White Paper

Expediting innovative drugs' market access in China

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Introduction

China's drug review and approval reform has made remarkable progress in the past few years. However, patients in China are still facing challenges brought by inaccessibility of innovative drugs. We have conducted research on innovative drugs approved by FDA, EMA, PMDA and NMPA from January 2009 to June 2019 and have analyzed the current gap of innovative drugs by therapeutic area, to highlight the importance of accelerating innovative drugs market access to China market.

Research background

The Plan of Health China 2030 puts forward the strategic theme of "National Health by Co-building and Co-sharing ". The accessibility of innovative drugs has become increasingly critical for people's health improvement. In October 2017, General Office of the CPC Central Committee and the General Office of the State Council issued the Opinions on Deepening the Reform of the Review and Approval System to Encourage Innovation of Drugs and Medical Devices. With a series of policies to encourage innovation, China's drug evaluation, the reform has achieved remarkable progress and the efficiency of the innovative drugs review and approval is significantly elevated.

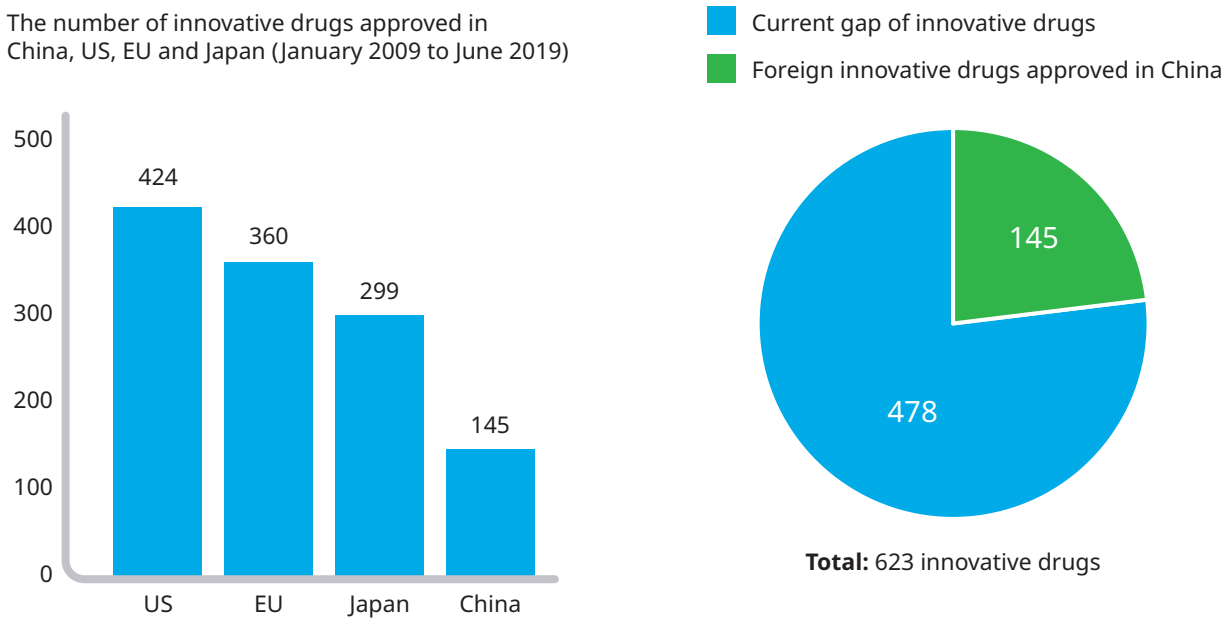
With the above mentioned, we conducted a research on innovative drugs in the United States, European Union, Japan and China, which were approved from 1st January, 2009 to 30th June, 2019, to understand China's current gap of innovative drugs compared with developed countries. We investigated the gap of innovative drugs by therapeutic areas and analyzed the role of innovative drugs in relieving patients disease burden to highlight the importance of accelerating innovative drugs market access in China.

