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Supplementary information

The impact of accelerated drug marketing registration procedures on the review and approval of new drugs in China

In the format provided by the authors and unedited

Data sources and analysis

The data for this analysis, including drug name, drug categories, acceptance date and approval date, mainly comes from the Drug Review Annual Reports and publicly available information on marketed drugs released by the Center for Drug Evaluation (CDE) of the National Medical Products Administration (NMPA) (https://www.cde.org.cn). The data for new drugs in 2024 are derived from official approval documents issued by the NMPA (https://www.nmpa.gov.cn), as the 2024 Drug Review Annual Reports had not been released before the submission of this manuscript. Generic drugs are not included in the analysis. Anti-COVID-19 drugs are excluded in the analysis due to the specificities.

The drug types, review timelines and therapeutic areas were analysed. Review times were calculated based on the acceptance date and the approval date. In addition, drugs were classified into different therapeutic areas according to ICD-11 (International Classification of Diseases 11th Revision), with some classified based on disease aetiology.

Four drugs with unidentified acceptance date or approval date were included in the total number but excluded from the analysis of review time. To ensure data rationality, drugs with review times exceeding 5 years were excluded from our analysis.

Supplementary Table 1 | Definitions of ADMRPs in the 2020 "Provisions for Drug Registration"

ADMRPs	Definition
Breakthrough Therapy Drug	During clinical trials, for innovative drugs or modified new drugs used for the prevention and treatment of serious life-threatening diseases or diseases but no effective means of prevention and treatment is available, or significantly clinically superior over current treatments with sufficient evidence is demonstrated, the applicant may apply for the breakthrough therapy drug procedure.
Conditional Approval	Drugs for the treatment of serious life-threatening diseases for which there is no effective means of treatment, and where there are data in clinical trials to confirm the efficacy and predict their clinical value; drugs that are urgently needed in public health, and clinical trials of drugs have shown efficacy and predict clinical value.
Priority Review and Approval	Shortage of drugs urgently needed in clinical practice, innovative drugs and improved new drugs for the prevention and treatment of major infectious diseases and rare diseases; new varieties, dosage forms and specifications of children's drugs that meet the physiological characteristics of children; urgently needed vaccines and innovative vaccines for disease prevention and control; drugs included in the Breakthrough Therapy Program; drugs that meet the conditions for approval, etc.
Special Approval.	When there is a threat of a public health emergency and after a public health emergency, NMPA may, in accordance with the law, decide to implement special examination and approval for the prevention and treatment drugs required for emergency response to public health emergencies.

Supplementary Table 2 | Review time of new drugs approved by NMPA from 2016 to 2024

Types of drug review	Mean (median) review time, day
ADMRPs	422 (421)
Non-ADMRPs	569 (425)

Supplementary Table 3 | Review time of new drugs approved by NMPA from 2016 to 2024

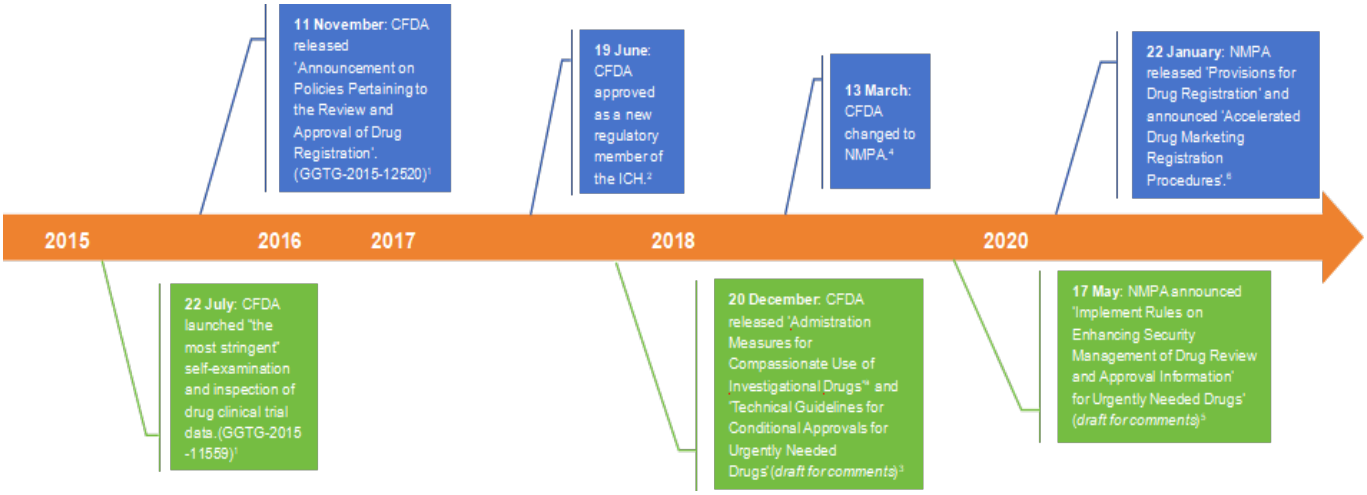
Types of drug review	Mean (median) review time, day	
	Imported drugs	Domestic drugs
ADMRPs	413 (421)	438 (420)
Non-ADMRPs	580 (424)	548 (424)

