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Supplementary information

Approvals by the China NMPA in 2024

In the format provided by the 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. Biosimilars, vaccines, and diagnostic reagents are excluded. The list of NDAs in 2024, along with their approval dates, was obtained from drug approvals published by the 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 or modified drugs, based on whether they were approved as new molecular entities or new biologics, or were approved for new indications, as new dosage forms, or as new combinations. 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 addition, the number of class 1 innovative drugs approved each year, as shown in Figure 1c, was based on drug approval documents released by the NMPA, and it excluded vaccines and 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.

Current drug registration classification in China*

<table>
<tr><th colspan="3">Chemical drugs</th></tr>
<tr><td>Class 1</td><td colspan="2">① not yet been marketed in China or overseas
② with clearly structured new molecular entities (NMEs), pharmacological effects, and clinical values</td></tr>
<tr><td rowspan="4">Class 2</td><td rowspan="4">① not yet been marketed in China or overseas
② with known active ingredients and significant clinical advantages</td><td>Class 2.1: Optical isomers, salts, esters, or other simple derivatives</td></tr>
<tr><td>Class 2.2: New dosage forms, new formulation processes, or new administration routes</td></tr>
<tr><td>Class 2.3: New compound preparations</td></tr>
<tr><td>Class 2.4: New indications</td></tr>
<tr><td>Class 3</td><td colspan="2">① manufactured by domestic applicants by imitating the original drugs that have been marketed overseas but not in China
② consistent with the reference listed drugs in quality and efficacy</td></tr>
<tr><td>Class 4</td><td colspan="2">① manufactured by domestic applicants by imitating the original drugs that have been marketed in China
② consistent with the reference listed drugs in quality and efficacy</td></tr>
<tr><td rowspan="2">Class 5</td><td rowspan="2">① already been marketed overseas
② under application for being marketed in China</td><td>Class 5.1: Innovative drugs and modified drugs with significant clinical advantages</td></tr>
<tr><td>Class 5.2: Generic drugs</td></tr>
</table>

<table>
<tr><th colspan="3">Therapeutic biological products</th></tr>
<tr><td>Class 1</td><td colspan="2">not yet been marketed in China or overseas</td></tr>
<tr><td rowspan="4">Class 2</td><td rowspan="4">① based on biologics that have been approved in China or overseas
② with improved safety, efficacy, quality control, and significant clinical advantages</td><td>Class 2.1: New dosage forms, or new administration routes</td></tr>
<tr><td>Class 2.2: New indications, or new target groups</td></tr>
<tr><td>Class 2.3: New compound products</td></tr>
<tr><td>Class 2.4: Major technical improvements</td></tr>
<tr><td rowspan="4">Class 3</td><td rowspan="4">already been marketed in China or overseas</td><td>Class 3.1: manufactured and marketed overseas, and applying for marketing authorization in China</td></tr>
<tr><td>Class 3.2: marketed overseas, and applying for manufacturing and marketing authorizations in China</td></tr>
<tr><td>Class 3.3: Biosimilars</td></tr>
<tr><td>Class 3.4: Other biological products</td></tr>
<tr><th colspan="3">Traditional Chinese medicines (TCMs)</th></tr>
<tr><td rowspan="3">Class 1</td><td rowspan="3">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</td><td>Class 1.1: Combination of multiple decoction pieces or extracts</td></tr>
<tr><td>Class 1.2: Extracts and preparations from single plants, animals, minerals and other substances</td></tr>
<tr><td>Class 1.3: New Chinese medicinal materials and their preparations</td></tr>
<tr><td rowspan="4">Class 2</td><td rowspan="4">① not yet been marketed in China or overseas
② with significant clinical advantages</td><td>Class 2.1: New administration routes</td></tr>
<tr><td>Class 2.2: New dosage forms</td></tr>
<tr><td>Class 2.3: New indications</td></tr>
<tr><td>Class 2.4: New production processes or changed excipients</td></tr>
<tr><td>Class 3</td><td colspan="2">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</td></tr>
<tr><td>Class 4</td><td colspan="2">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</td></tr>
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*As defined by the Provisions for Drug Registration 2020.