison



While NMPA's median approval time was broadly comparable to other agencies, it had the longest median submission gap, leading to a long overall rollout timeline.

The international rollout time of the 25 NASs was compared across the seven jurisdictions (Figure 4). This was assessed by examining the median submission gap, defined as the time from the first global submission to the local submission, followed by the median approval time within each jurisdiction. China had the longest median submission gap of over two years (822 days), while the other jurisdictions had much shorter submission gaps, all under nine months. Consequently, although the median approval times were broadly comparable across jurisdictions, the longer submission gap in China resulted in an overall extended rollout timeline of over 3 years.

Figure 5. A cumulative analysis of time taken from first worldwide approval to local approvals for the 25 internationalised NASs



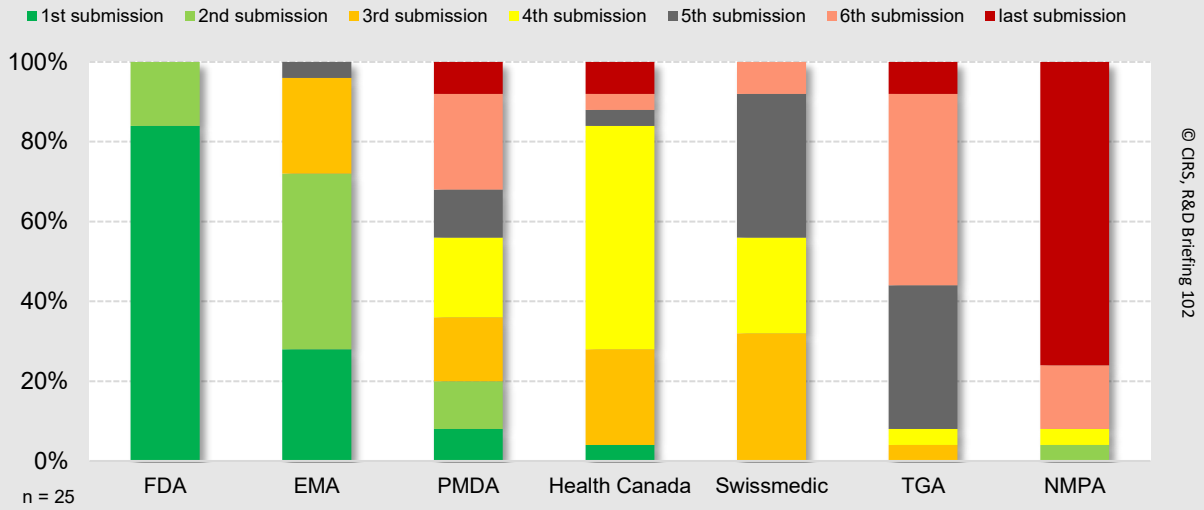
80% of the 25 NASs were approved by all agencies within 2 years apart from NMPA

A cumulative analysis assessed the time taken for the 25 internationalised NASs to receive local regulatory approval following their first global approval (Figure 5). FDA had the fastest and earliest approvals, with over 70% of NASs approved first by FDA or within one month of first approval. Approvals at the EMA, PMDA, Health Canada, TGA, and Swissmedic, followed relatively quickly.

There was a delay to NMPA approval, the observed differences reflect not only regulatory approval timelines, but also when companies choose to file in each market—likely influenced by commercial, strategic, and operational factors.

