

Supplementary information

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# Approvals by the China NMPA in 2025

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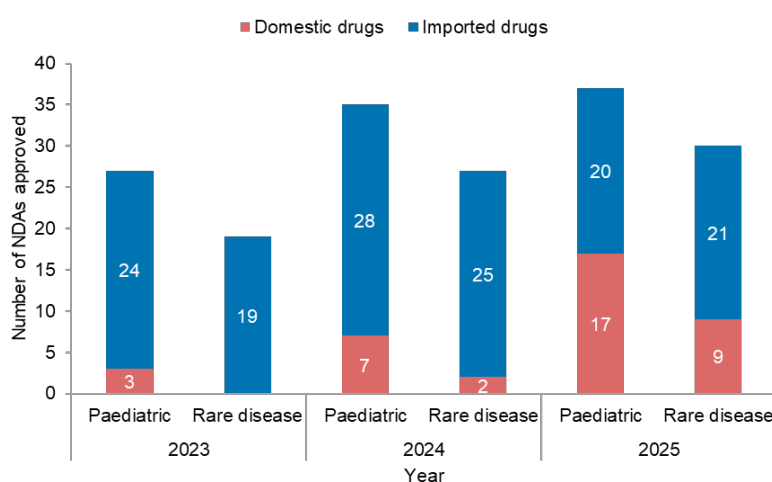
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authors and unedited

### Dataset assembly, analysis and classifications

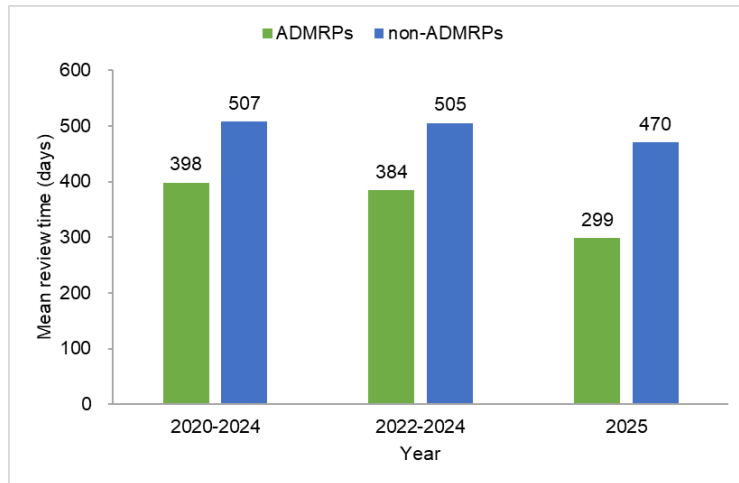
In this analysis, new drug applications (NDAs) include chemical drugs in classes 1, 2 and 5.1, therapeutic biologic products in classes 1, 2, 3.1 and 3.2, and traditional Chinese medicines in classes 1, 2 and 3, as defined by the Provisions for Drug Registration 2020. Vaccines, biosimilars and *in vitro* diagnostic reagents are excluded. The list of NDAs in 2025, along with their acceptance date and approval dates, was obtained from drug approvals published by China's National Medical Products Administration (NMPA) (<https://www.nmpa.gov.cn>). Additional information, including registration classification, marketing authorization holders and approved indications, was sourced from publicly available data provided by the Center for Drug Evaluation (CDE) of NMPA (<https://www.cde.org.cn>) and official releases from pharmaceutical companies.

In Figure 1a, drugs approved were categorized as “innovative drugs” or “modified drugs”, based on whether they were approved as new molecular entities, new biologics, or new prescriptions and preparations of TCMs not included in China's national drug standards, or were approved as new dosage forms or formulations, as new combinations, as new active ingredients, as new specifications or for new indications. In Figure 1b, indications approved were firstly classified into different therapeutic areas based on etiology, while indications with unknown or complex etiologies were classified by disease site.

