Cross-Border Life Sciences Collaborations in China

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Presented by Lester Ross, Kenneth Zhou and Belinda Juran

Belinda: Hello, everyone. Welcome to our webinar today on Cross-Border Life Sciences Collaborations in China. I'm Belinda Juran, a partner in the WilmerHale Corporate Practice in Boston with a focus on technology transactions and licensing for life sciences clients. I'm joined by my partners, Lester Ross and Kenneth Zhou, who are based in our Beijing office.

As we start, by way of background, this webinar was created because we, in the WilmerHale life sciences practice and licensing practice, are representing a number of US and other western life science clients in out-licensing rights to early stage and commercial stage drugs to Chinese investors in biotechs, as well as representing Chinese biotechs who are acquiring rights from US companies. In those transactions, we work closely with our partners and team in our Beijing office who have been extremely helpful in answering questions. We thought this overview for clients and those interested in potentially doing such deals would be helpful.

Let me now introduce today's speakers. Les Ross is a partner in our Beijing office. His practice focuses on mergers and acquisitions and regulatory matters, where he represents both foreign and local companies. He advises foreign companies on competition law and regulatory compliance in China. He's held various leadership roles in the American business and legal communities in China. Partner Kenneth Zhou is also based in our Beijing office, and his practice focuses on direct foreign investments, cross-border M&A deals, antitrust and regulatory matters, FCPA and international dispute resolution, and he's advised foreign companies on their strategic expansion in China. Kenneth is former GC of the American Chamber of Commerce in China.

I will now turn it over to Les and Kenneth for today's presentation. Just as a quick point, today's presentation will begin this topic and give an overview, and we expect to do a second session where we will dig even further into this topic in a few weeks.

Les: Thank you, Belinda. Just to clarify, I am actually in our Boston office today doing some business here in the States. I go back to Beijing on Saturday this weekend, and Kenneth is dialing in at a very different hour from Beijing. We're very pleased to be here. As Belinda indicated, the material we're presenting today is actually quite extensive. We thought that this would be most appropriate because the nature of the business that we're talking about, that is to say, extensive US and other foreign licensing deals into China. Of course, now China is also becoming an innovator country, so there is technology coming in reverse. But in addition to that, there is also a lot of investment flowing back and forth.

It's quite likely, as we go through this material, that we'll actually be stopping halfway, but you've got a slide on the table of contents. You see where we intend to stop, and then resume later on. I'd like to begin by just pointing out the basic trends that are motivating this. China, of course, after the Communist Party took power in 1949, they had extensive efforts to advance public health, and so a tremendous gain in terms of basic public health accomplishments, including combating the kind of endemic diseases as well as poor environmental and dietary issues that had existed in China for many years.

But in terms of the neglect of more advanced biotech and investment in the healthcare industry, and in addition to the provision of a higher level of healthcare for the population, that was relatively neglected until recently, until the last number of years. And that's shown, the reasons for that are shown in the slides that you see now. As you can see, longitudinal demographic profile in China indicates both that the people's health is improving, as shown by the fact that the population is aging, but also there is greater demand for more sophisticated healthcare to address the needs of the elderly population. And as a result of that, the demand is there, and now the Chinese government is attempting to satisfy that demand.

If you look at the next slide, you can also see that there has been a slight increase as grown over time in terms of the longitudinal mortality profile in China. And this again, indicates that there is a greater recognition, greater awareness the population is aging. It is in greater need of attention to the healthcare needs of the elderly. It also means, for those who are interested in different aspects of the healthcare industry, that there is greater need for elder care services, including nursing homes and the like, and that also is an important subject that our firm has been involved in for quite some time.

If we turn to the next slide, you look at the cancer incidence and mortality profile here in China, and as you can see, the number of cases is really very, very large. We have data going through 2014, and cancer, of course, here is just one indicator of the issues that are faced, including diabetes and various other conditions for which the demand for higher level of healthcare in terms of pharmaceuticals, also in terms of medical devices, is growing. We'll also turn to this later, and probably in the next session for a specific example of that.

Now if we look at the next slide, you can also see the same kind of dilemma that affects the United States also and many other countries affects China as well, albeit, currently lowest scale. The proportion of money that is being spent on healthcare is rising. Now, the government is making a tremendous effort to expand healthcare. So now, virtually the entire population is eligible for government-funded health insurance.

