

China Healthcare

Highlights from 2023 annual NMPA drug evaluation report

Industry Overview

Summary of the drug evaluation applications in 2023

Total number of applications reached 18,503 in 2023, a 35.84% YoY increase, including 16,898 drug/preparation registrations (+36.63% YoY) and API registrations at 1,605 (+28.09% YoY). Meanwhile, CDE finished review of 15,713 applications, up 29% YoY. Overall, 40 innovative drugs were approved in 2023.

TCM: The number of TCM applications rose to 1,163 in 2023, representing an increase of 176.2% YoY. The number of IND/NDA/supplementary applications came in at 75/26/1,054 in 2023, compared with 57/14/344 in 2022, respectively.

Chemical drugs: Overall, number of applications rose to 9813 in 2023, with the number of applications at 1,778/170/249/3,854/1,006/2,286/470 for IND/confirmatory trial/NDA/ANDA/CE/supplementary application/re-registration of drugs produced overseas, respectively. In addition, number of innovative drug applications continued to increase to 1,368/79 in IND/NDA stages in 2023 (compared with 1,046/29 in 2022), contributing 77%/32% of total IND/NDA applications of chemical drugs in 2023, respectively.

Biologics: In 2023, there were 2,168 biologics products applications, with 189 for vaccines, 1,969 for therapeutic biologics and 10 for in vitro diagnostic reagents. Specially, number of innovative drug applications increased to 876/46 in IND/NDA stages in 2023 (from 648/22 in 2022), contributing 77%/24% of total IND/NDA applications in 2023.

Acceleration of innovative drugs review process

Breakthrough therapy: It is usually applied during phase I and phase II clinical trials for the product which can prevent severe diseases and has significant advantages compared with the current treatment. In 2023, 70 drugs have been granted breakthrough therapy (43% YoY). Oncology (45 drugs) has been the major therapeutic area.

Conditional approvals: In 2023, there were 21 conditional approvals, including 16 new drug approvals and 5 approvals of new indications for already-approved drugs. Also, 10 drugs have accomplished their previous conditions and transferred to normal approval.

Priority review: For the drugs with priority review, during NDA, the review period can be shortened to 130 days, compared with 200 days in a normal review. If the drug is in urgent need for rare diseases and the product has already been approved overseas, the review period can be shortened to 70 days. In 2023, 108 applications have been granted priority review, a 56.9% YoY increase. Meanwhile, 85 applications (59 drugs) with priority review have been approved in 2023.

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CDE: Center for Drug Evaluation

NMPA: National Medical Products Administration

API: Active pharmaceutical ingredients

TCM: Traditional Chinese Medicine

IND: Investigational New Drug

NDA: New Drug Application

ANDA: Abbreviated New Drug Application

CE: Consistency evaluation

CNS: Central nervous system

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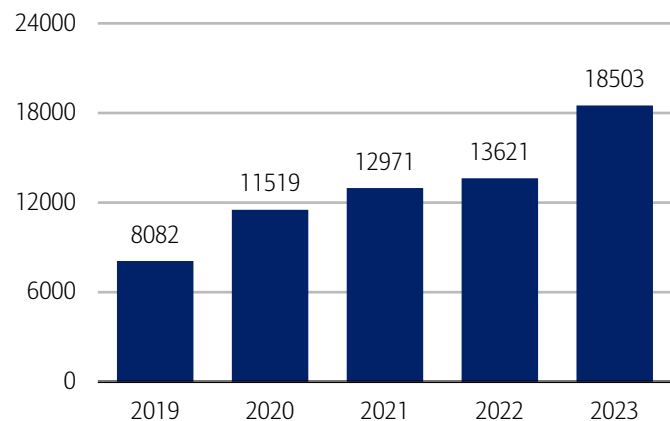
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Key summary charts

Exhibit 1: Total number of applications

18,503 applications were accepted in 2023

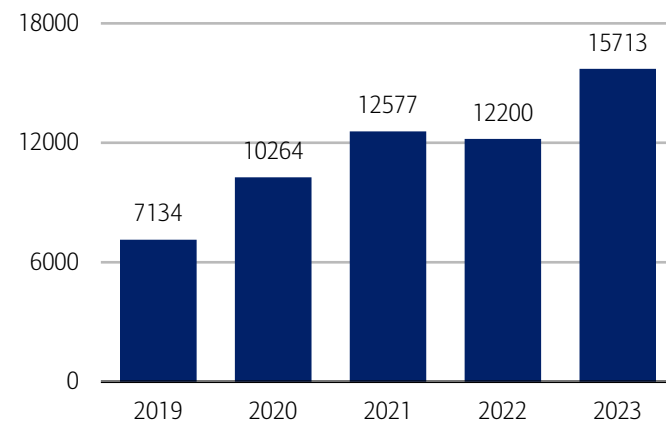


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Exhibit 2: Total number of applications reviewed

