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China's vision of pharma and healthcare sector

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Introduction:

China has entered into its 13th Five-Year plan for 2016 to 2020 and relays a strong message to reinforce its potentials within the healthcare sector. China has emphasized on changing the model from research and development to innovation with focus on making breakthroughs in biologics medicine and to facilitate better protection of intellectual property rights. In 13th five-year plan, China intends to develop and adopt cyber-medicine and optimized distribution of resources to improve the quality of basic health services.

The country is planning to adopt aggressive strategies to increase the free supply of HIV treatment medication, reduce the cost for treating other chronic diseases and support traditional Chinese medicine. China's plan is to invest in new drugs and bring innovative drugs targeted for diseases such as cancer, heart diseases, mental illness, pain drugs and ageing population.

In 2015, China's pharma industry had clocked revenue of USD175.4 billion out of which API marked USD71 billion and formulations earned USD104.9 billion. China's big names in pharmaceutical industry including Sinopharma, Shanghai Pharma, Yangtze Pharma, Fosun Pharma and CPSC have expanded their strengths in the last few years. China is the biggest exporter of APIs to developed countries. Its API export was valued a USD9.8 billion in 2015 out of USD26.8 billion of chemical export. Its formulation export is estimated at USD2.3 billion.

"There has been a greater emphasis on healthcare industry in 13th five-year plan and by 2020, the sector is estimated to be valued at eight trillion yuan with rapid developments, growing demand and a boost by the capital investors. The plan is to step up production for special APIs, improve development of new drugs and speed up the registration process to expand export." said Mr Guangcheng Pan, executive chairman, China Pharmaceutical Industry Association (CPAI).

Part 1:
AN IN-DEPTH ANALYSIS BY BMI RESEARCH

China's 13th five-year plan (2016-2020) will be a key guiding document shaping opportunities in the pharmaceutical and healthcare industry. In the 13th five-year plan, specifically for the healthcare sector, several key areas have been identified such as full implementation of the supplementary health insurance programme proposed for jobless rural and urban residents with major diseases; integration of rural and urban health insurance schemes; encourage the development of private health insurance policies and the involvement of insurance firms; advancing comprehensive reform of public hospitals, seeking to end a system focused on profits; optimised distribution of healthcare resources; improved basic healthcare services; encourage the development of traditional Chinese medicines; rationalise drug prices and improve reproductive health.

The government's initiatives will primarily reinforce existing trends in the pharmaceuticals and healthcare sector. Consequently, pharmaceutical firms and healthcare providers can expect the existing pace of change to accelerate over the coming years as the government seeks to achieve its objectives.
China has been relatively successful in achieving its broadly outlined goals in previous five year plans. For example, China has been able to make significant progress in making basic medical insurance universally available as outlined in its 12th five-year plan.

However, while the government's commitment to improving healthcare remains strong, other areas such as intellectual protection has not seen similarly strong reform. According to the Pharmaceutical Research and Manufacturers of America (PhRMA), China continues to have restrictive patentability criteria with low levels of regulatory data protection which will impinge upon patient access to innovative pharmaceuticals.

Health Insurance Reform

China's 13th five-year plan will reaffirm a push to mitigate inequalities in the country's healthcare system. Reflective of this is the government's commitment to fully integrate China's new rural cooperative medical scheme (NRCMS) with the urban resident basic medical insurance (URBMI). This is a landmark move that will reshape opportunities for both private healthcare providers and pharmaceutical firms alike. Cumulatively accounting for 81 percent of the total population with regards to health insurance coverage, a merger will see the number of reimbursable products and treatments available for the population shift. For example, under the NRCMS, only 800 pharmaceutical treatments were covered, as compared to 2,300 in the URBMI. For multinational drug makers, a stronger homogenous insurance landscape for rural residents will be especially propitious as access expands beyond tier one cities and into less developed regions.

Similarly, Chines e authorities will continue to support the growth of the private health insurance sector. Beyond alleviating the cost burden on the government, which will only grow as chronic diseases become a bigger feature of China's epidemiology - a strong private health insurance sector can provide a greater array of products that meet the needs of the country's divers e population. In this manner, private health insurance will provide additional coverage for patients and will provide access to high-value medical services and products.

