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HEALTHCARE

SELF-CARE FOR IMPROVED INDIVIDUAL HEALTH AND SUSTAINABLE HEALTHCARE
How an overburdened medical system in China can receive relief

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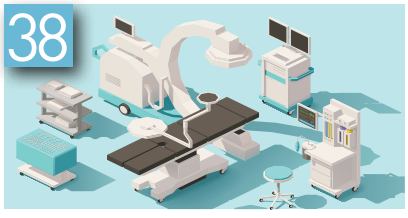

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A HEALTHY CHINA REQUIRES HEALTHY MARKET ACCESS

Mats Harborn
President of The European Union Chamber of Commerce in China

In few other areas does China display a range of conditions as broad as those found in the field of healthcare. Urban areas of China are already suffering from medical problems that many developed countries face today, such as diabetes and high-rates of obesity. At the same time, rural regions face a greater likelihood of disease outbreaks, such as avian influenza (H7N9) or hepatitis. In some cases, the developing world is only a short train ride away from China's most prosperous and developed cities.

Therefore, in addition to the rural-urban divide in the level of medical care available, China also faces health problems related to an ageing society and healthcare costs which have increased three times faster than China's gross domestic product. All of these issues are addressed in the Healthy China 2030 initiative, an ambitious roadmap for how China plans on navigating these challenges. In part, the government plans on tackling different health problems by expanding healthcare options available to Chinese consumers, a development that the European Chamber fully supports. However, further efforts need to be made as lengthy market-approval processes and a tendency to prioritise short-term cost savings over quality of care run contrary to the goal of expanding consumer choice.

Ultimately, this is bad for both China and Chamber members. Improving the availability of high-quality, European medical products would relieve overburdened doctors in lower-tier cities, and the countryside, where medical professionals struggle to treat the large numbers of patients they serve. Complicating the issue is the growing number of older patients that require more frequent and often more specialised treatment. In response to similar developments in Europe, European businesses have already developed products and equipment that are well suited to this need.

Higher overall costs, driven by economic development along with expanded options now available to a select few, risk alienating lower-income patients by preventing them from enjoying the recent improvements to China's healthcare system. Developing a more inclusive system is essential to reaching the stated goals of the Healthy China 2030 initiative. Over a lifetime of use, high-quality European medical equipment is often considerably more cost-effective. While domestic alternatives may involve a smaller initial investment, they often have to be replaced more frequently.

While more still needs to be done, in recent years some improvements to market access have already been witnessed. Partly as a result of the European Chamber's long-term lobbying efforts, the China Food and Drug Administration has established new industry standards aligned with international ones, potentially shaving several years off the approval process for pharmaceuticals to enter the market. The long-awaited updated version of the *National Reimbursement Drug List* (*NRDL*) was released in February 2017, the first update in eight years.[1] The 2017 *NRDL* comprises 2,535 items, 15 per cent more than in the 2009 version. Drugs listed in the NRDL can be reimbursed by public medical insurance funds, lowering the purchasing cost and making them largely affordable to the general public. This is good news for China and good news for European businesses.

We also hope to see further progress in the pharmaceutical and medical device fields. However, the China Manufacturing 2025 initiative, announced in 2015, includes domestic and international market-share targets for both industries. Calls at the highest political level to 'nationalise' the medical device sector would negatively impact consumer choice and public health if this misguided approach continues to be pursued.

This is why the European Chamber continues to work for better market access as well as the establishment of smart industry standards and regulations. The European Chamber will not stop advocating for the market conditions that can facilitate better healthcare. Chinese citizens deserve the best care that can be provided, which necessitates both an upgrade of the medical system as well as a level playing field for all industry players.

This issue of *EURObiz* outlines where the healthcare sector is going, as well as how our members can capitalise on new and important opportunities in the medical field.

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1 *Notice on the Issuance of the National Reimbursement Drug List of Medical Insurance, Work-related Injury Insurance and Maternity Insurance (2017 Version),* Ministry of Human Resources and Social Security (MOHRSS), 23rd February 2017, viewed 20th October 2017, <http://www.gov.cn/xinwen/2017-02/23/content_5170392.htm>

DOING BUSINESS IN XI'S ERA

Business implications from the 19th Party Congress

The Communist Party of China (CPC) has just concluded the first session of its 19th Party Congress. General Secretary Xi Jinping emerged from the week-long event as the nation's most powerful leader since its opening-up to the outside world in the 1970s. In this report, **Mark Rushton**, **Kevin Ma** and **Peter Folland** from **FTI Consulting** discuss some of the likely implications of Xi Jinping's Thought for China's economy, foreign business and Chinese outbound investment.

At the 19th Party Congress, General Secretary Xi strengthened his political position by elevating himself to a status only previously held by Mao Zedong, stacking the Party's highest-level executive bodies with his allies, and enshrining his own eponymous philosophy in the country's constitution as a guiding vision for a new third era in the century-long history of the CPC.

This new era starts now and will last until 2049 when the Party will celebrate the centenary of the founding of the People's Republic of China. 'Xi Jinping Thought on Socialism with Chinese Characteristics for a New Era' will therefore guide all aspects of China's development and policymaking over the coming decades. Whether foreign businesses like it or not, they should be paying attention as they will need to come to grips with its major thrusts and tenets.

One takeaway for foreign businesses from the 19th Party Congress is that China's leadership firmly believes that the country's current political and economic structure, underneath the leadership of the CPC, is capable and best placed to address the various challenges the country is facing. It recognises significant challenges in areas like income inequality and environmental degradation, and is intent on finding solutions to those problems by enacting smarter social and industrial policies and by enhancing existing regulations.

For foreign businesses hoping to understand where China is heading, this suggests that policy progress will probably be made in areas that are aligned with the government's overall political agenda and party priorities. This means a heavier emphasis on issues like environmental protection and an avoidance of financial risks – even if the government has to accept slower growth in the process.

This also suggests a prioritisation of state prerogatives, such as using industrial policy to boost innovation and move up the value-added production chain. The current administration will likely also emphasise and bolster perceived national security issues. Thus, cybersecurity will remain at the forefront, and the government will likely extend its push to regulate, control, and better access information and data flows. These initiatives are extensions of priorities that General Secretary Xi has focused on these past five years.

A strong industrial policy agenda

While an even stronger role for the Party was emphasised at the 19th Party Congress, this does not mean the CPC is averse to the market playing a larger role in the economy. Instead, recent events indicate that the CPC is determined to expand its hybrid model, mixing heavy state involvement in some sectors with liberalisation and openness in others.

While the days of central planning are long gone, now is the time of 'central guiding'. In other words, the Party will have a role to play in setting a framework for every sector of the market, even if different market segments are characterised by varying levels of state involvement and oversight. We see three broad categories for industry that will likely be relevant.

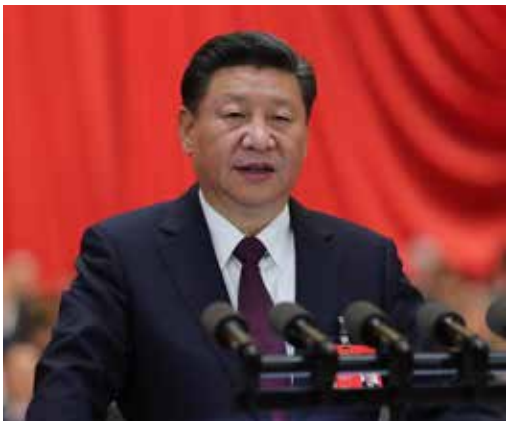
1. **The State will maintain a dominant role in key sectors of the economy**: Pillar industries and critical infrastructure sectors such as telecommunications, energy, construction and finance, will continue to be dominated by state-owned enterprises (SOEs) as these industry areas are considered vital to national security and economic control. However, there will be some liberalisation in these sectors, potentially creating new opportunities for foreign businesses. The government will most likely try to increase market competition in a way that pressures SOEs to improve their competitiveness without letting private or foreign interests dominate. Private investment will also be encouraged up to a certain point in order to deleverage debt and enhance corporate governance within SOEs.

2. **The government will expand industrial policy programmes in strategic sectors**: The economic areas of interest that the country has identified are closely aligned with the Party's innovation goals and have already been made clear in existing policies such as Internet Plus and China Manufacturing 2025. These policies target industries that the government has identified as areas of high growth, including high-tech manufacturing, robotics, environmental technologies, new energy vehicles, next-generation information technology, semiconductors, biopharmaceuticals and aviation technology, among others. This will mean continued regulatory risks for foreign firms that operate in these sectors. The government will not close these sectors off to foreign investment entirely, but will prioritise domestic industry and China's innovative capacity above openness to foreign players. Robust government spending and preferential market access treatment for Chinese enterprises will therefore likely continue in most of these sectors as the country uses its own massive marketplace as a springboard to develop domestic players that can compete globally.

3. **The government will still allow the market to play an important role in a number of industry areas**: The revised CPC charter that was approved during the 19th Party Congress called for market forces to play a decisive role in the allocation of resources. Following from this, it is expected that there will be continued efforts to increase market forces in the services sector and in industries that can promote productivity or satisfy the societal objectives Xi outlined in his vision for China's future. While Beijing may seek to increase its influence in

private firms, it will not claw back the free market entirely. Other sectors in which the government might look to inject more private competition include healthcare, environmental protection and education, although the jury is still out on whether this will involve significant market opening to foreign businesses.

Foreign investors have largely been frustrated with the slow pace of the opening-up of certain domestic markets over the past five years. However, the next few years may present an opportunity to achieve long-desired breakthroughs in a number of sectors. This is particularly the case as the government understands the need to attract further foreign investment to offset likely capital outflows as outbound investment starts to tick back up.



Chinese companies will go abroad again

While capital controls were not directly addressed during the 19th Party Congress, our overall view is that current restrictions on overseas mergers and acquisitions (M&A) will be loosened going into 2018. However, the theme of party empowerment over key economic and business decisions is also likely to become more formalised. China's regulators will push for a greater say over where and how China's financial resources are deployed. The government will likely only grant outward remittance of foreign currency if it regards an outbound investment as beneficial. This means that 'irrational investments' into areas like sports clubs, real estate and entertainment will continue to be reined in as the government attempts to direct capital into preferred areas.

Investments that are supportive of the Belt and Road Initiative—which was enshrined into the CPC constitution during the 19th Party Congress—as well as investments that serve to boost access to technology and R&D will be encouraged. However, the government is likely to step up its scrutiny of all outbound investments, even in these encouraged areas.

Regulators want companies to make investments that are aligned with their core business and to provide sophisticated analyses showing likely returns on their investments. The government will also use its regulatory oversight capabilities to try to ensure that all Chinese companies making overseas investments are financially healthy and will not be taking on risky levels of debt to fund such transactions.

Expect heightened tensions with Western governments

This targeted approach towards outbound M&A is also likely to increase government-to-government tensions with the West. A renewed push from Chinese businesses to acquire Western technologies and firms in industries related to the China Manufacturing 2025 policy will further pique governments in developed nations, particularly as China looks set to maintain market access barriers to foreign firms and continues to offer favourable conditions to domestic enterprises that operate in these sectors.

We are already witnessing rising resentment against Chinese investment in the West, which is leading to increased calls for reciprocity from politicians and businesses in both the European Union and the United States. The European Commission, for example, has this year tabled a proposed regulation to establish a framework for screening foreign investments into the bloc, which was drafted following pressure from the governments of Germany, France and Italy to develop a system that can counteract investment asymmetries with China. Chinese firms are thus set to experience increased levels of scrutiny, up to a certain point in order to SOEs and those investing in more sensitive, high-technology sectors.

Entering a third era

We have now entered the third chapter of modern China, and it is General Secretary Xi's chapter to write. From a business perspective, his consolidation of power at the 19th Party Congress should position him to more easily up to a certain point in order to his long-term strategies and economic reforms during his second term. General Secretary Xi and his administration clearly see daunting obstacles and impediments to China's future progress, and are eager to address outstanding problems ranging from financial risk to pollution and income inequality. The concern for foreign businesses is that the leadership may often perceive the best solutions to the country's economic and industry issues as being found in increased government oversight and additional policy rather than through free markets and liberalisation. Eb

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SELF-CARE FOR IMPROVED INDIVIDUAL HEALTH AND SUSTAINABLE HEALTHCARE

How an overburdened medical system in China can receive relief

As China's population continues to increase and universal healthcare access becomes a goal enshrined in *Healthy China 2030*, the feasibility of this has been called into question. To ensure sustainable healthcare, a tactic like self-care can be vital to alleviating an already strained system. **Grace Xu**, the head of communications in **Bayer's** consumer health division, outlines what needs to be done to improve individual health and ensure an overburdened medical system leaves no one behind.

The greatest healthcare challenge in the coming decades is not improved access to care, but the instability of the healthcare system as a whole. Ageing populations, combined with rising incidences of chronic disease, have placed an unprecedented amount of financial stress on healthcare systems around the world.

Healthcare systems in both developed and emerging economies face the same problem – insufficient resources to meet anticipated healthcare needs. An increase in the number of healthy people over the last century has been nothing less than astounding. However, as a World Health Organization (WHO) report outlines, despite "increasing health expenditures and unprecedented advances in modern medicine", people today are "not necessarily healthier; nor are they more content with the healthcare they receive". There is a crucial need, the report adds, to "improve the capacity for self-management and self-care".