15,713 applications were reviewed in 2023

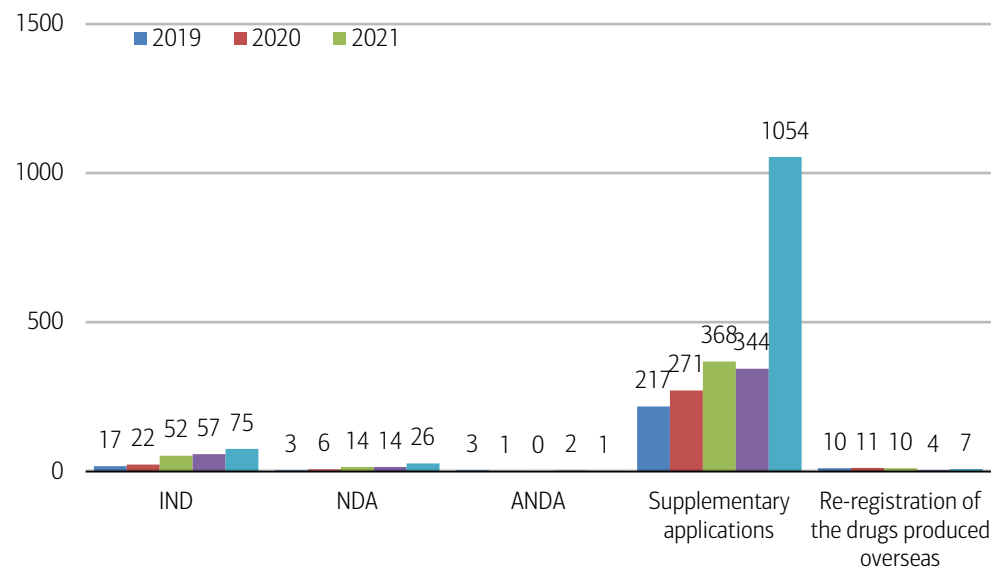


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Exhibit 3: TCM applications

There were 1,054 supplementary applications in 2023

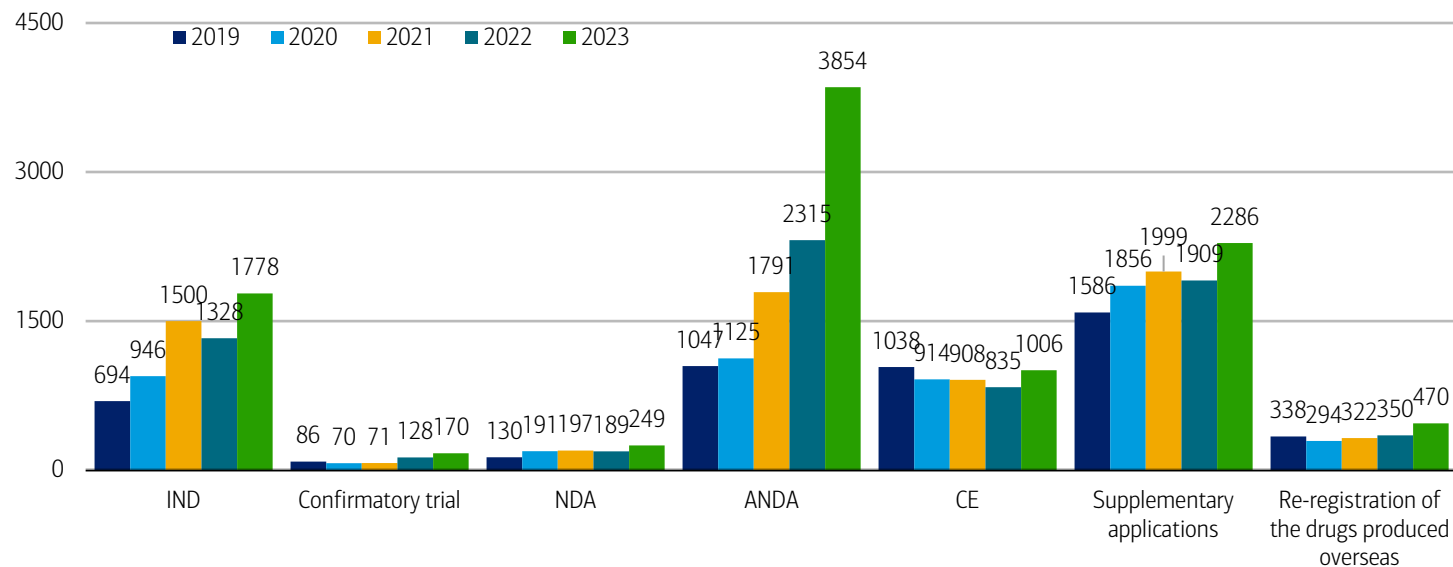


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Exhibit 4: Chemical drug applications