INTERNATIONAL SUBMISSION STRATEGY

Figure 6. Submission strategy of the 25 internationalised medicines



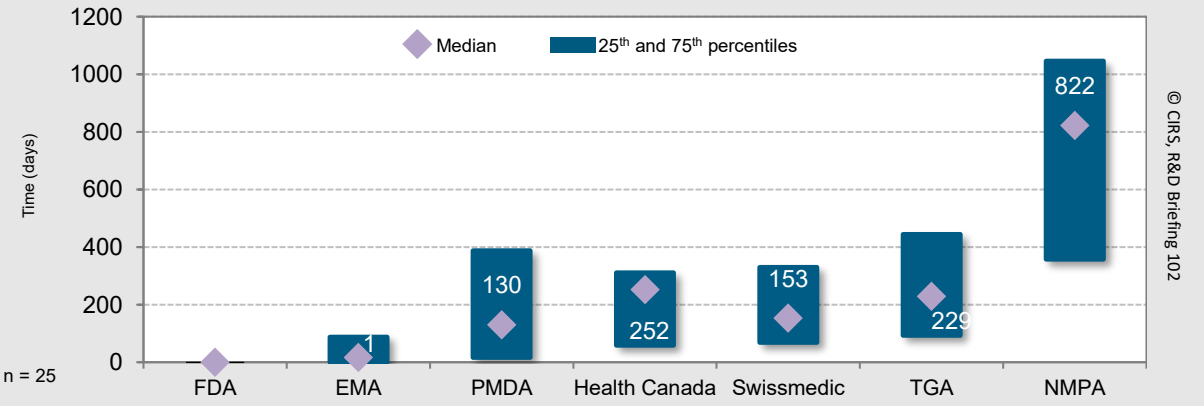
Over 80% of the 25 NASs were first submitted to the FDA. EMA followed closely, while China was often the last jurisdiction for submission.

For each product, the order of submission across the seven jurisdictions was ranked from first to last. Among the 25 NASs, the proportion of submissions at each submission rank was analysed by jurisdiction (Figure 6). The US was prioritised from a submission strategy perspective, with over 80% of the NASs submitted to the FDA first. The EU followed as either the first (28%) or second (44%) jurisdiction for submission. In contrast, most NASs were submitted to China last. Interestingly, submissions to Japan showed a diverse pattern with variation in submission order. Canada was most often the fourth jurisdiction in the sequence, while Australia tended to be the sixth among all seven jurisdictions.

Although China showed a longer median submission gap, there was considerable variation, with an interquartile range (IQR) of 688 days, suggesting that different approaches were taken when submitting these NASs to the NMPA (Figure 7). This variation may be related to factors such as company size, submission timing and registration type, which are discussed further on in the briefing (Figure 11).

In addition to jurisdiction level analysis, a global perspective was considered to reflect the importance of coordinated submission strategies. Timing from first to last submission across all jurisdictions (data not shown) showed that 14 of 25 NASs were submitted within two to three years, six within one year, and five took more than three years to complete submissions across all seven agencies.

Figure 7. Submission gap of NASs from first worldwide submission to local jurisdiction



FOCUS ON CHINA

A deep dive into the NMPA approvals of the 25 internationalised NASs, analysed by registration type:

- Class 1: Innovative chemical drugs that have not been marketed in China or overseas.
- Class 3.1: Therapeutic biological products that are manufactured outside China, have marketing authorisation outside China, and are applying for marketing authorisation in China.
- Class 5.1: Original or modified chemical drugs that have been marketed overseas and are under application for being marketed in China.

Nearly half of the internationalised NASs (12 of 25) received NMPA priority review to expedite the review process. Of these 12 priority NASs, two were granted as breakthrough therapies and four were approved under conditional approval by NMPA (Figure 8).

Figure 8. NMPA approvals through a flexible regulatory pathway

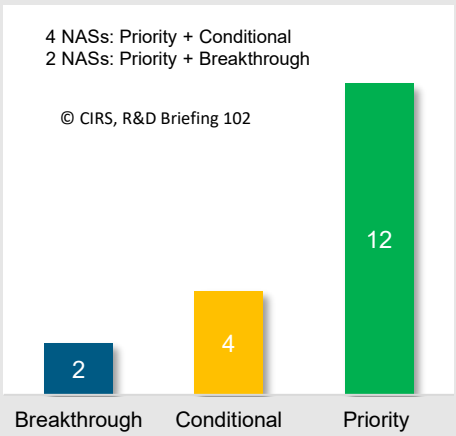


Figure 9. Approval gap: from first worldwide approval to NMPA approval date, by registration type

