Journal of the European Union Chamber of Commerce in China

EUROBIZ

www.europeanchamber.com.cn
November/December 2015

THE HEALTH OF A NATION

INVESTING IN HEALTH
A legal perspective on foreign investment in China's healthcare industry

YOUR FUTURE WELLBEING
The rise of digital healthcare

A HEALTHY CHALLENGE
WFOEs in the medical devices industry

A NOBEL PURSUIT
A profile of Tu Youyou, China's Nobel Prize winner

ALSO IN THIS ISSUE:

BALANCING REFORM AND GROWTH
China's 13th Five-Year Plan

INDUSTRY FOCUS
China's testing, inspection and certification industry

European Chamber
中国欧盟商会

Beijing · Nanjing · Shanghai · Shenyang · South China · Southwest China · Tianjin

EY 安永

Building a better working world

Fraud Investigation & Dispute Services

Within Fraud Investigation & Dispute Services, Forensic Technology & Discovery Services entails securing and preserving digital information that can be used as part of investigations (evidence collation) , or to assist in disputes, through discovery of information.

eDiscovery Management Services

- Early Case Assessment Services
- Hosted Processing & Review Services
- Mobile eDiscovery
- Data Governance Advisory

Forensic Data Analytics

- Forensic Look Backs
- Continuous Transaction Monitoring
- Anti-corruption Data Analytics
- Fraud Triangle Analytics
- Behavioral Monitoring

Computer Forensics

- Preservation & Collection
- Hosted Processing & Review Services
- Leakage Prevention & Investigation
- Employee Misconduct & Misuse
- Incident Response Advisory

For more information on FIDS, feel free to visit www.ey.com/FIDS or contact Jim Yuan at jim.yuan@cn.ey.com for any inquiries in China.

TABLE OF CONTENTS

SPECIAL REPORT

COVER STORY

FEATURES

REGULARS

Journal of the European Union Chamber of Commerce in China

EURObiz

www.europeanchamber.com.cn

Chief Editor
Carl Hayward

Art Director
Wenwen Gu

For European Chamber Membership:

National Membership Manager
Remei Lluch Pont
Tel: +86 (21) 6385 2023 ext 106
rlluch@europeanchamber.com.cn

For advertising in EURObiz:

Advertising and Sponsorship Coordinator
Erica Wang
Tel: +86 (10) 6462 2066 ext 27
ewang@europeanchamber.com.cn

EURObiz is published bimonthly by the European Union Chamber of Commerce in China, and is distributed free to all Chamber members.

European Chamber Chapters:

Beijing
Beijing Lufthansa Center, Office C412
50 Liangmaqiao Road
Beijing, 100125, PR China
北京市朝阳区亮马桥路五十号
燕莎中心写字楼C-412室
Tel: +86 (10) 6462 2066
Fax: +86 (10) 6462 2067
euccc@europeanchamber.com.cn

Nanjing
806, No.99 Zhongshan Road, Xuanwu District, Nanjing
南京市玄武区中山路99号
806室
Tel: +86 (25) 8362 7330 / 8362 7331
Fax: +86 (25) 8362 7332
nanjing@europeanchamber.com.cn

Shanghai
Unit 2204, Shui On Plaza
333 Huai Hai Zhong Road
Shanghai, 200021
PR China
上海市淮海中路333号
瑞安广场2204室
Tel: +86 (21) 6385 2023
Fax: +86 (21) 6385 2381
shanghai@europeanchamber.com.cn

Shenyang
Room 1606, Office Tower C, Shenyang Land Centre international Plaza,
No. 2-3 Wuai Road,
Shenhe District,
Shenyang 110016, PR China
辽宁省沈阳市沈河区五爱街2-3号，地王国际C座，1606室。邮编110016
Tel: +86 (24) 2334 2428
Fax: +86 (24) 2334 2428
shenyang@europeanchamber.com.cn

South China – Guangzhou
Unit 2817, 28/F, Tower A,
China Shine Plaza
9 Linhe Xi Road
Tianhe District
Guangzhou, 510613 PR China
广州市天河区林和西路9号
耀中广场A座2817室
Tel: +86 (20) 3801 0269
Fax: +86 (20) 3801 0275
prd@europeanchamber.com.cn

South China – Shenzhen
Rm 308, 3/F Chinese Overseas Scholars Venture Bld
South District, Shenzhen
Hi-tech Industry Park
Shenzhen, 518057
PR China
深圳高新区南区
留学生创业大
厦3楼308室
Tel: +86 (755) 8632 9042
Fax: +86 (755) 8632 9785
prd@europeanchamber.com.cn

Southwest – Chengdu
04-A, F16, Tower 1 Central Plaza
8 Shuncheng Avenue
Jinjiang District, Chengdu
成都市锦江区顺城大街8号中环广场1座16楼04-A
Tel: +86 (28) 8527 6517
Fax: +86 (28) 8529 3447
chengdu@europeanchamber.com.cn

Southwest – Chongqing
Lobby Gallery, 1F, Hilton Chongqing, 139 Zhongshan San Lu, Yuzhong District,
400015 Chongqing
重庆市渝中区中山三路139号
重庆希尔顿酒店1楼大堂精品廊
Tel: +86 (23) 8832 9803
chongqing@europeanchamber.com.cn

Tianjin
41F, The Executive Center, Tianjin World Financial Center, 2 Dagubei Lu,
Heping District, Tianjin
300020, PR China
天津市和平区大沽北路2号天津环球金融中心41层德事商务中心
Tel: +86 (22) 5830 7608
tianjin@europeanchamber.com.cn

THE TWO NEGATIVES AREN'T A POSITIVE

Jörg Wuttke
President of The European Union Chamber of Commerce in China

As China's economy continues to slow, European businesses operating there are increasingly asking a question that you might not expect of a country that's clearly in need of further high value-added investment: how welcome are we here? This conundrum was brought into sharp focus by the Chinese Government's announcement of the new roadmap on where investment is and is not wanted. This roadmap maintains the principle of two so-called negative lists: one governing domestic enterprises and another for their foreign-invested counterparts.

At best, this manifestation of unequal treatment sits uneasily with the landmark commitment made in the Third Plenum's *Decision* to allow the market to play the decisive role in the economy. Furthermore, as the list for foreign-invested enterprises is to be released at a later date—and may only come into force in 2018—European businesses may not see substantive improvements in China's restrictive business and regulatory environment any time soon.

In light of China's unprecedented economic development over the last 35 years, it isn't clear why unequal treatment should still even be seen as necessary or desirable. Is it due to lingering worries about the ability of Chinese companies to compete? If so, the fact that the ever-expanding flow of Chinese investment into the EU—funds that are roundly welcomed for the jobs and economic growth that they create—has dwarfed the now declining scale of European investment going in the opposite direction should have made it clear that they can.

Is it intended to support the Made in China 2025 initiative, which encourages advanced manufacturing and the next stage of economic development? If so, the yet-to-be implemented procurement restrictions for the banking and insurance industries, announced in December 2014, seem to signal an intent to promote national champions by depriving domestic and foreign companies alike of the most competitive IT solutions.

This is not the most effective approach to fostering innovation. In fact, China is now home to world-class private enterprises that successfully compete at home and abroad. This should provide sufficient reason for it to confidently welcome the benefits that competition creates for growth, innovation and the purchasing power of its growing middle class. Against a background of difficult WTO negotiations, and a smaller group of key countries having already signed the Trans-Pacific Partnership, economic relations with the EU are more important to China than ever before. Chinese leaders should therefore be debating a new question: why aren't we allowing European businesses to make larger contributions to the growth and innovativeness of our slowing economy? At this crucial juncture, the EU-China Comprehensive Agreement on Investment is an irreplaceable opportunity to enlist European investment for the cause of China's continued economic success.

China is no longer the world economy's only major engine of growth. European businesses with mastery of global best practices, advanced technology and plans for high value-added investments now have other attractive options in more open and predictable markets like the US. In response, and instead of maintaining discriminatory treatment, the Chinese Government should be doubling its efforts to create the conditions that will attract the attention of these most desirable of investors. As the OECD has ranked it in last-place among the 55 countries included in its Foreign Direct Investment Regulatory Restrictiveness Index, this is an area where China can make major improvements.

Ultimately, if China is to avoid the middle income trap and reach its goal of becoming a highly innovative economy by 2025, bold reforms—not half measures that protect vested interests—are necessary. This is further necessitated by the fact that the country's 'golden age' of double-digit growth that resulted from the boom in investments in infrastructure and a demographic dividend has reached its conclusion. Under these new conditions the continuation of a prolonged, discriminatory regime for foreign companies can only be described as a self-defeating measure. The treatment that European investors receive in China during the coming years will therefore reveal how far it wishes to take the bilateral relationship with the EU, and whether the Chinese Government wants to see European companies succeed.

It should also be kept in mind that the Chinese Government is entirely capable of bringing unequal treatment to a prompt end as well as negotiating an ambitious, comprehensive bilateral investment agreement. Whether it's been in joining the WTO, taking on corruption or pulling hundreds of millions of its citizens out of poverty, we have seen China succeed at the tasks that it has set its mind to, again and again. European businesses look forward to playing a central role in China's next big success story.

BALANCING REFORM AND GROWTH: CHINA'S 13TH FIVE-YEAR PLAN

At the recent Fifth Plenum China's leadership rolled out its proposal for the 13th Five-Year Plan (FYP), the only such plan that will be fully implemented under President Xi Jinping's term. **John Russell** of **North Head** looks at the key outcomes of this meeting and the opportunities that may open up for European companies.

China's leadership gathered in Beijing from 26th–29th October, for the Fifth Plenum of the 18th Communist Party of China (CPC) Central Committee. The meeting's main purpose was to approve the *Proposals on Formulating the 13th Five-Year Plan (Proposals)*. The 13th FYP will guide China's economic and social development from 2016 to 2020, and is the first since Xi launched an ambitious programme of market-orientated reforms at the Third Plenum in 2013. The *Proposals* provides valuable indications of the government's priorities and targets for the next five years, ahead of the formal release of the full plan in March 2016.

Takeaways from the Plenum

Central themes from the Fifth Plenum and other recent political developments will impact business. China's pace of reform will be tempered to allow growth and guarantee stability. This period will be key to redress imbalances of past decades with respect to income disparities, environmental degradation and looming demographic challenges. China's expanding international footprint, with emphasis on Eurasia, will exert a growing influence on markets. Underpinning these changes is reform of the CPC as an instrument for better governance, shaped by Xi's robust leadership.

Reform vs. Growth

Drafting of the 13th FYP has taken place in the context of China's ongoing economic slowdown and efforts to shift to a more sustainable growth model. This deceleration has exacerbated the dislocations that accompany restructuring. It is causing divergent growth across different provinces and sectors. A sharp slowdown that creates unemployment could retard or even derail reform, therefore balancing growth while progressing reform will be a defining theme for years to come.

President Xi announced that annual growth under the 13th FYP will be at least 6.5 per cent to achieve the CPC's targets of doubling 2010 GDP and income per capita by 2020, in time for the party's centenary. This is lower than the seven per cent target in the 12th FYP, but remains challenging under current conditions. Language on market reforms in the *Proposals* is less ambitious than during the Third Plenum, suggesting leadership has more moderate expectations given immediate concerns about growth and volatility. Stability remains the party's watchword. We can expect the pace of reforms to be recalibrated over the next five years, depending on China's economic trajectory.

Regarding key engines of growth, the 13th FYP will advance economic restructuring through policies to promote consumption and services. Investment is identified as the critical driver for China's economy, with continued spending on rebuilding urban areas, roads, railways, pipelines and other infrastructure. Exports are less significant than in prior plans, suggesting the drafting team is not confident external demand will recover sufficiently in the coming five years.

Access and innovation

China has announced that it will implement a nationwide negative list system for foreign investment by 2018, granting pre-establishment national treatment for all sectors not on the list.

Efforts to help Chinese companies climb the global value chain will intensify and China is on track to surpass the EU and the US in R&D spending during the 13th FYP period. Compared to previous indigenous innovation policies, the new approach is more holistic, encompassing not only favourable industrial policies and tax breaks, but also strengthened IPR and efforts to overcome human capital bottlenecks. These policies are designed to nurture national champions to compete globally, consolidating China's position in such areas as high-speed rail, hydropower and nuclear energy. Policy and financial support offered under such initiatives as *Made in China 2025* will help domestic companies gradually close the technology gap with MNCs. China's drive to boost innovation can also benefit companies that can provide enabling expertise and components.

The government's traditional top-down approach to R&D dovetails with its new emphasis on nurturing innovation by entrepreneurs and SMEs. An ecosystem of incubators, funding mechanisms and improved IPR protection aims to spur grassroots breakthroughs.

Re-defining the role of state and market

State-owned enterprises (SOEs) were previously predominant instruments for development, but the government is increasingly embracing the private sector as a vehicle for achieving policy objectives. The *Proposals* calls for further development of private banks, hospitals, third-party environmental service providers and private-public partnerships for infrastructure investment. Market reforms will see stronger Chinese private enterprises challenging for domestic and overseas markets, but will also create space and business opportunities for MNCs.