Current innovative drug gap

China's innovative drug gap is large compared to US, EU and Japan, but the gap has been narrowed in recent years

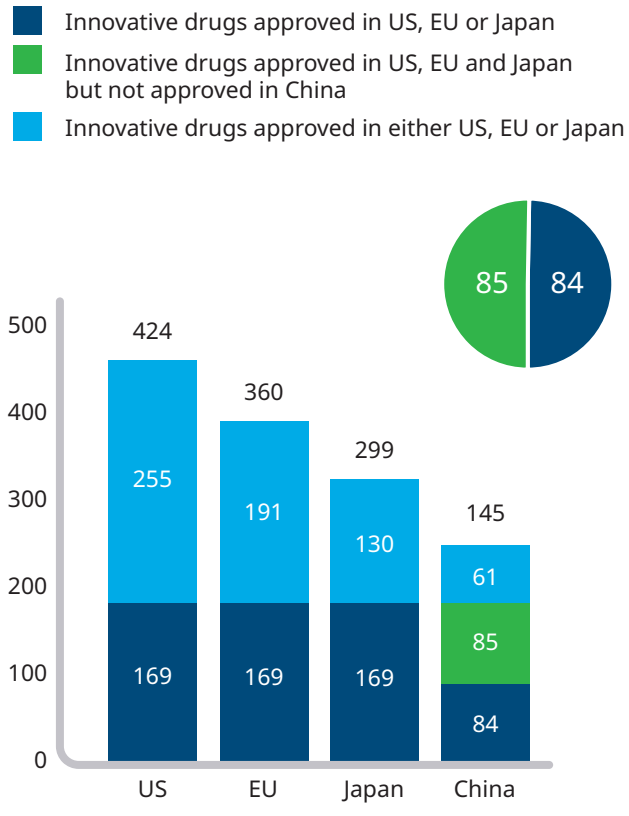
According to partial statistics, U.S. Food and Drug Administration (hereinafter referred to as "FDA"), European Medicines Agency (hereinafter referred to as "EMA"), Japan Pharmaceuticals and Medical Devices Agency (hereinafter referred to as "PMDA") have approved 623 innovative drugs from January 2009 to June 2019. Varying in countries, the three institutes approved 424, 360 and 299 innovative drugs respectively (innovative drugs refer to chemical drugs with new chemical molecular entities and originator biologics). The National Medical Products Administration (hereinafter NMPA, formerly known as the State Food and Drug Administration) approved 145 of the 623 innovative drugs, of which 478 products have not yet entered the Chinese market. However, stratified analysis showed that only 169 innovative drugs approved in all of the three countries, of which 84 were approved in China, with 85 products still have not entered China market (*Figure 1 and Figure 2*).

Figure 1: Innovative drugs approved in either US, EU or Japan vs. NMPA (January 2009 to June 2019)



Source: FDA, EMA and PMDA; DXY insight; IQVIA analysis

Figure 2: Innovative drugs approved in US, EU and Japan vs. China (January 2009 to June 2019)



Source: FDA, EMA and PMDA; DXY insight; IQVIA analysis

Since the drug, review and approval reform in 2015, the number of foreign innovative drugs approved in China has increased year by year, significantly improving the accessibility to innovative drugs (*Figure 3*). Through gradually introducing the remaining 85 drugs into Chinese market, we can further narrow the gap of innovative drugs compared with US, EU and Japan.

THE CURRENT GAP OF INNOVATIVE DRUGS COVERS MANY THERAPEUTIC AREAS, AND CAN SATISFY PATIENTS' UNMET MEDICAL NEEDS ONCE ACCESSIBLE

The 85 innovative drugs in gap are mainly in the therapeutic areas of antineoplastic and immunomodulating agents, or the respiratory system. The former, antineoplastic and immunomodulating agents, account for the 39% of the gap (*Figure 4*).