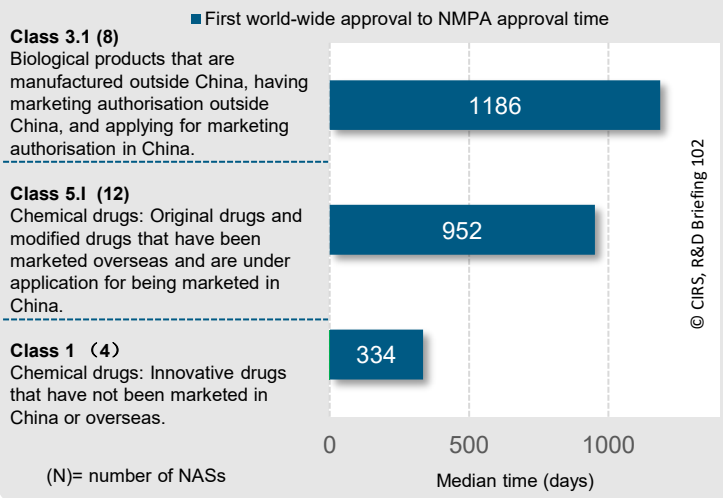
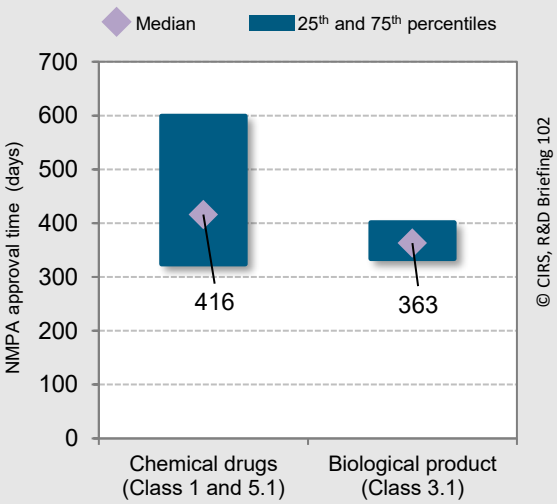


Figure 10. NMPA approval time by product type



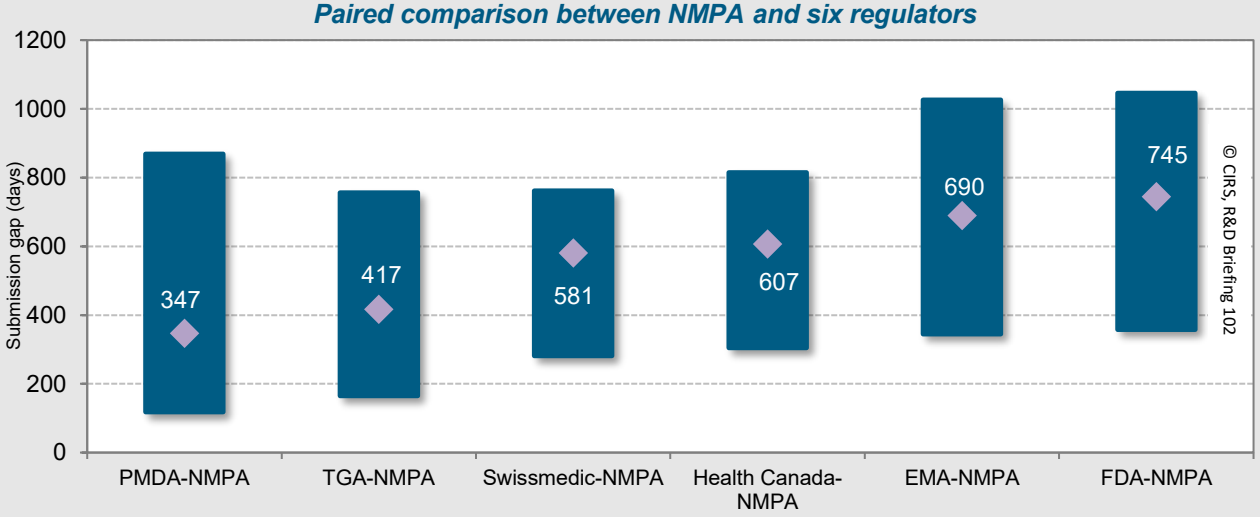
Class 1 innovative new chemical drugs were submitted to the NMPA before receiving their first worldwide approval, resulting in the shortest observed approval gap of 334 days between NMPA and the first worldwide approval.