Recently-released guidelines call for SOEs to become more profit-orientated and shift to mixed ownership while remaining under the control of the party. Over the 13th FYP and beyond, these reforms will gradually shape SOEs into more efficient competitors, could affect their behaviour in joint ventures and may allow MNCs to forge new strategic partnerships with them. The policy also allows state investment in private companies, which could lead to hybrid private-state enterprises in some sectors.

Addressing imbalances

Overcoming imbalances from the last 30 years of development will be a key theme of the 13th FYP. The social safety net will be strengthened to tackle inequality, with universal coverage for social and critical illness insurance and more rural migrants given access to government ser-

vices and welfare in cities. A 'two-child policy' will ease demographic pressures of an ageing population. While 90 million additional couples will be eligible for a second child, the short-term impact will be tempered by China's low underlying birth rate. These reforms will generate demand for consumer goods, particularly in smaller cities and interior China.

Balancing development and environmental protection is a top priority in the 13th FYP. Notably, the *Proposals* aims to reconfigure the chain of command for local environmental protection agencies. This will see them take a more independent and active role in enforcement. Use of market-based instruments will expand, including cap and trade mechanisms for energy consumption, water usage and industrial emissions. These trends will increase business costs in China, but MNCs should be better placed to weather such adjustments and leverage sustainability as a source of competitive advantage. There will be increased opportunities for companies that can provide energy-efficient or emissions-reducing solutions.

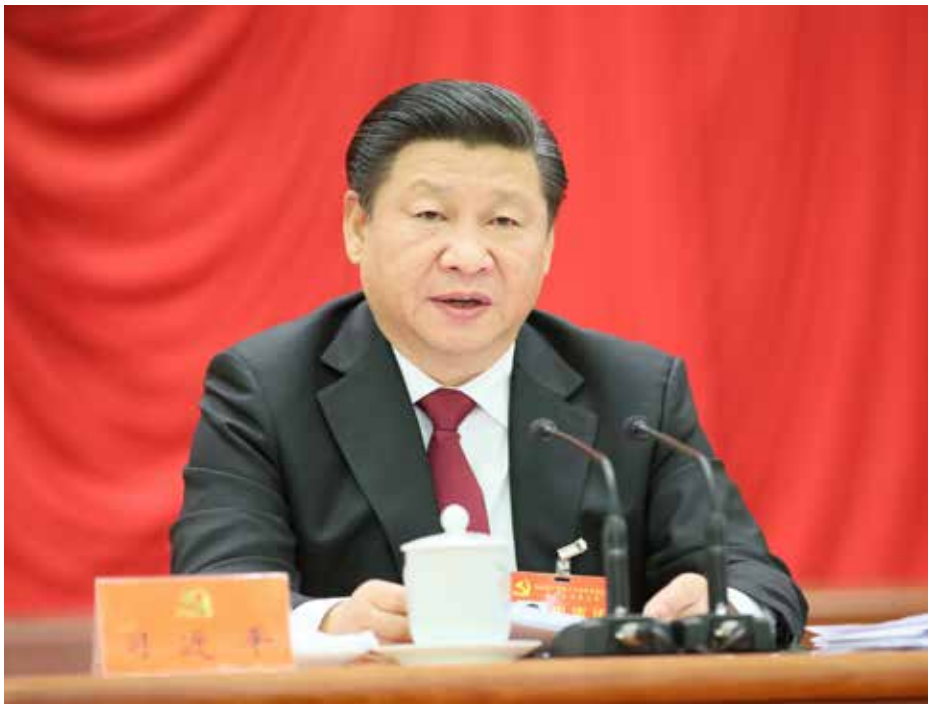
Reconfiguring party governance

The central project of Xi's first term is to strengthen and reconfigure the party for more effective governance. The primary tool for these efforts has been a sweeping anti-corruption campaign that has claimed over 120 senior officials thus far. Moving forward, measures to keep officials in check will become increasingly institutionalised through party rules, strengthening the disciplinary apparatus and building a comprehensive legal system that clearly delineates government powers. Increasing scrutiny on party discipline should help restrain ad hoc interference in business by the government. However, the campaign has had a chilling effect on many areas of government. Officials are more reticent to engage with business and the pace of decision-making has slowed.

The *Proposals* continues the trend of increasing CPC dominance in policymaking under Xi. It calls for party committees at all levels to play a larger role in overall economic and social planning – an area previously led by the government. This ascendancy is visible in many areas, from party leading groups issuing decisions bypassing state bureaucracy, to the grassroots, such as in Tianjin where reportedly 80 per cent of officials have placed party titles before government titles on name cards to stress duty to the party. Increased influence of party organs will contribute to a faster but less transparent policymaking process.

Xi in the driver's seat

Three years into his administration, the logic of Xi's reform strategy is more apparent than ever. China needs a rejuvenated party with a strong leader to implement economic reforms and achieve its international potential. While economic slowdown and market volatility may have caused the leadership to shift the reform process



down a gear, evidence from the Fifth Plenum suggests Xi remains very much in the driving seat. No major personnel changes were announced, but this year Xi has been gradually promoting loyal generals to strengthen control over the military. Political horse trading will gather pace leading up to the 19th Party Congress in 2017, when Xi has the chance to further consolidate his position as a host of senior leaders retire.

Significant challenges remain. Xi has presented himself as a transformational leader. This could be questioned if he cannot achieve meaningful progress in reform during the 13th FYP – the only FYP that will be fully implemented under his administration. Xi has thus paid special attention to 13th FYP planning, leading the drafting group for *Proposals* and introducing it at the plenum – tasks usually shouldered by the Premier.

China's international footprint and Eurasia

China's globalisation is expected to reach a significant milestone during the 13th FYP, with effective outbound investment exceeding inbound by some projections. The *Proposals* calls for accelerated efforts to develop free trade and investment agreements, such as the Comprehensive Agreement on Investment (CAI) currently being negotiated between Beijing and Brussels. The leadership sees deeper integration with the global economy as a source of growth and as an impetus for domestic reform, similar to China's entry into the World Trade Organization in 2001.

Europe has an important role in China's globalisation strategy, underscored by the recent flurry of bilateral visits between China and EU countries. China's leadership sees Europe as a favourable place for Chinese companies to build technological capabilities and serve as a springboard to access developed markets. There is also increasing interest in potential synergies between EU infrastructure plans and the One Belt One Road initiative.

Conclusions

The Fifth Plenum broadly confirms policy directions from the previous two plenums to strengthen the party and shift China to a more sustainable growth model. The *Proposals* will now feed into the final drafts of regional plans and the national plan to be approved in March. A series of industry-specific FYPs from ministries and industrial associations will follow, fleshing out the national plan's overarching goals. Companies doing business in China should use these policies and targets as important references. Where possible, they may also seek ways to provide input on these industry plans.

Despite slowing growth, policy directions mapped out for the 13th FYP are generally positive for European companies. Gradual market liberalisation will help to level the playing field for foreign investors. There are opportunities for companies with strengths aligned with government policy objectives, such as innovation and sustainability.

At the same time, MNCs will also have to adapt to slower growth, increasingly fierce competition from SOEs and China's private sector, and increased regulatory risk stemming from ongoing re-orientation of government agencies toward market supervision. Established business models are challenged by rapid change in China's markets, accelerated by reforms and disruptive trends such as digital innovation. Increased use of rules-based mechanisms and tightened party discipline is also significantly changing how companies develop government relations. Personal connections remain necessary but are less effective and carry more risk. As such, companies are devising strategies to engage a broader range of stakeholders, conveying business values, activities and partnerships that chime with changing government policy objectives. Eb

North Head *is a public affairs and strategic communications consultancy headquartered in Beijing that has a clear China and Asian focus. Its clients are a mix of multinational corporations and governments from China and the Asian region, Europe and North America. Additional information can be found at www.northheadcomms.com.* ***John Russell*** *can be contacted at jrussell@northheadcomms.com*

INVESTING IN HEALTH

A LEGAL PERSPECTIVE ON FOREIGN INVESTMENT IN CHINA'S HEALTHCARE INDUSTRY

While foreign investment in some sectors of China's healthcare market has been recently liberalised others remain restricted, and risky. **Ingo Vinck**, German Attorney-at-Law at **Taylor Wessing**, outlines the general legal landscape for foreign investments in healthcare in China, examines some typical legal problems and highlights some recent legislative developments.

Foreign Investment Guidance Catalogue

In the latest revision of the *Foreign Investment Guidance Catalogue*, which took effect on 10th April, 2015, the number of prohibited and restricted industries has been reduced, as has the number of industries for which a Sino-foreign equity joint venture is mandatory.

In the healthcare industry, manufacturing of a number of pharmaceutical products now qualifies as an 'encouraged' project. This includes, for example, the production of new compound drugs or drugs with active ingredients, the development and production of new anti-carcinogenic drugs, new cardio-cerebrovascular drugs and new nervous system drugs. The production of new pharmaceutical formulations and new products by employing new technologies such as slow release, controlled release, targeting and percutaneous absorption are further examples of encouraged businesses. Nursing homes for the elderly, the disabled and children, as well as retirement homes, were added to the 'encouraged' category of industries, too.

However, foreign investments in medical institutions remains restricted to those in the form of a Sino-foreign joint venture. Only in the Shanghai Waigaoqiao free trade zone and in some Chinese cities which function as pilot projects are there special regulations permitting the establishment of wholly foreign-owned hospitals.

Operational licences and deal structure

Most Chinese healthcare enterprises have special administrative licences in order to legally operate their business. For example, companies manufacturing or distributing medical devices or pharmaceuticals need medical device or drug manufacturing or distribution licences issued by the China Food and Drug Administration (CFDA). Hospitals need a practice permit for medical institutions, granted by the provincial department of the Ministry of Health (MOH). Since these operational licences are a mandatory requirement for most healthcare-related business in China, and since they are difficult to obtain and to maintain, they are considered a major asset of domestic healthcare enterprises by foreign investors. These operational licences play an important role when legally structuring an investment in the Chinese healthcare sector.

From a legal perspective there are basically two possible approaches when investing in China, each having its specific advantages and disadvantages. The foreign investor can either establish a new company or acquire an existing Chinese business through mergers and acquisitions (M&A). Setting up an entirely new business takes more time than acquiring an existing business. For a greenfield project the investor first has to find and acquire appropriate land, then construct buildings, procure the required equipment and materials, obtain all operational licences and hire qualified staff before starting business operations. The advantage of this approach is that every step is projectable and more or less under the control of the investor.

In contrast, every M&A deal is threatened by a number of imponderable factors, even from the beginning – a due diligence investigation of the target company may reveal liability risks unacceptable to the foreign investor or the M&A negotiations may impede the acquisition.

If the investor intends to acquire an existing business instead of setting up a new company, there are basically two possible legal deal structures (which can be combined and modified): a share deal and an asset deal.

In a share deal, the foreign investor can simply buy equity interest (shares) or subscribe increased capital in the target company. This has the disadvantage that the target company might have accumulated liability risks (for example, tax liabilities or liability risks resulting from incompliant business operations). This applies in particular to enterprises that have been existing and operating for many years.

Alternatively the investor can acquire all individual assets pertaining to the targeted business (without the legal entity owning and operating these assets). All assets are transferred individually. The major legal advantage of an asset deal is that the foreign investor does not take over existing liability risks of the target company. The disadvantages are that an asset deal can be legally more complex and lengthy. Further, the transfer of assets triggers VAT, business tax, land VAT and other taxes which can increase the acquisition price.

Since in the healthcare sector many companies have special operational licences that are not transferable an asset deal is often not a feasible deal structure for an investment. As foreign investors are often particularly interested in these operational licences more M&A deals take the form of a share deal in the healthcare industry than in other industries.

Typical due diligence findings

The idea behind conducting due diligence is that this type of investigation contributes

significantly to informed decision making by enhancing the amount and quality of information available to the investors. The scope of a due diligence investigation of a Chinese healthcare company normally covers, among others, legal, tax, financial and regulatory aspects such as operational licences and product registrations.

Many Chinese companies in the healthcare sector operate similar distribution models and have business practices that are customary in China but which create certain legal and economic risks from the perspective of foreign investors. Accordingly, due diligence investigations of Chinese healthcare companies often reveal risks which are typical and representative for the Chinese healthcare sector. Due diligence investigations often uncover that there are liability risks resulting from incompliant business operations: some Chinese healthcare companies bribe officials to maintain relationships or to solve problems with authorities. It is also quite common that in connection with the distribution of pharmaceuticals or medical devices customers, doctors or intermediaries offer or receive bribes, gifts or kickbacks.

Legally this qualifies as a form of unfair competition (leading to the risk of administrative penalties) and constitutes a crime and, unlike other jurisdictions, Chinese criminal law not only regulates the criminal liability of individuals but also of the legal entity itself. This means that an acquisition in the form of a share deal is often threatened by administrative and criminal liability risks applying to both the management and the target company itself. This is particularly the case if the foreign investor or any of its affiliates has to observe the Foreign Corrupt Practices Act (FCPA), the UK Anti-bribery Act or similar legislation.

