Eric Bouteiller, China

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02.11.2018

Tags: China, Investment, Innovation

Eric Bouteiller, formerly with Ipsen (most recently as SVP Asia PC Operations based in Beijing) and chairman of the R&D-based Pharmaceutical Association Committee (RDPAC) till December 2017, speaks in his personal capacity regarding the extraordinary changes within the Chinese healthcare and life sciences landscape. He highlights China's dramatic pivot towards innovation in the past couple of years and how all players need to learn and adapt to new rules of the game.

Eric, having spent 17 years in China with Ipsen and now acting as an independent advisor, what have been the most striking changes you have seen within the China healthcare landscape?

The Chinese healthcare landscape is totally different. Out of the past 17 years, the biggest changes in the market have occurred over the past three years, under Mr. Bi Jingquan as Director of what was then the Chinese FDA [as of September 2018, the Chinese FDA has been renamed the National Medical Products Administration (NMPA)]. He has had the vision, the political support as well as the capabilities to drive reforms and implement changes that I have not seen for 17 years. As an industry – both foreign and local – we should all bow in gratitude to his efforts.

Ultimately, there has been a definitive decision to shift China towards innovation. Without delving into granular policy changes – of which there is a multitude – there has been a dramatic change in the direction of Chinese healthcare policy, and therein lies China's hope to become a future

powerhouse for innovative medicines. However, in reality Chinese patients were not benefitting from innovation or very late compared to the rest of the world. The R&D-based Pharmaceutical Association Committee (RDPAC) at that time assessed a total drug lag of nine years. When a new product was launched in a foreign market, it would take nine years before Chinese patients could access it: half of this lag was regulatory and the other half was reimbursement. Commissioner Bi made it a priority to look at this backlog at the Center for Drug Evaluation and within a few years, has successfully reduced the backlog. He has also launched promising regulatory policies to align the Chinese system with international practice and norms.

Another profoundly positive change is that, today, key stakeholders in China agree that the development of innovation relies on the right ecosystem. This has now been understood. Regulatory reforms are moving in the right direction. What is still missing are the pricing and reimbursement system, and the clinical trials system.

Could you share your insights on what further reforms should be made?

While I speak today in my personal capacity, I had previously been very involved with RDPAC, serving as Vice-Chairman in (2014-2016) and Chairman (2016-2017), and even now as Honorary Chairman. I am grateful to have had the opportunity to build on the past achievements of RDPAC. Under my leadership, RDPAC focused on developing what I called the ‘Coalition for Innovation’ strategy. Previously, RDPAC had a reputation as a nay-saying association. We had different views from local actors and we always focused on what we wanted to see from our international perspective. We tended also to be reactive.

On the contrary, I guided RDPAC to follow a different path: working more with local associations and local industries. At the end, whether foreign or local, we care about the same things. We want an equitable and reputable regulatory system through which we can launch new products from abroad or develop new products locally. In fact, there was strong common ground between all of us. Therefore, from a policy standpoint, we developed progressively three key studies to look at the Chinese healthcare system in great detail. The first was on the need to develop an ecosystem for innovation, the second was on the development of the appropriate pricing and reimbursement system to provide the right economic environment for innovation, and the third was about improvements to be made to the clinical trials system to enable the development of innovation.

On the pricing and reimbursement side, we have seen some positive steps. The Chinese government has started to update the National Drug Reimbursement List (NDRL) more frequently

in recent two years, which is encouraging. China has also made the right move to cease the formal planning system, who no longer have direct administration over drug pricing. However, at the moment, there is still no agreed or defined system for the assessment of the value of a new product. This is a critical step: how should the value of a new, innovative product be assessed, and consequently, what level of pricing and what level of reimbursement? This has a huge impact, not just on foreign companies but also on local innovators. We all need to develop business cases. We need to be able to understand the rules of the game, which need to remain consistent and sustainable over the next decade – or even longer!