Since the drug, review and approval reform in 2015, the number of foreign innovative drugs approved in China has increased year by year

Figure 3: Innovative drugs approved yearly in China, US, EU and Japan (January 2009 to June 2019)

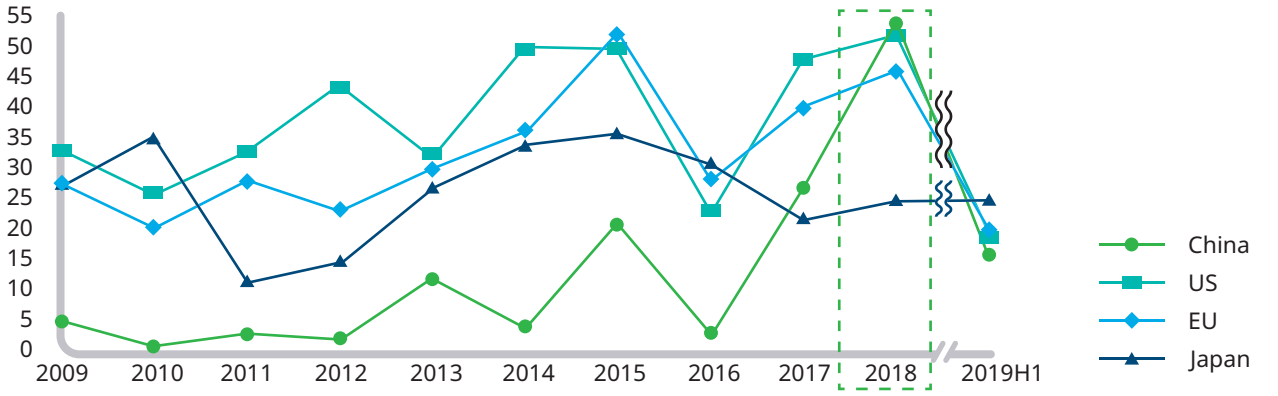
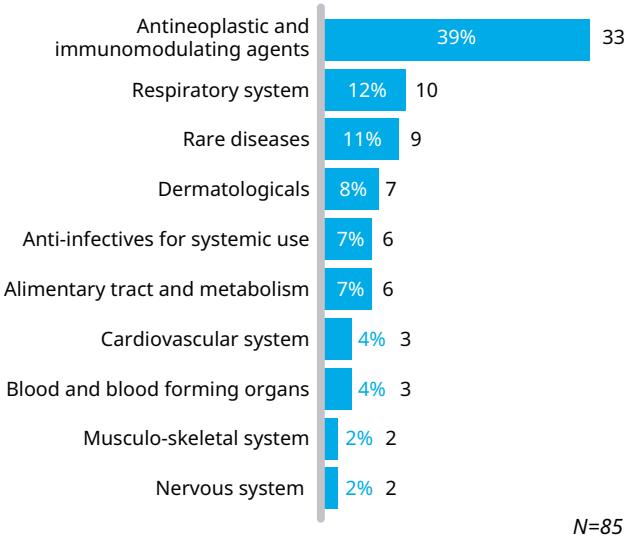
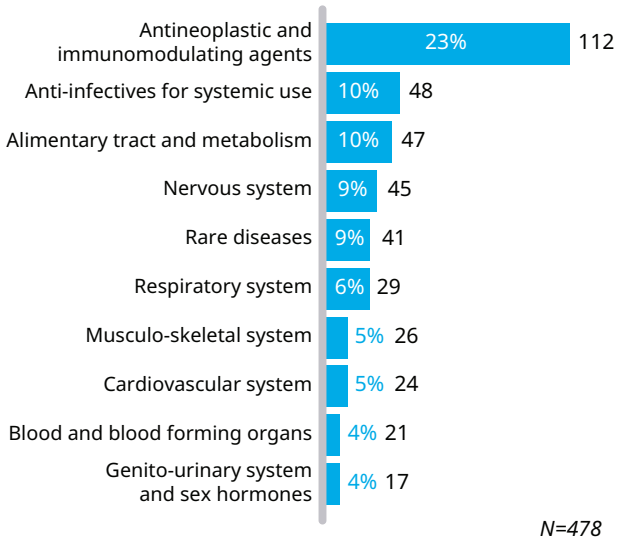


Figure 4: Therapeutic areas of the 85 innovative drugs approved in US, EU and Japan, but not in China (Top 10)



Source: FDA, EMA and PMDA; DXY insight; IQVIA analysis

Figure 5: Therapeutic area distribution of the 478 innovative drugs approved either in US, EU or Japan, but not approved in China (Top 10)



Source: FDA, EMA and PMDA; DXY insight; IQVIA analysis

We have also analyzed the therapeutic areas in which the 478 products were approved in either US, EU or Japan but not in China. The results showed that these products were mainly in therapeutic areas such as antineoplastic and immunomodulating agents, anti-infectives for systemic use, alimentary tract and metabolism and nervous system. Of which, antineoplastic and immunomodulating agents accounts for 23% (*Figure 5*).