Furthermore, manufacturers of drugs or medical devices in China typically distribute part of their sales through freelancers, agents and intermediaries who work on a commission-only basis. It is also often the case that distribution is done through unregistered sales offices or by using unregistered (i.e. illegal) local warehouses. From the perspective of a foreign investor these practices appear non-transparent, difficult to control, unstable and risky.

Mandatory payment terms

If a foreign investor acquires a domestic Chinese company in the healthcare industry the transaction is governed by the *Provisions on Foreign Investors' Mergers with and Acquisition of Domestic Enterprises (M&A Regulations,* 22nd June, 2009). These M&A Regulations play an important practical role for any foreign investment in China. They stipulate, among others, that many M&A transactions and the accompanying acquisition agreements are subject to examination and approval by the MOFCOM or its local branches.

They also stipulate a mandatory three-month payment period for the entire purchase price of a foreign investor's acquisition of a domestic enterprise (from the date of issuance of the new business licence). Although it is legally possible to apply for an extension, so that 60 per cent of the purchase price is to be paid within six months and the full price within one year, this extension does not apply in practice. When structuring a China investment and drafting acquisition agreements it is therefore worthwhile to always keep the mandatory three-month time period in mind.

New regulations for holding companies

On 28th October, 2015, the MOFCOM issued the *Decision to Amend Some Rules and Normative Documents* (*Decision*), with changes taking effect on the same day. The legislative intention of the *Decision* is to simplify the registered capital registration system for companies in China.

The *Decision* substantially lowers the capitalisation requirements for setting up foreign-invested holding companies in China. This is good news foreign investors who previously considered bundling their China business in a China holding company but were discouraged by the high capital requirements.

According to the *Decision* the previous minimum registered capital requirement of USD 30 million for establishing a foreign-invested China holding company has been abolished. In addition the previous mandatory time limit for full capital contribution has been repealed and a foreign-invested China holding company may now be established as a company limited by shares or as a limited liability company.

In future it will also become easier for medium-sized company groups to establish holding structures in China. Eb

Ingo Vinck *is a German Attorney-at-Law and a member of* ***Taylor Wessing's*** *China Group. He advises German and international companies on their business activities and investment projects in China. He specialises in corporate, contract and real estate law. As an M&A lawyer, Ingo has advised clients on many M&A projects in the healthcare sector in China. Ingo is based in Taylor Wessing's Beijing Office.*

A HEALTHY OUTLOOK

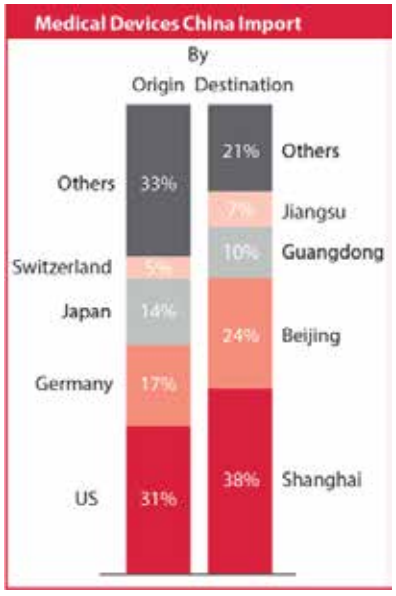
DEVELOPMENTS IN CHINA'S HEALTHCARE MARKET

China is one of the world's most attractive healthcare markets, and is by far the fastest growing emerging market. **Stefan Kracht**, Managing Director of **Fiducia Management Consultants**, looks at its development and explains the factors that are causing it to expand so quickly.

China's healthcare spending is projected to more than double from USD 395 billion in 2014 to USD 1 trillion in 2020. One of the key drivers for this is that China will have the largest elderly population in the world by 2016, with almost 10 per cent estimated to be over the age of 60. This, coupled with the rapid growth in wealth and disposable income, has resulted in a surge in demand for medical equipment. The Chinese Government prides itself on its expanded medical insurance coverage at an official 95 per cent of the country. While this number is debatable, it shows that there is increased emphasis being placed on the healthcare sector.

The current market

The medical technology market in China is the second largest in the world after the United States, totalling over CNY 250 billion in 2014, with an anticipated annual growth rate of 20 per cent over the next three years. While medical devices still take up the smallest share of the entire healthcare market (behind pharmaceutical sales and healthcare services), this segment is exhibiting the strongest projected growth rate and shows high potential for the future.



The local market consists of a large number of small-sized manufacturers geographically focused on the eastern and southern coastal areas. Eighty per cent of market revenue is driven by the provinces of Beijing, Guangdong, Hebei, Jiangsu and Shanghai.

Imported products dominate the high-end market, supplying high quality and high cost products that are not available locally. In fact, the number of new imported product registrations has increased by 49 per cent since 2010. With a total number of 9,300, over one third of all registrations came from international companies in 2014 alone, with 45 per cent being first time applicants.

Rise in domestic demand

The high-end segment is dominated by foreign products that are either produced abroad or locally but with a foreign design. These products typically have specialised functions as a result of more specific know-how from international experts. Targeted at large domestic premium customers, the main competition in this sector originates from top international and ASEAN companies.

The low-end medical devices segment, by contrast, is made up of mostly Chinese manufactured products aimed at small-to-medium domestic customers. Concurrently, there is much room for growth in the mid-end, which makes up 40 per cent of the total market. For this segment, some international companies have developed special 'eco' product lines adapted to the mid-range end-customer. These products can have a local design and be locally produced according to Chinese standards but incorporate specialised foreign known-how.

In China, medical devices are generally categorised into three classes:

- Class I: safety can be ensured through routine administration
- Class II: further control is required to ensure safety of use
- Class III: implanted into the human body, or used for life support, or pose potential risks to the human body and thus require strict safety surveillance

Product registration

From October 2014, the China Food and Drug Administration (CFDA) enforced a number of new regulatory reforms regarding the registration of medical devices in China. Its reasons for doing this were three fold. One, the aim was to create a more level playing field for domestic and foreign players, since previously all domestic Class II and III devices required clinical trials whereas most imported devices, unfairly, did not. Second, through these reforms, the CFDA was able to prioritise its workload by focusing on higher risk devices, requiring Class I products, for example, to be filed on record only, which streamlined the process. Third, the reforms encouraged the improvement of technical standards and increased transparency of the registration process.

While in theory these regulatory reforms are a positive change, they also present a number of challenges for companies planning to bring their medical devices to China. The CFDA now requires long clinical trials for a number of products, which can draw out the registration time substantially. Moreover, the amount of mandatory documentation applicants must submit has increased significantly in complexity and amount. This, coupled with noticeably higher fees, makes the decision to register a much more serious process.

Given this is a very complex and costly exercise, it is crucial to find a suitable advisor that can help with registration procedures. To give you some insight into what is expected, you can find the key steps below so you can prepare accordingly if you want to take the next step in bringing your medical devices to China.

The process

First, it is recommended to begin with a thorough analysis of the registration requirements, such as the classification (Class I, II, or III), the number of applications required for the portfolio and whether or not clinical trials are needed. At this stage, it makes sense to establish a project plan with your advisor. Keep in mind that several registrations per set of devices might be required, as is the case, for example, for dental implants. Your advisor must be able to compile a list of technical requirements and testing standards for your portfolio.

Testing and clinical trials precede the CFDA registration application and can be done in one of a handful of testing centres across the country. Be mindful of the fact that choosing the right one with suitable facilities and available capacity is an important decision. Only a few established agents are able to directly manage the clinical trial process, while most outsource it. Additionally, distributors are often involved in the clinical trial process, as they have access to key opinion leaders, such as medical doctors and other experts. To save time, it is recommended that the preparation and translation of registration documents be done concurrently with the testing process.

More likely than not, after the technical review, which takes 90 working days, the CFDA will issue a notice for supplemental information, which will take another 60 working days. If the device is highly innovative or of high risk an expert panel review may be required, which will add another three to six months to the process. In addition, locally producing companies will have to undergo a quality management system (QMS) audit, at this stage.

All in all, the registration procedure is a lengthy and costly process that can take up to several years if companies fail to submit the required information and necessary documentation in time. Working with someone who is experienced in dealing with the CFDA and is up-to-date with the current requirements is essential in increasing your chances of success.

***Fiducia** is a professional service provider focused on Greater China. For over 30 years, our team of more than 100 consultants and specialists in Beijing, Hong Kong, Shanghai and Shenzhen has provided integrated support in accounting, corporate and trade services, consulting and recruiting, to deliver practical solutions for international mid-market clients sourcing from, selling to, or investing in China.We successfully represent clients in complicated situations and during significant transactions requiring specialised knowledge and skills.*

THE BEST MEDICINE FOR CHINA'S AILING TENDERING SYSTEM

THE SHIFT FROM GOVERNMENT-FIXED PRICES TO FREE-MARKET TENDERING

The Chamber's Pharmaceutical Working Group has long advocated the reform of China's drug tendering process. **Daniel Sellers**, Business Manager at the **European Chamber** and manager of the Pharmaceutical Working Group in Shanghai, looks at some of the recent developments in this area. While there have been some general improvements, Sellers notes that there is still too much emphasis on price at the expense of quality.

Last spring, China made a series of legislative and policy reforms to relax the administrative controls over drug prices that have been in place for more than a decade, and which relate to the majority of drugs sold in China. The reforms are aimed at creating a new system whereby drug prices are mainly determined as a result of market competition rather than set by the authorities. However, the way pharmaceutical companies set prices will still remain subject to the scrutiny of the PRC pricing authority under the Price Law and the Anti-Monopoly Law.

This milestone reform has been largely welcomed by foreign drug makers, at least in theory, as the higher quality of foreign originator drugs would be expected to justify higher prices under free market conditions; however, in practice, the inequalities of China's provincial tendering system has undermined the reform's effect.

Tendering has been evolving in China for 20 years now. First established during the 1990s, the process was originally handled by the purchasing departments of hospitals and medical institutions with support from local information technology players. This remained the

status quo for about seven years, until the government stepped in to manage the process by establishing procurement platforms for each province.

This basic government purchasing model remained in place until 2010, when the double envelope system, adapted from Delhi, India, was introduced in Anhui Province and subsequently rolled out across China. The double envelope system is designed to allocate weight to competing tenders based on a technical quality evaluation (the first envelope), as well as price (the second envelope).

In China, in order to reach the end user and make a sale, pharmaceutical companies must first win a tender at the provincial or city level before being allowed to negotiate a procurement price with local hospitals and medical institutions. The problem faced by European pharmaceutical companies is that the first envelope has not been adequately designed and the threshold that defines quality remains unsuitably low, and therefore price, not quality, has become the principle criteria on which prospective tenders are evaluated. According to the European Chamber's Pharmaceutical Working Group, this fixation on price in provincial tenders and procurements has placed its members at an innate disadvantage – they simply cannot be expected to compete on price with domestic manufacturers of inferior generic drugs. Aside from the obvious imbalance between European and local players, at the end of the day it is Chinese patients who suffer most from this situation as they are denied access to the best and most innovative treatments available.

During a recent Pharmaceutical Working Group meeting, Professor Hu Shanlian of Fudan University's School of Public Health delivered his views on this topic and gave recommendations for the development of China's drug tendering system.

According to Professor Hu: "The two-envelope system is already beginning to see some changes. Previously, the problem was that the first envelope—the assessment of drug quality—did not provide a high enough threshold and, in fact, was ineffectual. This meant that the second envelope, based on cost, became the main focus, so that bidding was decided purely on the basis of price.

"This meant that it was sometimes possible for small companies of lower quality to gain approval through the bidding process, leading to quality problems or price bids lower than cost, and therefore supply issues."

Indeed, the European Chamber's Pharmaceutical Working Group targeted tendering as a key lobbying focus for 2015, recommending structural reforms to the tendering system so that drugs are classified according to quality and separated into different bidding groups accordingly. If implemented at the central level, it is the view of the working group that this measure would significantly benefit Chinese patients by encouraging provincial governments to bid for drugs according to the needs (in terms of quality and quantity) of local patients.

Professor Hu notes that there has been some progress on this issue at the local level: "The most significant change to the tendering system has been the shift in emphasis from cost to quality. This is chiefly seen in the use of drug tender categories, which vary according to a province's needs. The double-envelope evaluation system will continue to be used, this is not in doubt, but provinces have been told to make improvements. The second 'cost' envelope retains the basic method, but improvements are being made at the first envelope stage, known as the economic and technical evaluation envelope."

Mr Xuan Cui, Chair of the European Chamber's Pharmaceutical Working Group, notes that on the one hand the strategic direction of the government is clear, which is to allow pricing to be determined by market mechanisms. In addition, he says, recent policy developments should influence the positive development of the whole pharmaceutical industry and are welcomed by foreign pharmaceutical companies – foreign products have a strong reputation for quality and should be able to compete in a fair and balanced tendering system.

On the other hand, when a new policy system replaces an old one, multinational companies often need time to adjust, so adapting to change becomes a key core competency in the Chinese market. He adds that tendering and pricing will certainly remain a key focus for the working group for the time being, a message that resonated during Prof Hu's talk, when he stated:

"One of the key difficulties remains pricing. Up until now, products that successfully win bids and enter the tender system are very difficult to price appropriately, chiefly because there has been no volume-related consideration. Volume-based pricing is essential in order to achieve an appropriate price, and so we should see more price-volume agreements becoming evident."