There were 3,854 ANDA applications in 2023

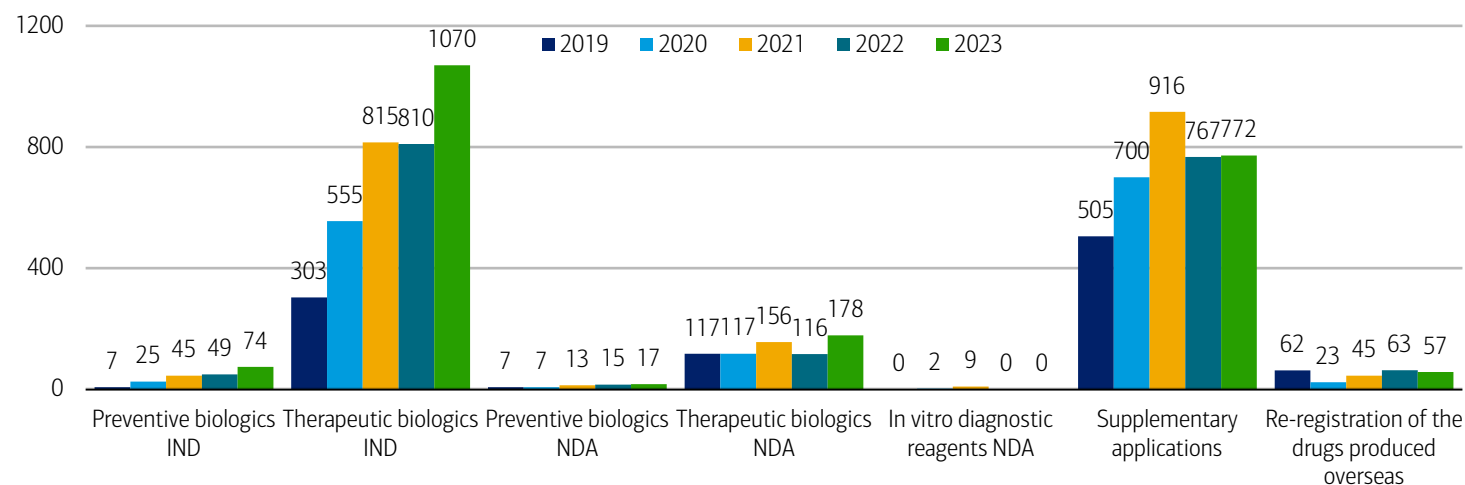


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Exhibit 5: Biologics applications

Number of biologics IND increased significantly in 2023

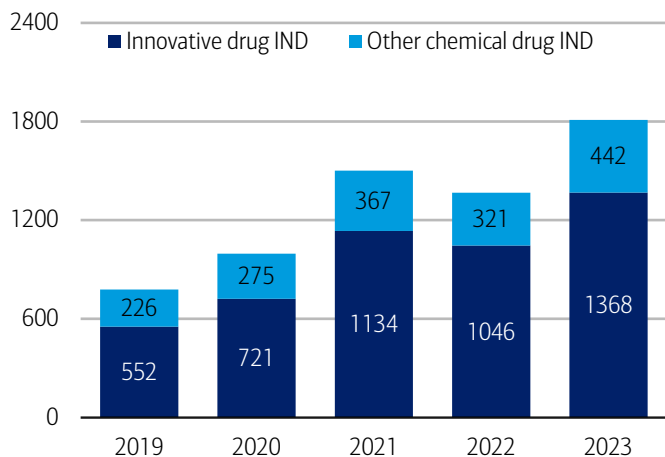


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Exhibit 6: Chemical drugs IND breakdown