There has never been a more urgent need, or greater opportunity, to unleash self-care's potential for improving individual health and making healthcare more sustainable. The Chinese government has recently put in place the *Healthy China 2030* initiative which aims to provide equal access to health services for every citizen by 2030. Self-care will be one of the key drivers to providing universal healthcare access in China.

It is important to note that self-care does not mean that a person chooses to not seek out medical care or treat any medical malady that may arise. Instead, this style of care is the first step in moving away from depending on overburdened doctors for medical treatment and to enable people to take care of themselves by providing the average citizen with the appropriate tools and knowledge to be able to self-diagnose and provide treatment. With the growing amount of resources required for the treatment of long-term conditions and any provisions on end-of-life care, the consensus has never been stronger that self-care must be a part of a medical regime to maintain health, promote wellness and treat minor ailments. Self-care can be defined as:

- healthy lifestyle choices, including physical activity and healthy eating;
- effectively using pharmaceuticals;
- self-diagnosis, which involves making an assessment of symptoms based on access to proper information and self-care learning tools and—when properly informed—maintaining health with the responsible use of self-care medicines;
- self-treatment with the responsible use of medication for minor ailments along with self-monitoring to detect if there is a change in one's health; and
- access to tools that improve health literacy, nutrition, overall wellness, and the prevention and-management of chronic diseases.

The economic value of self-care

There is a growing consensus that a greater emphasis on prevention, health promotion and self-care can help healthcare systems better cope with ageing populations, fiscal pressures and the increased prevalence of chronic diseases. A wider adoption of self-care practices can also direct resources to the patients who need them the most. In other words, self-care has an increasingly important role to play in strengthening the sustainability of global healthcare systems. Evidence suggests self-management interventions, including self-monitoring and decision-making, result in superior patient satisfaction and reduced hospital and emergency care costs.

For example, a May 2012 United Kingdom report titled, *Self-care and Self-care Support for People who Live with Long Term Conditions*, concluded that engaged patients "tend to have better clinical outcomes, a higher quality of life and make more informed use of public services than those with lower levels of activation."

Various studies have been done to estimate the economic impact of self-care on minor ailments. The results from some of these studies on the economic ramifications of self-care are as follows:

- According to a 2012 economic analysis conducted by Booz & Company for the Consumer Healthcare Products Association, each United States dollar (USD) spent on over-the-counter (OTC) medicines saves the United States (US) healthcare system USD 6 to USD 7. The current purchases of OTC medicines adds USD 102 billion annual profit to the US healthcare system.
- A study conducted in China that tested self-care education on more than 950 people with hypertension, diabetes and other chronic diseases revealed improvements in self-care behaviour, self-efficacy and health outcomes. The results also showed a reduced number of hospitalisations in the first six months of self-care education.

The barriers to making self-care more accessible

In order to make healthcare more sustainable, the principal barriers to greater adoption of self-care health habits must be addressed.

A review of more than 30 independent surveys conducted by the World Self-Medication Industry found that "there appears to be no fundamental difference between developed and developing countries in people's aspirations to participate to their level of ability and preference in self-care activities." In a survey on self-care, conducted with people in several different countries, the majority of respondents believe they are capable of making more decisions regarding their own personal health and wellness.

Yet, many of these similar surveys show a noticeable gap between people's desire to take greater control over their health and their confidence to actually do so. A 2013 consumer survey, conducted in 10 European Union countries by the Brussels-based think tank Epposi, found that nearly 90 per cent of respondents believed that self-care was necessary to remaining healthy and managing illnesses. However, fewer than 20 per cent of those surveyed actually engaged in self-care practices due in large part to a lack of confidence. Some people feel they lack the essential knowledge, skills, tools and encouragement to make self-care a way of life. For people to have the self-confidence needed to practice self-care, two critical gaps must be

addressed:

1. The knowledge gap: There is a clear link between a person's 'health literacy' and their willingness to take greater responsibility for their health. Currently there is a gulf between people's desire to care for themselves and the knowledge and skills they need to do so.

2. The leadership gap: As the Epposi study noted, "It is inappropriate to expect people to take on greater responsibility for their health and well-being without greater guidance and leadership." Self-care requires encouragement, support and promotion on the part of policymakers, as well as a commitment to provide people with the necessary tools to take care of themselves.

Global policy recommendations

To make self-care an integral component of a comprehensive health policy, the following things need to be done:

1. Develop a universal definition and framework for self-care in order to guide future research and policy reform.

2. Help people to help themselves by fostering greater self-care literacy.

3. Make self-care integral to overall health policy by increasing investment in health promotion and disease prevention.

4. Build-up institutional and leadership capacity for self-care promotion with a focus on developing countries.

5. Encourage healthcare professionals to support and facilitate the practice of responsible self-care.

6. Add to the body of literature on self-care effectiveness, and use this to guide self-care policies and practices.

7. Build stronger public-private partnerships and collaborations.

Right now, healthcare is at a turning point. Demographic changes, the emergence of new health conditions and the increased prevalence of non-communicable chronic diseases are creating substantial challenges both for individuals and healthcare systems globally. Absent important changes in how people around the world take care of their health, a potential health crisis might arise which could overwhelm health systems in the years ahead.

When it comes to addressing these challenges, self-care has a vital role to play. As stated in a WHO report, "promotion of effective self-care is...important to reduce health care costs, in an era of high medical technology and medical treatment, the concept has not been much emphasised and implemented." Eb

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TRIALS IN PHARMACEUTICAL INNOVATION

Why innovation and access in pharmaceuticals is the key to success

A new and simplified approval process is making it easier for foreign firms to sell pharmaceuticals and medical devices in China. This is a shift from the country's previous requirement for separate trials, which discouraged and delayed the launch of new products by foreign pharmaceutical firms on the Chinese market. To be eligible for faster pharmaceutical authorisation, foreign firms need to include Chinese people in their international multi-centre trials (IMCTs). **Jeroen Groenewegen**, **Amy Mao** and **Xu Meiying** from **China Policy** argue that this new trial system changes China's research and development (R&D) system with it having better access to international clinical data, research facilities, testing populations and investment.

Access to healthcare

This new approval process allows foreign pharmaceutical firms to launch first-in-human trials of pharmaceuticals in China. It allows China at the earliest stage, namely phase I, to focus on dosage and side-effects before moving on to larger-scale phase II and III clinical trials. Pharmaceuticals that go through all these trial phases abroad can be sold faster on the Chinese market due to simplified marketing permit procedures. This will substantially reduce development delays, providing Chinese citizens better access to medical innovations.

China still lags behind developed countries in the quality of its pharmaceuticals, according to the State Council's *Opinions on Deepening Approval System Reform to Encourage Pharmaceutical and Medical Device Innovation*, released 8th October 2017. Only 30 per cent of the 433 innovative pharmaceuticals (as opposed to 'me-too' or 'me-better' drug variants) that were launched worldwide between 2001–2016 gained approval for sale on the Chinese market, and those that were approved entered the market five to seven years after they were introduced in Europe and the United States (US) said Wu Zhen, the deputy director of the China Food and Drug Administration (CFDA), at a press conference. Policymakers hoped that domestic firms would make up for this gap, but unfortunately this does not seem to be the case. For instance, the slow approval of new treatments has contributed to the poor survival rate of Chinese cancer patients, says *Southern Weekly*, noting that China's five-year survival rate in 2015 was only half the 2012 US rate.

Access to healthcare is a national priority and is the focus of Healthy China 2030, which seeks to increase average life expectancy to 79 by 2030, up from 76 in 2015. This policy was mentioned in the 19th Party Congress report, which also called for ensuring there is an adequate supply of pharmaceuticals. Ongoing healthcare reforms will halt pharmaceutical mark-ups in most hospitals before the end of 2017, severing the linkages between pharmacies and hospitals and introducing new pricing models that value the time specialists spend on patients over the type of pharmaceuticals they prescribe them. To mitigate the rising cost that reforms, extended healthcare coverage and an ageing population bring, the State has been promoting synergy between healthcare, pharmaceuticals and insurance firms. The State aims to drive down the cost of healthcare imports through collective bargaining. For instance, the National Health and Family Planning Commission (NHFPC) issued a call for companies to join high-value medical device price negotiations in September 2017.

The latest measures call for state-owned insurers to include new pharmaceuticals in basic insurance packages. This could potentially conflict with cost control because imports tend to be expensive. On the other hand, the measures call for medical institutions to use effective and reasonably priced pharmaceuticals, and the State will seek to force prices down with collective bargaining. These negotiations will affect the de facto availability and affordability of innovative pharmaceuticals for the majority of the population.

International harmonisation

Even though the extent to which foreign pharmaceuticals will be covered by insurance is unclear, the new approval process makes it easier for multinational corporations (MNCs) to sell pharmaceuticals in China. The CFDA used to require a separate series of pharmaceutical trials to prove new drug safety and efficacy, says Wang Lifeng, the director of the CFDA's Pharmaceuticals and Cosmetics Registration Department. The new measures will cut down on red tape, for instance by allowing importers to hand in just two applications, one for international multi-centre clinical trials (IMCT) and one for marketing authorisation. Importers will also no longer need to have a marketing permit issued by the country its production is based in when they apply for participation in Chinese trials. To implement these changes, the Ministry of Science and Technology (MOST) released the *Regulatory Streamlining for Collecting Human Genetic Resources for IMCTs'* on 26th October 2017, which will take effect 1st December 2017.

These measures have increasingly aligned China's pharmaceutical policy with international practices. In June 2017, the CFDA became a regulatory member of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH), next to similar institutions representing Europe, the US, Japan, Canada, Switzerland, Brazil and South Korea. In response, the CDFA remarked how becoming a regulatory member would steadily move China towards adopting internationally endorsed technical standards and pharmaceutical guidelines.

Internationalisation is intended to make China more attractive for pharmaceutical foreign direct investment. For instance, at the CFDA's press conference, Deputy Director Wu cited insufficient resources as the principle reason for lagging behind other countries when it comes to innovation in the domestic pharmaceutical sector. In 2016, the total amount of Chinese pharmaceutical R&D investment was only US dollars (USD) 11 billion, a similar amount to what Swiss firm Hoffmann-La Roche's R&D department invested last year alone. China would like to attract a larger portion of global pharmaceutical R&D investment, but the trend is moving in the opposite direction. In September 2017, GE announced it was transferring its Shanghai-based China Technology Centre's basic R&D work to the US and India, while Eli Lilly and Company, GlaxoSmithKline, Novartis and others have also made major cutbacks to their Chinese research centres.

These companies' recent moves to outsource R&D have increased international competition over these investments. For instance, India already develops and produces 20 per cent of global generic pharmaceuticals by volume and has a workforce that is at least as educated and affordable as China's, but with better English. This adds urgency to Chinese government initiatives to improve regulatory frameworks and remedy problems with intellectual property (IP) protection.

Sharing data

To attract investment in pharmaceuticals, China needs to convince MNCs that it is a reliable place for international multi-centre trials (IMCTs). Foreign firms do not want clinical data they share with Chinese partners and watchdogs to end up with competitors. They also do not want any clinical data that Chinese partners may contribute to pollute the results data and jeopardise the entire trial. Chinese government agencies are currently attempting to address these concerns. Amendments to the Pharmaceutical Management Law, published for public comment on 23rd October 2017, proposed banning anyone caught for data fabrication in the pharmaceutical industry from operating for 10 years. It also seeks to improve data reliability with independent ethics and data-monitoring committees. The CFDA will improve IP protection by automatically checking applications to a patents database, so that potential IP conflicts can be identified and resolved before for instance a copycat pharmaceutical gets approved and marketed. Agencies will also offer patent holders reasonable compensation if the procedure caused them delays or otherwise infringed on their rights, and improve guarantees against submitted data being used commercially by others.

These steps align China with international practices, at least on paper. The CFDA announced stepping up training and oversight of its personnel, but because China has mostly developed generics for the domestic market, the organisation has limited experience with large, international trials of innovative pharmaceuticals.

Indigenous innovation

China has tried to boost pharmaceutical innovation for years. At least five documents that the CFDA issued since 2009 called for simplifying and speeding up the evaluation of pharmaceuticals for rare diseases, the so-called 'orphan drugs'. In 2015, policymakers centralised approval processes and unified standards and deadlines, with the State Council issuing *Opinions on Reforming the Approval System of Pharmaceuticals and Medical Devices*. Over the last three years the bottleneck has shifted from review and approval to clinical trial capacity, a senior pharma regulation expert told *Southern Weekly*. In response, the CFDA and NHFPC issued the *Announcement on Biological Equivalence Trials in Clinical Trial Agencies*, on 13th October 2017, which allowed 619 healthcare institutions to begin conducting clinical trials.