Approvals by drug origins. The origin of an approved new drug application (NDA) (domestic or imported) is determined by the sponsor's country of origin.

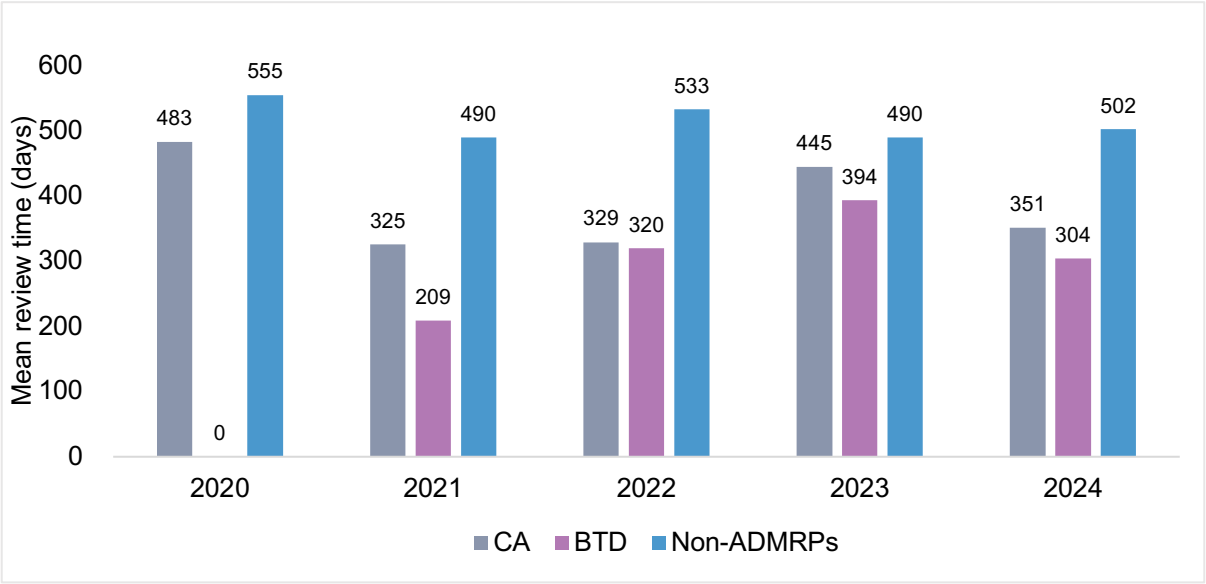
Supplementary Table 4 | Review time of new drugs approved by NMPA from 2016 to 2024

Drug categories	Mean (median) review time, day	
	ADMRPs	Non-ADMRPs
Chemical drugs	438 (421)	630 (425)
Traditional Chinese medicines	611 (408)	470 (422)
Biological products	389 (421)	468 (424)