Simply put, if we lack clarity on the system, innovation in China cannot flourish. There are many models the Chinese government can reference, be it the American model (which I personally do not recommend), the European (Franco-German) model or the British model. Of course, China will generate its own system. Whichever approach is selected at the end, I hope we will have clarity on the value assessment of a medicine, along with the economic implications that will have on pricing and reimbursement.

You also mentioned the need for reforms on the clinical trials side. What are the main challenges here?

The quality of clinical research and clinical trial data is still not at the level it should be. Innovator companies will inevitably require strong and reliable data. China has superb hospital institutions and world-class physicians and clinical researchers, but they are not being supported by the management systems in place. Clinical research is not currently valued by the hospital's internal assessment, so doctors interested in clinical research pursue it in their own time and interests. Sometimes they do it even at the expense of their own career advancement. They are not rewarded or positively graded for clinical research. Also, hospitals do not have compatible data systems, so multi-site clinical studies experience operational difficulties.

On the companies' side, we have a strong interest in conducting clinical trials in China! We are ready with training systems, we have CROs working with us, but our partners – the clinical researchers and doctors actually conducting the clinical trials – are not well-equipped. Chinese clinical trials data can be generated to meet international standards, but the overall system needs to be improved.

Drawing upon your 17 years with French midcap Ipsen, how would you say Big Pharma's perception of the Chinese market has changed over the past two decades?

Even back in 2012, China was not as high on Big Pharma's radar. Back then, Ipsen was one of the very few multinationals for which the Chinese affiliate was the number two affiliate within global operations. Today, many companies are now at that level because the Chinese market is itself the second-largest market. There has been a lot of catching up.

Undoubtedly, China is now one of the critical markets where the future of a company is decided. To succeed as a pharma company in the future, you have to succeed in China as a market. In 2012, China was a little forgotten. Today, a global strategy cannot miss China. It is not inconceivable that in a few years, China could become the number one market in the world over the long term. In volume, it is already the case. With innovation, China will re-look at its pricing and reimbursement system.

In the short term, if China does not have the right system in place and the price for innovation is too low, locals will not innovate in China and international companies will not bring international innovations to China. A balance between sufficient recognition of innovation and adequate social safety net for China's citizens – a balance that I personally believe European countries like France or Germany have established – is the key to long-term sustainability of the healthcare system.

How will all these developments impact China's domestic players?

The locals have to adapt themselves as well. There are roughly 4000 manufacturers in China. The biggest change for them is probably the secondary reforms associated with China's pivot towards innovation, such as the new Quality Consistency Evaluation (QCE) system, which is all about raising the quality standards of products from local companies and ensuring recognition and linkage with the innovator products. The general view is that Chinese companies are all generics manufacturers, but under the previous system, they were technically not generics, as their products were not linked to the innovators.

Under GQC, the concept of a 'generic' concept is now established. This means that local companies have to decide if they want to continue in this direction and become "real" generics players, which means competing on cost or going up the innovation route with the need to invest in R&D, develop new drugs, and all that.

This is forcing the transformation of local companies, who now need to differentiate. There are many potential partnerships to be formed between domestic and foreign companies based on their own strategies – but all are completely dependent on the policy decisions of the Chinese authorities.

A final message?

Everybody, international and local, big or small, has to adapt to the new rules of the game. It is not business as usual. What happened in the last two years is a dramatic pivot toward innovation. Companies have to adapt their portfolios and strategies.

Looking at the global picture, what has struck me most in the last couple of years is that everyone now is “talking science”. In our last interview in 2012, very few were talking about science. It was about registration, the bureaucratic process, launching, market, infrastructure building… Now, it is all about the science – the authorities, the companies, the CROs, the investors – all our stakeholders are talking about science. This shift is extraordinary. Where we used to talk about bureaucracy and business, now we are talking about science. That is why I have high expectations for the China market.

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