Recently announced policies have gone further than ever before in remedying issues in the industry. Foreign pharmaceutical firms will benefit in the short run. State-owned pharmaceutical companies complain that these new policies only benefit foreign companies and will eventually give them free entry into the Chinese market. However, an anonymous expert involved in drafting the document told *Southern Weekly* that this new pharmaceutical policy will enable local pharmaceutical R&D to catch up to the US, Japan and Europe in the next five years. Exposure to international competition will cause many domestic firms to fail, but it will make the ones that survive that much stronger. Eb

China Policy *is a research and strategic advisory based in Beijing. Working with clients at leadership, executive, and research levels, they deliver clear insight into China's policy world as it affects strategic and operational decision-making in China and around the world.*

BEYOND HEALTHCARE REFORM

Engineering a health-conscious society for the future

In August 2016, the Politburo Standing Committee announced the ambitious *Healthy China 2030* initiative which calls for both comprehensive healthcare reform and societal participation to create a more health-conscious society. In this exploratory piece, **Kirsten Lee Olson** of **Tractus Asia** discusses the population health challenges that China is facing and how *Healthy China 2030* plans to address them.

China's evolving economy has produced unanticipated challenges in population health. In the 1990s, China's healthcare system was developed to address infectious diseases and traumatic injuries which are the primary healthcare concerns of a developing economy. However, as China continues to develop, the country's healthcare system has not been able to manage the growing rate of chronic and other non-communicable diseases often associated with developed economies. According to the World Health Organization, non-communicable disease accounts for approximately 80 per cent of China's current annual mortality rate and 70 per cent of its total disease burden.[1]

Part of this may be due to increased life expectancy – people are simply living long enough to develop chronic illnesses. However, the preponderance of chronic disease is due to environmental pollution and lifestyle choices such as diet, inadequate exercise, and tobacco and alcohol usage. Type 2 diabetes, historically found in developed economies, now effects over 110 million Chinese citizens with upwards of 50 per cent of Chinese adults classified as pre-diabetic. The annual cost of diabetes treatment exceeds Chinese yuan (CNY) 173.4 billion and contributes to 13 per cent of China's total medical expenditures.[2] Clearly more investment in chronic disease prevention is needed.

Healthy China 2030

Faced with this unsustainable situation, China released the *Healthy China 2030* initiative in August 2016. It introduces plans for significant healthcare system reform, but also provides an integrative approach to population health that incorporates industry, environmental protection and individual accountability by means of social and market forces.

The *Healthy China 2030* initiative's plans for hospital organisation, the essential drugs list and foreign direct investment in healthcare have garnered the most attention in the press. Yet, previous campaigns have addressed similar reforms, such as the overhaul of social health insurance in 2014 and 2015. What is new in this initiative is the focus on environmental protection which brings a breath of fresh air to the topic, considering how long the central government has turned a blind eye to the correlation between pollution and disease. In 2017, major strides were made in environmental protection with 24.4 gigawatts of solar energy installed in the first six months alone.[3] What remains to be seen is how the central government will address the portion of the *Healthy China 2030* initiative on individual accountability, a section which will require much needed changes in population behaviour.

Diet

China has two seemingly opposite dietary challenges —malnutrition and obesity. *Healthy China 2030* hopes to address both issues through dietary education and by providing resources for nutritional management. However, the initiative does not go into any detail on how it plans to accomplish this goal.

In March 2017, the China Development Research Foundation shared the results of its six-year pilot nutrition programme. Eleven-year-olds who participated in the nutrition programme were on average six centimetres taller than the control group.[4] The programme provided a nutritionally balanced school lunch, valued at CNY 4/student, and supplemented insufficient nutrition at home. This pilot proved that a cost-effective nutrition programme is feasible, however the question still remains over whether a programme like this could be implemented on a national scale. In July 2016, the State Council announced its intention to address malnutrition by developing nutrition programmes for infants, pregnant women, students, the elderly, hospital patients and other at-risk groups.[5]

In contrast to malnutrition, which afflicts impoverished segments of China's population, the part of the population affected by obesity has the income and resources to support a healthy diet, but lifestyle and low health literacy has led them to make poor dietary choices.

What *Healthy China 2030* proposes to accomplish is nothing short of social engineering with the government's goal being the transformation of China into a health-conscious society. Even though this goal is admirable, many questions as to how it can be implemented remain unanswered. This is an area where market as well as social forces will likely be employed.

Exercise

Healthy China 2030 wants to implement a national physical fitness test and physical health monitoring system. Encouraging exercise participation is difficult but doable, whereas testing and tracking activity on the national level tends to be more practical in theory than in reality.

To increase participation in physical activities, China plans to construct a series of free public sports facilities, community sports programmes and outdoor fitness amenities such as fitness trails and cycling paths. However, making these new facilities available is not the same as getting people engaged to use them.

One strategy the government is employing to motivate people is to popularise sports. Basketball and table tennis have long been popular in China, and interest in football is steadily on the rise. A recent push to increase participation in winter athletics to 300 million people by 2022—in anticipation of the Beijing Winter

1 *Rate of diabetes in China "explosive"*, World Health Organization Representative Office, 6th April 2016, <http://www.wpro.who.int/china/mediacentre/releases/2016/20160406/en/>

2 Cheng, T.O., 2011, *Diabetes Epidemic in China and Its Economic Impact, International Journal of Cardiology*, vol. 149, issue 1, pp. 1-3.

3 Clover, Ian, *China installed 24.4 GW of solar in first half of 2017, shows official NEA data*, PV Magazine, 7th August 2017, <https://www.pv-magazine.com/2017/08/07/china-installed-24-4-gw-of-solar-in-first-half-of-2017-shows-official-nea-data/>

4 *160-billion-RMB nutrition subsidy spurs height increases in rural youth*, The State Council Information Office of the PRC, 23rd March 2017, <http://www.scio.gov.cn/m/32618/Document/1552955/1552955.htm>

5 *China issues national nutrition plan (2017-2030)*, The State Council Information Office of the PRC, 14th July 2017, <http://www.scio.gov.cn/32618/Document/1558348/1558348.htm>

Olympics—likely played a part in the National Hockey League's China debut in 2017. By initiating a mandatory hour of physical activity for all children enrolled in school the government hopes to encourage "sport-for-life". These initiatives are a good start to get China's population moving.

Tobacco and alcohol

China has 300 million smokers that make up approximately one third of the adult population, and consumes more cigarettes per annum than the next four countries combined. Each year 1 million deaths are directly attributed to tobacco usage and 100,000 deaths to second-hand smoke inhalation,[6] not including chronic disease associated with tobacco use.

The *Healthy China 2030* initiative is very clear on how to reduce tobacco usage. Increased restrictions on public smoking will reduce opportunities to 'light up' and will decrease exposure to second-hand smoke. Education campaigns, price controls and higher taxes will all be employed to help discourage new smokers from picking up the habit. For those already addicted, the government plans to strengthen smoking cessation services.

While efforts to combat smoking seem straightforward, attempts at reducing the prevalence of alcoholism are not. The general perception among the Chinese population is that alcohol abuse is not a nationwide issue and as a result few studies have been conducted on the subject. What has been documented is the volume of alcohol sold, which has increased rapidly since 1980. A 2003 article published by the Medical Council on Alcohol found a 3.4 per cent overall occurrence of alcohol dependency among study participants. These results put China on par with Australia's 3.5 per cent overall prevalence of alcohol dependency and makes alcoholism the country's third most prevalent mental illness.[7]

The first step in substance abuse treatment is admitting you have a problem.[8] The *Healthy China 2030* initiative is a lengthy document, yet it only dedicates two sentences to alcohol control. This shows that the central government shares the nation's misperception of alcohol usage. China does not have enough medical alcohol treatment programmes to address the actual need. Informal support groups, like Alcoholics Anonymous, are foreign run and conducted in English which makes them inaccessible to many. Along with a lack of available resources, obstacles such as social pressure, perception and stigma may also play a role in preventing addicts from seeking treatment.

Opportunities for European companies

China's health challenges are substantial, but not insurmountable. The *Healthy China 2030* initiative is heading in the right direction; however, China will need more resources and expertise to achieve its population health goals. With these changes in healthcare, European non-governmental organisations and companies now have an opportunity to bring their experience in diet and fitness management to an increasingly receptive Chinese market. Eb

Tractus Asia Limited *is an Asia-based foreign direct investment strategy and execution advisory firm with offices in Shanghai, Hong Kong, Chennai, Jakarta, Yangon, Singapore, Bangkok, and Ho Chi Minh City. Tractus advises corporations in developing effective market entry strategies and assists them throughout the execution process. For more information visit www.tractus-asia.com and follow Tractus Asia on LinkedIn.*

6 Tobacco in China, World Health Organization Representative Office, 2017, <http://www.wpro.who.int/china/mediacentre/factsheets/tobacco/en/>

7 Hao, W., et. al., 2003, Alcohol Use in China, Alcohol and Alcoholism, vol. 38, issue 6, pp. 537-542.

8 Why Acknowledging Addiction is the First Step to Recovery, AddictionTreatmentTherapy.com, <http://www.addictiontreatmenttherapy.com/why-acknowledging-addiction-is-the-first-step-to-recovery/>

NEW PAYMENT SYSTEMS

The process of Chinese hospitals adopting a commercial mindset

Choosing a fair and efficient payment system for hospitals is challenging for health authorities around the word. Calculating healthcare costs is no simple matter and has been complicated even further in China by how fast its medical system has developed. **Volker Müller**, business manager at the European Union Chamber of Commerce in China, looks at reforms in China's hospital payment systems and outlines the pros and cons of globally adopted payment methods.

The development of China's healthcare system has reached a turning point. China's life expectancy and overall healthiness have reached levels similar to middle to high-income countries. In 2016, the ratio of health expenses to the nation's gross domestic product reached six per cent, higher than Singapore (five per cent) and roughly the same as Poland. Since starting at an extremely low level, China's healthcare expenses have been growing at an annual double-digit rate. This growth rate is not sustainable, with an increase of expenses preventing further significant improvements to the population's health. One of the key elements of China's healthcare reform agenda titled *Healthy China 2030* is the reform of hospital financing. This seems to be a rather dull issue, but how hospitals get their money has a direct effect on the quality of health services and the industry's overall business environment.

Who pays and how?

Calculating the cost of surgery is not an easy thing to do. The main cost factors are: the type of drugs and disposable medical devices; salaries of the medical and administrative staff; the use of medical equipment and facilities; the expected lifetime of the equipment; and costs that occur before and after the operation such as sterilisation of surgical instruments, disinfection of the operation room and disposal of medical waste. From a financial standpoint each surgery is a project not a product. Expenses can only be roughly calculated until after the surgery has been completed and the patient is discharged.

There are basically three different sources to finance hospitals: direct payments by the State (financed by taxes), social or private health insurance and out-of-pocket payments by patients. In most countries, hospital income derives from a mix of these sources. In China, social health insurance pays for approximately 53 per cent of total expenses, while different levels of the government pay about 15 per cent. Unfortunately, patients' out-of-pocket expenses amount to a fairly high 32 per cent, although these figures vary considerably by province and town/countryside population.

The simplest method for hospitals to gain revenue is through direct financing by the state. A similar type of healthcare financing was used in most Eastern European countries until the late 1980s. An advantage to this type of system is that there is no administrative overhead for calculating the prices for select medical services. The problem with a system like this is the waste and lack of efficiency that comes from an absence of commercial thinking. Other hospital payment systems require a calculation of the estimated cost of treatment. Hospital payment systems need to strike a fair balance between the price of treatment and the amount of time it takes the administration to enforce the policy.

In China, the pricing departments of the provincial Development and Reform Commissions compiled very detailed price lists for different cost factors from a hospital treatment. Some of these cost factors included the cost of the prescribed drugs as well as the use of disposable medical devices and medical equipment. One major shortcoming of these price lists was the undervaluation of the work done by medical personnel. For each hospital visit the patient had to pay a small registration fee which amounted to only a few yuan. To make ends meet, the hospital was allowed to sell drugs from the hospital pharmacy at a profit with a mark-up that usually ranged between 20–30 per cent. The consequence from this was the widespread problem of over-medicating – in order to increase the income of the hospital, doctors regularly prescribed medicines that were not needed.

Starting in 2017, almost all provinces in China have banned mark-ups on medicine sold in hospitals. Patients are encouraged to compare prices and may choose to buy medicine in a pharmacy outside the hospital if the prices there are cheaper. As a consequence, drug prices in hospitals have decreased considerably. To compensate hospitals for the lost income, registration fees have increased. Considering that high registration fees may deter low-income patients from seeing a doctor, in some less-developed areas registration fees are kept constant with the government paying the difference. In November 2017, the National Development and Reform Commission published its *Opinion on Deepening the Reform of the Pricing System*, calling for a ban of mark-ups on disposable medical devices.

This new policy was widely welcomed by the public and helped address the problem of overmedication. However, this policy did not remedy the issues that come from taking a non-commercial approach to healthcare. The hospital is still not properly incentivised to choose an economical form of treatment.

To control healthcare expenses, in 2017 the National Health and Family Planning Commission (NHFPC) introduced a new concept called case-based payment. Treatment of certain common diseases receive a fixed price, which covers all parts of the treatment including drugs, medical devices and labour costs. This price is independent of the quantity of drugs used and the number of medical devices applied. The NHFPC published a catalogue of 320 common diseases. Each provincial Health and Family Planning Commission (HFPC) selects a minimum of 100 diseases out of the catalogue and sets the price for treatment. In this way,

the responsibility for cost control is passed down to the hospitals.