Reproductive Health

Notable new opportunities from the 13th five-year plan stem from the new focus on supporting the country's two-child policy. This marks a shift in China's stance and comes as government officials seek to address the rising number of dependents in the country (expected to increase from 368 million in 2015 to 553 million by 2050). Areas identified in the plan include reproductive health, women's health and child healthcare, beneficial for pharmaceuticals in the fields of paediatrics and fertility.
Drug Pricing pressure

In tandem with China's focus to improve health coverage, the 13th five-year plans affirm the growing push by authorities to more efficiently allocate resources for pharmaceutical spending. While specifics have not been mentioned in the five-year plan, it remains a key area of concern for drug makers. The bidding process that gained significant traction in 2015 has placed downward pressure on high-value pharmaceuticals. Most provinces employ a 'two envelopes elective tender' system, where firms submit drug quality information in one envelope and prices in the second. However, bidding procedures are not

standardised and the selection of a medical product based on price alone can occur. There are also varying priorities among local authorities. In Hunan, for example, domestic news sources reported that authorities have sought to cut prices by as much as 50 percent.

TCM Business through Silk Road

China's 'One Belt, One Road' (OBOR) initiative will have the potential to shape the growth trajectory in the country's healthcare sector. Given its scope, the OBOR will serve as a platform for Chinese authorities to actively promote traditional Chinese medicine across major markets in Europe, Asia and the Middle East. It also allows China to more proactively lead the advancement of disease surveillance particularly among its neighbouring countries. China's ambitious 'One Belt, One Road' initiative will have broad implications for numerous sectors including healthcare. First put forth by President Xi Jinping in 2013, it seeks to connect Asia and Europe through a re-imagination of the historical Silk Road. Specifically, the OBOR initiative consists of two key trade routes:

Silk Road Economic Belt: a land route starting from Xi'an in Shaanxi province that passes through Central Asia, the Middle East, Russia and Western Europe.
Maritime Silk Road: A sea route extending from Fujian in China to Europe, through the South China Sea, the Indian Ocean and the Red Sea before it joins the land route in Venice, Italy.

China will leverage upon the OBOR to facilitate the growth of the traditional Chinese medicine (TCM) industry. Posing a competitive threat to western pharmaceuticals, this intention was reflected in a strategic plan published by the National Health and Family Planning Commission (NHFPC) which argued that TCM use should be expanded across states in the OBOR. To that end, strategy adopted by Chinese authorities is twofold. Led by government agencies, China will first seek to promote the use of TCM across countries and affirm its healthcare benefits. This will be followed by an effort led by the NHFPC to establish common standards in the use of TCM across countries in the OBOR.

Part 2
Business environment in China to get more complex

Chinese pharmaceutical market will become more complex for multinational drugmakers. This is largely a result of the numerous ongoing reforms affecting the healthcare sector, including changes to the pricing regime and regulatory approval process. Sales practices employed by pharmaceutical firms in China will also evolve, driven by a need to better ensure compliance.

China's pricing environment will continue to evolve as authorities seek to balance greater medicines access while reducing healthcare costs. This aspect was emphasised in a new pilot programme announced by National Health and Family Planning Commission (NHFPC) in March 2016. Under this new scheme, five high cost drugs have been selected to undergo significant price cuts in exchange for a wider national insurance coverage. According to Li Bing, Director, NHFPC, this is part of the government's move to reduce healthcare costs for patients, with these pharmaceuticals being chosen due to their high cost.

Although the authorities have not officially disclosed the selected products, five key therapies that are likely to be covered are Gilead Sciences' Viread (tenofovir), Roche's Tarceva (erlotinib), AstraZeneca's Iressa (getfitinib), Celgene's Revlimid (lenalidomide) and Betta Pharmaceuticals' Conmana (icotinib)
Regulatory Reforms

In addition, regulatory pathways in China will continue to develop. As highlighted by the Center for Drug Evaluation under the Chinese Food and Drug Administration (CFDA), 2015 was marked by deepening reform to the approval process and this is expected to be continue in 2016, especially as the number of new drug applications submitted yearly remains high at 8,211 in 2015. Beyond expediting the process, authorities have begun to place a strong emphasis on quality. A circular released in March 2016 by authorities noted that pharmaceutical firms selling generic drugs must ensure that the quality and efficacy of their drugs are on par with the originator medicines.

In addition, it is expected from the government to diligently pursue the implementation of regulatory reforms. Beyond addressing the medical need within China, expediting the process will form an integral part of the country's strategy to position its pharmaceutical sector as an engine of economic growth.
Forming one of 10 sectors identified in the country's 'Made in China 2025' plan, the importance of the pharmaceutical industry will be accentuated by the ongoing economic slowdown in China.