However, the level of health insurance is extremely low for the great bulk of the population who is in the countryside. And you have the people in the municipal, in the cities, the level of care that's subsidized by government health insurance is still quite low. What the government is trying to do then is to expand healthcare, raise the level of healthcare, but it's also cognizant of the need to control the rise in healthcare expenses. And this creates, of course, a greater need for some of the policies that we'll see during the presentation, under which the government is taking active measures to control healthcare expenses.

Now part of the reason for the rise in healthcare is the growth of the middle class in China, which you see on the next slide. Per capita annual disposable income is rising very rapidly, and any of you who have been to China, you could see that certainly in the major cities, but even in the what we call the second, third, fourth tier cities, and to some extent, even in parts of the countryside, there is much greater wealth than existed before, and people are much more cognizant of the potential that exists for improved healthcare. And more demanding of that for themselves and for their family members, both their children and their elderly relatives.

On the one hand, it means that people can afford more, and on the other hand, it means they also put greater pressure on the government to improve things. This includes a variety of different measures. For example, the government is taking greater efforts to improve environmental protection in China because part of the problem that exists, aggravating, for example, lung cancer is the severe air pollution that exists in China, and in addition to that, water pollution, contamination of food supply, all of those kinds of environmental issues are of greater concern. But in addition to that, people are all aware of the possibility of improved healthcare, and to some extent, also have greater resources in order to pay for it. Nevertheless, and the ability to pay for their personal resources is limited, so the pressure on the government to do more is rising quickly.

If we look at the organization structure for town services or the, this is the basic structure for the government's science policy. It has been a major reorganization that was announced and approved in March at the Annual Meeting of the National People's Congress, China's legislature. As you can see, we don't mention the party here, but the party is on top of everything. As Xi Jinping has said,

> *"The party is on top of the economy, the party is on top of the military, the party is on top of the government, and the party is on top of schools. North and south, west, east, the party is on top of everything."*

Take that into consideration when you look at this reorganized structure here. The State Council, which is China's cabinet that are on top. But what the government did in March was reorganized by reducing some of the ministries, consolidating some of the ministries, restructuring some of the ministries, but also consolidating a number of regulatory functions into a single entity, the State Administration for Market Regulation, which comes below the State Council. And this is the entity that was directly responsible for the various healthcare responsibilities at essentially the level below the cabinet.

If we look to the left side of the chart, you'll see there's the National Health Commission, which is, in fact, the ministry level agency. It had previously been on as the Ministry of Health. Then when China decided that its extreme emphasis on family planning and birth control was not helpful. You can click back and look at the demographic profile and see the aging of the population as one indicator of what was probably recognized as a problem. Then the Ministry of Health was reorganized into the National Health and Family Planning Commission. But now that Family Planning has been seriously de-emphasized and people have had a period of time to adjust to that, and the government has been able to figure out what to do with all of the people who were part of the family planning bureaucracy, the name has been shortened, abbreviated to the National Health Commission.

But in many respects, the most important agency is the State Administration for Market Regulation, which is on top of a whole series of different regulatory agencies, including the new consolidated anti-monopoly bureau, the State Drug Administration, which until recently was known as the China Food and Drug Administration. The State Intellectual Property Office, the State Administration for Industry and Commerce. In other words, a whole lot of great deal of functions, which are involved with market regulation and product certification and registration, and the intellectual property. These are all different components that come under the State Administration for Market Regulation. The State Drug Administration is shown by its renaming. Food has basically been removed from its purview, and so it focuses more on drugs. And then under it, there's a Center for Drug Evaluation.

In many respects, China, it's a unitary government system, unlike the United States or unlike Canada. It's not a federal system. Nevertheless, it is a huge country. Geographically, it's approximately the same size as the United States. Population-wise, it's nearly four times the population. In many respects, what counts in terms of where people are going to be asking questions, and in terms of their immediate regulators, it is the provincial authorities. So that will be the Provincial Drug Administrations, or in some cases, of course if you were in Beijing or Shanghai, which are municipalities that have provincial status, then it'll be the Municipal Drug Administration.