However, case-based payment is also not an ideal solution. Hospitals may be tempted to discharge patients too early and use low-cost medical devices of lower quality. Expenses for different patients may vary considerably. For example, older patients may need to stay hospitalised for a longer period of time which increases the hospital's expenses without bringing in additional income. It is because of this, that hospitals may try and attract 'cheap' patients and reject the 'expensive' ones.

Two issues, aside from hospital payment, that need to be addressed is the price of treatment being too low and the lack of supervision by health authorities regarding medical services. So far there is only a limited pool of experience to draw upon when it comes to case-based payment in China.

A more elaborate way of utilising case-based payments is by using the so-called diagnostic-related groups (DRG). Originally designed for resource allocation within hospitals, DRGs now are often used to 'fine-tune' hospital payments. Rather than making a simple case-based payment, DRGs take a variety of different risk factors into account like the patient's age or blood pressure. If additional risks are found than the price of treatment is increased.

Back in 1992, Australia was the first country to adopt DRG as a nationwide standard for hospital payment. Based on the Australian model, several European countries adapted DRG to address their own healthcare needs. In 2004, Germany started to use what they called D-DRG, or German DRG, and is regarded as having developed the most sophisticated version of this system. China started research on DRG in 2010, and after six years of preparation a working group under the NHFPC created China's own DRG called the C-DRG. In June 2017, China's first trial using DRG started in 33 hospitals located in Shenzhen, Sanming (Fujian), Kelamayi (Xinjiang) and three provincial hospitals in Fujian. Based on the results of these trials the DRG may be rolled out nationwide.

Looking at the experience of widespread DRG implementation in Germany the main concern for China adopting a similar model is the massive expansion of bureaucracy it would entail. The D-DRG's 2018 manual has more than 5,000 pages. Hospitals would need to employ highly qualified personnel just for data entry. Increased supervision would be necessary to guarantee data accuracy and prevent fraud.

In conclusion, there is no perfect solution for hospital payment. Controlling the cost of expenses while at the same time ensuring high-quality medical services is a difficult undertaking. Ultimately, payment system reform needs to go hand-in-hand with other aspects of medical reform. For example, reform of the payment system may incentivise hospitals to shorten the average length of hospitalisation, but this desired outcome should be accompanied by improved home care and discharge management. Eb

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A PATIENT-CENTRED APPROACH

Achieving the digital transformation of health systems in China

Currently, global healthcare is under immense stress due to changes in demography, age and an increase in levels of chronic disease. To ensure a strong and sustainable healthcare system an integrated approach that utilises the latest tools in the medical field is necessary. In this article, **Nicole Denjoy**, secretary general of **COCIR**, and **Jessica Yuan**, manager of the **COCIR China Desk** and senior government affairs desk manager at the **European Chamber**, list the reasons why a patient-centred approach can not only benefit China, but the rest of the world.

Introduction

We urgently need to address global healthcare challenges, including demographic change, ageing populations and increasing levels of chronic disease. The stress of these burdens is increasingly rendering healthcare systems unsustainable.

We know that 'health is wealth', which is why investing effectively in healthcare will produce long-term economic and societal benefits. New technologies that contribute to better care include, but are not limited to, non-invasive techniques, medical imaging and radiotherapy. Digital health solutions also offer huge potential. Inexorably, healthcare systems will increasingly depend on digital technology.

Currently, health and social systems are designed for different demographics, epidemiology and lifestyles. Healthcare services, and service delivery, need to be reconfigured around people's needs and preferences. In 1960, the portion of the population over 65 years old was less than 10 per cent. The number of people over 65 doubled by 2015, and is projected to reach almost 30 per cent of the population by 2060. In addition, not only are people living longer, but as they become elderly they are increasingly facing complex medical problems. This complexity arises largely from co-morbidities that are often chronic, such as type 2 diabetes, hypertension, cardiovascular disease and pulmonary disease. In many countries, people with a single chronic condition make up 80 per cent of their disease burden, while people with multiple chronic conditions make up about half. The increasing number of premature deaths from chronic conditions are impacting economic performance, with falling labour market participation and reduced work productivity. Non-communicable diseases cause more than 550,000 premature deaths in people of working age each year,[1] a loss of 3.4 million years of productivity. This is especially true in China, a populous country whose population has been ageing rapidly.

In addition, there has been a profound shift in how society cares for its elderly. Only a generation ago, adult children helped care for the majority of the elderly in their own homes. However, as more women began working, families increasingly looked to nursing home care for their elderly relatives. Health systems

1 OECD 2016 Health at a Glance Ref. <http://www.oecd.org/health/health-at-a-glance-europe-23056088.htm>

are struggling to meet the challenges posed by this demographic shift to an ageing population along with the growing burden of chronic diseases and related co-morbidities.

Health and social care fragmentation

It is increasingly clear that too many health and social care systems are unnecessarily fragmented. They were not meant to provide specialised support for individual medical needs, as well as helping to cope with the challenges of independent living. The growing complexity of care generated by physical and mental health co-morbidity, combined with other factors related to ageing populations, translate into an increasing burden for long-term care services.

Information is not shared efficiently between service providers, meaning patients do not receive coordinated care focused on their needs. In fact, the reality for many citizens is that they have to navigate their own path between different healthcare providers. There is a lack of emphasis on engaging and empowering people. Health and care systems have failed to adequately engage, empower and support people to become health literate and manage their own care, share in decision-making, empowering them to become partners in health. In reality, overburdened patients face difficulties communicating complex care needs and medical histories across healthcare services. This approach inevitably drives up healthcare costs by relying on unscheduled or emergency care services. In addition, the fragmented and often underdeveloped data collection on health outcomes makes it difficult to compare the value of different care interventions, prioritise decision-making across care providers and assess health system performance. This frequently leads to inefficient health and care delivery, poorer medical outcomes, unjustified clinical variability in medical practices and decision-making across care providers.

Leadership from the government

What will it take to address this fragmentation and reconfigure services around people and their needs, preferences and expectations? The answer lies in transforming delivery mechanisms into a more person-centred approach that encompasses health and social care. Countries need to focus on the concept of 'integrated care' – essentially a person-centred and coordinated approach that crosses the boundaries between hospital, primary, community and social care. This new method of care requires support for: multi-year funding; stakeholder engagement; increased education; organisational changes; new financing mechanisms; a welcoming regulatory environment; and the scaling up of digital health innovation. Governments need to establish an enabling ecosystem to support integrated care. This enabling ecosystem could mean the implementation of new financing models, adequate incentives for health and care providers, and a regulatory environment that successfully strikes a balance between innovation and data privacy protection. Developing a process for multi-stakeholder collaboration,[2] could include a new organisational and communications platforms that help to implement shared care pathways, improve disease management and increase health literacy.

Governments should also promote interoperability[3] by supporting semantic and technical standards, standardised measurement of health outcomes including patient-reported outcomes. They should build on existing digital health solutions, such as citizen/patient identifiers or electronic health records that enable data extraction for care delivery and secondary purposes and incentivise healthcare professionals to standardise how they register clinical data. They could help develop integrated care models with specific initiatives, including sharing and replicating good practice and scaling up successful implementation.[4]

Governments need to provide political leadership and develop national and regional evidence-based roadmaps to drive the transition to integrated care delivery systems that are better tailored to people's needs. Digital health supports integrated and patient-centric care, encouraging a value-based healthcare approach that improves the outcomes and experiences for both patients and the wider population while ensuring the healthcare system remains sustainable.

Integrated care approach in China

China has worked hard to try to adopt a more integrated healthcare model by reviewing case studies and learning from the experiences of other high-income and middle-income countries. It has also undertaken its own innovations when it comes to health reform. Five ministries and commissions issued the report titled *Deepening the Reform of China's Medical and Health System*,[5] which aimed to develop the value-based, high-quality service supply system. It is encouraging to see China's health service system becoming more people-oriented and integrated. China is going to establish a strong primary health service that will not only provide an increased quantity and quality of different medical services for its citizens, but will also improve health services from a cost-saving perspective.

Health reform needs to be continually supported, not only in China, but in other countries as well. An integrated approach will be needed to ensure innovative medical technology and health service techniques can play a prominent role in modernising healthcare around the world. Eb

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2 Refer to multi-stakeholder initiative http://www.integratedcarealliance.org

3 Refer to Joint initiative on Interoperability http://www.cocir.org/uploads/media/17022_COC_Interoperability_web.pdf

4 COCIR publication on improving workflows http://www.cocir.org/uploads/media/16058_COC_eHealth_WORKFLOWS_position_paper_web.pdf;COCIR publication on Blue Print Roadmap http://www.cocir.org/uploads/media/17023_COC_Blueprint_24-04-17.pdf

5 *Deepening the reform of China's medical and health system,* World Bank Group, WHO, MoF, NHFPC, MoHRSS, <http://www.wpro.who.int/china/publications/health-reform-in-china.pdf>

HEALTH AND WELLNESS IN CHINA

Healthy China 2030 and its effect on the future of healthcare development in China

Medical advances have taken place rapidly since the onset of globalisation, but while China has made some strides in healthcare there is much that needs to be done. Although *Healthy China 2030* has been promoted as the initiative that will push domestic healthcare into the 21st century, there are a litany of health-related problems that still need to be tackled. **Dr Eduardo Yoshida**, from **Global Doctor China**, outlines what can be done to make China's medical system more flexible and sustainable.

The World Health Organization (WHO), proposed a definition, linking health to well-being in terms of "physical, mental, and social well-being, and not merely the absence of disease and infirmity".[1]

China has operated, in many ways, on the foundations of ancient cultural traditions despite profound global changes in society and the economy. In order to retain cultural traditions while adapting to the rapid changes in the global environment, China has tried to creatively transform traditional Chinese medicine, and promote the domestic development of Western medicine.

On the 19–20th August 2016, the China National Health and Wellness Conference was held in Beijing. Both President Xi Jinping and Premier Li Keqiang attended the conference and delivered important messages on healthcare. The *Healthy China 2030* initiative was presented as the action plan for the next 14 years, with its goal being the improvement of 1.3 billion people's health that live in China.[2] Five specific strategies were outlined in *Healthy China 2030* to improve healthcare nationwide, including: controlling major risk factors, increasing the capacity of health services, enlarging the healthcare industry, and perfecting the health service system. These strategies are themselves based on four core principles, which are health priority, reform and innovation, scientific development, and justice and equity. These core principles were assessed using 13 indicators by the Central Politburo of the Communist Party of China. The assessment results will be reported in 2020 and 2030.

Goal				
Put health on the priority list of development to a strategic position; promote the concept of health in the whole process of public policy implementation; enable everyone to be involved health and everyone to share health care services; focus on the health of all the people all their life in china.				
HC 2030: China's vision for healthcare				
1. Health Level	2. Health life	3. Health Services and Health Security	4. Environmental Health	5. Health Industry
Principles				
1. Health Level	2. Health life	3. Health Services and Health Security	4. Environmental Health	5. Health Industry
The 13 Core Indicators				
A. The average life expectancy B. The morality rate of infants C. The mortality rate of children below 5 years of age D. The mortality and mortality E. The proportion of those meeting the national physique determination standard among urban and rural residents	A. The level of health literacy among residents B. The number of people taking part in physical exercise	A. Premature mortality as a result of major non-communicable diseases B. The number of registered doctors per 1000 residents and registered nurses per 1000 residents C. The proportion of personal health spending in the total health expenses	A. Good air quality rate of all cities at prefecture level or above B. The rate of surface water quality better than	The total investment scale of health services

After years of effort, a basic national health insurance system has been created and remarkable progress has been made in reforming the healthcare system. As a result, improvements in healthcare and the environment —with some beneficial changes in air and water quality—have been seen. Despite these recent improvements, some serious health-related problems still exist, including: industrialisation and urbanisation; an ageing population; continuous changes in disease spectra; worsening ecological conditions; and people's unhealthy lifestyles.[3]

What are some new areas of Healthy China 2030 that have yet to be explored?

Due to China lagging behind in healthcare, the government must set clear and effective policies to effectively govern and enforce health system reforms. One area that requires more attention is primary healthcare. Currently, the Chinese healthcare system is struggling to keep up with rising medical costs, especially for serious illnesses, work-related injuries and the elderly.[4] The social and economic transformation of the population, including improved life expectancy, population migration from rural to urban areas and easing of the one-child policy in 2013, have resulted in a sharp increase in demand for medical services which threatens the healthcare system's ability to provide treatment on an equitable basis.

What do you think the chances are of successfully expanding healthcare to all citizens in China?

Healthcare development is a dynamic process that combines flexibility and strength in order to ensure that the system is adaptable and sustainable. Providing healthcare to all Chinese citizens is possible, but work must be done by the citizens themselves to ensure there is a healthy environment and that they are health literate.

