



Visioning the Next Ten Years from the Standpoint As a Second Tier Country of Drug Innovation

*RDPAC Report on Strategic Value of
R&D Centres of Multinational Companies in China*

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With the promulgation of the “Healthy China 2030” Planning Outline, significant and positive changes have taken place in China's drug innovation ecosystem in the past three years. On the one hand, there is support from the state level which has been guiding the transformation and upgrading of industrial innovation, continuously deepening the drug review reform, and improving the efficiency of approval of clinical trials and listing of new drugs; on the other hand, there is progress in medical insurance reimbursement and market access system for innovative drugs since 2017, and increasing investment from companies and investors driven by the market return of innovative drugs. While the policy environment continues to improve, capital is flooding in and talents are gathering in China. The tremendous changes in China's innovation ecosystem stimulate the vitality of China's pharmaceutical innovation industry. According to a report named “Fostering a Sustainable Ecosystem for Drug Innovation” jointly issued by RDPAC and other three associations in 2016, China ranked among the third tier of drug innovation worldwide based on the two major indicators, namely the pre-market R&D pipeline and the proportion of the number of the listed new drugs in China to that in the world. The latest analysis by RDPAC shows that by 2018, China has moved from the third tier of drug innovation to the second tier, playing a more important role in global drug R&D. In terms of pre-market R&D pipeline, China's share of the world has increased from 4.1% in 2016 to 7.8%, second only to the US; in terms of the number of the listed new drugs, China's share of the world has increased from 2.5% in 2016 to 4.6%, second to the US, Japan and the UK.

In order to maintain the vitality of China's drug innovation in the long run and substantially improve the fruition, breakthrough and originality of China's drug innovation, in the next ten years, we need to think deeply about and seek ways to improve the

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following three aspects. First, focus on the needs of Chinese patients. The large patient population is not only a driving force but also a unique advantage of China for drug R&D. Second, encourage pharmaceutical companies from both home and abroad to jointly promote innovation. There are overlapping interests between multinational pharmaceutical companies who have plans of accelerating “localized” innovation investment, and Chinese pharmaceutical companies who have goals of developing “global” new drugs. While the cooperation and competition coexisting between the multinational and local pharmaceutical companies, both of them should make joint efforts to promote talent training and strengthen the ecosystem capacity building. Third, activate the source of innovation. In addition to pharmaceutical companies, all parties involved in innovation, including hospitals, physicians, universities, scientific research institutions, etc., should keep deepening the cooperation so as to facilitate the output of more breakthroughs and original innovations.

Focusing on the needs of Chinese patients

Medical innovation has fundamental significance in solving people's livelihood issues, and unmet clinical needs should be an important consideration for drug innovation in China. The large patient population provides unique advantages for R&D based in China, which covers both widely-affected and high-growth diseases such as hypertension, diabetes, and tumors, and rare diseases that affect a relatively large number of patients (due to the large population base). Different from major European and American medical markets, diseases such as stroke, liver cancer, gastric cancer, and esophageal cancer are high-incidence diseases in China. The burden of these diseases on China is much

heavier than that on European and American countries, and there is still much room for improvement in terms of drug innovation to treat these diseases. According to a survey conducted by Chinese Phase 1 Oncology Trial Consortium, among the 180 on-going phase I clinical trials conducted in China in 2017, 116 targets specific cancer types, but only 12 of them targets high-incidence cancer types in China (such as esophageal cancer, liver cancer, stomach cancer, nasopharyngeal cancer) .

Encouraging pharmaceutical companies from both home and abroad to jointly promote innovation

The R&D centers in China set by multinational pharmaceutical companies are deeply integrated into global R&D strategies and systems with their positive progress in multiple dimensions such as R&D function setting, clinical trial participation, innovative product launches, and R&D model exploration in recent years. In terms of R&D functions, as the scale of the existing R&D centers in China set by multinational pharmaceutical companies continues to expand, new R&D centers are constructed and completed. Multinational pharmaceutical companies in China have been diversifying R&D models. In addition to self-built R&D centers, they have continuously made new attempts in recent years, including cooperation with local companies on specific product development, and cooperation with Chinese scientific research institutions, as well as the establishment of open platforms for innovation, etc. In terms of clinical trials, Chinese participation in international multi-center clinical trials has gradually become the new normal for multinational pharmaceutical companies, thereby making China a better part of the global R&D network, shortening the time gap of the launch of innovative products between

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Chinese market and European and American markets, and also helping to provide data support for products listing worldwide. Innovative products of multinational pharmaceutical companies are entering the Chinese market at a higher speed. There were 40 and 44 new drugs listed in China in 2017 and 2018 respectively, which is a significant progress compared with 3 new drugs listed in 2016.