But the higher-level agency sets the rural policy. It's the subordinate level that administers the policy. But it has a lot of discretion. The distinction between these different levels is very important, and it also means that in terms of actually doing business in China, it's important both to recognize what Chinese law and regulation provides, seeing, too, where there is opportunity or additional benefit because discretion is allowed. It also means that it's important to have good relations if one

is actually doing business in China with the regulator in order to enhance the possibility that you'll be treated fairly. It is, unfortunately, the case that the foreign business community, including the American business community, has continual complaints about the lack of a level playing field. There have been improvements in this regard, but there continues to be shortcomings in this regard.

If we turn to the next slide, we can see the major laws and regulations. Looking at the dates, you will see that there has been, and we'll go into greater detail on this, a lot of legislative and regulatory activity in this particular sector. The drug administration law, which existed for some time was amended just three years ago. The regulations for the implementation of that law, and that's typically the way in which the regulatory system operates. Any law, rule or regulations for the implementation of that law, and then there were various measures in policy documents, guidance documents, and so forth, that go into greater detail on how the law is being implemented and on what the provisions of the law actually mean.

So those regulations were amended a little more than two years ago. But as you can see, below the fundamental measures of the Administration of Drug Registration, those haven't been updated in quite the same extent. They're 11 years old or so. But it's important even there to recognize that the government is moving in the direction of faster drug registration for critical diseases and for innovative drugs, and we will go into that in some considerable detail as we move forward.

If we turn the next slide, we can see that there are key, the key legislative and regulatory developments in somewhat greater detail. And as I mentioned, China has been engaged in comprehensive regulatory reform of policy with respect to drugs and medical devices since 2015. Part of the purpose has been to encourage innovation while reducing costs and reducing to some extent, or at least improving, modernizing the regulatory burden on life sciences companies. There are multiple motivations for this, as we mentioned, the improvement is higher demand for improved healthcare, the government's ability to do so, but at the same time, still limiting cost increases.

The government is also engaged in a major effort to enhance China's innovation, to move Chinese industry forward across a whole range of industries. Some of these are encapsulated in what's called the Made in China Program, which began in 2013 under Xi Jinping's leadership. Xi Jinping, of course, is the General Secretary of Party and now President of the People's Republic of China, and it identified ten sectors of principal importance for innovation, for essentially moving China forward in terms of its industry capabilities, and to some extent, also its ability to be self-reliant as necessary. One of those ten sectors is the biotech sector, both with respect to medical devices and pharmaceuticals. And part of the purpose of Made in China is to introduce what they call Internet Plus or smart manufacturing, and artificial intelligence, into the select industry sectors, and also to provide greater government subsidies for companies that are investing in those industries and, of course, to succeed in those industries so that those which are most capable should be benefiting the most.

The Internet Plus aspect of this means that there's a greater emphasis on the cross-fertilization of technical skills that are emerging in different ways, and so that the manufacturing process as well as the creative process itself can advance to a greater degree than has been the case before. The secret that the Chinese leadership sees for policy development goes forward, is the ability to harness the capabilities of automation, the capabilities of, basically, the internet, and applying those across all sectors of the economy.

If we look at the key legislative and regulatory developments, we can see that in 2015, the State Council, again, the State Council is the cabinet, they issued opinions on the reform of the review and approval system for drugs and medical devices. They indicated the basic regulation hasn't been amended since 2007. But that hasn't prevented the policy, the government from making specific changes in terms of the registration process. Beginning in 2015, with that State Council directive, the government has begun a more fundamental regulatory system, reform of drugs and medical device policies, particularly with respect to registration. Registration has been a key holdup in the system. It's taken a long time. It's a fundamental concern of domestic scientists in domestic industry, and also for foreign companies thinking to introduce their products into China for licensing or manufacturing directly in China.

The government has belatedly, 2015, doesn't sound belated, but considering the number of years in which people have complained about it, the government just moved forward now to advance this process in order to bring higher quality, more innovative, and to some extent, less expensive drugs and medical devices available, make them available in China. Then we go ahead. You can see in 2016, the China Food and Drug Administration. Again, that's the former label for the State Drug Administration. It issued opinions, which are not just opinions. These are authoritative decisions. They're issued in the form of an opinion.

When they're issued in the form of an opinion, it means there's some latitude in terms of compliance. It's not strictly defined how you're going to comply, but it is an authoritative statement of government policy, and it will be enforced in some respects, of course, what they're saying here is there's a new procedure. It's up to you to take advantage of them. What the government did in this instance was it announced a new procedure for priority review of particular drugs and medical devices, those which were innovative, those which promised to bring the greatest benefit to the Chinese population, those which addressed the chronic diseases and so forth, which hadn't been addressed before, unmet medical needs. And also to encourage overseas manufacturers to enter the China market, to operate in China, to make their products more widely available in China.

