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After so many years of globalization, it is clear that we are interdependent and interconnected. Cutting off the channels of cooperation would lead to harm on both sides

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Prof. Song Ruilin outlines the Chinese (bio)pharmaceutical industry's progress across the three key pillars of innovation, industrialization, and internationalization in recent years. While a downturn in the global economy and a capital freeze in the biotech sector present significant challenges, Song is optimistic about his sector's prospects, with increased international collaboration and proactive government policies set to spur growth in 2024 and beyond.

When we spoke to you in 2018, you introduced PhIRDA's key principles as "Innovation, Industrialization, and Internationalization". How well has the Chinese (bio)pharmaceutical industry progressed on these three pillars since then?

Innovation, industrialization, and internationalization are the aims of PhIRDA. We have set this goal since 2009. Now, in these three aspects, China's pharmaceutical innovation has made significant growth and achievements.

From the perspective of industrialization, China's innovative drugs have now been launched on the market. For instance, the proportion of cancer patients using targeted drugs has surged by nearly 40 percent, marking a significant shift in this field.

In terms of internationalization, it will come from two dimensions. First is the MRCT (multi-region clinical trials), where the number of trials initiated by China's domestic pharmaceutical companies has risen sharply.

Moving to the second dimension: licensing-out. Here, China's pharmaceutical companies have made noticeable progress, particularly in recent years. China's pharmaceutical innovation is transitioning from a focus on licensing-in to producing more licensing-out opportunities after collaborative R&D, effectively going from technology buyers to sellers.

Recently, MNCs like Pfizer, Novartis, and AbbVie have been collaborating with Chinese biotech firms. The abundance of these deals demonstrates the growing international capabilities of China's pharmaceutical innovation on the global stage. Particularly in 2023, the value of licensing-out deals from Chinese companies, convert into US dollars, was approximately 2.5 times greater than the total capital raised by Chinese enterprises within China.

Therefore, in these three aspects, innovation, industrialization, and internationalization, China has taken a solid step and is gradually integrating into the global pharmaceutical innovation industry chain.

Would you say there is now a better level of trust between multinational and Chinese companies?

Yes, the collaboration between both parties is becoming increasingly close. A considerable number of multinational corporations are pushing hard to get 'local', while Chinese enterprises are equally determined to go 'global'. It's a two-way street.

The Healthy China 2030 focuses on prevention and access. How is the innovative domestic industry working to achieve progress in these two areas?"

The *Outline of Healthy China 2030* is the Chinese government's ten-year work plan related to health in the overall process of China's socio-economic development. The COVID-19 epidemic in 2020 has caused global challenges, and in this process, the Chinese government has focused more on disease prevention, especially the prevention of infectious diseases.

The second aspect is the prevention and treatment of chronic diseases. Another point is the attention to the field of rare diseases in children. China's innovative industry has achieved results in these fields that we can be proud of. In the prevention and control of the COVID-19 epidemic, China's vaccines, which have received WHO certification, have been introduced to dozens of countries around the world. Regarding therapeutic drugs, the American companies, Pfizer and

Merck, are at the forefront of developing original medications.

Prominent Chinese firms, such as Junshi Pharma and Simcere, are both PhIRDA members, have localized these products and have also developed their own COVID-19 therapeutic drugs with the same targets. Therefore, China is not only a country that has COVID-19 vaccines but also COVID-19 therapeutic drugs, a relatively rare occurrence on a global scale. No patent disputes arose during this development process. So from this perspective, China's pharmaceutical industry has made significant contributions to global disease prevention and containment, as many developing countries use China's drugs. This represents substantial progress in this area.

Does the Chinese regulatory body have sufficient flexibility to deal with the innovation being brought before them, in your opinion?

We are actively pursuing and exploring regulatory policies for orphan drugs. At present, in the field of rare diseases, we primarily rely on imported drugs. In importing drugs for rare diseases, we've implemented a range of specialized policies. For example, we've adjusted the requirements for the quantity of clinical trials to align with the specific characteristics of rare diseases. We also recognize a substantial amount of clinical data already approved in other countries, which greatly facilitates the entry of orphan drugs into China.

Regarding rare diseases, China introduces new policies annually. Whereas in the past, policies concerning rare diseases were few, now almost all healthcare-related documents encompass aspects of rare disease prevention and treatment. Importantly, we now have not just a group of patient organizations for rare diseases, they are very active. Moreover, the PhIRDA, the Chinese Hospital Association, and Peking Union Medical College Hospital have established the China Alliance for Rare Diseases. Every year on International Rare Disease Day, we hold the China Rare Diseases Conference, thereby raising societal awareness about the significance of preventing and treating rare diseases.