A well-educated and health literate population is now possible with advances in technology and easier access to information from the media. This increase in easily accessible medical information means that people are now in a better position to take responsibility for their own health. Organisations that provide opportunities for cross-cultural medical exchanges can be vital to healthcare reforms and can contribute to educating a populace on health issues. Given the complexity and time required for the development of a fully functional national healthcare system, it would be prudent to utilise all existing health resources. Ensuring a healthy populace is not just about healthcare education, but going above and beyond pharmaceutical interests to push for medical innovation and compliance with existing international protocols. Eb

Dr Eduardo Yoshida *is an extensively qualified medical physician with 20 years working experience in both hospitals and clinics and is currently the medical director of the Global Doctor Nanjing Medical Centre.* ***Global Doctor China*** *is a healthcare group started in 1999. It has a 24-hour call centre and 10 medical centres with multi-lingual medical teams. The group offers outpatient primary care, corporate healthcare services and medical assistance. It also provides medical access to Hong Kong and worldwide medivac.*

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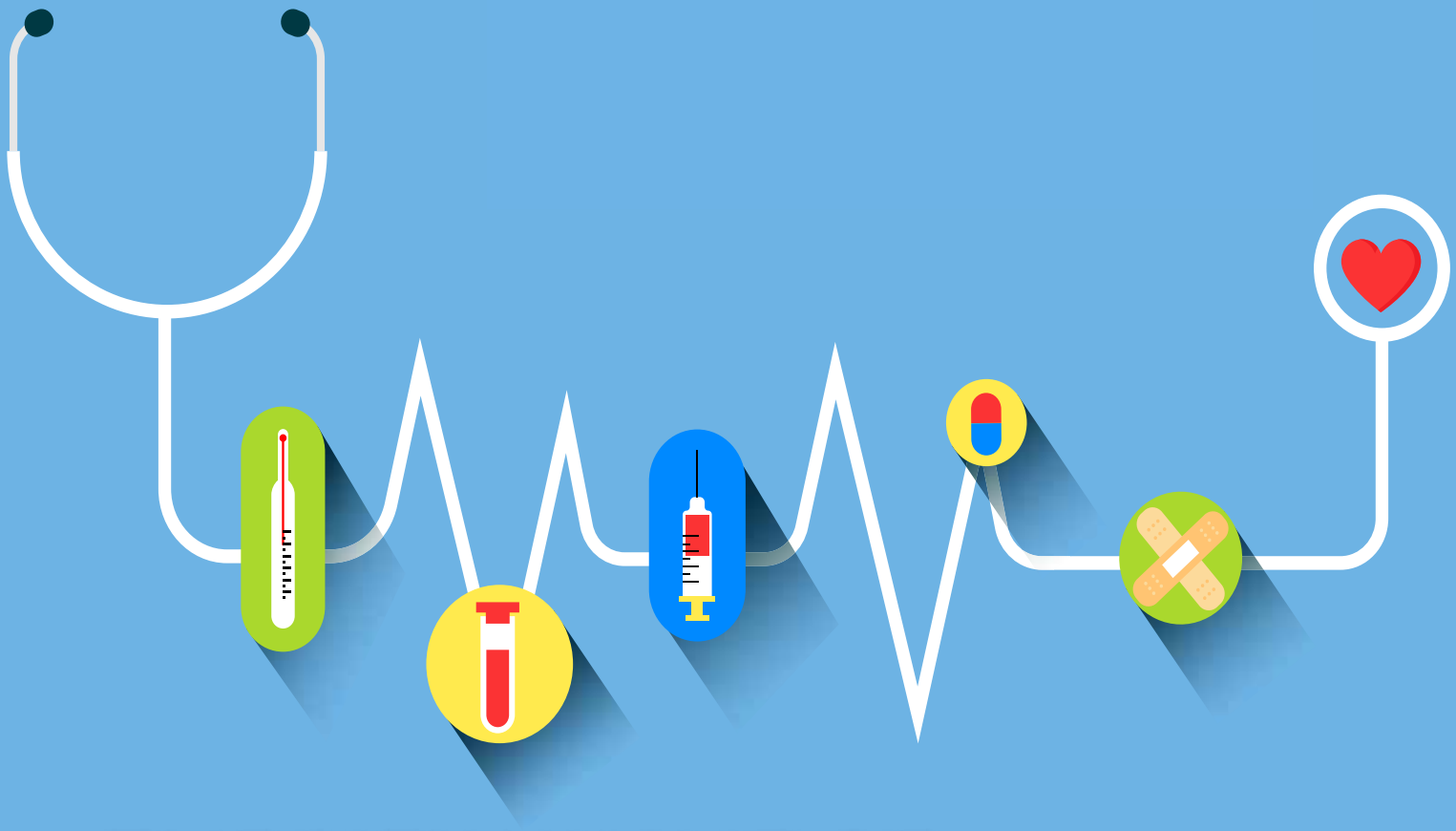
4 *China spends trillions on health care improvement, China Daily*, 29th April 2016, <http://usa.chinadaily.com.cn/china/2016-04/29/content_24952168.htm>



THE NEW WAVE OF HEALTHCARE INNOVATION

China is set to accelerate innovation in drugs and medical devices

China's healthcare industry has been innovating at a rapid pace, and it now has one of the largest innovative pharmaceutical industry markets in the world. Despite this success, China's drug and medical device policies have not caught up with many of the recent global advances in healthcare. **Wang Hongyu**, from **Smith & Nephew Shanghai Ltd**, discusses the most recent actions undertaken by the central government to try and correct this issue and what the impact of this will be on the future of China's drugs and medical device industries.

In 2015, the market size of the innovative drug industry worldwide was United States dollar (USD) 600 billion. However, according to statistics found in the blue paper *Fostering a Sustainable Ecosystem for Drug Innovation in China*, China only accounted for 6.2 per cent of the innovative drug industry market. For the medical devices industry, the market size in China is expected to reach Chinese yuan (CNY) 450 billion (USD 68 billion) by the end of 2017, while worldwide it is estimated to reach USD 398 billion, according to Visiongain and the China Medical Pharmaceutical Material Association. Chinese leadership understands that they need to restructure the pharmaceutical and medical device industry by encouraging innovation in drugs and medical devices. The government also realises they need to improve industrial competitiveness and

meet the public's medical needs.

Discovering, designing and developing new medicines and medical devices is extremely complex. In order to prevail, powerful new scientific insights need to be gained, followed by rigorous testing and clinical trials. Success ultimately depends on policies that reassure the public that new and innovative therapies and technologies are safe, effective, accessible and affordable. The four essential policy components that form the bedrock of life science innovation are:

- strong research and development (R&D) infrastructure;
- effective intellectual property protection;
- harmonisation of global standards for drug and device regulation and trade; and
- sufficient reimbursement.

Unfortunately, the China Food and Drug Administration's (CFDA) drug and device approval policies have lagged behind. Formed in the late 1990s, China's drug authority focused initially on establishing a simple regulatory system and improving the supply of generic drugs and 'me-too' devices for basic medical care. However, in the past four years the CFDA has changed both its mission and approach in order to conform to the central government's healthcare strategy.

The government has taken steps to try and align the entire life science policy environment closer to international norms. The State Council issued the *Opinions on the Reform of Evaluation and Registration Process for Drugs and Medical Devices (Opinions)* in August 2015. The *Opinions* identified a number of issues relating to the drug and medical device registration system. Some of these problems included long registration times, a significant application backlog, poor generic drug quality assessments, low-quality or incomplete drug application clinical data and a difficult registration system for innovative drugs. In October 2017, the General Office of the Communist Party of China's Central Committee and the General Office of the State Council jointly announced the *Opinions on Deepening the Reform of the Review and Approval System and Encouraging the Innovation of Drugs and Medical Devices (2017 Opinions)* to further encourage innovation in drug development and medical device innovation. This directive attempts to address a wide range of issues and seeks to: speed up the drug registration process; provide a more efficient registration system for imported drugs, innovative drugs and medical devices; establish a catalogue of rare diseases and expedite registration for their treatment; and address compliance issues in drug promotion and data integrity issues in clinical trials.

In response to the *Opinions*, since late 2015 the CFDA has issued a series of orders to address these concerns. Addressing these problems has meant carrying out equivalence evaluations on the quality and efficacy of generic drugs, cracking down on clinical trial data fraud, introducing a pilot market authorisation system and establishing green channels for the registration of medical devices. The CFDA has been busy publishing several draft orders in 2017, especially after the *2017 Opinions*. Some draft orders and decisions are extremely important and will have a far-reaching impact on China's drug and medical device registration system. If passed, these orders will speed up the entire innovation drug and device registration process, benefiting R&D drug and innovation device manufacturers.

New policy highlights

The most significant change since the *2017 Opinions* was issued, is that qualified data obtained from overseas multi-centre clinical medical devices can now be used for innovative drug and medical device applications in China. As a result, China's innovative drug approval time could be significantly shortened. The *2017 Opinions* seeks to streamline the clinical trial process by shortening and simplifying clinical trial approval, improving the Institutional Review Board review process and encouraging social forces to invest in clinical trial institutions.

This State Council document promises fast-track approval for two kinds of drugs and medical devices: new drugs and devices that have urgent clinical need, and drugs and devices for rare diseases. These drugs and devices can be quickly approved if trial data collected in the early to mid-stages shows they have clinical value. These drugs and devices can also be fast-tracked for rare diseases if they have already been approved for marketing overseas.

Measures will be introduced to promote and protect innovation, including the creation of a catalogue for marketed drugs, building a system linking the drug approval process with their patents and increased protection of drug trial data. Drug and medical device manufacturers are encouraged to increase R&D input, strengthen R&D on new products and continue studies on marketed products to improve production quality.

China's recent life science policy announcements suggest that the best science and the strongest, most innovative companies—regardless of country of origin—can thrive in China, the second largest healthcare market in the world. However, having a successful outcome largely depends on China's willingness to aggressively implement these emerging policy changes. Equally, success or failure for firms depends on how rapidly companies reshape their thinking, strategies and operating models to align with China's future medical needs, scientific capabilities and policy objectives. Eb

Wang Hongyu *is Chair of the European Chamber's Healthcare Equipment Working Group and Vice President, Regulatory & Clinical Affairs, Quality Assurance at* ***Smith & Nephew Shanghai Ltd****, a leading manufacturer of implantable medical devices, headquartered in London with 16,000 employees in more than 100 countries.*

POST-ACUTE HEALTHCARE PROVIDERS

Emerging stars in the booming private healthcare sector in China

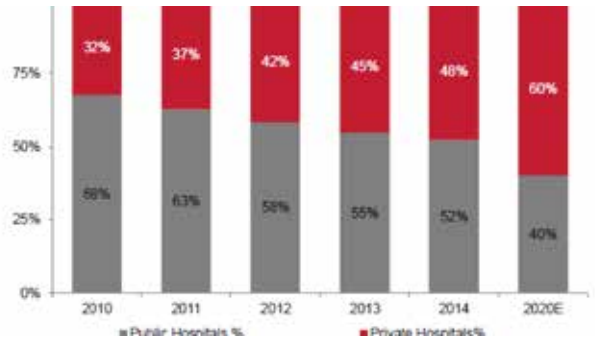
China's overburdened public healthcare system has led to private hospitals playing an increasingly key role. **Shuai Yuan**, co-founder and co-CEO of **Care Alliance**, describes how post-acute healthcare providers can help make China's health system more sustainable.

In China, there are currently more than 200 million people over 60 years old, and this number is expected to double in the next three decades. This is creating an elderly population that is larger than the total population of the United States. As the elderly are more susceptible to sickness, an ageing population creates the need for a more robust healthcare system. In recent years, a larger part of China's population has been made up of those that came into adulthood in a more modern China, and when it comes to healthcare

quality they want to ensure they receive the best. The increased demand for high-quality healthcare services by this modern generation, and the necessity for an increase in the availability of treatment for a quickly ageing population, has driven the Chinese Government to encourage the development of private hospitals.

As part of China's five-year healthcare reform road map from 2015–2020, the government is seeking to increase private hospital participation in order to alleviate pressure on the under-resourced public healthcare system. Private hospitals are garnering long-term benefits from healthcare reform, leading to an increase in private hospital coverage. Private hospitals provide an alternative for people who are no longer satisfied with subpar service and care in public hospitals – they attract patients to their hospitals with their premium services, accessibility and more modern environment. Thus, among different types of private hospitals the most immediate beneficiaries are the more service-orientated specialty hospitals with lower medical risks, less reliance on doctors, lower operational hurdles and more replicable business models. Cosmetic surgery and obstetrics and gynaecology are the two medical specialties that have the largest number of private hospitals – over 90 per cent of these specialty hospitals are private. Orthopaedics, otorhinolaryngology and ophthalmology have also seen a rise in private operators.

Number of Hospitals in China, Public vs Private



Source: WIND

With the rapid growth of private hospitals, a lesser-known but well-positioned category of specialties is rapidly emerging that is known as post-acute medical services. This can include rehabilitation centres and long-term nursing facilities. These facilities not only share the same traits found in private hospitals such as low medical risk, low operation difficulty and high scalability of its business model, but they also follow the same healthcare reform guidelines and serve to meet the growing demand from the elderly for access to healthcare.

In China, the allocation of medical resources to various medical institutions is severely imbalanced. China's hospital system is primarily broken up into three distinct tiers as follows:

1. The top tier is class III, which includes large-scale hospitals that typically have the best doctors, facilities and resources for research and development.

2. The next tier down is class II which is also known as an above mid-sized hospital.

3. Lastly are the class I ranked hospitals that are considered primary clinics and mainly offer community healthcare services.

In 2016, class II and III hospitals accounted for only 35 per cent of the total number of hospitals, but contributed to 87 per cent of the total patient visits, indicating that these hospitals were operating at over capacity. The stress is so great on these classes of hospitals that additional beds are placed in corridors. Subsequently, efficiency problems arise: long queues, overstretched doctors, inadequate attention spent on patients, and diagnoses made with the minimum amount of time allowed.

