Song Ruilin â?? Executive President, PhIRDA, China

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Song Ruilin, executive president of the China Pharmaceutical Innovation and Research Development Association (PhIRDA), discusses his associationâ??s mandate, key achievements and the future of innovative Chinese pharmaceuticals and biotech.

Mr Song, could you please introduce PhIRDAâ??s mandate to our international readers?

The China Pharmaceutical Innovation and Research Development Association (PhIRDA) is a rather distinctive entity amongst the various industry associations in China because we are defined by the core objective of â??innovationâ?? rather than any industry-defined boundaries. We have first identified a focal point instead of first establishing boundaries for our membership. As an organization, PhIRDA aims to promote innovative pharmaceutical development. This can be seen in our associationâ??s principle, â??Innovation, Industrialization, Internationalizationâ?•.

Innovation is at the core of PhIRDA. Any organization that supports innovation, realizes the countryâ??s dream of biomedical innovation and meets the unmet clinical and medical needs of the healthcare system and patients, can become a PhIRDA member. Our members include not merely companies, but also academic institutions and investment entities, as you can see from PhIRDAâ??s roster of previous annual chairmen, who include outstanding entrepreneurs and first-tier scientists such as Director of Institute of Materia Medica, Chinese Academy of Medical Sciences, and Director of Shanghai Institute of Materia Medica, Chinese Academy of Sciences etc.

Therefore, PhIRDA is not merely an industry association but rather an association that acts as a platform centred on pharmaceutical innovation. Innovation is the standpoint of PhIRDA. Ultimately, we hope to develop a platform to foster dialogue and communication across the entire industry value chain.

What have been the key achievements of PhIRDA during your term as President?

During PhIRDAâ??s development, we have found ourselves in a very opportune position within the current era of dramatic healthcare reforms. Thus, PhIRDA has always been playing its important and indispensable roles.

Under the principle of â??Innovation, Industrialization and Internationalizationâ?•, we have made serious efforts to foster Chinese biotech innovation policies, facilitate international dialogue, and promote inter-industry collaboration and alignment. One of the most notable developments was PhIRDAâ??s acceptance into the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) because we are the only representative of the local Chinese industry. There is another China-based association, RDPAC, that is also an IFPMA member but they represent the multinational pharmaceutical enterprises in China, not the local Chinese industry. Now, as an IFPMA member, we have approved the *PhIRDA Code of Ethics* in accordance with international standards.

As an IFPMA member, we also participate actively in all of ICH guidelines discussions and decisions, training seminars in China as well as expert recommendations for IFPMA EWGs.

Invigorated by the recent innovation-driven development strategy, the innovative environment in China is developing rapidly. In the process, PhIRDA has also united many of the Chinese academics, professors and researchers who studied and worked at top institutions abroad that are now returning to China as â??The Thousand Talents Planâ?• experts (who are popularly referred to as â??sea turtlesâ??). Many of the innovative biotech start-ups that they have founded are PhIRDA members. The main reason is that our philosophy is completely aligned with the philosophy of innovators.

From another perspective, throughout the healthcare reforms process, including the implementation of the National Science and Technology â??Major Project for Major New Drug Research and Developmentâ??, â??Healthy China 2020â?? Strategy and â??Healthy China 2030â?? Blueprint, as well as the key transformative period for Chinese drug review and approval regulatory reforms (from 2015 to 2018), PhIRDA, representing innovative Chinese companies, has also played an important supporting role.

In early December 2016, PhIRDA submitted its suggestions regarding the reform of drug review and approval system and the promotion of innovative new drug development in China to what was then the China Food and Drug Administration (CFDA, now renamed the National Medical Products Administration (NMPA)). These suggestions received the highest consideration by top CFDA officials. In this way, PhIRDA has made noteworthy contributions by sharing industry insights that ultimately supported the *Opinions on Deepening the Review and Approval System Reform and Encouraging the Drug and Medical Device Innovation (The Opinions)* released by the General Office of the CPC Central Committee and General Office of the State Council of China in October 2017.

