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The R&D-Based Pharmaceutical Association Committee (RDPAC) under the China Association of Enterprises with Foreign Investment (CAEFI) represents 46 multinational pharmaceutical companies with a strong R&D presence in China. Managing Director Renaud Gabay discusses how member companies are leveraging synchronized approvals to accelerate access; the evolution of Chinaâ??s regulatory framework that has taken clinical trial approval times from ten months to 60 days, and the impact of the National Reimbursement Drug List (NRDL). He also weighs in on the surge in licensing deals with Chinese biotech companies and the qualities that can help leaders succeed in China.

As the R&D-Based Pharmaceutical Association Committee (RDPAC) celebrates its 25th anniversary, where does the association stand today and what are the key items on your current agenda?

RDPAC, which was founded in 1999, now represents 46 multinational pharmaceutical companies with strong R&D capabilities in China. We have evolved significantly over the years. RDPAC now operates as a working committee under the China Association of Enterprises with Foreign Investment, known as CAEFI, which reports to the Ministry of Commerce. Our role has expanded to collaborating more deeply with both central and provincial governments to improve the biopharmaceutical ecosystem in China.

Over the past 25 years, our member companies have made substantial contributions to Chinaâ??s biopharmaceutical innovation, employment, and patient care. To give you a few figures, collectively, we have over 40 factories and around 30 R&D centers in China, employing more than 130,000 people. Our collective mission is to discover, develop, manufacture, and commercialize breakthrough innovations that transform patient lives. Together, our members have launched more than 800 innovative medicines that have made a significant difference in patientsâ?? lives.

RDPAC advocates for innovation around 3 key pillars: accelerate innovation, reward innovation and protect innovation. As for the key items on my agenda, one of the hottest topics right now is accelerating access to innovative medicines for Chinese patients. This involves shortening the clinical development time and achieving simultaneous approval, which is a critical goal. Additionally, we are focused on speeding up access to hospitals for these innovative medicines.

You have had an outstanding career in the pharmaceutical industry, both globally and in China. What made you decide to take on this new role with RDPAC?

I have spent my entire career in the pharmaceutical industry. Most recently, I was the General Manager of Abbott Pharmaceutical, in Shanghai. I had already spent 11 years in China, 10 based in Shanghai, and now in Beijing for more than a year at RDPAC. Before that, I held various roles in different companies. I started as a medical representative at Eli Lilly and later became the Marketing Director at Fujisawa, which is now part of Astellas. I also spent over six years at Novartis, overseeing their marketing activities.

At this stage in my career, I felt it would be wonderful to leverage my experience across different geographies and companies to work for an association that has a broader impact. RDPAC allows me to collaborate with the government on designing favourable policies for Chinaâ??s biopharmaceutical ecosystem. It is an opportunity to contribute to a collective cause with a noble mission, and that really appeals to me.

You mentioned that part of RDPACâ??s agenda is to foster an environment that allows shortening the time to the clinic and simultaneous approvals. Could you clarify how this works in practice?

The idea is that by participating in a global clinical trial, our member companies complete the data required by the FDA, EMA, and the NMPA simultaneously. This allows them to potentially file in the US or Europe and then in China at the same pace. By doing so, if the dossier is filed in China before being approved in the rest of the world, it is granted the status of Innovative New Drug, meaning â??New to the World,â?• which gives benefits for patent term extension for example. Even though the submission might happen later in China, the approval could occur in a much shorter timeframe compared to the traditional method. In the past, companies used to conduct separate clinical trials in the US, Europe, and then in China. Now, with simultaneous approvals, Chinese patients can access new drugs much earlier. In 2023, three drugs benefited from this simultaneous approval, this year, in the first siw months already six drugs have such a status.

China is today the second largest medicines market, however, it tends to be viewed as something apart. What makes healthcare needs in China different, and how does RDPACâ??s role adapt to those unique challenges?

Chinaâ??s healthcare landscape is quite distinct. If you compare RDPACâ??s activities with similar organizations in other parts of the world, the differences become clear. Chinese innovators have made impressive strides, and multinational companies continue to play a crucial role in transforming healthcare in China by bringing global expertise, advanced technology, and innovative medicines.