This is very important to broader trade and investment issue in part, but it also involves recognition that unless foreign cooperation, unless foreign manufacturers, foreign research institutions and the like, unless they were given greater access to the China market, it would be difficult for Chinese industry and for Chinese researchers to advance. There is a greater opportunity now to bring

products forward into China from overseas at an earlier stage, and also to establish manufacturing operations in China to a greater degree than it was the case before.

If we came back, the first China manufacturing joint venture in China, in the pharmaceutical space was 1981. And this was Squibb, Shanghai Squibb, which of course is now, it became BMS in several iterations. Foreign involvement in the pharmaceutical industry in the People's Republic of China, has history of only about 35 years, and at the onset for many years, you could only operate through a joint venture if you chose to operate in China directly. Off course, the licensing arrangement would be quite different, if we were only, if we were complying to licensing.

It ended many problems associated with the joint venture structure. It may be attractive to some because it involves lower contribution of capital. Of course, you got Chinese partners, who can address many of the issues that are associated with running a company in China. On the other hand, there are also a lot of difficulties in establishing and operating a joint venture in any part of the world, and it's particularly true in China because China has its own rules that define joint ventures. So joint venture is not just a company with two or multiple shareholders. It’s actually based upon a specific form of governance structure, and assuming that the minority is a Chinese partner, or it's 50-50, or if the foreign party is a minority partner.

There historically have been great difficulties in operating such joint ventures successfully. If we look at the statistical history, we will find that joint ventures have diminished greatly in popularity among foreign investors once they were allowed to establish wholly foreign owned industries—that is 100% foreign owned in at least some sectors of the economy.

Even if there is to be effectively a joint venture with a Chinese party, we recommend that the joint venture essentially be established as a joint stock company overseas, and then in turn, that company operates the wholly owned company in China, because that briefly simplifies the difficulties of operating in China, and it makes it much easier to address issues between the shareholders, you know, based on a basis that is much more conventional than the rest of the world, whether it's in United States, Canada or UK, or whatever. Nevertheless, the government has moved in the direction of encouraging a greater degree of foreign investment than was the case before.

If we turn to the next slide, we can see that the government has moved forward also. Again, the former CFDA just two years ago, they issued work plan for reforming the classification system for chemical drugs for their registration purposes. What it does is distinguish, clarify the distinction between new drugs and generic drugs, and it also established a system of priority in terms of registration, so that the eligibility for the highest priority, new drugs, is limited to those drugs which haven't been marketed anywhere in the world. Whereas the previous generation concept was not marketed in China.

As a result of that, it means, essentially, that if the drug has already passed a registration in the United States or another accepted, widely accepted foreign jurisdiction, it can, in many instances, qualify for the priority review procedure, and be introduced more quickly in China than was the case before. This is the major reform that's taken place in just over the last two years or so.

We can see the basic genesis of these reforms in terms of the words of Xi Jinping. Again, if you want to call him Supreme Leader of China, you can call him Supreme Leader. At the August 2016 National Health Conference, which is an important conference, he gave his prestige publicly, to a greater extent, that had been the case before, to the need for reforms in terms of the development of the medical industry in China, and to the organization of healthcare in China. There were about 10 different points that he emphasized. One broadly promotion of a healthy lifestyle, a recognition, of course, that if people are comfortable and get used to a more sedentary lifestyle with the kind of diet that is familiar and more similar to the US in a stage from an earlier period in time, that, by itself, presents greater issues, greater demand for healthcare. But a lot on the strength and health delivery services that is improving and increasing the development of the delivery of healthcare services. This includes, for example, the delivery through personal physicians.

For the most part, Chinese people have relied upon clinics which existed, low-level institutions and hospitals—and the hospitals were tremendously overburdened. The occupancy rate in public hospitals in China today, and almost all hospitals are public (although that is diminishing). There is now a private healthcare industry in terms of hospitals, albeit subject to 70% foreign ownership count. The occupancy rate on average 115%, which means that people have been going to hospitals for illness that didn't necessarily require hospitalization, and it also meant that because it was less ability to care for people after discharge, that they tend to stay in hospitals for longer period of time.