To truly cement China's position as a global innovation powerhouse in healthcare, more Chinese life science companies must shift from 'me-too' drugs to 'me-better' and 'me-first' innovative drugs. What specific strategies have been implemented to assist this transition and what more needs to be done?

There are always some people who use double standards when viewing China. In reality, the global standards for innovation are consistent. There is no dichotomy between ‘real’ innovation and ‘false’ innovation; there are simply different levels of innovation. For instance, in the United States, terms such as ‘first in class’, ‘best in class’, ‘me-too’, and ‘me-better’ all fall within the spectrum of innovation.

However, no one believes that me-too drugs approved by the FDA represent a lack of genuine innovation. There seems to be a general misunderstanding on this matter. We acknowledge that China’s contribution to original innovation has been limited, and our capabilities in this area need strengthening.

Despite this, China is actively pursuing a path of innovation aimed at achieving groundbreaking discoveries. As we progress, we are open to transitioning from ‘me-too’ to ‘me-better’ products. Our ultimate aspiration is to become ‘best in class’, gradually approaching ‘first in class’ status. This is the effort we are making at present.

We hope that, in the future, China will be capable of approving two to three first-in-class drugs for marketing each year. Actually, China has already achieved this goal. Thus, in this respect, the argument that China lacks innovation is without theoretical backing or factual support. By applying the same standard, one could wrongly conclude that the US is the only country capable of innovation, which is clearly not the case.

2023 was a difficult year for biotechs around the world, including in China. What were your impressions of 2023 and what are your predictions for 2024 in terms of Chinese biotechs’ valuations and capital raisings?

Indeed, as you’ve mentioned, in recent years, the global economy has experienced a downturn, which includes disruptions in international trade due to the COVID-19 pandemic. We also cannot deny the impact of geopolitical decoupling, led by the United States, that has contributed to increasing difficulties in the global economy. Furthermore, the post-2022 conflict between Ukraine and Russia, along with the ongoing hostilities between Israel and Hamas, has further strained the world economy. I believe the primary driver behind these escalating issues is geopolitical.

Even now, when things are tough, some are trying to break apart the global market that used to be whole. Consequently, China’s biotech sector has also faced a severe capital freeze under this situation.

However, I believe that this situation has made China's strong interest in research and development more practical. We have always believed that within every crisis lies both danger and opportunity. Without an external force to compel the industry and the R&D process to return to rationality, how can we possibly set forth to embrace a better future?

The year 2023 has brought significant challenges to China's biopharmaceutical industry, one of which is the considerable financing difficulties encountered by several biotech companies. However, we have also observed that capital is still highly enthusiastic about truly innovative enterprises. Those products lacking in innovation and market competitiveness may well be abandoned by investors.

This represents a norm from which China cannot escape. Accordingly, the Chinese government has now proposed a new concept of high-quality development. The introduction of 'New Quality Productive Forces' emphasizes 'quality,' essentially meaning superior production standards.

Therefore, in 2024, I predict that the Chinese government will adopt more proactive policies to spur the entire development of China's biopharmaceutical sector. This intention is apparent from the government work report delivered by the Chinese Premier at the two sessions of the 14th National People's Congress (NPC).

We're focusing on enhancing capabilities throughout the entire chain: starting with drug discovery and moving on to research, approval, marketing, and finally, usage. The Chinese government aims to foster this comprehensive approach, rather than merely concentrating on the achievements of individual pharmaceutical companies in developing new drugs. This is my outlook for China's pharmaceutical industry in 2024. Just like today's weather, we've quickly moved from the cold to warmth because spring has arrived.

We are seeing a lot of fluctuation in the Hong Kong stock market, is that a cause of concern to the Chinese biotech industry?

During these slightly uncertain times, we should bear in mind the continuing high regard that the Chinese government has for innovation in the biopharmaceutical industry. This is because the Chinese government has explicitly identified biotechnology as a strategic emerging industry. This implies that China is not focused on the immediate present but is looking towards the future. Thus, understanding China should not be based on short-term occurrences.

What are the regulatory improvements that you would like the Chinese NMPA to make to help biotechs?

Regarding regulation, we are currently focusing on two dimensions, with one being the standards for drug approval.

Firstly, since China joined ICH in 2017, our clinical guidelines and standards have been fully aligned with those of ICH. The subsequent step is to strengthen the entire clinical trial process. For instance, we need to consider whether positive control studies are essential. For first-in-class drugs, single-arm studies are definitely required. However, for 'best-in-class' or 'me-better' drugs, the requirement for positive control (bioequivalence balance) trials comes into question.