The time from first worldwide approval to NMPA approval were analysed for the 25 internationalised NASs (Figure 9). By definition, Class 1 chemical NASs were submitted before worldwide approval (a median of 151 days in advance), whereas the approval gap for non-Class 1 NASs largely reflected delayed submissions, with Class 5.1 chemical drugs and Class 3.1 biologics filed in China a median of 527 and 838 days, respectively, after first global approval. NMPA review times were comparable, with medians of 416 and 363 days for chemical and biological NASs, respectively.

All 4 Class 1 NASs were developed by top companies (defined in the study as a pharmaceutical company with R&D spending >3 billion USD in 2021). Class 5.1 NASs were submitted to the NMPA a median of 527 days after their first global approval. Class 3.1 biologics showed the longest gap, with a median of 838 days between global approval and NMPA submission, but they had the shortest approval time among all three registration types.

FOCUS ON CHINA (CONT.)

Figure 11. Submission gap of 25 internationalised NASs
Paired comparison between NMPA and six regulators



Submission gap = Time from the submission date of examined regulator to NMPA submission

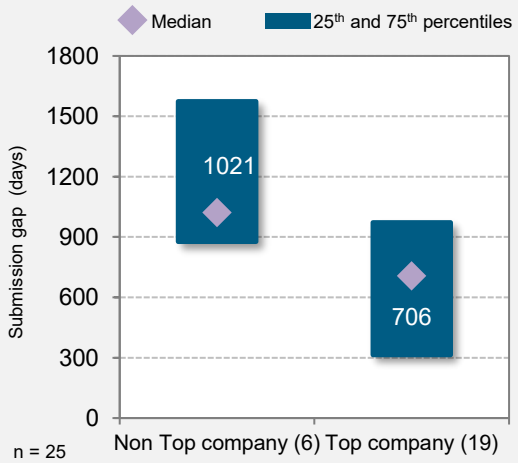
Submission gaps between NMPA and the six regulators varied widely, with the shortest gap occurring between NMPA and Japan's PMDA.

The analysis of submission dates among the 25 internationalised NASs showed varying gaps between NMPA and the six major regulators. The shortest median gap was with Japan's PMDA (347 days), followed by Australia's TGA (417 days). The longest gap was with the FDA (745 days), which was most often the first to receive submissions (Figure 11).

In a few cases, NMPA received earlier submissions than other agencies: four NASs were submitted to NMPA before TGA, three before Health Canada, two before PMDA, two before Swissmedic and one before EMA (data not shown). While limited, these cases reflected early signs of companies' consideration of China in their global regulatory strategy. Monitoring future trends will be key to tracking progress, considering the NMPA's goal of simultaneous global development, regulatory submission, and market launch in China.

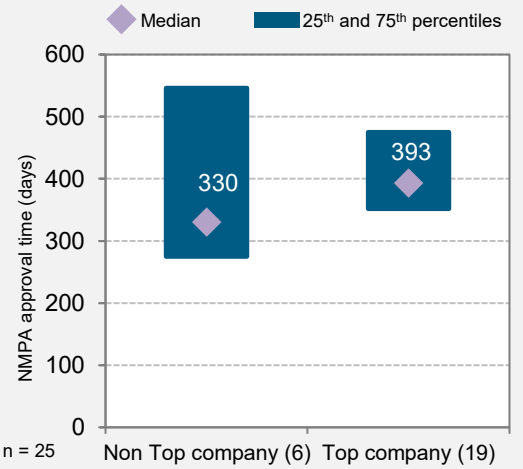
Company size may be a potential driver in the rollout of the internationalised medicines (Figure 12 and 13). The top companies generally showed a quicker submission to NMPA, when compared to non-top companies. Slightly longer NMPA approval times but less variance were observed for NASs developed by top companies.