The fundamental role we have played in this period of reform has left a deep impression on the Chinese central government ministries.

Finally, we believe that pharmaceutical innovation and venture capital investment have an intimate relationship. To drive Chinaâ??s pharmaceutical innovation success, and to enable the successful transformation of basic research into innovation, innovation and investment must be closely interrelated. This is why, since 2016, we have organized the annual China BioMed Innovation and Investment Conference (CBIIC) in Suzhou. In three years, it has become Chinaâ??s largest and most influential biomedical innovation and investment platform, with the number of attendees increasing steadily from 1200 in 2016, to 2200 in 2017, and finally to 2800 in 2018.

It is notable that J.P. Morgan has been a highly supportive sponsor since the inaugural conference in 2016. I have also personally been invited to attend the annual J.P. Morgan Healthcare Conference in San Francisco for three consecutive years, and in the January 2018 Conference earlier this year, I delivered a special report on the significant reform of China pharmaceutical administration in 2017, as China had just published *The Opinions* back then. I have also been invited to the 2019 J.P. Morgan Healthcare Conference to deliver a speech. In November 2018, I was also invited to introduce Chinaâ??s recent biotech innovation and development, policy reforms as well as its impact and achievements for Citi Bank and Goldman Sachs in Hong Kong.

In 2017, we also played an instrumental role in supporting the Hong Kong Stock Exchangeâ??s (HKEX) decision to allow pre-profit biotech companies to IPO. During this process, I had a number of meetings with HKEXâ??s Chief Executive, talking about the implementation plan. HKEX also sent delegations to PhIRDA, and subsequently, both sides finalized the reform plan. We also supported HKEX in the organization of the inaugural HKEX Biotech Summit 2018. In addition, we have signed a strategic partnership MOU with HKEX. I have also been invited to be a biotech advisory panel member for the Stock Exchange of Hong Kong Limited.

All of these achievements are set against the backdrop of the stunning development and achievements of the Chinese biotech and healthcare sectors. For this reason, PhIRDA is occupying an increasingly important role within the Chinese biotech and healthcare industry landscape. For instance, I attended the Hong Kong IPO ceremony of our member company, Innovent Biologics on October 31. Since August 1, 2018, all four pre-profit biotech companies that have successfully listed in Hong Kong are PhIRDA members â?? and the ones waiting to list are also PhIRDA members!

What lessons can you share with other associations?

PhIRDA has extremely close relationships with industry associations internationally like PhRMA in the US and our counterparts in European countries like UK, France and Germany.

Even before we joined the IFPMA, we have always held close dialogue with other international associations. Within the global atmosphere of trade liberalization and multilateralism, I hope pharmaceutical associations in other countries can help to drive closer cooperation and dialogue between the industries of various countries. This is why we were very happy to see representatives and roadshow speakers from over 70 foreign companies attending the 2018 China BioMed and Innovation Conference (CBIIC). Representatives of Embassies from European countries, the US, Canada, Australia and associations such as JPMA, LEEM and so on also participated in the CBIIC. This is a great indication that the China BioMed Conference is becoming a global platform bringing together innovation and capital elements. We hope that this platform can showcase Chinaâ??s full innovation, capital and market potential.

In particular, we hope that industry associations across the world can attend the CBIIC each year. In the words of Chairman Xi, share in Chinaâ??s economic development and prosperity, and at the same time, we hope that as both Chinaâ??s biotech innovation and her economy develop, the country will be able to contribute productively to the worldâ??s healthcare and biotech development.

Amongst the many successful developments within the Chinese biotech landscape, could you single out one or two more notable casesï¼?

I have to admit, in the areas of healthcare and biotech innovation, there is still a gap between China and more developed countries. But ever since China implemented the National Science and Technology â??Major Project for Major New Drug Research and Developmentâ?• in 2008 and confirmed the National Strategy of Innovation-Driven Development, the pace of pharmaceutical innovation has accelerated greatly.