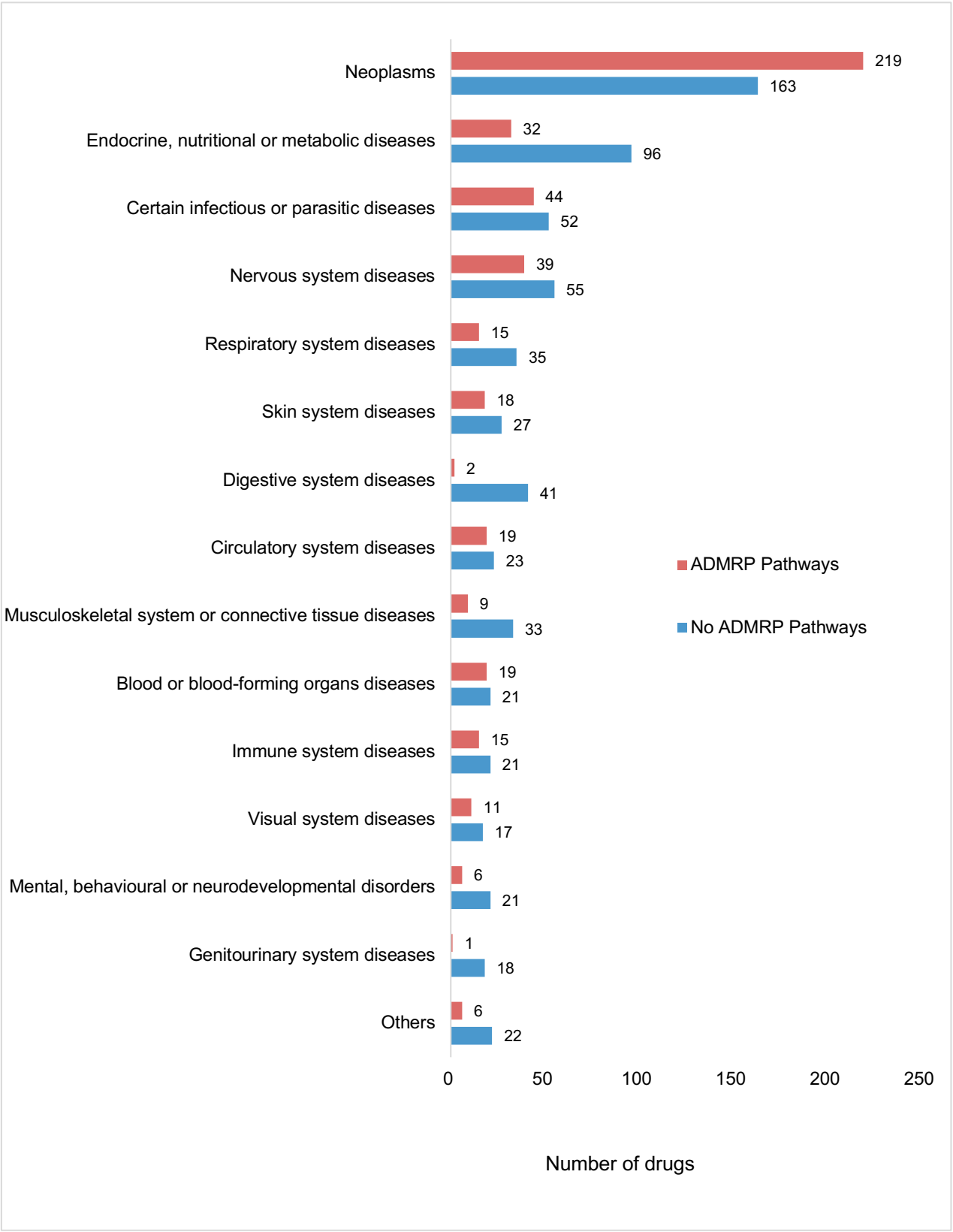
Approvals by drug categories.



Supplementary Figure 1 |Timeline of China's drug regulatory system reform.
[1] The policy can be retrieved by the index number on the website of NMPA.
[2] ICH website: https://www.ich.org/pressrelease/ich-assembly-montreal-canada-mayjune-2017
[3] NMPA website: https://www.nmpa.gov.cn/zhuanti/ypqxgg/ggzhqyj/20171220172701894.html
[4] PRC website: https://www.gov.cn/guowuyuan/2018-03/14/content_5273856.htm
[5] NMPA website: https://www.nmpa.gov.cn/zhuanti/ypqxgg/ggzhcfg/20180517135601947.html
[6] NMPA website: https://www.samr.gov.cn/zw/zfxxgk/fdzdgknr/fgs/art/2023/art_3275cb2a929d4c34ac8c0421b2a9c257.html



Supplementary Figure 2 | Mean review time of new drugs approved by NMPA from 2020 to 2024. Approvals by the types of drug review. CA, Conditional Approval; BTD, Breakthrough Therapy Drug.



Supplementary Figure 3 | Distribution of therapeutic areas for new drugs approved by NMPA from 2016 to 2024.