Figure 12. Variation in submission gap to NMPA by company size



Submission gap = Time from first worldwide submission to NMPA submission
Top company = Top R&D Spend Companies in 2021

Figure 13. Variation in NMPA approval time by company size



Approval time = Time taken from submission to NMPA to approval by NMPA
Top company = Top R&D Spend Companies in 2021

DEFINITION: Flexible Regulatory Pathway

	What is it?	Advantage
FDA Priority Review	A process that directs resources to the evaluation of drugs that represent significant improvements in safety or effectiveness compared with standard applications	• Review time shortened from 10 to 6 months
FDA Accelerated Approval	Regulation allowing drugs for serious conditions that fulfil an unmet medical need to be approved based on a surrogate endpoint	• Conditional approval granted using surrogate endpoint(s) from phase 2 trials or interim phase 3 data; confirmatory trials with hard clinical endpoints required
FDA Breakthrough Therapy	A process designed to expedite the development and review of drugs that may demonstrate substantial improvement over available therapy	• All Fast Track designation features • Intensive guidance on an efficient drug development program from phase 1 • Organisational commitment with senior managers • Option for priority review
EMA Accelerated Assessment	A process designed to expedite NASs of major interest in terms of public health and therapeutic innovation	• Committee for Medicinal NASs for Human Use (CHMP) opinion shortened from 210 days to 150 days
EMA Conditional Approval	Regulation allowing drugs fulfilling unmet medical need for severe, life-threatening or rare diseases to be approved with limited clinical safety or efficacy data, provided a positive benefit-risk balance	• Conditional approval is granted before all data are available (valid for one year, on a renewable basis; once pending studies are provided, it can become a "normal" marketing authorisation)
PMDA Priority Review	A process that provides faster access to new therapies responding to high medical needs; includes NASs such as orphans, HIV medicines	• Review time shortened from 9 to 6 months
PMDA Conditional Early Approval	A system to put highly useful and effective drugs for treating serious diseases into practical use as early as possible	• Early application through confirmation of a certain degree of efficacy and safety • Shorten overall review times for priority review NASs
Health Canada Priority	A fast-track status for medicines for severe, debilitating or life-threatening disease; to address unmet medical need and where a high therapeutic benefit can be expected	• Review time shortened from 300 to 180 days
Health Canada Conditional (NOC/c)	Authorisation to market a new promising drug with the condition that the sponsor undertakes additional studies to verify the clinical benefit	• Earlier marketing of promising drugs for serious conditions before the drugs have definitively demonstrated clinical efficacy