This month, the National Health and Family Planning Commission (NHFPC) will implement new reforms related to tendering. It is the ongoing objective of the European Chamber to work with the authorities on this important issue to ensure the effective implementation and optimisation of policies in this area.

This article was written by Daniel Sellers, using input from Mr Xuan Cui and other members of the Pharmaceutical Working Group, as well as adapted sections from an interview with Professor Hu Shanlian that featured in CPB Review Volume 86.

YOUR FUTURE WELLBEING: THE RISE OF DIGITAL HEALTHCARE

Digitalisation is rapidly transforming China's healthcare industry. The proliferation of new technologies—big data, cloud computing, APPs and telemedicine—is expanding the industry's horizons. In doing so, it has affected a shift in the way that patients, healthcare practitioners and pharmaceutical companies interact, towards a relationship that involves increased communication, transparency and efficiency. **Bayer HealthCare** looks at the rise of digital healthcare and how China is increasingly applying it to overcome inherent problems in its healthcare system.

Patients in China are now engaged more than ever before in health management and disease treatment as digital tools provide them with unprecedented access to information and experience sharing. According to the China Internet Network Information Centre (CNNIC), the total number of Chinese Internet users rose to 668 million and the proportion of those who access the Internet via smartphones had jumped to a new high of 88.9 per cent by the end of June 2015. Empowered by the vast amounts of information that they now have access to, they tend not to rely on advice from their doctors as much as they previously did, referring to online resources to perform self-diagnoses and take responsibility for their own health instead.

Disruptive technologies have also altered the behaviour of Chinese healthcare practitioners. For example, they increasingly turn to the web to access new medical knowledge and professional information using convenient digital tools such as tablets and smartphones. According to a recent survey conducted by Kantar Health and DXY (one of the largest professional pharmaceutical industry websites in China), in 2015, Chinese physicians spent an average of 12.5 hours per week on the Internet engaged in professional-related activities, an increase of 30 per cent compared to the 9.6 hours that were reported in 2014.

The way that pharmaceutical companies interact with patients and physicians has changed, too. They are partnering with e-commerce providers due to an increasing number of consumers who are beginning

to purchase medicine online. They also need to provide disease management solutions and deploy big data analytics to improve the efficiency of sales and marketing. As new business models and processes have made the healthcare industry increasingly more customer-centric and outcome-focused, pharmaceutical companies are called to understand the changing landscape, identify opportunities, threats and risks, and find out ways to achieve better healthcare outcomes.

Despite the fact that China has successfully built one of the largest medical insurance networks in the world, which is stated to cover more than 1.3 million people, or 95 per cent of the national population, noticeable tension still exists among different parties, partly due to the insufficient supply of medical care services as well as the imbalanced distribution between urban and rural areas, large and small hospitals.

To tackle these problems, China is actively exploring the possibilities offered by digital healthcare: information technology is regarded as a key factor in the country's ongoing medical reform. In addition to the *Healthy China 2020 Strategy Research Report*, released by China's Ministry of Health (now the National Health and Family Planning Commission, NHFPC), which stated that in the upcoming few years the central government will invest CNY 61.1 billion on the National Electronic Health System Project, the State Council recently promulgated the *National Medical and Health Care Service System Planning (2015-2020)*. This report states that the government is pledging to utilise emerging information technology, such as the Internet of Things, to improve the overall standards of it healthcare services.

Supporting the government's digital healthcare pursuits and embracing opportunities to meet the country's huge, as-yet-unmet medical needs, pharmaceutical multinational corporations (MNCs) have astutely taken action. Many of them already employ digitally-enabled, customer-centric marketing, which is epitomised by closed-loop marketing (CLM), a system used in the pharmaceutical industry to fine-tune the understanding of physicians' interests and to create more value for them. When medical representatives visit physicians and deliver information to them via tablets, the CLM system is able to document what particular information aroused a physician's attention and for how long they stayed on a particular page. This allows them to understand more clearly what is already working and what requires a greater level of focus, which in turn allows for customisation of product information to match each physician's patient profile and interests. In turn, physicians feel more prepared because they can learn about the aspects that are relevant to their specific patients, and are thereby more able to provide a better standard of care.

Digitalisation is also helping to push the boundaries of doctor-patient interaction. For example, in the past, out-patients in China usually had to wait for an average of 1.5 hours in large hospitals before being able to talk to a physician. What is more, physicians spend only 3-5 minutes with each patient on average, with nearly half of this time spent inquiring about basic disease information to get a clear health picture for their records.

To make this process more efficient, the NHFPC joined hands with some leading pharma companies to install touch-screen devices in the Cardiovascular and Endocrinology Departments of some Chinese hospitals. During their waiting time, patients are able to enter personal information such as age, weight, family disease history, blood pressure, blood cholesterol and blood glucose levels into the device. The system can assess their cardiovascular risk based on pre-set algorithms, translate the result into a risk profile and print out the results on a slip of paper that the patient can present to the physician. This innovation effectively saves physicians' time, makes patients' waiting hours more productive while helping patients to understand more about their own health condition.

The transition to digital healthcare is seeing a fundamental shift of focus from 'product-and-service' value to 'meaning-based' value. A recent study conducted by Boston Consulting Group estimates that the digital healthcare market in China, measured by spending on the sector, will expand more than 36-fold from USD 3 billion in 2014 to USD 110 billion in 2020. The advent of a digital age is creating tremendous opportunities for healthcare companies, if they are ready to embrace the complexity and speed of change that digitalisation entails.

Looking to the future, by leveraging digital innovation products and services will become more personalised, physicians and patients more engaged, decisions and product evidence more data driven, and business processes more immediate. Every company that wants to capture this opportunity will need to think carefully how the digital changes will affect them, understand how it can succeed in the digital age, and design its own roadmap to finally provide better care for patients. Eb

*The **Bayer Group** is a global enterprise with core competencies in the fields of healthcare and agriculture. Its subgroup Bayer HealthCare is one of the world's leading, innovative companies in the healthcare industry. The company proactively uses new technologies to harnesses the full potential of digitalisation for better healthcare outcomes for customers and society at large.*

MADE IN CHINA, FOR THE WORLD

Dr Pan Huaiyu started his career with **Siemens** 14 years ago. He began working as an applied physicist in 2001 at Siemens Magnet Technology Ltd in Oxford, UK, before moving to Shenzhen in 2006 to take up a senior management post with Siemens Shenzhen Magnetic Resonance Ltd (SSMR). Dr Pan is also a board member of the Chamber's South China Chapter. He speaks to *EURObiz* about China as a research and manufacturing base, and some of the challenges of operating in the medical devices industry.

Why did Siemens select Shenzhen as its location when SSMR was established in 2002?

China held huge potential in the healthcare market, and it has gained even more importance to Siemens Healthcare over the years. There were a number of practical issues that were taken into consideration with the decision to locate to Shenzhen.

Shenzhen held, and still holds, the status of special economic zone, offering flexible policies and a favourable overall investment environment for foreign enterprises. It also has close proximity to Hong Kong, which is extremely convenient for import and export, and there is a great deal of existing industrial material resources for MRI production in Guangdong and the surrounding areas. Shenzhen also holds the advantage of having gathered an abundance of high-tech human resources.

Can you briefly explain what an MRI device is, including its application?

Magnetic resonance imaging is an advanced, non-invasive and extremely accurate medical imaging technology which can be used on all parts of the body. As MRI does not use ironizing radiation it is particularly valuable in the examination of chronic diseases that require repeated examinations. For many diagnostic issues, MRI has developed into the gold standard.

Apart from manufacturing, what other

functions are carried out at SSMR?

In addition to manufacturing, research and development (R&D), logistics, marketing, technical support and comprehensive services are all carried out under one roof.

In terms of Siemens global output, what is the percentage of MRI devices produced at SSMR?

One out of every three Siemens' MRI systems has been delivered from SSMR since 2012. We serve customers in the Asia Pacific region, the west coast of the United States, South America and Africa.

Of these devices, how many are produced for the China market and how many are exported overseas?

Each year, over 70 per cent of SSMR's products are exported to overseas users.

In terms of the China market, is there a clear difference in the numbers of MRI devices that are purchased by healthcare facilities in tier-one cities compared to those in tier-two or tier-three cities?

The purchase of MRI devices differs widely due to such factors as the level of hospital classification, its income and location, among others. In general, Class III hospitals[1] in tier-one cities, like Beijing or Shanghai, usually purchase at least two MRI systems for advanced diagnostics and treatment, and even research at the same time. For county-level public hospitals [Class II], they would typically buy one MRI or have none at all due to a lack of trained technicians.

Another trend we have observed is that more and more private hospitals are starting to purchase their first MRI systems.

What are the key criteria that guide purchasing of medical devices in healthcare facilities in China?

For hospitals that already have at least two MRI systems, they usually source high-end medical devices that can be utilised for advanced clinical applications and clinical research. The focus at county-level hospitals tends to be more on MRI devices that can satisfy their demand for routine clinical applications and patient throughput.

Are products manufactured at SSMR considered to be domestic or foreign?

Our products are considered Siemens' MR products created in China. We are pursuing our strategic concept: 'Created in China, For the World'.

In terms of manufacturing, the number of MRI devices produced each year is relatively low compared to, say, low-cost consumer products. Does this pose any challenges in terms of sourcing the raw materials and components required for production?

For certain materials that we use, such as superconducting wire and liquid helium, we do not really see any challenge – these materials are used in a number of other industrial applications and are therefore readily available. For other, specific mechanical materials there are certainly some challenges, but developing long-term strategic partnerships with international and domestic suppliers has helped in this respect. For the purchase of key MR components we have now established a full industrial value chain in China.

Are raw materials and components sourced in China or imported from overseas?

Both. Some strategic materials are purchased from large international enterprises, and we have developed local resources for other components and materials. Another important development was when a business line of Siemens Healthcare called CV—an internal supplier of electronic components and cabinets for MR systems—moved their R&D and production line from Germany to SSMR. This makes the transit of the components that they supply immeasurably easier.

Can you tell us about some of the innovations that have been developed at SSMR?

We place a lot of emphasis on developing local talent and strengthening the local R&D team in Shenzhen. This is bearing real fruit – so far more than 100 patents—both international and domestic—have been granted to SSMR. For us, it is important that SSMR develops MR products that are innovative and have excellent performance-price ratio. A good example is the MAGNETOM Spectra, which is the first 3T MRI system that has been both developed and manufactured in China. This is a breakthrough in the industry and is helping to ensure that the most advanced technology is available and accessible to hospitals in China. Eb

Siemens Shenzhen Magnetic Resonance Ltd *is the biggest research and manufacturing centre outside Siemens MR headquarters in Germany. It serves global customers with consolidating R&D, manufacturing, logistics, marketing, technical support and comprehensive services under one roof. SSMR has the full capacity for developing and manufacturing entire MRI systems and key components.*

[1] Class III hospitals are large, public medical institutions with more than 500 beds, at the city, provincial or national level. They provide comprehensive healthcare services, and also carry medical education and scientific research; Class II hospitals are mostly in medium-sized cities, counties or districts and have between 100-500 beds. They also carry out some education and research on a provincial level; Class I hospitals are township hospitals with less than 100 beds. They perform preventative care and some other healthcare and rehabilitation services.

A HEALTHY CHALLENGE

Obstacles faced by manufacturing WFOEs in China's medical devices industry

China presents a challenging environment for foreign manufacturing companies. This is true across the board, from garments to electronics, but wholly foreign-owned enterprises (WFOEs) manufacturing medical devices face additional obstacles, especially if they also sell on the Chinese market. In the following article **Renaud Anjoran**, Operations Manager for **China Manufacturing Consultants** and vice chair of the Chamber's Sourcing Forum in South China, lists some of the biggest challenges.

Ensuring a high quality standard

A faulty medical device might lead to a deadly outcome, therefore quality is first and foremost. Medical devices need perfect quality and need to be manufactured to very strict specifications and standards.

By and large, foreign companies that have been manufacturing in China for a number of years have successfully set up the right quality systems, trained their staff and got their operations in order. However, purchasing quality components from local suppliers is an ongoing challenge. I see high incoming quality control reject rates (often above 30 per cent for some components) in most foreign-owned factories I visit. And the lower the order quantity, the higher the reject rate. Manufacturers need to keep a constant eye on what suppliers are shipping – for example, are the electronics explosion proof (since they will be used with oxygen), is the plastic medical grade?

The design and development of new products is also a source of many issues. Many engineers are falsely under the impression that they can simply copy designs without knowing and understanding the design intent. The result is that while the external appearance of a product may be identical, the function may be flawed. This can lead to dangerous and potentially deadly outcomes. For example, some chemotherapy drugs that are used for treating cancer patients have very aggressive chemical compounds that can cause plastic materials to become brittle and crack. In the West, this is a commonly known design feature and (more expensive) materials are selected because of their crack-resistant properties. In China, this risk is often overlooked and (cheaper) plastic materials that are inappropriate for the design are selected, leading to product failures where patients and caregivers are exposed to hazardous drugs. The solution to this is either to learn from mistakes, a costly and dangerous process, or to invest in the foreign talent capable of educating Chinese engineers and suppliers about these potential risks.