Shift in marketing practices

Changes in China's pharmaceutical sector will not be limited to the pricing and regulatory environment. Sales practices, for example, will continue to evolve as firms look to change incentive structures and ensure regulatory compliance following the GlaxoSmithKline bribery trial. More recently, Bristol-Myers Squibb was fined USD14 million in October 2015 by the Securities and Exchange Commission over charges that its joint venture in China made cash payments and provided other benefits to healthcare providers at state-owned hospitals in exchange for prescription sales. Subsequently, the firm noted in March 2016 that it has stopped 'certain initiatives ' in China, which, according to local industry sources, involved a clampdown on the use of expenses and speaker fees for doctors.

Multinational pharmaceutical firms will adapt to the evolving regulatory landscape in China. A top priority will be the new drug approval process, whose implementation will receive strong support given the medical and economic need in China for the medicine industry to develop. Amidst the uncertainty from these changes, there will be opportunities such as the priority review which confers an expedited approval process for products that align with the government's focus.

The year 2016 will be a key year for regulatory reform in China as policymakers implement new reforms to expedite the drug approvals process. The Chinese Food and Drug Administration (CFDA) disclosed in February 2016, that it had approved a total of 342 medicinal products for the year of 2015, of which 70 percent were simple chemical compounds, 22 percent traditional medicines and 7 percent biologic products. This is a 27 percent decline from 2014 when the CFDA approved a total of 470 treatments, and it follows growing concerns among multinational drug makers regarding regulatory delays.

Critically for multinational pharmaceutical firms, 2015 saw the approval of several key products. This included Johnson & Johnson' s Zytiga (abiraterone) for prostate cancer and Novartis' Galvus (vildagliptin). Roche was also able to obtain approval for Avastin (bevacizumab) as a first-line non-small cell lung cancer treatment, providing access to a highly significant disease area. Similarly, Novo Nordisk received approval for Levemir (insulin detemir), which will aid the firm's position in the highly competitive diabetes market in China.

New Policies Take Effect

There will be opportunities for multinational pharmaceutical firms to enhance their operations through the regulatory reforms in China. Central among these initiatives has been the decision by the CFDA to create a priority review programme, which will assess products on their clinical value and use of advanced technology. The CFDA has also identified seven areas that will be the focus of this fast-track scheme that includes cancer, rare diseases, HIV/AIDS, Tuberculosis, Viral hepatitis, Pediatrics and Geriatrics.

Benefits disclosed so far include shortened regulatory timelines through the development and approval process. In the notice announcing the scheme, the CFDA has also committed to specific timeframes which will create greater transparency and facilitate the operations of pharmaceutical firms.

A BMI Research Report
Part 3
China to boost medical industry

China's State Council has issued a guideline on March 11, 2016 to give the medical industry a healthy boost. It said that by 2020, innovation capacity of the medical industry should be greatly increased, supply of urgently-needed clinical drugs will be increased, and the scale of the industry will expand, with annual growth rate of the main business revenue higher than 10 percent.

The guideline states that in order to achieve these goals, innovation and entrepreneurship should be encouraged, more innovation-driven middle and small-sized enterprises with technologies and high-end talents should be set up, and the research ability of new medical products should be increased.
It also required efforts to upgrade the medical equipment, mainly developing the key devices such as digital detectors, superconducting magnets and X-ray tubes with high heat capacity, and technologies such as 3-D printing and data collecting and analysis.

The new rule Good Manufacturing Practices on Medicines will be strictly implemented to perfect the product tracking systems. It also encourages using modern bio-technology to improve the traditional drug production methods, build environmentally-friendly industrial parks and recycle the byproduct materials to reduce pollution.

To better integrate this industry, the government will promote pharmaceutical enterprises to implement cross-sector mergers and acquisitions while optimizing the industrial structures.

Development of the pharmaceutical industry also needs the coordination of different regions, according to the guideline. It suggested building international-level research centres in eastern areas with abundant capital and high technologies, and production and export bases of the traditional Chinese medicine (TCM) in the western and the northeastern areas that have large amounts of TCM resources.
The guideline also states that to better develop this industry, the country should also perfect the medical service systems, relieve patients' burden by controlling irrationally high expenses and reduce repetitive and unnecessary medical examinations in different hospitals while encouraging doctors to work in several medical institutions.

In addition, the pharmaceutical industry should also take the advantage of the Belt and Road Initiative to go global, promoting big medical enterprises to invest overseas, build research centers, production bases, and sales and services networks. Efforts should also be made to develop internationally influential brands.
The government should also step up efforts to improve legislation on supervision of drugs and medical equipment, punish illegal enterprises, protect intellectual property rights, and crack down on fake and shoddy products.
As published by China's National Health and Planning Commission

Can China and India be ace partners in pharma sector?

