nature portfolio

https://doi.org/10.1038/d41573-024-00034-2

Supplementary information

Approvals by the China NMPA in 2023

In the format provided by the authors

Supplementary Box 1 | 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 yet 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>
<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>
</table>

<table>
<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><td colspan="3">Traditional Chinese medicines (TCMs)</td></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>
</table>

*As defined by the Provisions for Drug Registration 2020.

Supplementary Box 2 | Criteria of the priority review and approval procedure by NMPA

Priority Review and Approval Procedure	
①	Drugs with urgent clinical needs in shortage, innovative drugs and modified new drugs for the prevention and treatment of major infectious diseases or rare diseases.
②	New products, dosage forms and strengths of pediatric drugs complying with the physiological characteristics of children.
③	Vaccines urgently needed for disease prevention and control, and innovative vaccines.
④	Drugs included into the breakthrough therapy drug procedure.
⑤	Drugs included into the conditional approval procedure.
⑥	Other circumstances of priority review and approval specified by the NMPA.