Certifications and client-specific requirements

Medical certification for ISO13485 and other medical standards are usually mandatory, and in many cases factories need a clean room that needs to be certified. In addition, manufacturers have to comply with client-specific needs. For example, General Electric imposes some of its own standards. In short, players in the medical industry need to deal with many levels of approval.

One serious challenge is the special treatment Chinese manufacturers tend to receive from certifying bodies in China. It represents unfair competition for foreign companies and ensures there are always lower-cost competitors on the market. Which leads to the next challenge...

Competition from local players

Medical devices are normally sold at a premium and high quality is a must. However, all customers take cost into consideration, too, and competition from Chinese companies can be deadly. The problem is that some local manufacturers take the liberty of copying products and production processes freely, while at the same time they can afford to sell these products at a lower price because they face more relaxed controls and enforcement.

Fifteen years ago, local players used to compete with (very) low prices and suffered from poor quality. However, some of them have upped their game by hiring professional managers and putting systems in place – often under the guidance of large foreign customers. Many have made the leap from what we call 'level 1' to 'level 3' (see below).

The four levels of Chinese manufacturers

Compounding the challenge already presented by local competition, Chinese government agencies have repeatedly stated that China wants to develop top-class medical companies and that Chinese state-run hospitals should preferably source medical devices from local Chinese brands. This is clear discrimination against foreign-owned manufacturers.[1]

The solution for manufacturing WFOEs is to always be one level higher than the competition. One such strategy is to adopt lean manufacturing principles and tools – so far, only a tiny proportion of Chinese-owned factories have made the efforts required for a lean transformation, and most of the success stories are still in the automotive industry.

[1] *European Business in China Position Paper 2015-2016*, European Union Chamber of Commerce in China, September 2015, p. 202, <http://www.europeanchamber.com.cn/en/publications-archive/364/Healthcare_Equipment_Position_Paper_2015_2016>

China-specific issues

In addition to these issues, selling in China presents its own challenges.

The first one is selling on the domestic market. Sitting between the manufacturer and the hospital is a distributor. The primary role of the distributor is to make sure everyone in the hospital system is 'taken care of'. He needs to mark the price up significantly. The main issue that arises for foreign companies is the risk of violating anti-corruption policies followed in the West.

The second issue is insurance reimbursement. The reimbursement rate is sometimes higher for Chinese companies than it is for foreign companies, since some Chinese manufacturers have managed to get away with additional unfounded claims – however, the government is scrutinising product claims more and more closely and this situation is showing signs of improvement.

Another issue is China's unique standards. For example, the standards for many in vitro diagnostics (IVD) products are not scientifically sound, some specifications are contradictory and some test methods laid down in these standards cannot actually be carried out.[2]

Looking forward

Beijing has launched a vast reform of the healthcare system. It is currently underway and it is hoped that this will result in better conditions for foreign manufacturers of medical devices, since China is moving closer to international regulatory practices.

Whether the new regulations will be truly implemented and fulfil their promise remains to be seen and this is an issue the Chamber will be paying close attention to over the coming months. Eb

Renaud Anjoran *and the rest of China Manufacturing Consultants' team have been helping China-based manufacturers reduce their costs, improve their quality and get better organised through lean manufacturing techniques and supply-chain reorganisations. In 2005 and 2006, Renaud worked in a Hong Kong-based trading company, before moving to Mainland China in 2007. He received his MS in International Business from Bordeaux Business School and an MBA from Wake Forest University. Renaud may be contacted at renaud.anjoran@cmc-consultants.com.*

[2] Ibid, p.208

EUROBIZ APP OUT NOW

*Available for iPhone and iPad

THE HOTTEST TOPICS FOR EUROPEAN BUSINESS IN CHINA ALWAYS AT YOUR FINGERTIPS

www.eurobiz.com.cn

REGULATING THE MARKET

MEDICAL DEVICE REGULATIONS IN CHINA

China's fast-growing medical device market presents numerous opportunities for European companies. However, understanding the practicalities of accessing the market is not simple. In order to enter the Chinese market, all medical devices are required to obtain a pre-market approval, known as medical device registration, from the Chinese Food and Drug Administration (CFDA). In the following article the **EU SME Centre** look at the regulations pertaining to medical devices in China and describe some of the more notable aspects.

The *Regulation for Supervision and Administration of Medical Devices (Regulation)* is currently the highest level of legislation in China's medical device sector. The latest version has been in effect since 1st June, 2014, which, in comparison to the previous version, has nearly doubled in length and changed significantly in terms of scope of the medical devices sector.

It is therefore advisable that European SMEs doing business in the medical device sector take a close look at the *Regulation* and seek professional advice before taking any concrete steps to enter the Chinese market.

Definition of medical devices

The definition of medical devices—based on the 'purpose' of use—has been amended and expanded in the *Regulation*. Previously, the definition included the following purposes:

- Prevention, diagnosis, treatment, monitoring or remission of diseases.
- Diagnosis, treatment, monitoring, remission or compensation of injury or physical disability.
- Research, replacement or adjustment of an anatomical or physiological process.
- Control of pregnancy.

The new regulation adds an additional two categories: "support or maintenance of life" and "samples taken from humans to provide information for medical treatment or diagnostic purposes".

Classification

Medical devices in China are categorised into three different classes – Class I, II and III, with risk levels ranging from low to high. The criteria for classification is based on the purpose of use, the structural features of the device, whether the device has direct contact with the human body and the methods and status of use.

This classification is used predominantly for risk management where different rules are adopted:

- **Class I**: low level of risk, safety and effectiveness can be ensured through routine administration.
- **Class II:** medium level of risk, further control is required to ensure their safety and effectiveness.
- **Class III:** high levels of risk, special measures with strict control and administration must be enforced to achieve safety and effectiveness.

Even though this classification system may appear similar to the European system, European applicants are still advised to carefully check the Chinese classification list published by the CFDA, which is the foundation of registration requirements and procedures.

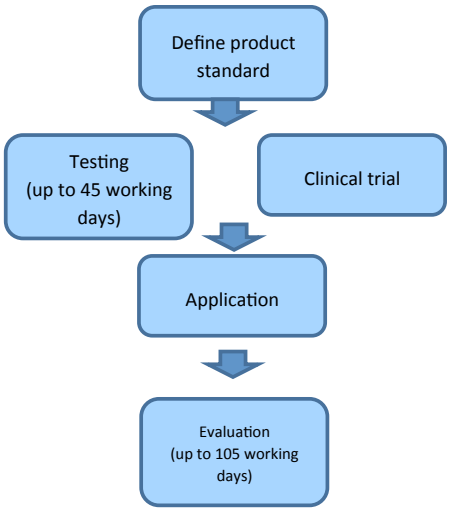
Device registration

The new regulation eliminates the pre-marketing registration requirement for Class I devices, but not for Class II and Class III devices, which still need to

register through a licensing procedure. Class I devices only need to undergo a 'filing' procedure with a municipal regulator (i.e. below the provincial level).

The application procedure and timeframe for medical device registration can be seen below:

The CFDA point out on its website that the application



procedure can take 105 working days, however, this includes the time period for testing or conducting a clinical trial. Overall, the process can be divided into five steps:

1. **Appointing an agent** – the agent must be a legal Chinese entity.
2. **Standards and testing** – compliance testing must take place at a designated laboratory in China.
3. **Clinical trial** – depending on approval and classification a clinical trial may be required.
4. **Application** – application and supporting documentation must be submitted.
5. **Evaluation** – the Centre for Medical Device Evaluation (CDME) conducts a technical evaluation of the information provided then issues a registration.

Clinical Trials

With respect to clinical trials, significant clarifications and modifications have been made in the *Regulation*. Class I devices are no longer required to have China-based trials prior to registration, whereas most Class II and Class III devices must successfully undergo China-based clinical trials before registration and approval for marketing can be given.

The *Regulation* clarifies that some Class II and Class III devices can be exempted from the clinical trial requirement. You can find the complete list on CFDA's website: http://www.sda.gov.cn/WS01/CL0087/105224.html.

Distribution

The notification and licensing requirements for entities distributing Class I and II devices have also been simplified. When distributing Class I devices, going through a filing procedure with the municipal-level food and drug regulatory authority is no longer required, however, distributors of Class II devices still need to follow this step. While Class II device distributors are released from the obligation of obtaining a distribution licence, which sometimes can be a lengthy procedure, this does not apply to distributors of Class III devices.

The *Regulation* also adds a requirement for keeping records of sales, which applies to wholesalers of Class II and Class III devices as well as retailers of Class III devices.

Further resources

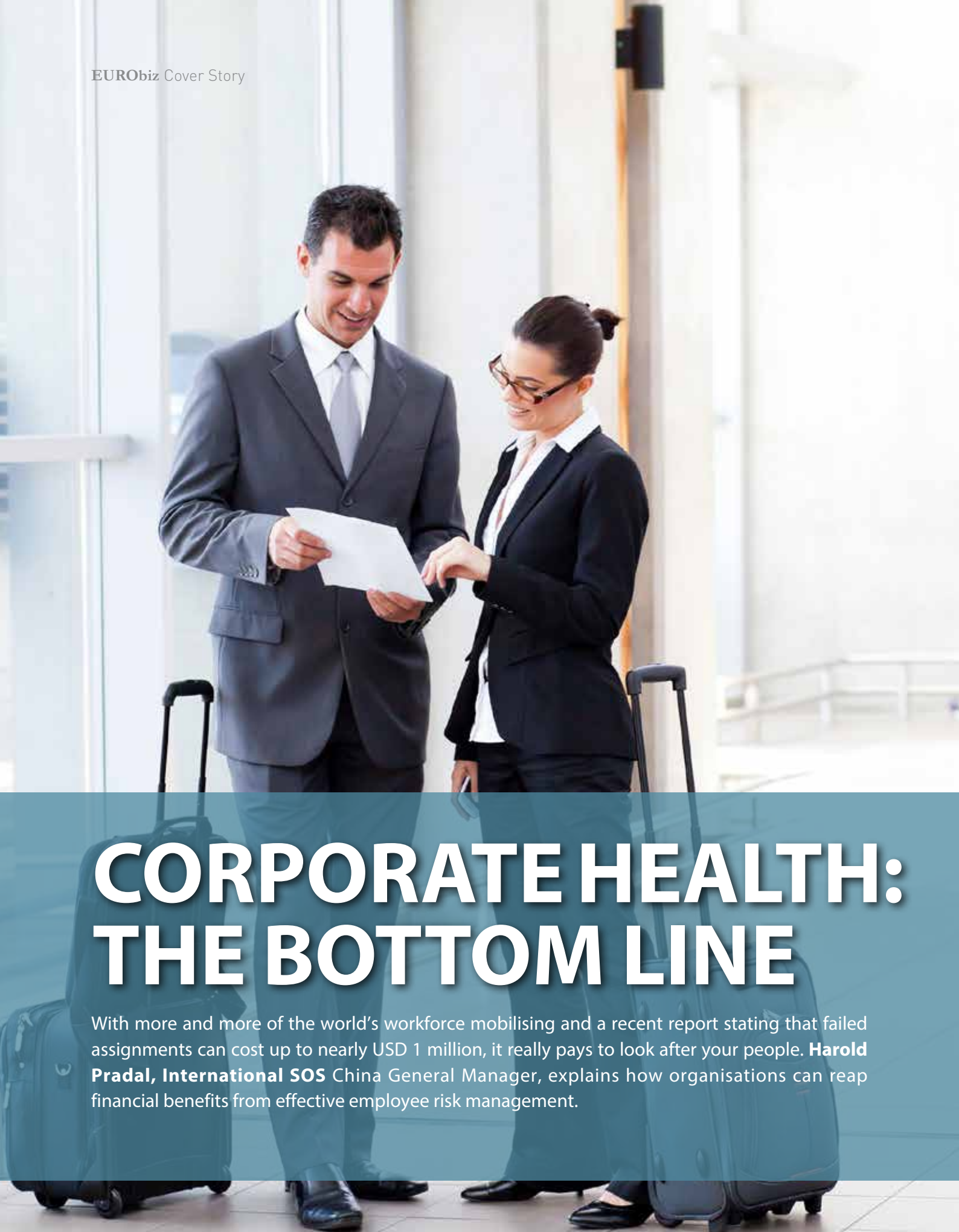
More comprehensive information on medical device regulations in China can be found at www.eusmecentre.org.cn. If you have questions specific to your products, please contact our experts at www.eusmecentre.org.cn/expert.

The EU SME Centre *in Beijing provides a comprehensive range of hands-on support services to European small and medium-sized enterprises (SMEs), getting them ready to do business in China.*

Our team of experts provides advice and support in four areas – business development, law, standards and conformity and human resources. Collaborating with external experts worldwide, the Centre converts valuable knowledge and experience into practical business tools and services easily accessible online. From first-line advice to in-depth technical solutions, we offer services through Knowledge Centre, Advice Centre, Training Centre, SME Advocacy Platform and Hot-Desks.