One key component of the government's healthcare reform is the establishment of a tiered health service system, where patients are classified into different tiers and transferred by referrals to allow for a more efficient allocation of medical resources.

Ideal Triple-tiered Health Service System

Source: Morgan Stanley: PBM - Public Benefits Manager, HMO- Home Management Organisation

The purpose of post-acute healthcare providers aligns perfectly with China's healthcare reform. They take care of patients referred from over-crowded class III hospitals so these same hospitals achieve higher bed turnover and save beds for patients with more severe conditions in need of stronger medical support. This increases service capacity without having to invest into additional hospital beds and facilities. For an elderly person who requires only basic medical support but long-term nursing care, they would be more suited to a long-term nursing facility than a large general hospital.

Despite the benefits of having more efficiently allocated medical resources, the tiered health service system will not work without the endorsement of large general hospitals. In China, the government insufficiently investing in public healthcare has led most large general hospitals to essentially be responsible for both revenue and incurred costs. Conventional thinking indicates that large general hospitals lack the interest to follow

the tiered system, which restricts their patient sources and limits their financial gains.

Interestingly, the data suggests otherwise since large general hospitals could be financially incentivised to transfer patients with a lesser need for medical attention down to lower-tier facilities. The following is a case that supports the economics behind complying with a tiered healthcare system.

The payment curve of a typical orthopaedic surgery patient with a stay of 10 days, suggests that approximately 70 per cent of the patient's total medical expenses happens in the first three to four days. While in the remaining six to seven days of their hospital stay, patients are usually paying much less since they are mostly on bedrest to recover. In this scenario, if a large general hospital were to discharge the patient on day five of his normal 10-day stay, leaving the recovery time for post-acute facilities, then the hospital could take another patient, which would double their revenue during that same five-day period.

Of course, this model depends on two key assumptions. First, large general hospitals need to quickly admit a new patient in a severe enough condition to fill the bed that the previously discharged patient left empty. Second, large general hospitals need to fully understand and identify how they can measure financial gains by taking advantage of the tiered process. The reality is, that most general hospitals are still reluctant to let go of the more immediate source of profit and often hold onto patients that could have been discharged. As more and more hospitals test the water and see improved financial results, they will eventually be incentivised to start supporting the tiered health service system.

On the patient side, they can now resort to post-acute facilities in order to address their functional and chronic problems that have been previously neglected at large general hospitals. Surgeons are too busy to pay sufficient attention, as many see a successful surgery as the end of their job. Post-acute facilities provide more than clinical treatments. While commonly overlooked, the psychological and sociological aspects of care and support from the medical staff are equally essential to a patient's recovery as clinical treatment is. For example, rehabilitation hospitals focus on returning patients' physical, mental and sensory capabilities to a normal condition. Rehabilitation can help a body achieve normal functionality through constant care, supervision and recovery techniques. Studies show that nearly 95 per cent of first-time stroke patients are able to have fully restored bodily functions if they receive timely rehabilitation intervention. Needless to say, as post-acute recovery tends to take much longer than clinical treatment, most newly-constructed post-acute facilities offer a warmer, more modern design with more patient-centric services that allow patients to have a much more enjoyable experience than in traditional public general hospitals.

One obstacle still remains, however, and that is patient awareness. Take rehabilitation for example. Conventional wisdom in Chinese culture suggests bed rest after surgeries and because of this, few people are aware of the need for rehabilitation. Same goes for long-term nursing facilities. It is traditionally a symbol of filial piety to attend to your own parents so most Chinese people are reluctant to send their parents to nursing homes, despite inconvenience and unprofessional care at home.

China is facing an ageing population and a rising demand for quality healthcare services. The government is wasting no effort in strengthening healthcare and building up the tiered health service system. Admittedly, such developments will take years to play out, but with strong government support, a proper incentive mechanism in the tiered service system, patients' demand for better services and more holistic care, and the use of post-acute healthcare providers, these initiatives will ultimately become reality. Eb

Care Alliance *operates post-acute rehabilitation hospitals and clinics, geriatric hospitals and long-term nursing facilities. It is committed to promoting modern principles and practices as well as cultivating talents in post-acute care in China.*

A NEW DIRECTION FOR CHINA'S PHARMACEUTICAL MANAGEMENT MODEL

The effects of adopting international pharmaceutical standards

In recent years, China's pharmaceutical industry has rapidly evolved. A large number of international pharmaceutical standards and best practices have been adopted by the Chinese healthcare system. **Vincent Zhu**, a senior partner, and **Mireia Paulo**, director of the European-American Market and Overseas Investment Project, from **A&Z Law Firm**, outline how these changes have had a drastic effect on the country's pharmaceutical management model.

A change in China's leadership facilitated the modern medical regulatory system taking off in 1978, six or seven decades after Europe and the United States (US) got their regulatory systems off the ground. In 2015, Bi Jingquan, former specialist at the National Development and Reform Commission, became the director of China's Food and Drug Administration (CFDA). Due to Mr Bi's relative inexperience with regulating pharmaceuticals, the CFDA has increasingly looked to international models for advice on how to best run the organisation.

In July 2016, the CFDA appointed Dr He Ruyi as the chief scientist at the Centre for Drug Evaluation (CDE). Dr He previously worked at the US Food and Drug Administration (FDA) and as the chief scientist in a pharmaceutical examination centre for 17 years. In June 2017, the CFDA officially joined the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). Becoming a member marked a real turning point for Chinese medical regulation, since joining this international body put the CFDA for the first time on par with other pharmaceutical regulatory bodies. After joining the ICH, the CFDA has been striving to be included in the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S).

On 29th August 2017, during the inaugural meeting of the 11th Chinese Pharmacopoeia Commission, Mr Bi stated that "the overall goal of reform is harmonisation with international standards". In fact, since undergoing reform, China's pharmaceutical management model has endured drastic changes and has consistently moved towards a more European or American-style management system.

Three steps towards improvement

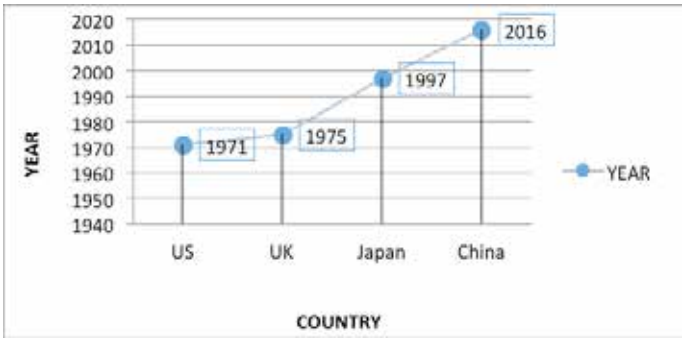
China's pharmaceutical regulatory body has taken three crucial steps for improvement.

1. China adopted a quality and consistency evaluation framework for generic drugs.

In 1971, the US launched a bioequivalence evaluation of generic drugs. By accelerating market entry and focusing on therapeutic equivalence of generic drugs, the FDA eliminated 6,000 types of drugs from the market.

Compared to the US, Chinese laws and regulations pertaining to generic drug evaluation have been executed at an extremely slow speed. Despite making remarkable improvements, China has fallen behind the international community the past three to four decades. For instance, even though a work plan was drafted on generic drugs in 2012, the *Opinions of the General Office of the State Council on Quality and Efficacy Consistency Evaluation for Generic Drugs (Guobanfa No. 8)* was only recently promulgated on 6th February 2016. *Guobanfa No. 8* stated that the consistency evaluation of certain drugs has to be completed by the end of 2018, with the remaining having to be evaluated by the end of 2021.

Country Comparison on Enforcement of Generic Drug Evaluation



Source: A&Z Law Firm, 17 October 2017.

2. China has established a marketing authorisation holder (MAH) system.

The internationally available drug licensing system can be divided into two categories. The first category separates drug market licensing and production license management, which can be observed in the European and North American pharmaceutical systems. The second category, which is used in China, is a merger of the two different licences into one.

Since 5th November 2015, 10 regions in China became a part of the marketing authorisation holder system (MAH) for drugs. These areas have taken part in a three-year pilot programme that will end on 4th December 2018. The MAH system is fairly similar to approaches already taken by Europe, the US and Japan. It has given Chinese pharmaceutical research and development institutes, as well as individuals, in select areas the ability to apply for a drug product licence. Recently, the draft *Drug Administration Law of the People's Republic of China*, published on 23rd October 2017, has expanded the programme's scope to include international applicants and licence holders.

Comparison Between China, US and EU MAH Systems

	CHINA		US	EU
	Pilot Policy	Drug Administration Law (Draft for Comment)		
Marketing Authorization Holder	Being a drug research institute or drug manufacturer in the established pilot administrative region concerned in accordance with the law, or a researcher working in the pilot administrative region concerned with the nationality of the PRC	Foreign MAH shall appoint a domestic legal person to assume obligations and bear responsibilities	No limitations	Drug R&D institutes, manufacturers, corporates, trading enterprises and individuals

Source: A&Z Law Firm, 17 October 2017.

3. China has established a pharmaceutical patent linkage system, test data protection system and patent term compensation system.

Currently, these three systems cooperate with one another and were originally derived from the *US Drug Price Competition and Patent Term Restoration Act 1984*, otherwise known as the *Hatch-Waxman Act*.

To encourage innovation and the use of generic drugs, China reaffirmed the three-systems approach in the *Opinions on Deepening the Review and Approval System Reform and Encouraging the Drug and Medical Device Innovation* (*Tingzi No. 42*), published on 8th October 2017. This document intended to clarify and improve existing laws and regulations. After publishing *Tingzi No. 42,* the CFDA issued on 11–12th May 2017, four circulars pertaining to drug and medical device innovation. Included in those drafts was the *Relevant Policies on Encouraging Innovation in Pharmaceuticals and Medical Devices, and Protecting the Rights of Innovators* (*Innovation Policy*). After ending the call for comments, the assessment of the *Innovation Policy* was that it improved both the pharmaceutical patent linkage system and data protection system.

Pharmaceutical Patent System Comparison

	China		US
	Innovation Opinions	Innovation Policy	
Patent Linkage	Patent Claim: Relevant patent and its ownership status of the patent Pending Period: Limited time	Patent Claim: 1. Ownership status of the patent; 2. It does not constitute an infringement Pending Period: ≤24 months	Patent Claim: 1. No relevant patent; 2. Overdue; 3. It will be overdue and the generic drug will go to market after expiration; 4. Relevant patents are invalid or non-infringing Defined period: ≤30 months
Test Data Protection	Test data exclusivity period: Limited time	Four types of test data exclusive period: 1.5, 3, 6 or 10 years	Two types of test data exclusive period: three or five years
Patent Term Compensation	Suitable compensation period	N/A	A maximum of five years of protection [it could be extended]

Source: Own elaboration

In summation, the accelerated internationalisation of the pharmaceutical management model can be best represented by Mr Bi leading the CFDA. He has continued to gradually modify domestic policy and explore international models. An illustration of this is the conditional acceptance of using multi-regional clinical trial data to approve market entry with certain conditions for preferential approval and examination of rare diseases. This is to ensure that foreign innovative drugs can enter and adapt to the Chinese market. This will inevitably result in strong market competition between domestic and foreign pharmaceutical companies. Those companies that take the initiative to adapt to new market conditions now, will conquer the pharmaceutical market in the future. Eb

A&Z *is a leading Chinese law firm, which employs over 55 experts consisting of attorneys, legal practitioners and business analysts across 11 jurisdictions. The Shanghai, Beijing, Dalian, Wuhan and Tokyo offices provide a full range of services covering foreign investment, overseas investment, competition and antitrust, intellectual property, M&A and corporate restructuring, labour and social security, dispute resolution, compliance and corporate social responsibility, finance and capital markets, customs logistics and maritime commerce, and environment, health and safety.*

EUROPEAN CHAMBER LOBBYING HIGHLIGHTS

EU Tour 2017/2018

A European Chamber delegation of 22 people, led by Chamber President Mats Harborn, visited Brussels from 25th to 29th September. The delegation included vice presidents Massimo Bagnasco, Michael Chang, Patrick Horgan and Carlo D'Andrea; President Emeritus Davide Cucino; local board members Paul Sives and Serafino Bartolozzi; Secretary General Adam Dunnett; and the directors of government affairs, Xavier Sans Powell and Ziting Zhang.

In addition to presenting key messages from the Chamber's *Position Paper 2017/2018* to the European Commission they also updated European Union (EU) leaders on the evolving business environment in China. The European Chamber delegation held nearly 65 meetings with both high- and working-level officials to discuss the future of EU-China economic relations, and also communicated to leaders what the most significant challenges facing European businesses in China are. Some of these challenges include: ambiguous rules and regulations, administrative issues and an unpredictable legislative environment.

Key messages
While some positive developments have taken place as China moves towards globalisation, the European Chamber have several concerns over the lack of reciprocal market access and the absence of a level playing field. The Chamber made clear that these areas must be addressed by EU leaders when engaging in future dialogue with China.