At the same time, Chinese biopharmaceutical companies are making more and more contribution to drug innovation. Taking 2018 as an example, 9 innovative products of Chinese pharmaceutical companies were listed in China. At present, Chinese innovative pharmaceutical companies have three characteristics: external cooperation to introduce assets, a great amount of pipeline assets, and concentration on certain disease areas. Leading companies are accelerating domestic drug R&D and listing, and also actively targeting global development, aiming to benefit patients in China and around the world. Chinese pharmaceutical companies have already begun to explore differentiated innovation models, including differentiation in therapeutic fields and technology platforms, extended coverage of value chain, and multi-party cooperation in R&D and commercialization.

Competition has already begun between multinational and local pharmaceutical companies in all aspects of R&D, production, and sales, which has been elevating the rapid development of China's pharmaceutical innovation capabilities. At present, there is a serious shortage of talents in the industry. Taking the clinical medicine sector as an example, the current demand for talents is about 1,600, while the supply is only about 1,000. Facing the future, multinational and local pharmaceutical companies should work together to cultivate talents and build capabilities for the sustainable development of the industry and companies.

Activating the source of innovation

At present, local drug innovation is still dominated by incremental innovation, with relatively fewer breakthroughs and original innovations. One of the main reasons is that breakthrough and original innovation require long-term investment in basic research, the investment on which is still at a low level in China. In terms of the ratio of total R&D investment to GDP, China was narrowing the gap with developed countries (for example, the US hit 2.7% in 2016) with an increase from 1.3% in 2005 to 2.1% in 2016. However, when it comes to the proportion of basic research investment in the total R&D investment, China still lagged behind the developed countries (for example, the US hit 16.8% in 2016) in the past ten years with a slightly drop from 5.3% in 2005 to 5.2% in 2016. In terms of scientific research environment, in an environment where the number and influence of published papers are the main criteria for promotion and fund applications, the number of papers published in high-level biomedical basic research journals in China has increased significantly, but there is still a lack of real breakthrough innovation and transformable result. In terms of the transfer mechanism of scientific and technological achievements and the construction of the translational medicine system, China still has much room for improvement to guide the direction of scientific research and ensure the efficient transformation of scientific research results.

In order to further improve the multi-party cooperation of the drug innovation ecosystem, in addition to pharmaceutical companies, universities, and scientific research institutions, the role of hospitals and physicians should also be given full play. Hospitals and physicians with a deeper understanding of clinical needs should cooperate with

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universities, scientific research institutions and pharmaceutical companies to establish research platforms. In the clinical stage, the participation of Chinese investigators in the design of international multi-center trials can also provide a better insight into China's clinical practice for pharmaceutical companies.

As China striding into the second tier of global drug innovation, we are faced with unprecedented historical opportunities. Looking forward to the next ten years, multinational and local pharmaceutical companies should jointly promote multi-party collaboration based on the patient needs in the drug innovation ecosystem, benefiting patients in China and around the world with drug innovations originating from China, and shaping a drug innovative industry with vitality and international competitiveness.

This report is contributed by nine RDPAC member companies

(sorted by initials of the English name of member companies):

Amgen, Baxter, Bayer, Eli Lilly, GSK, Lundbeck, Merck, Novo Nordisk, Roche



China Association of Enterprises with Foreign Investment
R&D - based Pharmaceutical Association Committee

Address: Rm 506, Office Bldg 1, Landmark Tower, No.8 North
Dongsanhuan Rd., Chaoyang District, Beijing, P.R.China

Postcode: 100004

Tel: 8610-6590 7696

Fax: 8610-6590 7697

Website: www.rdpac.org