However, China is one of the most competitive markets globally. This means we must collaborate closely with local stakeholders to ensure that Chinese patients have access to the best possible treatments, while also supporting the global expansion of Chinese innovation. RDPAC advocates for initiatives that benefit both international and local companies, improving the entire ecosystem. Access to healthcare is always a key topic on Chinaâ??s agenda. The various routes to market here create a unique environment that we need to navigate carefully.

When we spoke with your predecessor in 2018, she mentioned that multinational corporations (MNCs) held around 22 percent of the Chinese pharmaceutical market, which was slightly below the global average for patented drugs. What is the situation today? Has the recognition of innovation improved, or is it still a struggle to gain acceptance from payers and society?

The situation has indeed improved. Since the regulatory reform of the pharmaceutical sector in 2015, we have seen positive trends in the market dynamics for MNCs in China, particularly in terms of innovation. Today, MNCs represent 28 percent of the total Chinese pharmaceutical market, which is a significant increase from the 22 percent mentioned earlier. Similarly, the proportion of patented drugs in the market has risen from around five percent back in 2018 to eight percent now.

This progress reflects the governmentâ??s strong support for innovation and high-quality development in the pharmaceutical sector. While the percentage improvements may seem small, given the size and complexity of Chinaâ??s healthcare system, even a one percent market share increase represents a substantial impact. It is a continuous journey, and while there is always room for improvement, these changes are a testament to the evolving regulatory framework, better reimbursement policies, and the overall push for innovation. RDPAC continues to work closely with the government to enhance the ecosystem and support initiatives like the Healthy China 2030 goals.

How does the government ensure that the Healthy China 2030 initiative is making tangible progress, especially in areas like life expectancy and disease eradication? Is there a system in place to monitor and assess collective achievements over time?

The Healthy China plan comes with very specific and tangible KPIs, particularly around areas like life expectancy and certain diseases, such as oncology. The government closely monitors progress through a dedicated agency that checks these KPIs every two or three years. It is a very serious effort.

To support these goals, China has implemented a multi-layered health security system, which includes basic medical insurance, supplemented by commercial health insurance, and other forms of coverage. These measures are designed to help achieve the set KPIs and ensure the healthcare system evolves in the right direction.

For those who may not be familiar with it, what can you tell us about the driving forces behind the healthcare system and reimbursement specifically?

There have been many changes in recent years. The backbone of the system today is still the Basic Medical Insurance (BMI), which covers most medical needs when you visit a hospital. Unlike some other countries where you might see a general practitioner first, in China, patients typically go straight to the hospital. The BMI covers a significant portion of the costs, with patients paying a percentage out-of-pocket. On top of the BMI, people can also purchase city insurance or complementary commercial insurance, creating a multi-layered payment system.

For pharmaceutical companies, a critical development has been the National Reimbursement Drug List (NRDL), which is reviewed and negotiated annually with the government. This annual process started in 2017 and has drastically reduced the lag time for drugs to be included on the listâ??from 7.8 years on average in 2017 to just 1.6 years in 2022.

This improvement reflects Chinaâ??s commitment to patient access to innovative drugs. However, getting on the NRDL is just the beginning. The next step is hospital listing, which requires significant effort from multiple stakeholders within our companies, including market access and medical teams.

In 2024, one of RDPACâ??s key priorities is to work with both the central government and local governments like Beijing, Shanghai and Guanghzhou to create favourable policies that accelerate hospital listings. Encouragingly, early results from the 2023 NRDL batch show good listing coverage, with NRDL drugs now representing 18 percent of the pharmaceutical market. In contrast, innovative medicines not yet on the NRDL account for just 1.5 percent of the market. So, getting on the NRDL is essential for any company looking to make an impact in China.

During our pre-COVID interview the NRDL system was just coming into force, and many industry executives saw it as a possible dead end. Now with the system in place, price negotiations are paramount. What factors besides pricing are taken into account?

NRDL negotiations are a critical task for our members, and yes, companies often need to make concessions to access such a vast market. We maintain a constant dialogue with the National Healthcare Security Administration (NHSA), the authority managing this process. Every year, they seek input from RDPAC, asking for suggestions on how to improve the process, and we see a good dynamic in place.