Defined as Expedited Review in the briefing

Defined as Conditional Approval in the briefing

DEFINITION: Flexible Regulatory Pathway

	What is it?	Advantage
Swissmedic Fast-Track	A rapid review of applications for severe, debilitating or life-threatening disease; to address unmet medical need and where a high therapeutic benefit can be expected	• Review time shortened from 330 to 140 days
Temporary authorisation	Temporary and conditioned authorisation of medicinal NASs for life-threatening or debilitating diseases, if they are compatible with health protection, a major therapeutic benefit can be expected, and no therapeutic alternative is available in Switzerland.	• Review time shortened from 330 to 140 days • A temporary authorisation granted for a maximum of two years
TGA Priority	A formal mechanism for faster assessment of vital and life-saving medicines for severe, debilitating or life-threatening disease, to address unmet medical need and where a high therapeutic benefit can be expected	• Review time shortened from 220 to 150 working days • Dynamic process with rolling questions and more flexible arrangements for accessing advice
TGA Provisional Approval	Time-limited provisional registration for certain promising new medicines where the benefit of early availability of the medicine outweighs the risk inherent in the fact that additional data are still required	• Conditional approval is granted based on preliminary clinical data (valid for a maximum of 6 years)
NMPA Priority Review	• A process designed to expedite the review of drug marketing authorisation applications for NASs with significant clinical value, including treatments for urgent clinical needs, major public health concerns, and rare diseases.	• The review timeline for drug marketing authorisation applications is 130 days; • For rare disease drugs with urgent clinical needs that have been marketed overseas but not marketed within the territory of the People's Republic of China, the review timeline is 70 days; • Where inspection, testing and approval of the adopted name are needed, priority will be given; • Technical dossiers may be supplemented after confirmation through communication.
NMPA Conditional Approval Procedure	A regulatory pathway allowing early market entry for drugs addressing serious or urgent health needs, based on preliminary clinical data, under the condition that further studies will be completed post-approval.	Conditional approval granted for • Drugs used for treating serious life-threatening diseases for which no effective treatment is available, whose efficacy has been verified by data in drug clinical trials and whose clinical values can be predicted • Drugs that are urgently needed for public health, whose efficacy has been demonstrated by data in drug clinical trials and whose clinical values can be predicted
NMPA Breakthrough Therapy Drug Procedure	A regulatory mechanism to expedite the development and review of innovative or modified new drugs for serious or life-threatening diseases, where existing treatment is unavailable or the new drug shows significant clinical superiority.	• The applicant may, during key stages of the drug clinical trial, submit consultation and communication requests to the CDE, and the CDE shall assign reviewers for communication; • The applicant may submit staged study data to the CDE, and the CDE shall, based on available study data, give comments or suggestions to the applicant on the study protocols for the next stage.

DEFINITION

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/Biotechnology product
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.

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.

Interquartile range (IQR)
The interquartile range is calculated as the difference between the 75th percentile and the 25th percentile of a distribution of measurements.

Internationalised medicine
For the purpose of this briefing, an internationalised medicine is defined as an NAS approved by all six major regulatory agencies in Australia, Canada, EU, Japan, Switzerland and the US between 2019-2023 that have also been approved by NMPA in China by January 2025. A total of 25 NASs fit this criteria and were included in this briefing.

New active substances (NASs)
A chemical, biological, biotechnology or radiopharmaceutical substance that has not been previously available for therapeutic use in humans and is destined to be made available as a 'prescription only medicine', to be used for the cure, alleviation, treatment, prevention or in vivo diagnosis of diseases in humans.

The term NAS also includes:

- An isomer, mixture of isomers, a complex or derivative or salt of a chemical substance previously available as a medicinal product but differing in properties with regard to safety and efficacy from that substance previously available
- A biological or biotech substance previously available as a medicinal product, but differing in molecular structure through changes to the nature of source material or manufacturing process and which will require clinical investigation
- A radiopharmaceutical substance that is a radionuclide or a ligand not previously available as a medicinal product.

Alternatively, the coupling mechanism linking the molecule and the radionuclide has not been previously available.

Applications that are excluded from the study:

- Vaccines
- Biosimilars
- Any other application, where new clinical data were submitted
- Generic applications
- Those applications where a completely new dossier was submitted from a new company for the same indications as already approved for another company
- Applications for a new or additional name, or a change of name, for an existing compound (i.e., a 'cloned' application).
- Emergency use or special authorisations derived from an emergency (e.g. COVID-19 pandemic)

NMPA registration type
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.
Class 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, have marketing authorisation outside China, and are applying for marketing authorisation in China.

Submission gap
Time calculated from the date of first worldwide submission to the date of submission to local regulator.

Top company
Pharmaceutical company with R&D spending ≥3 billion USD in 2021.

Company R&D spending data was obtained from the Pharm Exec Top 50 Companies (2022) available at https://www.pharmexec.com/view/2022-pharm-exec-top-50-companies

R&D Briefing 102

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