One of the most notable milestones in that journey was in 2011 when a local company, Betta Pharmaceuticals, launched a new drug called Icotinib. This drug was used for the treatment of non-small-cell lung cancer. At that time, Icotinib was highly innovative and represented a breakthrough in a therapeutic area that had previously been dominated by imported drugs. This drug was also the first Chinese-developed drug listed within the *Pharma R&D Annual Review 2012* New Active Substance (NAS) Drug Launches 2011. Looking at current trends, more and more innovative drugs developed in China will receive market approval. The pace of the progress is accelerating.

Coming to the present, there have been some notable achievements and remarkable new drugs being approved, such as the cancer drug, Anlotinib, developed by the company Chiatai Tianqing, which managed to expand the number of treatment targets from one to three.

We also have the example of the company Frontier Biotechnologies, which has improved on the existing HIV/AIDS treatments on the global market and developed a long-acting injection called Albuvirtide, which come in the form of a daily injection, by launching a treatment that just requires a weekly injection! Albuvirtide is the first ever long-acting injection for HIV treatment to be approved globally â?? and for it to happen to China is remarkable. The NMPA has already approved this global first-in-class new drug. From these examples, we can see that the Chinese biotech industry has gradually moved from a position of â??catching upâ?? to â??running alongsideâ?? to even â??leadingâ?? in some areas.

Looking forward then, what are your current priorities for PhIRDA for the next few years?

China has taken a great leap forward in terms of reforms in the past three years. The impact and significance of these healthcare reforms have reverberated across the globe. At their core, they demonstrate a regulatory system underpinned by scientific principles and an objective of putting patients first.

For instance, this is why, for products that can help with severe unmet medical needs, not only have regulatory approval times been shortened significantly, they can now also be exceptionally approved for compassionate use or under certain conditions. For some products that may be the only option available for a critical unmet need, clinical organizations may even accept patients that do not qualify to join the target patient groups. Also, ever since the CFDA (now NMPA) joined ICH, clinical trials data from other ICH members are now accepted for regulatory approval by NMPA, which will expedite regulatory approval timelines.

All of these top-level reforms now need to be implemented step-by-step. We are confident that this will happen soon to encourage and inspire new healthcare innovations in the process.

At the same time, PhIRDA recognizes that we carry heavy responsibilities and face high pressures. As the representative of Chinaâ??s most promising healthcare industry entities, our opinions and insights are requested and considered. Our duties to both companies and government entities are also increasing (including promoting the improvement of regulatory policies and the reform of market access policies), so we are conscious to work hard in order to fulfil the important responsibilities entrusted to us every day. To us, this brings pressure and challenges but also reflects the faith in PhIRDA.

To advance, regulations and policies need to match the fast pace of the industryâ??s development. While there may be areas of improvement in terms of existing policies and systems, we are nevertheless heartened by the close relationships and open communication channels between PhIRDA and various government ministries.

Even as the world is in the midst of a global economic downturn and there are tensions related to the US-China trade war, the unchanging reality is that China will continue to open up in order to drive its economic development.

2018 marks the 40th anniversary of Chinaâ??s opening up and reforms. These reforms have allowed China to develop economically, becoming the second-largest economic power in the world today. Therefore, across government, industry and society, there is a shared understanding of the importance of opening up. We have already seen the results of healthcare reforms, and China is now the second-largest healthcare market in the world. The approval and reimbursement timelines for imported patented drugs and innovative drugs have shortened dramatically. All these augur well for the future openness and growth of the Chinese healthcare market, therefore we are full of hope for the future.

Final messageï¼?

Firstly, I hope that CEOs of pharmaceutical enterprises globally see China as a platform for future growth and international cooperation.

Secondly, just as an example, the number of new cancer patients in China each year is 3.8 million, equivalent to a small country. With this kind of medical need, market size and economic muscle, why would you not come to China? This is to say, the Chinese market is Chinaâ??s but it is also the worldâ??s market. At the same time, China will inevitably exert influence and weight on the global market that is commensurate to its size and potential.

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