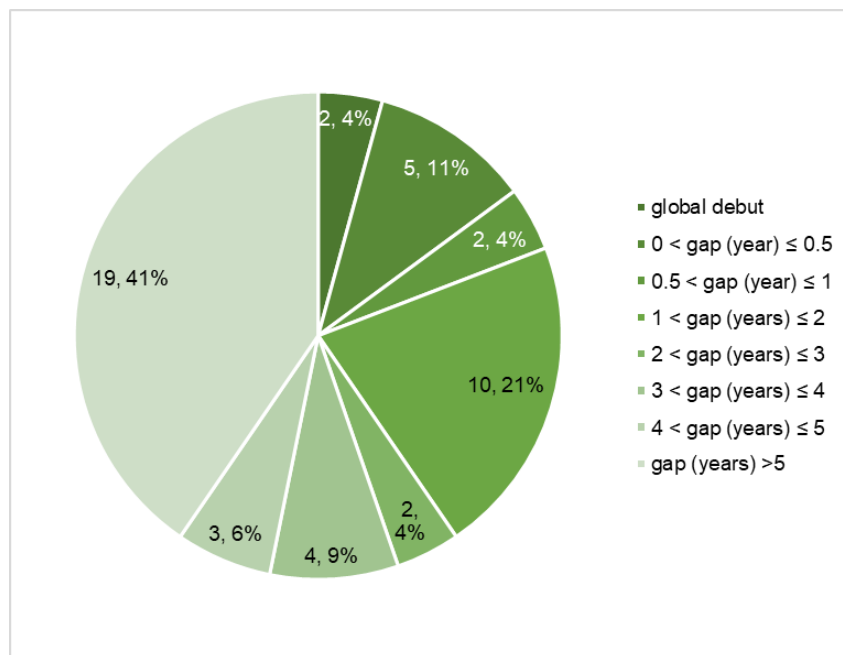
In Figure 2a, the number of class 1 innovative drugs approved each year was based on drug approval documents released by the NMPA, and it excluded vaccines and *in vitro* diagnostic reagents. This count might differ from the number of class 1 innovative drugs reported in the Drug Review Annual Reports published by the CDE, because the annual reports listed class 1 drugs that were recommended for NMPA's final approval. For instance, the CDE might have recommended Takeda's mobocertinib succinate for approval in late 2022 and therefore included it in the 2022 Drug Review Annual Report, but it was finally approved on January 10, 2023.



**Supplementary Fig. 1 | Numbers of paediatric and rare disease drugs approved by the NMPA from 2023 to 2025.** Data are based on drug approval documents issued by the NMPA. Vaccines, biosimilars and *in vitro* diagnostic reagents are excluded.



**Supplementary Fig. 2 | Mean review time of approvals through the Accelerated Drug Marketing Registration Procedures (ADMRPs) or non-ADMRPs across three periods: 2020-2024 (5-year average), 2022-2024 (3-year average), and 2025.** The review time for drugs approved in 2025 was calculated based on their respective acceptance and approval date, with two drugs excluded due to missing acceptance dates. Data on the review time for new drugs from 2020 to 2024 was derived from the study “The Impact of Accelerated Drug Marketing Registration Procedures on the Review and Approval of New Drugs in China” (DOI: <https://doi.org/10.1038/d41573-025-00070-6>).



**Supplementary Fig. 3 | Time gaps between the approval of an imported innovative drug in China and its first approval globally.** The chart shows the number and proportion of drugs with the time gap indicated for the 47 imported innovative drugs approved by the NMPA in 2025.

**Supplementary Box 1 | Current drug registration classification in China as defined by the Provisions for Drug Registration 2020.** Translated and modified from the Chinese version of official documents.