Of course, price is a major factor, and the reimbursement discussion is multifactorial, which often require compromises. We are working to ensure that these negotiations are increasingly clinical value-based, focusing on the clinical benefits of innovation. This includes assessing clinical efficacy, addressing unmet needs, improving quality of life, and even considering surrogate endpoints like less re-hospitalisation or prolonging life.

Over the years, RDPAC companies have registered more than 161 innovative drugs through the NRDL process. MNCs play a crucial role in addressing major diseases, like diabetes, which represents 30 percent of these innovative drugs and are making a significant difference in patient care.

While there is still work to do in making the system more clinically oriented and in bringing prices closer to international reference price levels, the improvements have been significant.

Also is important to note that in China, you do have to renew your listing every two years, and during that renewal, you can provide a new set of data.

Given the disparities within Chinaâ??where cities like Shanghai have incomes on par with high-income countries while many rural areas have more in common with developing nationsâ??how do you balance this when setting a national reimbursement price?

The national government sets a reimbursement price that needs to cater to all citizens, from wealthy urban areas like Shanghai to rural regions. They aim to ensure that innovative medicines are accessible not just in Tier three hospitals but also in county and grassroots hospitals.

For pharmaceutical companies, it is essential to have geographic expansion to fully capitalize on Chinaâ??s potential, but it is also a balance. The government is trying to meet the needs of both urban and rural populations, and companies need to adapt to this wide-ranging landscape.

We understand the benefits and challenges of being on the NRDL, but is there another strategic option and what are the benefits and pitfalls?

One option is to go with what we call a market-based price, where the company sets its own price. However, if you choose this path, you are essentially targeting a niche marketâ??patients who are willing to self-pay for the drug. While this segment is not insignificant, as it represents about 1.5 percent of the total pharmaceutical market in China, it is still relatively small compared to the broader market.

For context, those 1.5 percent of sales come from innovative drugs launched in the last five years that have not entered the NRDL yet. On the other hand, being on the NRDL gives you access to a much larger marketâ??about 18 percent of the pharmaceutical market. Once your drug is listed, even though it may take some time for hospitals to adopt it, after one or two years, you will have much broader coverage. Doctors can then prescribe it more easily, and patients benefit from reimbursement. So, while going the market-based route is possible, the NRDL offers a more secure and expansive path to reaching a larger patient base.

Chinaâ??s NMPA is now recognizing data from international clinical trials. How is this progress being felt by your members? In which areas are you seeing alignment with global standards, and where might there still be room for improvement?

Chinaâ??s regulatory environment has indeed made significant strides in recent years. The time to get clinical trial approvals has decreased notablyâ??from previously over 10 months to 60 days, Now NMPA is piloting 30 days clinical trial approvals in major cities like Beijing and Shanghai. This positions China as a competitive clinical hub globally. Additionally, the time from clinical trial protocol finalization to the first patient visit has improved from 35.9 weeks in 2020 to 22.1 weeks in 2023, as noted in our RDPAC survey.

Chinaâ??s commitment to aligning with international standards is evident through its participation in global committees like the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH), the ICMRA, and the IMDRF. These efforts showcase Chinaâ??s dedication to enhancing its regulatory framework and aligning with global practices.

As for recognition of foreign clinical trial data, China has increasingly accepted international data, which facilitates global clinical development. This is crucial because it allows for more synchronized approval processes and leverages Chinaâ??s vast patient pool to accelerate global trials.

However, despite these improvements, there are still areas for refinement. For example, while the regulatory framework is evolving, continuous dialogue and collaboration with industry experts are essential to address any gaps and ensure that China remains aligned with international standards. RDPAC plays a key role in bridging communication between the government and industry, offering expertise and advice to refine regulatory pathways and maintain high standards of patient safety and product quality.

In summary, leading hospitals in Beijing, Shanghai, and Guangzhou are emerging as major hubs for global clinical development. Chinaâ??s vast patient pool, combined with the size and capabilities of these hospitals, offers a unique opportunity for simultaneous drug approval. By running clinical trials in parallel with the US and Europe, China provides flexibility in patient recruitment, helping to accelerate global clinical trials. If recruitment lags in one region, China can quickly ramp up, making it a key contributor to early access to innovative medicines worldwide.