There were 1368 innovative chemical drugs IND in 2023

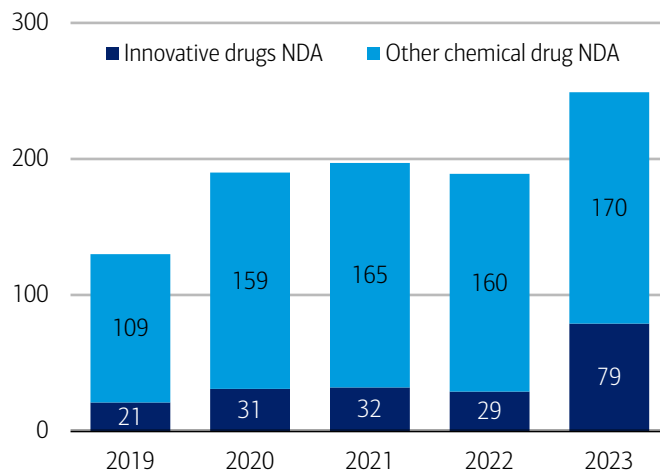


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Exhibit 7: Chemical drugs NDA breakdown

There were 79 innovative chemical drugs NDA in 2023

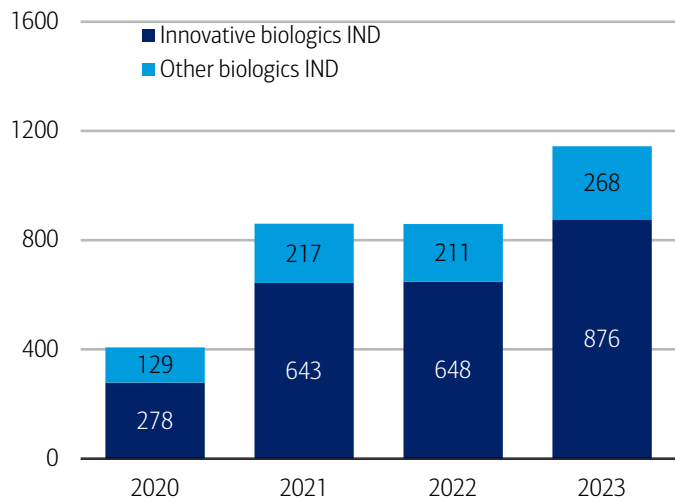


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Exhibit 8: Biologics IND breakdown

There were 876 innovative biologics IND in 2023

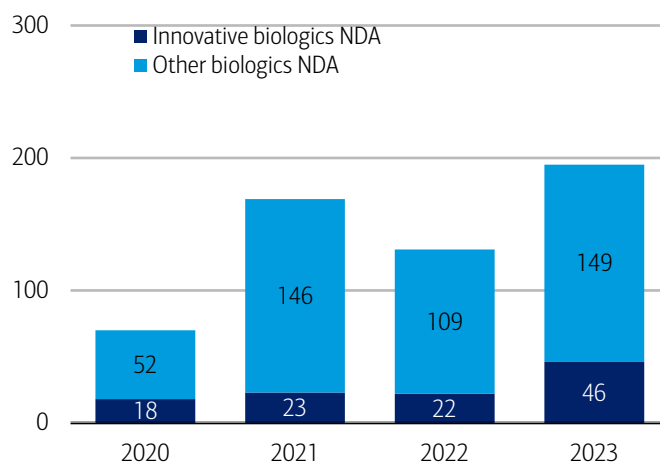


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Exhibit 9: Biologics NDA breakdown

There were 46 innovative biologics NDA in 2023

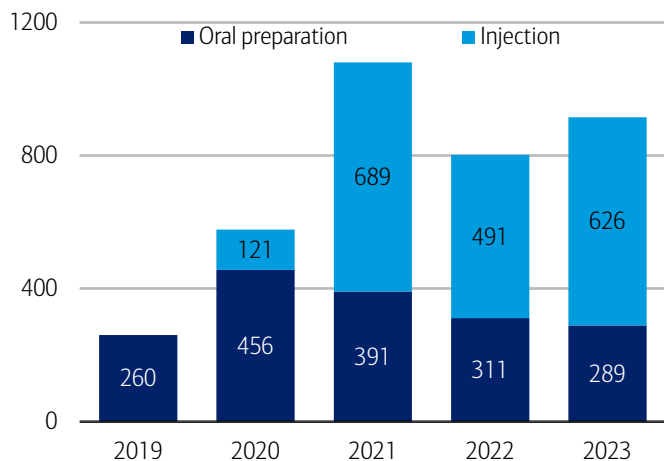


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Exhibit 10: Number of drugs passed CE