The Centre is an initiative implemented with the financial support of the European Union. It is managed by a consortium of six partners - the China-Britain Business Council, the Benelux Chamber of Commerce, the China-Italy Chamber of Commerce, the French Chamber of Commerce in China, the EUROCHAMBRES, and the European Union Chamber of Commerce in China.

To learn more about the Centre, visit website www.eusmecentre.org.cn



CORPORATE HEALTH: THE BOTTOM LINE

With more and more of the world's workforce mobilising and a recent report stating that failed assignments can cost up to nearly USD 1 million, it really pays to look after your people. **Harold Pradal, International SOS** China General Manager, explains how organisations can reap financial benefits from effective employee risk management.

In search of new markets and greater profits the global workforce is mobilising in a way never seen before. Employees are now travelling in greater numbers, with more frequency and to more far flung destinations. Within this context, the health risk exposure of an organisation is increased significantly, causing a giant headache for HR staff, CFOs and CEOs. Modern mobility risk exposure means hospital bills that go on and on, complex medical evacuations and disruption of business operations. Or does it? Our recent study on *Return on Prevention* seems to point to the opposite.

To give this topic some background and highlight the increasing importance of mobility in the global economy, a recently released PwC report, entitled *Talent Mobility: 2020 and Beyond*, highlights the dramatic change in mobile workforce trends across the globe. International assignees have increased by 25 per cent over the last decade and by 2020 there will be a further 50 per cent growth. Additionally, the report points to the diversification of business travel by 2020, stating that alongside the growth of cross-border acquisition, a more mature developing world and greater security cooperation, borders will be broken down, allowing for more liberal and diverse business travel.

This will manifest itself through a change in the make-up of the mobile workforce. No longer will expatriates be made up of middle-aged men from the developed world travelling to the developing world for long-term assignments. Instead, there will be an increase in short-term assignments of staff from developing economies. One only has to look at the increase of globalisation of BRICS countries to see this trend. In the 2015 *Fortune Global 500 List* there are 98 Chinese companies, three of which are in the top 10. Employees from China's leading organisations are travelling across the globe in droves, notably to the Middle East and Africa – this is the perfect example of the changing face of global mobility.

With the diversification of mobility, corporations need to adapt the methods with which they look after those most valuable, and most at risk, staff away on assignment. As the aforementioned report states, employees are travelling to more risky and remote locations and this means healthcare is of primary importance. Indeed, it has been found that 38 per cent of business travellers suffer health impairment, ranging from minor to major health issues. Additionally, 14 per cent of business travellers are incapacitated, either for a short or long period of time. Taking corporate health seriously and implementing a stringent policy also means that staff can continue working with no ill effects on normal business operations. After all, no one can be effective working from a hospital bed.

Seeing the changing face of mobility and the increase in health risks that employees face, we embarked on a study to coincide with our 30th anniversary and to reflect the changing business landscape. Why is this important, you may ask? Well, with the *Return on Prevention* report uncovering that international assignments cost on average USD 311,000, and the cost of a failed assignment falls somewhere between USD 570,000 and USD 950,000, organisations need to take note.

With these serious figures in mind, how can businesses ensure that these costs are avoided? The *Return on Prevention* study points to a solid duty of care policy that can not only protect staff, but can somewhat surprisingly even bring positive financial returns.

The first area the report looks at is the benefits of pre-health screening – that is, a medical programme to check mobile employees for their ability to complete assignments. The study found through a cost-benefit analysis that every USD 1 spent on medical check programmes for international assignees results in a maximum return of USD 2.53. Medical checks can uncover pre-existing conditions as well as ensure that the staff member in question is fit to take the role prior to departure. If you were to think of a large multinational corporation, and how many business travellers they must have, this return per traveller is by no means small change.

The report highlights another crucial area of corporate health. In 2015, the World Health Organization reported that there have been roughly 214 million cases of malaria across the globe resulting in an estimated 438,000 deaths. Malaria for many companies—especially Chinese companies with their recent huge investments in Africa—causes significant business disruption. The *Return on Prevention* study reports that every USD 1 invested in a malaria prevention programme, returns on average USD 1.32. With a malaria programme encompassing employee education, provision of prophylaxis medication and a testing kit, it also reduces malaria-related deaths by 70 per cent on average – a statistic that matters far more than corporate cost savings.

The *Return on Prevention* study shows the importance of having a rigid duty of care policy for employees, a concept that is just taking off in China. Not only are staff better cared for and feel more highly valued, but they are also better equipped to face medical risks whilst on the road. This in turn means that employees are less likely to get sick, causing business disruption and incurring massive costs for failed assignments. Essentially, taking preventative measures is a win-win approach for businesses and business travellers: it keeps HR staff, CEOs and CFOs happy, but most importantly it keeps our people safe. Eb

International SOS *is the world's leading medical and travel security risk services company, caring for clients across the globe, from more than 850 locations in 92 countries. International SOS pioneers a range of preventive programmes, helping clients put Duty of Care into practice and strengthened by in-country expertise. The expertise of International SOS is unique: more than 11,000 employees are led by 1,400 doctors and 200 security specialists. Teams work night and day to protect clients.*

A NOBEL PURSUIT

FROM AN ANCIENT CHINESE RECIPE TO INDUSTRIAL PRODUCTION IN EUROPE

On 5th October, a Chinese pharmacologist was awarded the Nobel Prize in Natural Sciences for the first time: Professor Tu Youyou was recognised for her immense contribution towards reducing instances of malaria worldwide. **Volker Müller**, Business Manager at the European Chamber, pays tribute to Professor Tu's remarkable career.

A few years ago when I was preparing to go to Namibia as a volunteer on a conservation project, my major health concern was, of course, malaria. Internet research revealed several preventative drugs, but all of them had potentially severe side-effects and were very expensive. Besides this, certain parasites had become partly resistant to them, so their use was not recommended for long stays in high-risk areas. When asking for advice at the Beijing Healthcare Centre for International Travellers, I heard about Artemisinin[1] for the first time, a cheap, herb-based drug that can be used for treatment after the onset of malaria symptoms which has few side-effects, making it ideal for self-medication if no medical assistance is available.

A Nobel (sur)prize

On 5th October this year, it was a big surprise for the Chinese academic community when Professor Tu Youyou, a pharmacologist at the Chinese Academy of Chinese Medical Science in Beijing, was awarded half of this year's Nobel Prize in Physiology or Medicine "for her discoveries concerning a novel therapy against malaria".[2] The award made her the first Chinese Nobel Prize Laureate in Natural Sciences.

Professor Tu's career was somewhat non-academic compared to most individuals involved in mainstream science. She never gained a post-graduate degree and never took part in any international exchange programmes. Described as a modest person, Professor Tu's work was characterised by field studies in malaria-infested tropical villages and research on a shoe-string, rather than by an academic environment of perfectly equipped laboratories.

Before China's reform era, personal fame of researchers wasn't exactly encouraged, and the Chinese academic system (as in most other countries) has difficulties acknowledging, let alone celebrating, an unconventional career path. In all likelihood it is a combination of these factors that prevented her from being awarded a top science award in China and being admitted to the Chinese Academy of Sciences. The Nobel Prize Committee, however, based their decision solely on the outcome of her research and her contribution to human health.

A profound discovery

Malaria is one of the most dangerous infectious diseases in the world. In 2013, the World Health Organization

[1] Chinese: 青蒿素, pinyin: qinghaosu.

[2] *The Nobel Prize in Physiology or Medicine 2015*, nobelprize.org, Nobel Media AB 2014, 5th November, 2015, viewed 2nd November, 2015, <http://www.nobelprize.org/nobel_prizes/medicine/laureates/2015/>

(WHO) recorded 198 million new cases, leading to the death of 584,000 people. Ninety per cent of all malaria-related fatalities occur in Africa, mainly in children less than five years of age, who account for 78 per cent of the deaths.[3]

In the 1960s, mosquitoes developed resistance to Chloroquine—the only available anti-malaria drug at that time—and the mortality rate from malaria increased dramatically, and China certainly wasn't immune to the problem. Up until the late 1970s, large parts of Southern China, including Guangdong Province, were plagued by widespread malaria. In 1967 Professor Tu became part of a large national project to find new ways of treating the disease.

By this point, scientists worldwide had screened 240,000 chemical substances without success. Professor Tu and her team turned to traditional Chinese medicine (TCM) to continue the search. Although TCM did not have a treatment for malaria per se, it did have various treatments for different kinds of intermittent fever, which provided valuable clues as to which herbs might be useful. Eventually, the leaves of sweet wormwood (*Artemesia annua*), described in an ancient recipe from 340 AD,[4] were identified as being the most effective for treating the symptoms of malaria. Professor Tu continued her research applying methods of modern pharmacology, testing Artemisinin first in animals and then in human clinical trials, which she was the first to volunteer for.

Food for thought

Premier Li Keqiang was effusive in his praise of Professor Tu, stating that the Nobel Prize "showcases China's growing strengths and rising international standing."[5]And of course, the Nobel Prize award was celebrated on Chinese social media. However, while Professor Tu's contribution to worldwide healthcare—especially in developing countries—is indisputable awarding a scientist whose career and approach are both somewhat out of mainstream science provides some food for thought.

Today, China spends around 5.5 per cent of its GDP on healthcare, in central Europe this figure exceeds 10 per cent, yet there is still a lack of resources in healthcare, so it is crucial that money is allocated in the most efficient way. Much like China in the 1960s, in today's developing countries many people only have access to traditional medicine, due to economic reasons. For example, in Ghana self-treatment of malaria with herbs costs 1/16 of hospital treatment.[6] Meanwhile, pharmaceutical companies have to spend billions of euros to develop new drugs. Perhaps this Nobel Prize award can motivate both health authorities and medical companies to reconsider the balance between traditional and modern medicine. Almost all countries and nationalities have their own traditional medicines, and it is likely that there is still a great deal of potential to be released.

From discovery to production

Production of Artemisinin in commercial quantities through natural methods is limited by the volatile nature of sweet wormwood—it takes up to 10 months to cultivate, and its yield is affected by the weather, region and growing practices—and so far, synthetic production has not been possible. As an alternative approach, PATH, a global non-profit organisation, raised funds to develop a method for turning a living organism into Artemisinin. In 2013, French-based pharmaceutical manufacturer Sanofi announced the launch of large-scale production of semi-synthetic Artemisinin as an anti-malaria treatment.[7]

The positive impact that Professor's Tu's work has had in the fight against malaria is clearly stated in the scientific background of the discovery, provided on the Nobel Prize website:

"Artemisinin-based Combination Therapy has profoundly reduced the incidence of malaria, saving millions of lives worldwide." [8]

"Artemisinin-based therapy has contributed to the significant reduction in mortality, particularly for children with severe malaria (>30%). The overall global death toll from malaria during the last 15 years has declined by 50% (WHO, 2015)."[9]

From ancient TCM that led to the outstanding research work of Professor Tu Youyou and finally to commercial manufacture by a European company – it has been a long but successful journey on the way to ensuring a stable supply of one of the most important drugs in the fight against malaria.

The 2015 Nobel Lectures in Physiology or Medicine will be held on 7th December and is webcast live at www.nobelprize.org. Videos of the lectures will also be available on the webpage a few days later.

[3] *Scientific Background Avermectin and Artemisinin - Revolutionary Therapies against Parasitic Diseases*, The Nobel Assembly at Karolinska Insitutet, viewed on 2nd November 2015, <http://www.nobelprize.org/nobel_prizes/medicine/laureates/2015/advanced-medicine-prize2015.pdf> p.5

[4] *The Handbook of Prescriptions for Emergency Treatments*, written in AD 340 by Ge Hong

[5] *Chinese premier congratulates Tu Youyou on winning Nobel Prize for medicine*, Peking University, 6th October, 2015, viewed 2nd November, 2015, <http://english.pku.edu.cn/news_events/news/media/3966.htm>

[6] *Traditional and Complementary Medicine Policy*, chapter 5.2, *Why people use traditional and* complementary medicine, World Health Organization (WHO): viewed 2nd November, 2015, <http://apps.who.int/medicinedocs/documents/s19582en/s19582en.pdf>

[7] *Sanofi and PATH announce the Launch of Large-scale Production of Semisynthetic Artemisinin against Malaria*, Sanofi, 11th April, 2013, viewed 2nd November, 2015, <http://en.sanofi.com/Images/32474_20130411_ARTEMISININE_en.pdf>

[8] *Scientific Background Avermectin and Artemisinin - Revolutionary Therapies against Parasitic Diseases*, The Nobel Assembly at Karolinska Insitutet, viewed on 2nd November 2015, < http://www.nobelprize.org/nobel_prizes/medicine/laureates/2015/advanced-medicine-prize2015.pdf> , p.1

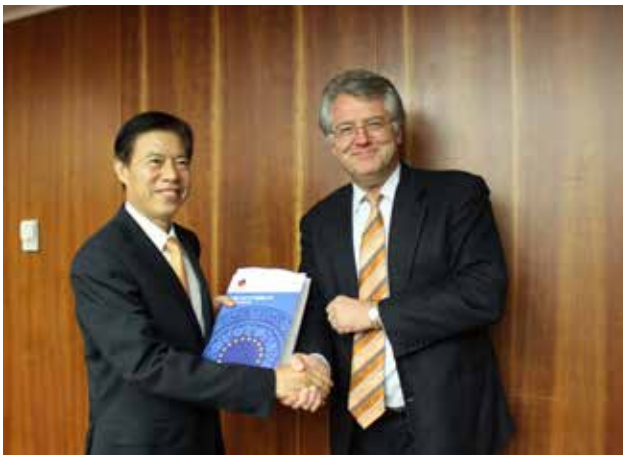
[9] Ibid, p.6

EUROPEAN CHAMBER LOBBYING HIGHLIGHTS

MOFCOM Vice Minister Pledges Transparency

On 22nd October, European Chamber President Jörg Wuttke and Vice Presidents Bertrand de La Noue and Sara Marchetta met with Ministry of Commerce (MOFCOM) Vice Minister Zhong Shan. The Chamber introduced its *Position Paper 2015/2016* as well as the local position papers for Beijing, Shanghai and South China and the results of the *Business Confidence Survey 2015*. The Chamber delegation outlined its stance on the State Council's *Negative List Guidance Document*.