Improved protection of health. This includes as I mentioned before, the environmental protection and the like, indeed, the healthier environment. A greater emphasis on prevention rather than treatment. Then the development of the health research-based health industries. As I mentioned that's tied in part to Made in China 2025, which includes medical devices and pharmaceuticals as one of the ten priority sectors for industry development, but especially it means the focus on the research and the commercialization of research, accelerating that process. The government is very determined to move forward with advancing China's capabilities with respect to innovation in the economy.

Then expanding the healthcare delivery services at the grassroots level. This means that people shouldn't necessarily have to go to hospitals at the big cities for this purpose. One of the things that China is doing is enhancing digital healthcare so that one principle, in many respects, can go to your local clinic, and then if there's an ailment recognition at the local clinic cannot handle on its own, it can then tap into a system bringing advice from the country's top hospitals down to them. A lot of things can be accomplished in terms of healthcare without having people travel to the big

cities for cluster and line at the big city for a few minutes of consultation at most. There's greater emphasis on sort of establishment peer-based system.

Then also recognizing that the Chinese private sector has advanced to a great degree. There's a lot of wealth in China. There's a lot of capability. Companies go public. People have much more money. Mobilizing the private sector, what we refer to here as the silo investment as well as governmental investment. A combination of public and private resources to advance healthcare in China. But at the same time, China is also recognized that cost cannot (or should not) be allowed to escalate without control and looking in part to the United States as an example of how that could get out of hand.

China has also moved in this effect the ability of companies to, or what companies can expect when they license their drugs into China. The government has embarked on a major effort to curb excessive drug prescription, and also to lower medical costs. And lowering medical costs means, in part, to a significant extent in fact, demanding lower cost pharmaceuticals through a complex system of negotiations to bring those costs down. And then in addition to that lowering barriers to foreign investment and the participation of foreign personnel in China in the economy, including the healthcare industry, and in universities and other research institutions.

China, historically, have relied on a system which they called "foreign experts," which were essentially either people who was, back in the 1950s, who have come from the Soviet Union and elsewhere to share their knowledge in China. More recently, it had become a more open system, but it was still handicapped to a great degree by treating people just as experts. Now there's a greater effort to recruit foreign doctors and foreign research scientists, including allowing them to create their own labs or to participate in the commercialization of their discoveries, so there's much greater emphasis in this regard, and this applies not just to people from United States, but to people from Southeast Asia, East Asia, anywhere in the world. Important changes. And again, because Xi Jinping is so powerful, when this conference was convened, and some aftermath of this, it really...it further accelerated the reforms that were already beginning to take place in China in the legislative and regulatory space.

Now, we turn to the next slide, we also see that there are direct reform policies taking place, and these drafts for foreign policies, again, began on the CFDA. Now they're the responsibility of the State Drug Administration. Although they haven't yet been finalized, they are beginning to be implemented in practice. And there is a degree of flexibility that exists in the Chinese regulatory system, for certain purposes, at certain times with respect to certain products, or certain issues. One of them, you can see, circular 52. Circular is a Chinese term meaning a notice. It's distributed by a government agency to those parts of the bureaucrat structure, and those companies and so forth, which are involved in the area, so that they now know that there has been a change in government policy. And these are consecutively numbered. In this case, of course, we have four that are consecutively numbered, but this is the classification system. This would be year 2017 circular 52.

And one is to expedite the review and approval at new drug registration applications. One is to deregulate, to make more flexible the concept of clinical trials. Again, to encourage innovation. Another importantly though, and to some extent, it's counterpart of the somewhat more expedited registration of clinical trial approaches is to enhance supervision of a particular drug after it has reached market, because, otherwise, there's a risk that something that is wrong could create problems.

Circular 55 seeks to protect the ones of drug innovators. There are major changes in this regard. We should mention, China has rightly been criticized for its shortcomings in terms of intellectual property protection. There continue to be shortcomings in this regard. Trade secrets, for example, continue to be less well-regulated than in the United States, even though the operative law was amended last year. Some improvements but not nearly enough, as many associated had wanted to see. There are shortcomings in that regard, and though the Chinese judicial system is not as good as it was, and of course, there are still some degree of theft.

