The registration pathways in China for globally developed novel anticancer drugs

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Abstract

**Background**
- Since China implemented the regulations on adjusting the approval process of imported drugs in 2017, the integration of China into the global development of novel anticancer drugs has accelerated. The changing registration pathways for these products inspire us to present this data analysis.
- Based on the review reports of approved global anticancer drugs from the database of the Center of Drug Evaluation (CDE) of China, the cancer type, scope and timeline of pivotal supporting trials for each indication were extracted by the end of 2022. The distribution of registration pathways was explored using the number of indications as the key indicator.

**Methods**
- A total of 83 approved indications were retrieved. Participating in synchronous global studies (39, 47.0%) was the most common registration pathway, which was divided into dose expansion/phase II (4, 4.8%) and confirmatory studies (35, 42.2%). Launching China-dominant studies was another main pathway (15, 18.1%), including bridging (26, 31.3%) and confirmatory studies (10, 12.0%). Clinical studies in China were exempted in 15 (18.1%) indications. Multiple pathways were used to support 7 (8.4%) indications.

**Results**
- The number of indications supported by China-dominant studies decreased from 19 (2017-2019) to 15 (2020-2022), while that of synchronous global studies increased from 15 (2017-2019) to 23 (2020-2022). Among the 9 indications for esophageal, gastric and hepatocellular cancer, eight (88.9%) were approved by global studies. The median days between China and the first global approval was 371 in indications supported by global studies, compared with 1326 in that supported by China-dominant studies.

**Conclusions**
- Participating in synchronous global studies is the most common and time-saving registration pathway in China for globally developed novel anticancer drugs in recent years, especially for local high-prevalence cancers. Efforts should be made to help China join more global early-phase studies in the future.
- All authors declare no conflict of interests.
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**Disclosure**

![Diagram showing the categories of registration pathways and the annual numbers of approved indications by registration pathways.](image-url)