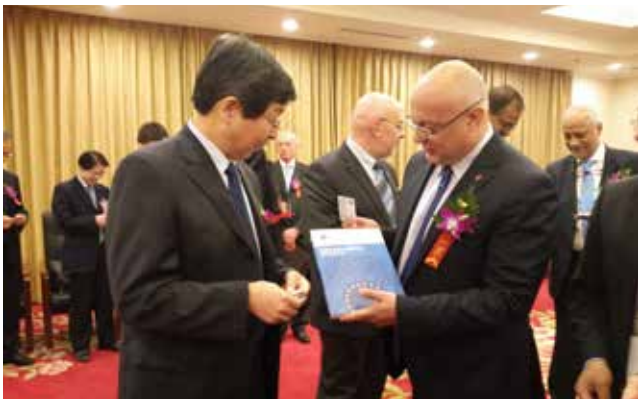
Vice Minister Zhong Shan committed to working toward solutions within the MOFCOM and coordinating with other ministries to deal with challenges where necessary. He also stated that going forward China's opening up would be wider and more transparent. Vice Minister Zhong went on to say that he understood foreign business' concern over security-related laws and regulations such as the National Security Law and the Draft Foreign NGO Law.



Considerations related to the EU-China Comprehensive Agreement on Investment (CAI), China's market economy status and ongoing reforms were also discussed.

AQSIQ Vice Minister Wu Haiqing Receives Position Paper

On 4th November, Massimo Bagnasco, States' Representative and member of the Chamber's Executive Committee, delivered a speech at the 2015 International Engineering Consultants Forum, where he highlighted European companies' opportunities and challenges in China's engineering consulting sector. Before the event, Mr Bagnasco met with Wu Haiqing, Vice Minister of the General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ), and presented him with a copy of the Chamber's *Position Paper 2015/2016*.



European Commission and European Investment Bank Come to Dinner

On 28th September, members of the Chamber's Advisory Council hosted a unique dinner with Jyrki Katainen, Vice President for Jobs, Growth, Investment and Competitiveness, Gunther Oettinger, Commissioner for Digital Economy and Society, Violeta Bulc, Commissioner for Mobility and Transport and Ambroise Fayolle Vice President for Innovation at the European Investment Bank (EIB).

With the formal exchanges out of the way, the dinner livened up with many discussions opening up between the visiting EU officials and Advisory Council members.

Commissioner Oettinger insisted upon meeting the Chamber again when it conducts its European Tour in January 2016, and he shared news of a major cooperation agreement between the EU and China on 5G networks.

Commissioner Bulc proposed the idea of developing an EU-China Summit focusing on transportation and even suggested the Chamber could organise the business side of such an event.

Vice President Katainen said he recognised the Chamber as the Commission's 'eyes and ears' in China.

NDRC Welcomes Foreign Input

On 28th September, the European Chamber was invited to attend a meeting chaired by NDRC Secretary General, Mr Li Pumin, and to comment on China's investment environment.

Government officials from the MOFCOM, the Ministry of Industry and Information Technology (MIIT), the Ministry of Finance (MOF), the State Administration of Industry and Commerce (SAIC), the Standardisation Administration of China (SAC), the State Intellectual Property Office (SIPO) and the National Copyright Administration of China (NCAC) were also in attendance.

Officials provided briefings on the progress China has made with its reform and opening up agenda and the latest policies and strategies to further open up, and reassured participants of China's economic outlook.

Chamber Vice President Mats Harborn voiced the major concerns and recommendations of European business in China and asked for further clarification on "state strategic interests", as defined in the newly released *Guiding Opinions of the CPC Central Committee and the State Council on Deepening the Reform of State-owned Enterprises*. He also expressed the Chamber's willingness to provide comments in the process of drafting the *13th Five-Year Plan*.

Secretary General Li concluded by saying that the government welcomes input from foreign-invested enterprises, including their recommendations on and contributions to the development of China's economy.

SHIAC Seeks Deeper Cooperation with the Chamber

The Chamber's Legal and Competition Working Group in Shanghai met with officials from the Shanghai International Arbitration Centre (SHIAC) on 21st September. Carlo D'Andrea, Vice Chair of the Shanghai Chapter and Chair of Legal and Competition Working Group, presented the *Position Paper 2015/2016* to Mr Huang Wen and Ms Wang Weijun, Vice Secretary Generals of the SHIAC. He briefly introduced the Chamber and highlighted key recommendations from the *Legal and Competition Working Group Position Paper*. These included increased access to the Chinese market for foreign legal professionals, higher transparency of Anti-monopoly Law enforcement actions and improving the general environment for rule of law.

Mr Huang introduced the SHIAC's recent developments and the overall situation of arbitration in China. He welcomed more engagement of foreign experts in legal and other related fields in arbitration work. Both parties identified the fields in which further cooperation can be expected, such as co-organisation of events and dialogues with local scholars.

THE QUALITY CONTROLLER

Cyrus Ma is currently Vice Chairman of the Chamber's Quality and Safety Services Working Group, having previously done a stint as chair. A holder of a PhD in economics from Peking University, Ma worked as a corporate international trade compliance officer before moving into the testing, inspection and certification (TIC) industry with Bureau Veritas, when he first became involved with the Chamber. He has been in his current position with **SGS** for the past five years. In the following interview, Ma shares his views on China's TIC industry, his expectations for the EU-China investment agreement and some of the working group's lobbying successes.

When did you first become involved with Chamber?

I have been a member since working at Bureau Veritas but my actual involvement began when I started working for SGS.

What was it that made you want to become involved?

In my industry there has historically been a lot of government involvement in daily operations. Companies find themselves in situations where they have to comply with laws that are not particularly lawful, laws that have been conceived somewhat randomly. They are not comfortable raising their concerns with authorities in case they have more pressure exerted on them for doing so. I realised that lobbying is an effective way of solving these kinds of problems, and the Chamber is the perfect place for this to take place.

Why did you decide to run for the position of vice chair?

The idea is that everyone in the Chamber should be more actively involved, in order to have better cooperation. I was the chairman at the beginning, when this working group was created. In the second year, Bureau Veritas took the chair and in the third year TÜV became the chair. In this way we are able

to coordinate much more fluently and make the working group more efficient.

What are the main contributing factors to China's poor track record in quality and safety?

The system. The system is the primary problem. Some people claim that it is because China is still in a developmental stage, yet most of the population in coastal regions have an income that has reached the same level as developed countries. This means that the relatively low pace of development in the industry does not really relate to GDP development. China has a system that *cannot keep pace* with economic development, this is the key issue.

What fundamental things need to change to improve this situation?

On the legislative side, the laws that empower the government allow them to go beyond their jurisdiction, but also beyond their capabilities. This has resulted in too many, extensive mandatory standards covering the industry. This is a typical service market, but the government is not able to act as a typical service provider because they are law enforcers. That's one thing.

The evolution of China's civil law has had a big impact. In 2010, China introduced a Tort Liability Law, which deals specifically with product liability. In the same year China also introduced a law that enforced citizens' personal rights and property rights. We believe that these two laws are good enough, but some procedural laws must be introduced that empower consumers on the one side to play the game with producers on the other. The government should not come in between, but instead function in a supervisory capacity and allow the two sides to deal with each other.

On the administrative side, we try to introduce best practices from other countries, compare with the situation in China, and then try to convince the government to go in the direction that the State Council has pointed to. This means that in certain sectors market mechanisms should play the fundamental role: we always highlight Hong Kong as a good example – it is a part of China where market forces are allowed to play a crucial role and the safety and the quality of its products is high.

Have any reforms piloted in the China (Shanghai) Pilot Free Trade Zone (CSPFTZ) had a positive impact on the TIC industry?

When the Chinese Government announced its plans to pilot reforms in the CSPFTZ, we asked, through the European Chamber, if testing centres could be permitted to operate there free from administrative intervention, and make the CSPFTZ a real testing site for reform. However, to date, we have not been successful with this request.

What are your expectations for the EU-China Comprehensive Agreement on Investment (CAI)?

We hope that the articles relating to the TIC industry in the agreement will be concrete. It should address the principles set out in the agreement, and there should be a mechanism for continuous review between the two sides. For these kind of agreements it is extremely important to have an inherent mechanism for dispute settlement so that service providers have the ability to appeal and bring certain things to the table.

Through the Chamber we put forward a request to the European Commission that the TIC industry has a dedicated chapter in the CAI. This is important because what our industry represents is a horizontal issue for all other industries. Improvements in our sector will result in improvements across all sectors. This has so far not been nailed down, but we are still trying.

What would you consider to be lobby successes for the QSS Working Group?

There are many things. On almost the final day of consultation for the latest *Foreign Investment Catalogue*, we were successful in lobbying to have the TIC industry removed from the 'restricted' category. We cited the *12th Five-Year Plan* [and its statement that the TIC industry should be developed] as well as the position of the Ministry of Science and Technology that this sector is a high-tech sector that should be supported. When we stated these two points it was agreed that this sector should not be restricted.

We also advocated that vocational training should be an encouraged and supported industry – in our industry there is a lot of training provided on the certification side. Skilled training is something that is very much needed by the Chinese, so there is no reason that this should be a restricted industry. Vocational training is now in the 'encouraged' category.

EUROPEAN CHAMBER EVENTS GALLERY

BEIJING CHAPTER


1


2


3


4

European Business Organisation Worldwide Network meets in Beijing (1&2)
The European Business Organisation Worldwide Network (EBOWWN) met from 12th–14th November for its annual regional conference.

Improving profitability through strategic pricing (3)
On 22nd October the Chamber held a seminar on the importance of pricing strategies and how to price products or services accurately. The event was sponsored by Simon-Kucher & Partners.

Human Capital Conference 2015: The Business Critical Role of HR (4)
On 4th November, more than 120 people attended the European Chamber's Human Capital Conference. We would like to thank our sponsors Peking University BiMBA, Cornerstone International Group, International SOS, YCIS, ARRAIL Dental, CEIBS and HAYS, and lucky draw sponsors Blueair and Rosewood Hotel.

NANJING CHAPTER


1


2

CSR Cases Competition (1)
On 29th October, the Nanjing Chapter held a competition to judge CSR case studies, as preliminary preparation for their CSR awards event. All applicant companies presented their CSR initiatives which were then scored by the judging panel.

Green and Clean Forum (2)
The Nanjing Chapter held its 2nd Green and Clean Forum on 11th November, sponsored by BASF-YPC. Around 120 participants took part, including government decision-makers, industry leaders, academics and representatives from NGOs. Representatives from 13 media outlets, both local and national, also attended.

SHANGHAI CHAPTER

1


2

China Investment Conference (1)

On 23rd September, the Shanghai Chapter held the China Investment Conference focussing on relevant key issues at a time when China's market is undergoing a major structural shift.

Compliance Conference (2)

The Compliance Conference was held on 15th October with the theme *Prevention is better than cure*.

SOUTH CHINA CHAPTER


1


2

Training on Effective Email Writing (1)

On 19th October, the South China Chapter held a training course on Effective Email Writing, aimed at helping attendees to improve their writing skills and confidence.

Factory Visit (2)

On 29th October, Carl Zeiss Vision Technologies hosted a tour of their factory in Guangzhou.

SOUTHWEST CHINA CHAPTER


1


2

Logistics Seminar (1)

On 28th October, the Southwest Chapter held a logistics seminar in Chongqing on the inbound Yu-xin-ou (Eurasia) railway, which connects Chongqing and Duisburg and is set to play an important role for the One Belt, One Road project.

Position Paper Launch (2)

The *Position Paper 2015/2016* was launched in Chongqing on the 3rd November. Following President Jörg Wuttke's presentation to local members, European Consulates and Chongqing government representatives, a lunch meeting was held with European Consuls General in Chongqing.

TIANJIN CHAPTER


1

2

10th European Business Gala Dinner (1&2)

The European Chamber Tianjin Chapter hosted its 10th annual business gala dinner on 16th October. Themed Festival Celebration, members and invited guests celebrated the 10th anniversary of European Chamber's Tianjin Chapter.