<b>Chemical drugs</b>		
Class 1	<ul style="list-style-type: none"> <li>① not yet been marketed in China or overseas</li> <li>② with clearly structured new molecular entities (NMEs), pharmacological effects, and clinical values</li> </ul>	
Class 2	<ul style="list-style-type: none"> <li>① not yet been marketed in China or overseas</li> <li>② with known active ingredients and significant clinical advantages</li> </ul>	Class 2.1: Optical isomers, salts, esters, or other simple derivatives
		Class 2.2: New dosage forms, new formulation processes, or new administration routes
		Class 2.3: New compound preparations
		Class 2.4: New indications
Class 3	<ul style="list-style-type: none"> <li>① manufactured by domestic applicants by imitating the original drugs that have been marketed overseas but not in China</li> <li>② consistent with the reference listed drugs in quality and efficacy</li> </ul>	
Class 4	<ul style="list-style-type: none"> <li>① manufactured by domestic applicants by imitating the original drugs that have been marketed in China</li> <li>② consistent with the reference listed drugs in quality and efficacy</li> </ul>	
Class 5	<ul style="list-style-type: none"> <li>① already been marketed overseas</li> <li>② under application for being marketed in China</li> </ul>	Class 5.1: Innovative drugs and modified drugs with significant clinical advantages
		Class 5.2: Generic drugs
<b>Therapeutic biological products (TBPs)</b>		
Class 1	not yet been marketed in China or overseas	
Class 2	<ul style="list-style-type: none"> <li>① based on biologics that have been approved in China or overseas</li> <li>② with improved safety, efficacy, quality control, and significant clinical advantages</li> </ul>	Class 2.1: New dosage forms, or new administration routes
		Class 2.2: New indications, or new target groups
		Class 2.3: New compound products
		Class 2.4: Major technical improvements
Class 3	already been marketed in China or overseas	Class 3.1: manufactured and marketed overseas, and applying for marketing authorization in China
		Class 3.2: marketed overseas, and applying for manufacturing and marketing authorizations in China
		Class 3.3: Biosimilars
		Class 3.4: Other biological products

### Traditional Chinese medicines (TCMs)

Class 1	① not been included in the national drug standards, drug registration specifications and the Catalogue of Ancient Classic and Famous Prescriptions ② not yet been marketed in China or overseas	Class 1.1: Combination of multiple decoction pieces or extracts
		Class 1.2: Extracts and preparations from single plants, animals, minerals and other substances
		Class 1.3: New Chinese medicinal materials and their preparations
Class 2	① not yet been marketed in China or overseas ② with significant clinical advantages	Class 2.1: New administration routes
		Class 2.2: New dosage forms
		Class 2.3: New indications
		Class 2.4: New production processes or changed excipients
Class 3	① compound preparations of TCMs originated from classic recipes ② complying with the provisions of the Law of the People's Republic of China on Traditional Chinese Medicine ③ with definite curative effects and obvious clinical advantages	
Class 4	① with identical name and identical recipes, dosage form, indication, usage and daily dosage as those of the listed Chinese traditional medicine ② no less safe, effective and controllable in quality	

**Supplementary Box 2 | Four accelerated drug marketing registration procedures (ADMRPs) in China as defined by the Provisions for Drug Registration 2020.** Translated and modified from the Chinese version of official documents.

ADMRPs	Definition
Breakthrough Therapy Drug Procedure	During clinical trials of a new drug (including innovative drug and modified drug), if it is intended for the prevention and treatment of a disease that seriously endangers life or significantly impacts the quality of life, and there is currently no effective method of prevention or treatment, or there is sufficient evidence demonstrating that the drug has a significant clinical advantage over existing treatments, the drug may apply for the breakthrough therapy drug procedure.
Priority Review and Approval Procedure	When applying for drug marketing authorization, the following drugs with significant clinical value may apply for the priority review and approval procedure: <ol style="list-style-type: none"> <li>1. Innovative drugs and modified drugs for the prevention and treatment of major infectious diseases and rare diseases, as well as drugs that are in clinical shortage.</li> <li>2. New varieties, dosage forms and specifications of paediatric drugs that conform to children’s physiological characteristics.</li> <li>3. Vaccines urgently needed for disease prevention and control, and innovative vaccines.</li> <li>4. Drugs included in the breakthrough therapy drug procedure.</li> <li>5. Drugs that meet the conditions for conditional approval.</li> <li>6. Other circumstances specified by the NMPA for priority review and approval.</li> </ol>
Conditional Approval Procedure	The conditional approval procedure applies to drugs for the treatment of serious life-threatening diseases without effective methods of treatment, or drugs urgently needed in public health, where the existing clinical trial data do not yet fully meet all requirements for a standard marketing authorization but have demonstrated efficacy and predictive clinical value. Approval under these circumstances can be based on surrogate endpoints, intermediate clinical endpoints, or early-phase clinical trial data, provided the applicant commits to fulfilling specific post-approval obligations.
Special Approval Procedure	When there is a threat of a public health emergency or after such an event has occurred, in order to expedite the approval of drugs needed for the emergency response, the NMPA may implement special approval procedure for drugs urgently needed in response to the public health emergency.