On the other hand though, things have greatly improved. If we go back to the organizational chart under the state market administration, the State Intellectual Property Office has now been pushed under that administration. And the State Intellectual Property Office's stature, to some extent, has been enhanced because it now is not responsible only for patent, but it's also responsible for trademarks and other forms of intellectual property. So that it could provide a consolidated preview and take into a greater account the possibility of IP infringement by using, essentially, a copycat name for the same kind of product or by implying that something is a drug that has been properly registered when in fact it is really not a properly registered drug.

There is now a greater capability to address those intellectual property issues. Having said that again though, there are still shortcomings, and therefore, anybody who's seeking to introduce their product to China really has to make a fairly firm preliminary effort to take the maximum protection available. If you don't do that, then the possibilities are very, very limited.

Then we go to the next slide. As you can see, the State Council just within the last six months, further opinions on improving the review and approval system for drugs, again, all of the things which we've mentioned before are there, plus promoting the production of generics. Again, that's the challenge perhaps for some people, and establishing the new marketing authorization holder system. And this is a new system that will essentially provide that this, who is entitled to market the drug. So that's another effort to move things forward. St the same time, just two days later, the government moved to facilitate the review and approval process for imported drugs, particularly innovative and imported drugs.

These things are happening in terms of innovation with respect to the regulatory system, are now happening in a very rapid timeframe. The drug administration law, there are new draft amendments. If we turn to the next page, the measures on the Drug Administration Drug Registration, there are now draft amendments in this regard. New marketing drugs catalog similar

to the "Orange book" has been issued. The process is moving forward very, very rapidly. And in fact, just two weeks ago, on the 25th of April, the State Council issued opinions on promoting Internet Plus medical treatment and healthcare, which means, essentially, digital healthcare.

All of this is moving forward in a very rapid pace. One of the things that you would have seen is the Ping An Insurance Group, it's Ping An Insurance, it's Ping An Banking, they have many subsidiaries, and one of them, healthcare and technology company limited, which the brand name is Ping An Good Doctor. It went public in Hong Kong. It raised over a billion dollars. And that share price has subsequently fallen from the initial offering price, but the government is very intent upon, and Chinese companies involved in the IP space are very intent upon advancing digital healthcare.

This also applied, of course, to digital insurance as we call it in the United States, digital health insurance, in a very rapid way. It's important to recognize how important this is. I will stop here and turn it over to my colleague, Kenneth Zhou, who's in Beijing.

Kenneth: Thank you, Les. I would like to talk about the priority review procedure for innovative drugs. The CFDA, which is the Chinese equivalent of FDA in the US, accommodated these opinions on resolving the backlog of drug registration applications and implementing the priority review and approval procedure in February 2016.

The backbone of this opinion was that it was taking so long in China, the order for CFDA, and its provincial offices to process any sub-applications for clinical trials and applications for new drug. If I give you one sort of example in the past, a novel clinical trial application to China can take as long as a year to a year and six months to process. For new drug applications, it can take two years, three years, four years, or even longer in order get approved. In order to get marketing authorization approvals, from the Chinese authorities.

That delay drew a lot of criticism in the industry with respect to not only from the Chinese domestic pharmaceutical manufacturers, but also from international pharmaceutical manufacturers. CFDA, in response to the criticism, had a very strong need to putting in place a system where it can sort of speed up the process in order to encourage local and international new drug innovations to meet unmet medical needs.

That was the background of this opinion. And under this opinion, the key thing is this priority review procedure was established. The purpose of the opinion as we mentioned in the slide, is basically to encourage innovation, an international drugs to meet unmet medical needs, and also to encourage overseas manufacturers to plan and perform clinical development in China, in parallel with the US, European and other jurisdictions, which is also very important.

Having said that, this new priority review process or procedure does not apply to all applications. By contrast, it applies to certain applications, which, you know, meets the certain criteria. As we listed here, the criteria would include the registration applications for drugs with apparent clinical

value, which really means that government does have the discretion, including innovative drugs not marketed in China or elsewhere in the world, including innovative drugs for which manufacturing facilities or process is going to be transferred to China, also including drugs with advanced formulation technologies, innovative treatment methods, and apparent treatment advantage.

There are other applications, which can also use the priority review process, which really could include global clinical trial applications in China, in parallel with the US or EU. In other words, China does not need to wait until the US or EU approves relevant applications. Innovative drugs for certain diseases, HIV, AIDS, hepatitis, etc. These are the main criteria where an application could be reviewed on a more expedited basis under the priority review process.