This presents a significant challenge for China's pharmaceutical industry. Moving forward, I believe it is necessary to enhance the standard of drug regulation in China. Additionally, it's crucial to enhance both the quantity and the quality of the personnel involved in pharmaceutical reviews. I'm encouraged to see that the National Medical Products Administration is actively working towards the refinement and enhancement of drug regulatory capabilities and is already considering action plans.

How important is it that the Chinese NMPA attains tier-one regulator status?

As you mentioned drug pricing, it's indeed a substantial challenge for the pharmaceutical industry throughout China. PhIRDA is also actively engaged in providing suggestions to the government for reforming the current medical insurance payment system. A month ago, the General Office of the State Council have released an *Implementation Plan for the Pilot Comprehensive Reform of Pudong New Area of Shanghai*. For the first time, they proposed setting prices for innovative drugs developed there based on international reference prices.

So, we have suggested to the Chinese government that, given the limited nature of the government's health insurance funds, China needs to address a fundamental problem. With the current scale of China's health insurance fund pool, it is exceedingly difficult to reimburse innovative drugs at the same rate as generic drugs. Such high reimbursement rates are unsustainable.

Given China's population size, this kind of coverage might be unrealistic…

With a population of 1.4 billion, China has now covered more than 95 percent under basic medical insurance, which is an extraordinary achievement. However, due to the large population and significant healthcare demands, China's health expenditure as a percentage of GDP has soared from 4 percent to over 7 percent in just under a decade. This near doubling is unimaginable in other countries. Therefore, your visits to China every few years are of substantial importance, as you can witness the rapid changes in this nation firsthand.

Indeed, our medical insurance can decide how much to pay based on its capacity, with the establishment of commercial insurance to cover the remaining costs. This approach is crucial because controlling the market for innovative drugs can inhibit the original source of innovation.

Therefore, the Chinese government is also taking measures to encourage the development of commercial insurance. The lack of development in commercial insurance is due, in part, to the need for mature regulations to manage it. On the other hand, it also requires that our basic medical insurance system leaves reasonable room for it.

China is still an unignorable market opportunity for multinationals, with companies like AstraZeneca, Roche, and Eli Lilly making major recent pushes into the Chinese market. What role do you see for collaboration and cooperation between Chinese companies and multinationals in the future?

Multinational corporations are increasingly significant in China's healthcare system. This is evident from the fact that for our top ten critical illnesses, medications from these corporations make up over 50 percent of the market. This not only shows the substantial potential for growth in China's pharmaceutical industry but also highlights China as a highly attractive market for the leading products of multinational pharma companies. So, have you ever heard of these corporations considering exiting the Chinese market? It's common for people to express dissatisfaction with life, as we all strive for improvement. When people are content with their current situation, they may lack the drive to advance. Complaints, in a sense, are born from hope – they indicate a belief in the possibility of better conditions. Without hope, there is no complaint, only despair.

Regarding multinational corporations, I believe we have excellent cooperation with them in China. We understand they want us to adopt the best policies from the United States while avoiding the less effective ones. However, finding a balance is essential. I see that both multinational and Chinese companies may express certain complaints. The existence of such complaints is precisely why we need a bridge like industry associations including PhIRDA. They play a crucial role in

addressing these concerns.

We continually engage in and resolve complaints. Just yesterday afternoon, I visited the National Healthcare Security Administration of The People's Republic of China to voice my concerns about a pricing policy they are currently drafting. In their presence, I become a complainer myself, which is a completely normal occurrence.

Do you have a final message for PharmaBoardroom's international audience?

From the outset of China's innovation journey, we recognized the necessity of embracing an international approach, a topic I touched upon in response to your initial question. As it strives to become a leader in the innovation nation, the Chinese government has consistently stressed the importance of maintaining an open policy and the commitment to international collaboration. Therefore, in our collaborations with innovative partners across the United States, Europe, and Asia, we strive for increasingly closer ties and deeper cooperation.

The Chinese government has never enacted any legislation that forbids international collaboration, yet it's Washington that seems to be instituting such measures, such as the BIOSECURE Act. They seem set on targeting China's CDMO industry. I find this to be completely unreasonable because the phase we are transitioning into is characterized by a dramatic rise in irrationalism, especially among politicians. Thus, hindering the exchange of scientific and technological ideas, as well as industrial collaboration, under the guise of national security is, in truth, quite injudicious. There are no winners in this scenario.

After so many years of globalization, it is clear that we are interdependent and interconnected. Cutting off the channels of cooperation would lead to harm on both sides. There's a saying in China: 'One stands to gain from cooperation and lose from confrontation.' I've also observed that American pharmaceutical companies are fraught with anxiety at every step of their processes, and that US policies have not succeeded in expanding the market for these companies, on the contrary, they are creating barriers.

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