European countries are the dominant consumers of drugs however, it will slowdown in future giving way to developing countries like India, China, Russia and Brazil that are estimated to grow at 10-15 percent and would be the major drivers of global pharmaceutical industry. Can India and China grasp these opportunities with strategic plans to drive development of pharmaceutical industries of both countries?
In next five years, important drugs are on the edge of expiry. By 2015-2020 drugs worth of USD250 billion is estimated to expire and the market share will be taken by generic drugs. In next two decades, India and China will be the pillar of development for pharma industry. India has a unique advantage of language to better understand the regulatory of global companies. India and China can also have broader cooperation in production and clinical trial data.

"We should learn from India to speed up development of talent pool, registration and certification process. The way India has grown phenomenally in generics business is very impressive. China should also grasp such opportunities, nurture China local talent and scientific knowledge and strengthen drug production for exports," Mr Guangcheng Pan, executive chairman, China Pharmaceutical Industry Association (CPAI).

"We should support China companies to produce generics drugs and be prime exporter to US and Europe. We need to improve the quality and efficacy of our drugs to international standard and need to implement hassle free policies and regulation procedures. In 13th five-year plan, China is aiming to achieve growth rate of 13-15 percent in generics business," he further said.

Me Pan commented that both India and China are developing countries. Pharma manufacturing incurs huge cost and a collaboration between India and China on manufacturing would save cost to both the countries.

Mr Song Min Xian, former registration director, Sichuan FDA, remarked that although China and India have memorandum of understanding on exchange between regulators, however, there is a lack of communication between regulators of two countries.

China has over 5,700 chemical companies and 4000 chemical products. China imports 1400 products of which 940 are formulation products.

Sharing his views on the current state of India-China partnership, Mr J. Jayaseelan, Chairman, Indian Drug Manufacturers' Association (IDMA) said that, "India and China need to build an environment of partnership that enables the two countries to grow in future. Collaboration is possible only when we have the intention to grow together and not competing but complementing. We recognize China as a great neighbour and civilization and there are many aspects in common where India and China can work together. Although we have signed MoU for many years now but there has been no real benefit for the manufacturers or the drug companies. India has a great R&D base, manpower base and there are agencies than can help in building the strengths of two countries together."

Mr Daara Patel, Secretary-General of IDMA mentioned that global pharma market is more than 1 trillion. If India and China join hands and collaborate instead of competing, the industry of both the countries will expand phenomenally. Both the

nations need to consider the strengths and weaknesses, support each other for local consumption and global tenders.

"To further improve the pharmaceutical industry, India and China can exchange views on the challenges they face regarding regulatory norms and procedures and take steps to make it better. India and China have been very old business partners, however, India has been primarily an importer of APIs from China. There is a trade deficit and this need to be balanced. One of the way could be if China identifies India as a centre for importing formulations," suggested Mr Pate.

The turnover of India's pharmaceutical market is estimated at USD31 billion in 2015 and is expected to touch USD55 billion by 2020. The current domestic sale is around USD15 billion and export is valued at USD16 billion out of which 77percent is formulations and 23percent is APIs. 90 percent of the Indian pharma market is driven by generics drugs which is estimated to grow at a CAGR of 10-15 percent in next five year. India accounts for 10 percent of the global production of pharma products out of which formulations are valued at USD12 billion of export and APIs at USD4 billion.

"US, UK, Russia, South Africa and Nigeria are major export destinations for India and we hope that China also become one of the major buyers for India pharma products. India accounts for 10 percent of global pharmaceutical production and manufacture more than 400 different APIs. It is a good opportunity for China to invest in India and strengthen bilateral trade between the two countries," said Mr S. V. Veerramani, president, IDMA.

He further said that China has emerged as India's largest trading partner, replacing US. China accounts for nearly 73 percent of Indian imports of API and other organic compounds. "While we are buying, China shall consider buying formulations from India. We support their APIs and China shall consider supporting India by buying formulations."

Throwing light on hassles that Indian exporters has to face while registering in China, Mr Veerramani, mentioned that it takes several years for Indian products to get approval in China whereas India grants product registration in less than a year. "We need a better support to understand regulations in China to increase the trade. China should import drug formulations from India to offset trade deficit against API imports. China has over 6000 domestic pharma companies out of which 70 percent are in API production and India has over 10,000 manufacturers comprising over 77 percent in formulation."

Highlighting avenues through the partnership between India and China can be strengthened, he also shared his though that China can consider doing contract manufacturing of formulations in India. Also, both countries can set up regulatory offices in each other's countries for direct inspection of facilities and faster approval. "There is a need of frequent interaction between regulatory of each countries and we can build a harmonized environment."

He concluded that partnership between IDMA and CPAI should grow more for broader market penetration.