Basically, if an application qualifies for the priority review process, the applicants will be given. What does that mean? It really means one thing, which is the approval timeframe could be significantly sharpened. In other words, why there were so many delays in the past with respect to these applications, the main reason was the CFDA as well as the Center for Drug Evaluation in China were understaffed. They did not have the capacity to process a lot of applications at the same time, and also, people have difference of experience level. That was the main reason why there were so many delays in the past.

But once an application now qualifies for this priority review, which really means that the CFDA and then the Center for Drug Evaluation will allocate their resources on a priority basis to these applications. They will give applicants green channels to communicate with the CFDA and the CDE, on a sort of fast track basis. The ending result is, if an application corresponds for priority review, the approval can be obtained as quickly as six months or within six months, which is a significant change to the general, timeframe for new drug applications for clinical trial applications, which could take years.

Next, we talk about conditional marketing approval. This is also very important. The State Council issued this innovation opinion just last year, in October last year. Basically, the opinion talked about a lot of different things, but the most important thing is this conditional approval. Under the opinion, drugs that offer new solutions for treating life-threatening disease or address critical unmet medical needs, may be eligible for conditional approval. Even before the completion of phase 3 clinical trials. Of course, there are other sort of conditions. For example, the early-middle stage study data indicates their efficacy and predicts their clinical value.

This conditional approval allows companies to receive marketing authorization on an expedited basis. But of course, in order to receive conditional approval, the company also needs to meet additional requirements. For example, the companies will have to develop a risk management plan and initiate a confirmatory post approval study based on the requirements of the government and of the conditional approvals. The same conditional approval procedure will also be given to treatments for rare diseases, under certain conditions. We will talk later about the case where this conditional approval was granted.

Belinda: We had a question come in that we thought was probably appropriate to answer before we go into the reform slide. The question is: can you please discuss the Chinese government's view on digital healthcare, especially how data should be managed, used, and regulated?

Les: Let me take the first crack at the question, which is very important. The government, on the one hand is moving to provide greater protection for what is defined as personal information. This means, in terms of individuals, that the recipient of personal information, will have, and healthcare already does, have an obligation to provide protection for that healthcare, for that information. And to require consent from the individual patient or patient's guardian to transfer that data to other person's. So that is one of the issues that exist.

But the larger issue is in terms of the government's broad concern about cyber security. And this means that in terms of data that is generated within China, for it to be transferred cross border, say, for example, the clinical trial is conducted in China, or if data is obtained on the performance for the drug or a medical device after it is introduced into China, but is essentially on the basis of a license from a foreign company or the subsidiary in China of foreign company. Of course, it needs to be taken to satisfy China's evolving, rapidly evolving requirements with respect to data. And that means that for cross-border transmission of data, there has to be anonymization, not just the personal consent of the individuals, but it also has to be subject to anonymization. That's one.

Then second is China has a very broad definition of national security. A national security includes health security. It is possible in this regard that if a particular condition had widespread incidence in China, such that it created an impact on national security, that the transmission of the data cross-border, would be impeded, would be blocked. Furthermore, certain kinds of medical devices, for example, and let me just finish up with one more point, medical devices are subject to cost monitoring or indeed, drug performance. In the course of these barriers that exist, it becomes very difficult then to constitute, to monitor from overseas, putting pressure on foreign companies to relocate functions into China, which is a substantial cost as well as intellectual property risk.

Kenneth: I just had one comment on this particular point. I mean it is very clear that the Chinese government has been tightening up data privacy, and sort of national security rules. What does that mean? Being cross-borders of a licensing deal, for example, technology licensing deal between a US company and a Chinese company, it really means that in terms of clinical data, we wanted to make sure, as the US licensee if we license the drug, the indications, the technologies to the Chinese licensee, in order for them to conduct clinical trials in China, and then transmit back the clinical trial data. We wanted to make sure that when they do that, they do not violate any sort of Chinese data privacy law, which really means, certain reps and warrantees will have to be added into the licensing agreement.

Belinda: That's a good additional point, Kenneth. Thank you, Les. We have couple of additional questions, but we're just about time for today's session. I'd like to you all to come back to our session on May 30th, to get not only the answers to those questions, but also the rest of the

discussion. We will move the reform of the registration procedure for imported drugs to that session and continue from there. More information about that will be sent out to you by email this week. If you have any additional questions, feel free to reach out to any of us.

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