It was made clear that the European Chamber is continuing to follow the developments of *State Council Document No. 5* and *State Council Document No. 39* to see if the reforms outlined in those documents, along with the commitments made in President Xi Jinping's speech at Davos in January 2017, will come to fruition. Accepting that reforms require a great deal of time, coordination and effort, the Chamber reaffirmed their commitment to closely monitor and follow-up on the state of the reform agenda and stated their intent to publish a special report on the aforementioned documents.

Chamber President Mats Harborn Addresses European Parliament on New Challenges in China

On 25th September, European Chamber President Mats Harborn presented recent developments in the Chinese business environment to the European Parliament's Committee on International Trade. President Harborn discussed the problems with investment in China as well as some positive trends that have taken place in the country's business environment. Concerns were then raised over promises that were made to further open-up the economy that have not yet been translated into action. His concluding remarks were on the imbalance of trade between China and Europe and the lack of reciprocal market access. After President Harborn finished, parliamentarians discussed the content of the presentation and thanked the Chamber for its efforts.

Meeting with European Commission on Opportunities for a Stronger EU

On 28th September, Chamber President Mats Harborn and European Commission Vice President Jyrki Katainen discussed recent changes in the EU-China relationship as well as opportunities for deeper economic engagement between the two. Vice President Katainen expressed confidence that the EU's growing strength and unity will allow Europeans to make the most of opportunities that come with engaging China. Echoing the Vice President on unity, President Harborn went on to raise

concerns about the slow pace of reform in China. Vice President Katainen took note and expressed his hope that change in China could be implemented more quickly.

Discussing Globalisation and Trade Reciprocity with Secretary General Italianer

An in-depth dialogue was held between European Chamber representatives and European Commission Secretary General Alexander Italianer, on 26th September. They discussed the rising importance of the EU-China relationship along with shared concerns over a lack of reciprocity and imbalance of trade, with Secretary General Italianer outlining how these imbalances are driving a backlash against globalisation. However, along with these concerns the secretary general expressed optimism that new free trade agreements in the Asia-Pacific region could present new opportunities for Europe. After discussing shared concerns, the Chamber went on to provide insight on other issues such as market access and the Belt and Road Initiative.

European Chamber Advises European Agriculture on China

On 27th September, Chamber President Mats Harborn met with Commissioner Phil Hogan of the Directorate-General for Agriculture and Rural Development. Commissioner Hogan expressed concerns over the lack of reciprocity in the dairy and meat sectors between the EU and China. President Harborn made recommendations on how Commissioner Hogan could approach his Chinese counterparts in his future 2018 trade mission to China on improved market access, and also discussed food safety challenges.

Other Lobby Activities

Exclusive Dialogue with MOFCOM on Expanded Market Access

On 8th September, Ye Wei, the deputy director general of the Foreign Investment Administration, MOFCOM, took part in an exclusive dialogue hosted by the European Chamber. Chamber Vice President Michael Chang delivered opening remarks before moderating a question and answer (Q&A) session with more than 90 members. Deputy Director Ye presented the latest Chinese trade and investment data before reaffirming the government's stated intentions to further open-up the domestic market to foreign investors. He later summarised the impact of the *Notice of the State Council on Several Measures for Promoting Foreign Investment Growth (State Council Document No. 39)* on the investment market.

Chamber Discusses Green Development with MIIT

On 13th September, Gao Yunhu, the director general of the Department of Energy Conservation and Resources Utilisation, MIIT, met with the European Chamber's Environment Working Group. Gianluca Ghiara, the national vice chair of the Environment Working Group, summarised the Chamber's participation in the recent public consultation on the draft *General Principles for Assessment of Green Plants*. Prior to the Q&A session, Director General Gao discussed the challenges involved in establishing a green manufacturing system in China. Noting these challenges, the Chamber pledged to continue cooperation by participating in future seminars and exchanges. Director General Gao concluded the meeting by recognising the impact of European business on this issue.

HOW B2C COMPANIES CAN WIN

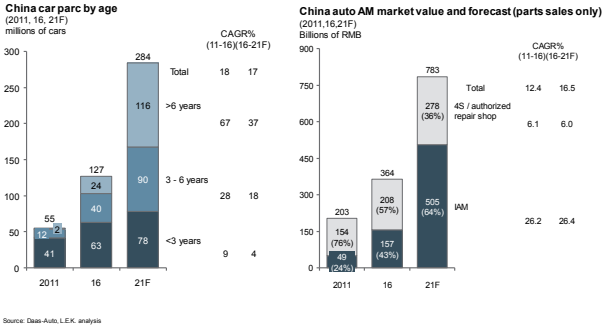
Navigating the increasingly competitive Chinese automotive aftermarket

The competition in China's auto aftermarket has been skyrocketing as e-commerce puts businesses in touch with consumers more easily than ever before. Understanding how to effectively navigate the automotive aftermarket is crucial in this high-stakes business environment. **Justin Wang**, **Yong Teng** and **Solodias Wu**, from **L.E.K. Consulting**, provide advice on how companies can develop their own sustainable, cutting-edge business models to compete in China's automotive industry.

In the booming automotive aftermarket, business-to-consumer (B2C) online business is increasingly the focus of development. The average vehicle age in China is nearly four years and will reach five years by 2022. An increasing number of cars with expired warranties will move into the aftermarket for servicing, providing greater opportunities for participating companies.

By 2016, China's automotive aftermarket (parts sales only) reached Chinese yuan (CNY) 360 billion with 40 per cent of the revenue coming from the independent aftermarket (IAM). Business opportunities will arise as parts sales in China's automotive aftermarket, by 2021, will reach CNY 800 billion with 60 per cent of total revenue coming from the IAM.

Figure 1: Car parc of China passenger vehicle and aftermarket value



Source: Daas-Auto, L.E.K. analysis

The automotive aftermarket has been driven by a group of increasingly diverse players with B2C companies playing an especially active role. There are four companies that have a prominent role:

1. Online service catalogues: consolidate resources from 4S stores and IAM repair stores, leading car owners to offline repair facilities.

2. B2C e-commence platforms: operate under the guise of large e-commerce companies, facilitating parts suppliers/wholesalers to sell directly to car owners.

3. Online parts sales and onsite services: operate as online repair service providers whereby car owners can make appointments online and then maintenance teams provide repair services onsite.

4. Online parts sales and repair shop services: sell parts online to car owners and enter into franchise agreements with repair shops that provide installations and repairs.

Rapid expansion and loss of direction

According to L.E.K. estimates, total investment in the B2C segment of China's auto aftermarket in 2014–2017 reached CNY 9–10 billion. Over 60 per cent of investments occurred before mid-2015 with the market slowing down significantly in the second half of the year.

Many B2C companies are under financial pressure. At least 30 well-known B2C aftermarket players have gone into bankruptcy. One of the bankrupted ventures is the once high-flying start-up Bopai. Despite receiving United States dollar (USD) 18 million in funding from Jindong and Yiche in early 2015, the company declared bankruptcy in 2016. Zhegexiuche received over CNY 500 million in 2015 and 2016. However, it was sold at a discounted price in early 2017.

Why did these companies fail? It might appear that the slowdown of investment starting in mid-2015 was the cause. In truth, it was not only the slowdown but the following three reasons for companies declaring bankruptcy.

1. **Deficiencies in business models made companies unable to generate a sustainable customer base:** Many B2C companies adopted business models that required limited investment in physical assets but heavy investment online. These players attracted customers via the Internet and provided the actual services either onsite or through cooperation with brick and mortar businesses. In the former model, the types of services provided were limited. In the latter, quality of the service was not guaranteed. Due to the problems associated with either option, B2C retailers struggled to develop a sustainable customer base.

2. **Non-differentiated products and services resulted in an inability to operate in a competitive market:** Many B2C aftermarket companies focused on low margin, low barrier to entry products (e.g., retail sales of tyres and windscreen wiper blades). These product categories were highly substitutable with varying quality and price points. These B2C retailers had difficulty in outlining their value proposition which made securing consumer loyalty difficult.

3. **Limited internal capabilities and an inability to scale up:** Most car owners had to go to an offline provider for vehicle diagnostic testing, service and parts installation. Hence, a core competency for B2C e-commerce platforms was the ability to manage the relationship with offline outlets. Managing suppliers to achieve agreed service levels was critical to success.

Build up core competencies

Despite B2C companies positioning themselves as online players, the key is to success is offline service fulfilment and operations. Connecting the online customer experience with offline service delivery, and managing service delivery effectively are two ways to ensure success. Knowing how to innovate and having core competencies are also ways B2C companies can succeed.

Differentiate core competencies

Market players should design business models and build core competencies based on customer needs. A B2C company choosing a light asset business model should consider how to retain customers over the long term and how to optimise offline partners' resources. For instance, market players can leverage unique, proprietary technology alongside high-quality partners to ensure customer satisfaction and loyalty along with return business.

Establish brand advantages

Current B2C companies need to provide differentiated products and service items in order to establish branding advantages and create market entry barriers for competitors. For instance, B2C companies should consider how to introduce high-quality branded auto parts that are recognised by customers to establish customer awareness.

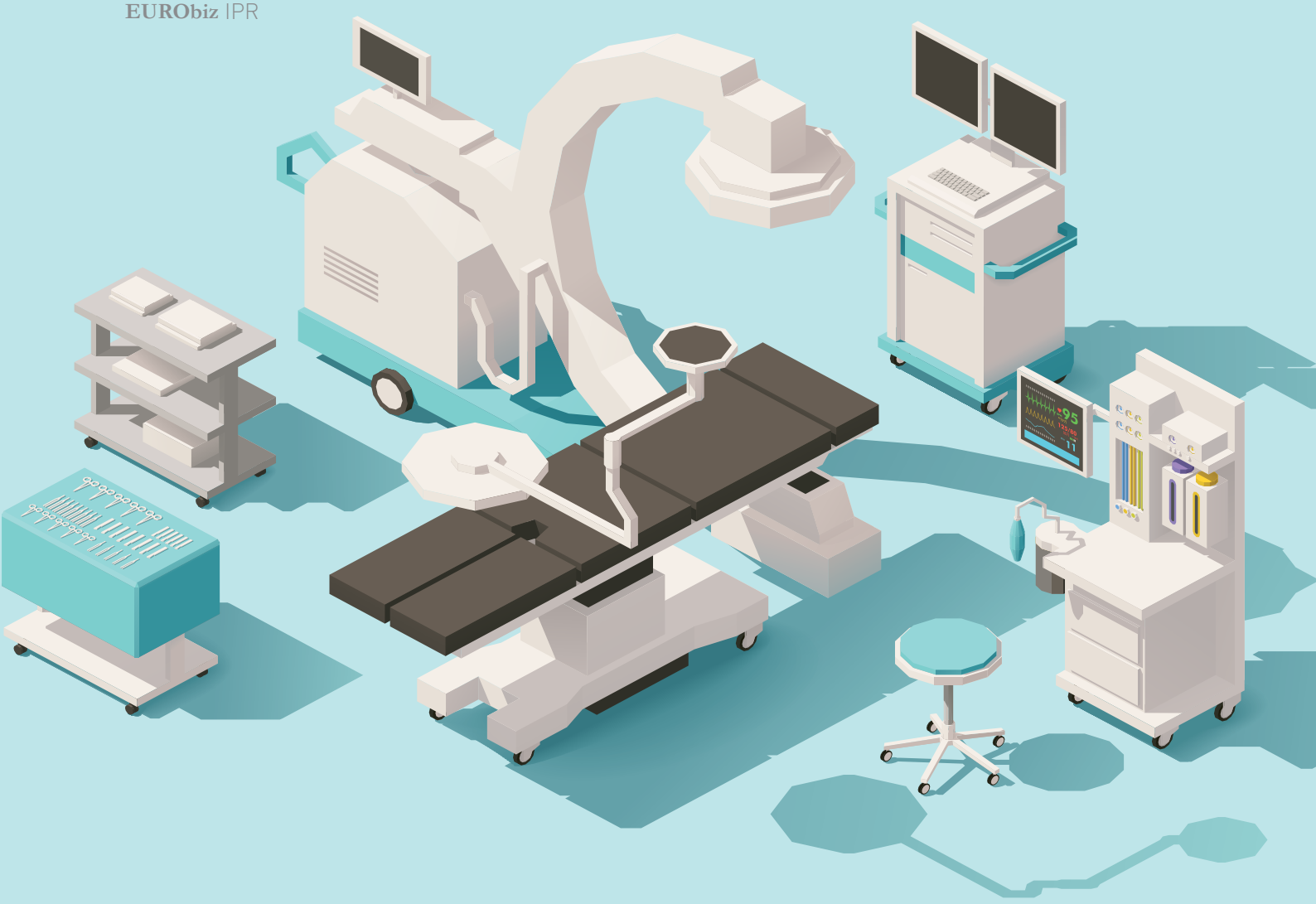
Establish high-efficiency internal capabilities

These companies should have full control over their whole operation's value chain starting from upstream parts sourcing, logistics planning, warehousing and transportation all the way to downstream outlets' operation and management of customer complaints.

In conclusion

The next five years will be a crucial period of transition in the auto aftermarket. Clearly positioning core competitiveness, designing sustainable strategies and business models, and establishing efficient internal competencies will be key for B2C companies to convert customer flow to profit.