626 injections passed CE in 2023

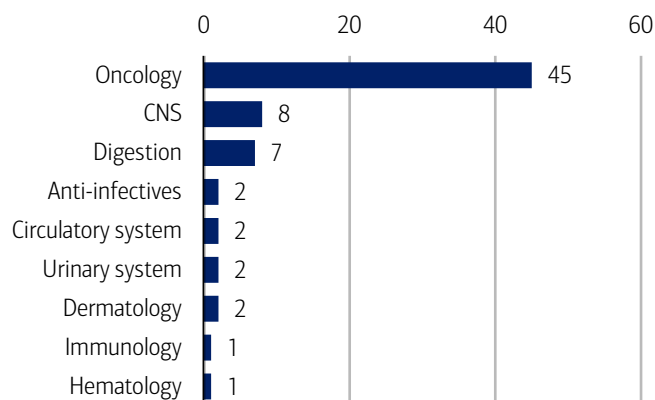


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Exhibit 11: Breakdown of the applications granted breakthrough therapy in 2023

45 are oncology drugs

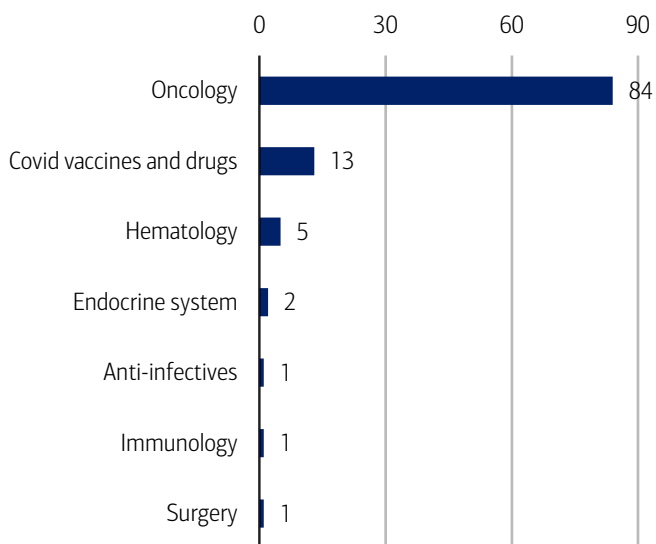


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Exhibit 12: Breakdown of conditional approvals in 2020-2023

13 Covid-related vaccines and drugs were approved with conditions

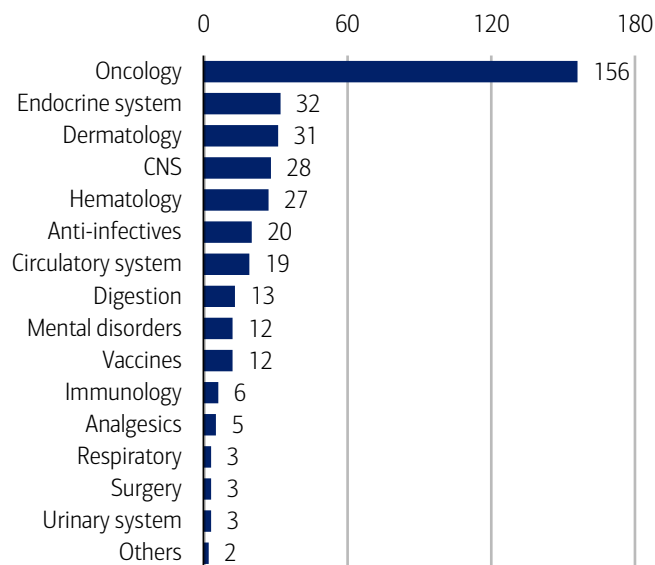


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Exhibit 13: Breakdown of priority reviews in 2020-2023

Major applications with priority reviews are still oncology drugs



Source: NMPA, BofA Global Research

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