EXECUTIVE COMMITTEE OF THE EUROPEAN CHAMBER


President
Jörg Wuttke
BASF


Vice President
Bertrand de la Noue
Total


Vice President
Mats Harborn
Scania


Vice President
Sara Marchetta
Chiomenti


Vice President
Stefan Sack
Comau


Treasurer
Lars Eckerlein
ABB


States'
Representative
Massimo
Bagnasco
Progetto CMR


States'
Representative
Frederik Cornu
Bureau Veritas


States'
Representative
Eduardo Morcillo
InterChina


Secretary
General
Adam Dunnett

NANJING BOARD


Chairman
Helmut Güsten
EMZ


Petra Grandinson
Atlas Copco


Udo Looser
Willi Elbe Steering
Systems


Andrea Raviolo
Brembo


Bernhard Weber
BSH Home
Appliances
Holding (China)
Co Ltd

SHANGHAI BOARD


Chairman
Stefan Sack
DMG MORI SEIKI
Machine Tools
Trading Co Ltd


Vice Chairman
Mick Adams
Somerley


Vice Chairman
Carlo D'Andrea
D'Andrea &
Partners


Celina Chew
Bayer


Iris Duchetsmann
Clyde & Co


Manuel Ramos
Bureau Veritas


Marcus
Wassmuth
Landesbank
Baden-
Württemberg

SHENYANG BOARD


Harald Kumpfert
Smartheat


Stephen Magor
Individual
Member


Martin Winter
BMW


Kemal Yener
Star Mall Real
Estate

SOUTH CHINA BOARD

Chairman
Alberto Vettoretti
Dezan Shira &
Associates

Vice Chairman
Vivian Desmonts
DS Avocats Law
Firm (Guangzhou)

Sandra Fuld
International SOS

Pan Huaiyu
Siemens
Shenzhen
Magnetic
Resonance Ltd

Donato Vairo
Meta System
Electronics
(Shenzhen) Co Ltd

Saul Vazquez
Gates
Management

Yushun Wong
TÜV Rheinland
(Guangdong) Ltd

SOUTHWEST BOARD

Chairman
Ulrich O. Birch
Consenec Ltd
(ABB Group)

Vice Chairman
Paul Sives
Proton
Products

Alan Chen
Leman
International
School

Shirley Ling
KPMG Advisory

Robin
Niethammer
Bayer Healthcare

Torbjorn Sternsjo
Sapa Chalco
Aluminium
Products Co Ltd

TIANJIN BOARD

Chairman
Christoph
Schrempp
Airbus

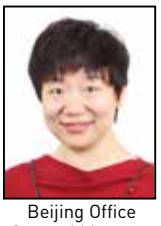
Gabriele Castaldi
Flexbo

Stephane Metay
Veolia

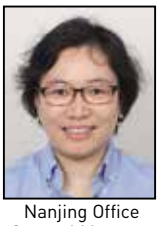
Frank Redecker
Asia Power
Systems

Michael Stengele
Siemens

EUROPEAN CHAMBER OFFICE TEAM



Beijing Office
General Manager
Maggie Xie



Nanjing Office
General Manager
Mei Zhang

Shanghai Office
General Manager
Ioana Kraft

Shenyang Office
Assistant Office
Manager
Marine Chen

South China Office
General Manager
Francine
Hadjisotiriou

Southwest China
Office
General Manager
Sally Huang

Tianjin Office
General Manager
Kitty Wang

Secretary
General
Adam Dunnett

AN INSPECTOR CALLS

CHINA'S TIC INDUSTRY

Despite some recent opening up of China's testing, inspection and certification (TIC) industry there is still some way to go before foreign-invested players can be considered to be on an equal footing with their Chinese counterparts. **Yushun Wong**, Executive Vice President of **TÜV Rheinland** Greater China and board member of the European Chamber's South China Chapter speaks to *EURObiz* about the TIC industry in general and specifically their work with sustainable energy solutions.

What is your general opinion of China's TIC industry?

In the domestic testing market, foreign-funded players are in the minority. In November 2015, the application for China Compulsory Certification (3C) testing laboratories for four types of products was opened. However, although testing labs can now submit applications any time, international inspection and certification bodies can still only compete in the non-mandatory or voluntary certification market. The reason is that most international inspection and certification bodies have a limitation in the testing scope of GB[1] standards. Meanwhile, the China Quality Certification Centre dominates the local mandatory CCC certification market for 146 types of products under 18 types of product categories.

What are your thoughts on China's plan to integrate TIC institutions?

March 2015 saw the General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ) issue the *Guidance for Consolidation of National Quality Management Inspection, Testing and Certification Organisations (Guidance)*.

The *Guidance* proposes the conversion of inspection and testing agencies into enterprises, to open up the TIC market, with sectoral monopolies and industrial barriers being broken down to allow for market supervision. The *Guidance* further recommends the introduction of a competition mechanism, the establishment of a mechanism for external evaluation and a constraint mechanism that penalises dishonest behaviour, in order

[1] *Guobiao*: China national standards issued by the Standardisation Administration of China (SAC)

to safeguard the public credibility of the TIC industry.

While this seems to be an opportunity, it is also poses a challenge. State-owned inspection agencies used to have a market share of over 50 per cent, leaving around 30 per cent for foreign counterparts and around 10 per cent for private players. The *Guidance* suggests gradually opening up 50 per cent of the TIC market, and transforming state-owned agencies into enterprises for full participation in market competition. As third-party agencies, TIC players face challenges in improving business competence, integrity and public credibility. Following consolidation, the highly accessible TIC market would be able to encompass an improved and more orderly inspection mechanism, while providing a higher level of service.

Integration will be a gradual process due to the fact that there are just too many state-owned enterprises (SOEs) and local inspection bodies managed by various government offices amassed on the market, each with its own varying pace of marketisation in different applications. Most local inspection agencies have their own niches, including accumulated reputation, extensive knowledge on related regulations, policies and technical markets, and years of industry experience. These happen to be areas that global participants that operate in China are lacking in. Meanwhile, there are many small players on the local front seeking a means to stand out. International TIC agencies may decide to explore various cooperation possibilities with local peers, such as technical cooperation.

What are the biggest market access problems for foreign TIC companies in China?

Following the Third Plenum's *Decision,* issued in November 2013, the Chinese Government introduced a management model of pre-establishment national treatment with a negative list to simplify and streamline the registration process for TIC companies, decrease accreditation items and allow enterprises to apply for a business licence before applying for accreditation.

However, too many administrative examinations and approvals are required for TIC companies to start business in China in comparison to other countries, and accreditation items often overlap in some way. In addition, the AQSIQ, local Quality and Technology Supervision Bureaus, and local Entry-exit Inspection and Quarantine Bureaus are currently gradually imposing higher requirements on routine supervision for TIC companies and setting strict access requirements for carrying out Chinese mandatory certification business. We are looking forward to further opening up.

Can you tell us a bit about your work in the area of the certification of battery electric vehicles (BEVs)?

We first established our Battery Lab in 2009, and have been successfully testing commercial batteries and light electrical vehicle (LEV) batteries for all world markets. In 2014, we issued about 600 IECEE CB certificates and will increase that number to 900 in 2015. In 2014 our laboratory expanded, and we have now incorporated the testing of electric vehicle (EV) batteries and electrical storage systems (ESS). Since the opening of the new lab facility we have engaged in several research projects for Huawei (ESS), and in research testing for VW, Ichi and others.

You're also involved in the inspection and certification of photovoltaic products aren't you?

We entered the testing and research of related photovoltaic products 30 years ago. As early as the 1990s, we started to participate in the photovoltaic roof plan launched by the German Government, and played a leading role in the establishment of standardisation for related photovoltaic products and systems. Of late, we have founded test laboratories with advanced facilities in major photovoltaic production bases and application markets, including Germany, China, Taiwan, Japan, India and the US. Our testing and inspection area covers almost the entire industrial chain, including solar cells, photovoltaic modules, photovoltaic parts and photovoltaic systems.

How is TÜV Rheinland positioning itself in light of China's economic slowdown?

From our perspective, there has been a noticeable decrease in Chinese exports and weak customer demand from outside China, affecting the certification industry as a whole. Fortunately, during our 26 years in China we have diversified into the industrial, railway, food, renewable energy, e-mobility and e-commerce markets, with increased local demand ensuring the continuous expansion of our operations. Eb

***TÜV Rheinland** is a global leader in independent inspection services, founded over 140 years ago. The group employs 19,300 people in 69 countries worldwide. Our independent experts stand for quality and safety for people, technology and the environment in nearly all aspects of life. TÜV Rheinland inspects technical equipment, products and services, and oversees projects and processes for companies. Our experts train people in a wide range of careers and industries. Our service scope includes industry and energy; transportation; machinery; electric and non-electric products; food; management systems; and training and consulting.*

ANSHAN:
STEEL CAPITAL OF CHINA

Anshan, located in the mid-south of Liaodong Peninsula, is hailed as the 'steel capital of China'. With the famous port city of Dalian to its south and the Liaoning's provincial capital city of Shenyang to its north, Anshan covers a total area of 9,252 square kilometers and is home to four million people. The GDP of Anshan hit RMB 272.1billion in 2014. It is the third largest city in Liaoning province, and the fifth largest in Northeast China.

Anshan boasts a widespread transportation network, covering air, railway and highway. It is only 260 kilometers to Dalian Port and 90 kilometers to Bayuquan Port. Anshan airport operates daily direct flights to major cities including Beijing, Shanghai and Guangzhou.

Anshan is richly endowed in mineral resources. It possesses one seventh of China's iron ore reserves, three fifths of China's magnesite ore reserves, one fifth of China's talcum ore reserves and one sixth of China's jade reserves. It also owns dozens of kinds of non-ferrous metals, rare metals and non-metal mineral resources such as gold, oil, manganese, copper, marble and mica. It boasts abundant geothermal energy and mineral spring resources.

Anshan is keen to attract investors from around the world. To find more please visit our website at www.aswjm.gov.cn or contact us on aswjmjwlc@163.com.

THE **ADVISORY COUNCIL** OF THE EUROPEAN CHAMBER

The 31 members of the European Chamber's Advisory Council are particularly active in representing and advising the Chamber, and make an enhanced contribution to the Chamber's funding.

ABB

AIRBUS

AkzoNobel

amadeus

Atlas Copco

BASF
We create chemistry

BAYER Bayer

BNP PARIBAS
法国巴黎银行

Deutsche Bank
德意志银行

ENGIE

ESI
EURO SINO INVEST

EVONIK
INDUSTRIES

FINMECCANICA

KPMG

MAERSK

米其林轮胎
MICHELIN

NOKIA

novozymes
Rethink Tomorrow

PHILIPS

PROGETTO CMR
MASSIMO ROJ ARCHITECTS

Roland Berger
Strategy Consultants

SCANIA
Scania Sales (China) Co., Ltd

Schneider Electric

SGS

SIEMENS

法兴银行
SOCIETE GENERALE

rethink.
storaenso

ThyssenKrupp

TOTAL 道达尔
COMMITTED TO BETTER ENERGY

VEOLIA

VOLKSWAGEN
GROUP CHINA

CORNERSTONE
INTERNATIONAL GROUP

WHEN RESULTS MATTER : CORNERSTONE

Executive Search + Leadership Consulting Experts

ACHIEVE MORE WITH CORNERSTONE

CORNERSTONE's mission is to help CEO and their companies SUCCEED

Great companies don't only depend on strategies—they also depend on people. The CEO's primary job is to first define strategies and then the larger part of his role is to attract and retain A level talent to join & stay with the team, as well as coaching B players to turn themselves into A players. This is what makes successful organization.

But that's easier said than done. When you engage with Cornerstone, you receive a result based relationship, instead of a service only. In addition to helping you acquire the best leadership talent, we are committed to customizing leadership solutions that meet the company's challenges in today's marketplace.

Our approaches are:

Integrity based: Defining and doing what is right.
Result driven: Metrics to measure and sustain success.
Satisfaction guaranteed: Percentage of fees or risk.

RETAINED EXECUTIVE SEARCH : WHEN RESULTS MATTER !

CORNERSTONE's mission is to help CEO and their companies SUCCEED

We accomplish this by providing the best in class "talent acquisition" supports in hiring middle to senior-level executive.
We do this through a focused, thorough, efficient, and values-based approach to Executive Recruiting.
Our comprehensive search process ensures that we select from the best skill sets available to fit the unique requirement of each client.
With 7 offices in China since 1995 and 70 offices worldwide, we are able to extend our reach beyond the local market. Whether you need to identify leaders with very specific skills or to hire leaders in other geographic locations, Our tested and proven talent acquisition process helps to ensure that we pinpoint the best possible leaders for your organization.

We do it faster, better, and at a value that serves you.

SPEED: Finalists in 20 business days guaranteed!
QUALITY: One year guarantee for each general manager placed.
VALUE: Fees are agreed in advance in advance and are based on first year's total cash compensation.

CORNERSTONE
INTERNATIONAL GROUP

CONTACT US FOR A FREE CONSULTATION

Beijing : Laure O'Donnell Email : laure-odonnell@cornerstone-group.com
Shanghai : Simon Wan Email : simon.wan@cornerstone-group.com
Hong Kong : Dominic Yim Email : dominic.yim@cornerstone-group.com