L.E.K. Consulting *is a world leading management consulting firm founded in Europe in 1983 and started business in China from 1998. L.E.K. Consulting now has 20 offices in Europe, USA, Asia and Australia, with over 1,200 employees and over 100 partners.*



A CASE STUDY ON IPR PROTECTION IN CHINA

Protecting intellectual property in the medical devices industry in China

New medical devices are being created faster than ever before and ensuring that one's intellectual property (IP) is not stolen has become increasingly important. European experience in the medical device industry has been important to China as they have begun developing their own products. The **China IPR SME Helpdesk** provides a case study, along with some helpful advice on what recourse a European business can take when a Chinese competitor copies their product.

Case background

A European company in the dental instruments sector was selling their product in China through a Chinese distributor. They discovered a competitor in China was offering a similar product, but built to lower-specifications that used an identical exterior design, colour scheme and control interface. The technical manual, diagrams and parts of their sales brochure appeared to be directly copied from the European dental instruments company. Overall, the competitor's product gave the appearance of being similar in function to that of the European company, although its performance level and price were much lower.

What actions did the European company take?

The European company's representatives had previously approached the company at a trade fair to complain about the infringement of the company's IP but had not received a positive response.

The European company then proceeded to seek legal advice on what could be done. The company did not have a design patent to protect the overall appearance of their product, nor were there any patents covering the product's function, so trying to claim the Chinese company committed patent infringement was legally possible but extremely difficult to do. The only legal recourse the company had was to argue copyright infringement of the technical manual.

Instead of taking the legal route, the company decided to send a warning letter through their local lawyers that alleged infringement of the product's shape—even though they were not on strong legal ground—and copyright. The letter implied that the company would take the matter to court. The law firm, and representatives from the European company, followed-up the letter and met with the Chinese company. The European company argued that a lawsuit would be waste of time for both parties and that even if they were not successful in court, the Chinese competitor's imitation of the European product would harm their corporate image in the long run. As a result, the infringing company decided to change a number of exterior features of the product and produce new manuals and brochures which greatly reduced the similarities to the European product.

Although the European company did not have a very strong legal case to make, in this instance, a warning letter followed by a round of negotiation was able to produce a satisfactory result.

Lessons to take away

- The European company would have had an even better result if they had a design patent or a standard patent for their product in China, which would have given them clear rights over the design. Therefore, European small and medium-sized enterprises (SMEs)
- should make sure they register their IP as soon as possible, to ensure maximum protection.
- Do not assume that litigation is the only way forward. Make use of the full intellectual property rights framework that exists in China.
- The use of a warning letter can be a viable alternative to criminal prosecution or civil litigation. Issuing warning letters in combination with determined negotiations can, in some cases, lead to satisfactory results.
- Always enforce IP rights. If a business manages to create an image of being litigious then infringers are less likely to steal its intellectual property. Eb

*The **China IPR SME Helpdesk** supports SMEs from European Union (EU) member states to protect and enforce their Intellectual Property Rights (IPR) in or relating to China, Hong Kong, Macao and Taiwan, through the provision of free information and services. The Helpdesk provides jargon-free, first-line, confidential advice on intellectual property and related issues, along with training events, materials and online resources. Individual SMEs and SME intermediaries can submit their IPR queries via email (question@china-iprhelpdesk.eu) and gain access to a panel of experts, in order to receive free and confidential first-line advice within three working days.*

The China IPR SME Helpdesk is co-funded by the European Union.

To learn more about the China IPR SME Helpdesk and any aspect of intellectual property rights in China, please visit our online portal at http://www.iprhub.eu/.

CHINA IPR SME HELPDESK

EUROPEAN CHAMBER IN THE MEDIA

Chamber Holds Launch Event for its European Business in China Position Paper 2017/2018

The European Chamber launched its *European Business in China Position Paper 2017/2018* during a press conference held on 19th September in Beijing. This was followed by additional launch events in Shanghai, South China, Nanjing and Southwest China. A number of different media sources attended each launch event with Chamber President Mats Harborn taking interviews with five internationally televised media outlets: *CNBC, ARD, NOS, CGTN* and *ZDF*.

President Harborn told CNBC, "We don't know if China will implement its promises. As business people we have to be accountable for our business today, we can't build our future plans on only dreams." He went on to say, "We need to have tangible measures from the Chinese state to show that China is going down the path of more openness."

Wall Street Journal Publishes Chamber President Mats Harborn's Op-Ed

On 18th September, European Chamber President Mats Harborn had an Op-Ed published by the *Wall Street Journal* titled, *China's Economy Needs Concrete Reform*. In the article, President Harborn stated that European companies welcome public commitments by Chinese authorities to further open up the country's economy, but now the Chinese Government must follow through on those promises of economic reform. President Harborn goes on to say that the completion of a Comprehensive Agreement on Investment within the next 12 months can help address economic tensions between the European Union and China.

Wall Street Journal Quotes Chamber on Delayed Food Safety Management System

"The new measures indicate that China is replacing its risk-based food safety management system with a one-size-fits-all approach," the European Union Chamber of Commerce in China said in a statement on Tuesday. "This is not in line with international practice."

European Chamber Holds Event on China Investment

On 14th September, the European Chamber's Shanghai Chapter held the *China Investment Conference* with media in attendance. Several board members took interviews with *CGTN* to discuss their views on the current business climate in Shanghai.

Shenyang Chapter Interviewed by AFP on Doing Business in Northeast China

On 24th September, *Agence France-Presse* (AFP) interviewed the European Chamber's Shenyang Chapter board to share opportunities and obstacles that European Union (EU) businesses face in Northeast China. The Shenyang Chapter board reiterated the need for more market opening in order to attract additional foreign investment in the region.

"'The local government offers many benefits, such as easing company registration, providing discounts for factory and office space and giving family members three-year visas,' said Harald Kumpfert, chairman of the EU chamber's Shenyang chapter."

"Still, the Chamber has observed an uptick in foreign entrepreneurs arriving in Shenyang in recent years. Businesses that specialise in renewable energy, tourism, agriculture or advanced technology are well positioned to succeed in Shenyang as the city addresses pollution and undergoes a 'painful restructuring process', Kumpfert said."

CEIICC Conference on Investment and Innovation in Guangdong

On 13th September, the 2017 China (Guangdong)-Europe Investment and Innovation Cooperation Conference (CEIICC) was co-hosted by the Guangdong Provincial Government and the European Chamber. Chamber President Mats Harborn, Ambassador Hans Dietmar Schweisgut and the Chamber's South China Chapter Chair George Lau all delivered speeches at the event. President Harborn and Chairman Lau were interviewed by several media outlets, including *Nanfang Daily, GDTV* and *NDTV*. This event received 10 mentions in the media with all of them stating that CEIICC was an important platform for EU-China relations. President Harborn outlined how the Belt and Road Initiative is an important part of globalisation and highlighted findings from the *European Business in China Business Confidence Survey 2017* to illustrate that if China further opened its market, European enterprises would likely invest more.

CHAMBER NEWS

The European Chamber is a people-based organisation whose operational success depends on the hard work and education of its staff. We are particularly proud to honour those staff who are celebrating milestones in service to the European Chamber. In this issue, we recognise and thank:

Tiantian Qi
Senior Business Manager,
Shanghai Chapter,
five years award

Qiulan Zhu
Events Coordinator,
Beijing Chapter,
five years award

Carl Hayward
General Manager and Director
of Communications,
Beijing Chapter,
five years award

Kitty Wang
General Manager,
Tianjin Chapter,
ten years award

EUROPEAN CHAMBER EVENTS GALLERY

BEIJING CHAPTER

1

Exclusive Dialogue with MOFCOM: State Council Document No.39 (1)
On 8th September, the Chamber hosted Ye Wei, deputy director general of the department of foreign investment administration, MOFCOM, to discuss the impact of *State Council Document No. 39* on members.

2

European Business in China – Position Paper 2017/2018 Launch (2)
The Beijing Chapter held the official launch of the *Position Paper 2017/2018* on 19th September.

3

China Automotive 2017: Legal Opportunities and Challenges for OEMs and Automotive Suppliers (3)
On 17th October, the Beijing Chapter hosted an automotive conference on legal topics important to European and Chinese automotive markets. We would like to thank our sponsor Bird & Bird, for their commitment.

4

China Outbound: Down but Not Out (4)
On 26th October, the Chamber held a conference where the underlying reasons for the 2017 outbound investment crackdown were discussed.

NANJING CHAPTER

1

Panel Discussion with Nanjing Customs: Clearance Integration Process (1)
On 25th October, the Chamber attended a panel discussion with Nanjing Customs, where they discussed the clearance integration process and aired members' concerns regarding customs regulation.

SHANGHAI CHAPTER

1

China Investment Conference 2017: Industrial Restructuring and Production Expansion (1)

On 14th September, the Shanghai Chapter held its annual China Investment Conference. This conference provided participants an overview of China's current economic strategy and foreign business environment.

2

Position Paper Launch Event (2)

The *Position Paper 2017/2018* was launched in Shanghai on 19th September to prominent international and domestic media, and members.

3

Compliance Conference 2017: What if the 'What Ifs' Come True? (3)

On 20th September, the Shanghai Chapter held its annual China Compliance Conference.

4

China Automotive 2017: Legal Opportunities and Challenges for OEMs and Automotive Suppliers (4)

On 12th October, the Shanghai Chapter held a conference in cooperation with Bird & Bird on legal issues faced in the automotive market.

SOUTHWEST CHAPTER

1

2

Position Paper Press Conference (1&2)

On 20th September, European Chamber President Mats Harborn presented the *Position Paper 2017/2018* to local media.

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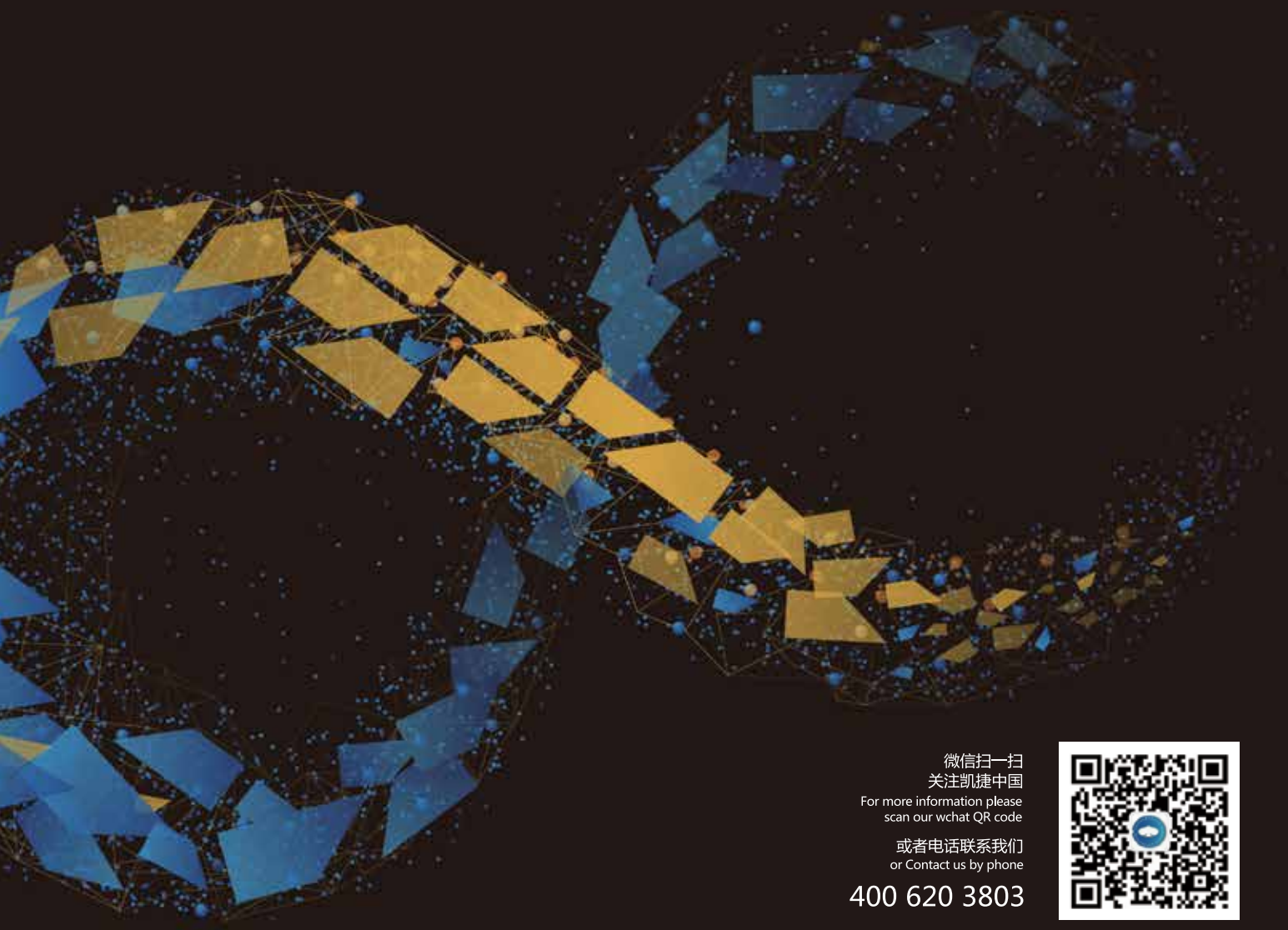

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