According to the China Health Statistics Yearbook 2019, cardiovascular diseases, cancer, respiratory diseases, alimentary tract and metabolism diseases and central nervous system disorders were the leading causes of death in China in 2018, where the patients' medical needs have not been met. However, of the 85 gap products approved in US, EU and Japan, a total of 60 products fall into the above therapeutic areas. Of the 478 innovative drugs approved in either US, EU or Japan, a total of 275 products

Figure 6: Distribution of gap products in therapeutic areas that cause death in China

	DEATH COMPOSITION RATE (%) OF URBAN INHABITANTS	DEATH COMPOSITION RATE (%) OF RURAL INHABITANTS	NUMBER OF GAP PRODUCTS
CARDIOVASCULAR SYSTEM	43.8	46.66	3 21 24
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS	25.98	22.96	33 112 112
RESPIRATORY SYSTEM	10.83	11.24	10 29 29
ALIMENTARY TRACT AND METABOLISM	5.68	4.57	6 41 47
NERVOUS SYSTEM	1.84	1.62	2 43 45
GENITO-URINARY SYSTEM AND SEX HORMONES	1.09	1.08	17
TOTAL	89.22	88.13	

Gap products approved in all of US, EU and Japan N=60

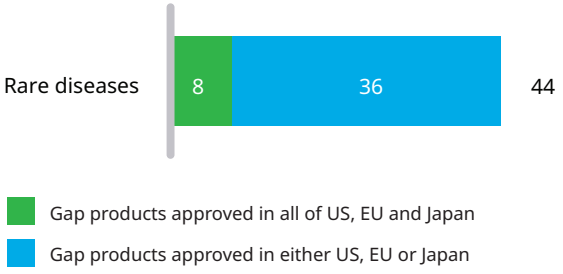
Products approved in either EU, US or Japan N=275

* Death composition rate refers to the proportion of deaths caused by the disease area in relation to the total number of deaths.

fall into the below disease areas (*Figure 6*). Therefore, accelerating the market access of gap products can satisfy patients unmet needs and improve people's health.

In addition, currently there is a great demand for treatment of rare diseases in China. Most patients with rare diseases are facing problems with drug accessibility. Under the First List of Rare Diseases, 8 drugs for rare diseases are in the range of the 85 gap products approved in US, EU and Japan, and 44 drugs are in the range of 478 gap products approved in either US, EU or Japan (*Figure 7*). Timely introduction of these innovative drugs will solve the drug inaccessibility problem for patients with rare diseases.

Figure 7: Distribution of gap products in rare diseases



Source: FDA, EMA and PMDA; DXY insight; IQVIA analysis

Conclusion

China has delivered significant achievements in accelerating the review and approval of innovative drugs, but there is still a gap compared to other developed countries. Previous analysis has shown that most of the gap products are able to reduce the disease burden of China. Therefore, the timely introduction of innovative drugs from abroad into Chinese market is of great importance in providing more disease treatment options and meeting the medical needs of patients.

The drug review and approval reform will continue to deepen as we move forward. With the continued enhancement of drug regulatory capacity, the implementation of the newly revised Drug Administration Law and the Drug Registration Administration Law as well as the continuous improvement of other regulatory documents and technical guidelines in the drug registration management system. It is expected that Chinese patients will eventually have quicker and ready access to world's new innovative drugs.

About the authors

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Yan Chai, DBA, is an Associate Director responsible for leading the public health practice and healthcare policy consultation in China. Yan has rich experience in strategy consulting and policy research on China's medical system reform. He has spent 12 years in consulting and investment services in the pharmaceutical industry, and now focuses on public health research and industry policy shaping in China. Prior to joining IQVIA, he was with McKinsey & Company and Harvard Management Company. Yan earned his MS in International management from the University of Nottingham and Doctor of Business Administration from Arizona State University.

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