Also many of our member companies have established substantial R&D facilities in China, indicating that these centers are crucial not just for patient recruitment but also for initiating and designing trials. This integration highlights Chinaâ??s role as a key player in global R&D, contributing to both local and international drug development efforts.

There seems to be a notable increase in biotech licensing deals between international companies and Chinese biotechs and many RDPAC members have large business development teams scouting on the ground. What makes China so attractive as a partner in these deals, and how do these collaborations benefit both parties?

The surge in biotech licensing deals with Chinese biotechs reflects the countryâ??s growing capacity for innovation. Chinese biotech firms are developing cutting-edge research and leveraging shared labs and facilities, making them valuable partners for international companies. These collaborations are attractive because they offer a way to accelerate global cooperation. By partnering with Chinese biotechs, companies can facilitate the approval of drugs in China, benefit from the large market potential, and potentially export these drugs globally.

Chinaâ??s biopharmaceutical landscape is becoming increasingly sophisticated, supported by favorable mechanisms that encourage innovation and investment. For example, the biotech islands and parks in Guangzhou, Beijing, and Pudong, Shanghai, are hubs of activity that provide an ecosystem for research and development. These environments foster high-quality development in the biopharmaceutical industry, supporting both local and global innovation.

What qualities are essential for leading organisations in a complex and dynamic environment like China?

From my experience, particularly as a French national who has spent a decade in the pharmaceutical industry in China, the key qualities for leadership in this market include a blend of strategic foresight and meticulous attention to detail. Leaders must be adept at distinguishing between future impactful policies and those that are less likely to materialise. It is crucial to have a well-defined vision for the organisation within Chinaâ??s rapidly evolving landscape. Moreover,

effective leaders must be deeply involved in the regional specifics of the market.

China is vast and diverse, functioning almost like a continent within itself. Different regions, such as Guangzhou or Chengdu, have unique operational challenges and market access complexities. Successful leadership requires hands-on management and the ability to coordinate across regions and functions. For instance, during a challenging Value-Based Procurement (VBP) negotiation in Guangdong, I had to visit the region several times in a single year. This level of engagement and regional focus is often necessary.

Communication is also crucial. Effective leaders must excel at listening and must be able to approach problems from multiple perspectives. This involves asking the same questions to different people and re-evaluating the answers to gain a comprehensive understanding. The ability to navigate and adapt to cultural differencesâ??beyond just languageâ??is vital. The Chinese culture, like others I have encountered in Japan, the UK, Switzerland, and South America, requires a unique set of communication skills. Emotional intelligence and a genuine ability to connect with people are indispensable in building strong, effective teams and making informed decisions.

As China becomes a strategic market, how can MNCs leverage senior leadersâ?? experience there globally, and what qualities should an ideal executive for a China affiliate have?

We are indeed seeing more senior leaders from China taking on global roles. For example, some General Manager of China transitioned to senior global position within headquarters. This trend is likely to continue as the skills developed in Chinaâ??s complex market can be highly transferable to global leadership positions.

Leading in China requires a deep understanding of the marketâ??s nuances, the ability to quickly navigate its complexities, and the skills to interpret both what is said and unsaid by stakeholders. These abilities are valuable for any global leader. Chinaâ??s dynamic environment serves as an excellent training ground, equipping leaders with the agility and cultural insights needed for global roles. Therefore, it is reasonable to expect that more CEOs will emerge from China in the next 5 to 10 years.

Do you have any parting message you would like to share?

As you can see 2024, the year of the Dragon, is an acceleration point for the improvement of the Chinese biopharmaceutical ecosystem, with faster clinical trial and regulatory approvals, better policies for market access and reinforcement of patent protection, which is also another strong pillar of RDPACâ??s advocacy work.

Thus, I would like to highlight that China is increasingly becoming an international hub for clinical trials and innovative market access strategies. The country is well-positioned to pilot new approaches, such as early diagnosis and early intervention for diseases like Alzheimerâ??s and metabolic syndrome. These initiatives can provide valuable insights and improvements in patient care.

At RDPAC, we are fortunate to work closely with government stakeholders and other companies with a shared goal of enhancing the ecosystem. Despite the challenges, our collective efforts aim to ensure that pharmaceutical innovations benefit Chinese patients and enable China to play a more significant role on the global stage.

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