

Pharmaceutical Cold Chain in Emerging Economics - The Case of China

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Summary: Because of the high market growth of biologics drugs- temperature sensitive pharmaceutical products, the cold chain management has become an increasingly important component of the overall pharmaceutical supply chain. On the other hand, the emerging economics have been the main driving force of global pharmaceutical market, especially China, with nearly 20% CAGR in pharmaceutical market in the past 5 years, is the most promising region and could be the second largest pharmaceutical market in the world by 2020. To explore the opportunities in cold chain management in emerging economics, this research chooses China as a case for study. As a pioneer study, this research is to analyze the market trend and policy effects on pharmaceutical cold chain in China, to map the key supply chain issues on cold chain management, and to point out opportunities in the near future.

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KEY INSIGHTS

1. 3PL could be a new business opportunity in China's pharmaceutical cold chain in long-term. The current cold chain logistic is mostly self-build by big pharmaceutical companies. However, once the new regulation completely implemented in the near future and also the industry standards are practiced well, 3PL could be a solution to the industry.
2. From now to 2016, new technology and equipment will be highly in need to build a modern pharmaceutical cold chain system in China.
3. To design a successful new business model in China's pharmaceutical cold chain, the model should highly align with the new regulations and the new China's national healthcare reforms.

The global and emerging pharmaceutical market

Driven by scientific and technological advances, coupled with increasing demand for medicines from aging population, the economics growth of emerging countries and trade liberalization, global pharmaceutical market is growing steadily, with sales reaching \$1.08 trillion in 2011—a year-on-year increase of 7.8%, and could be worth nearly \$1.6 trillion by 2020.

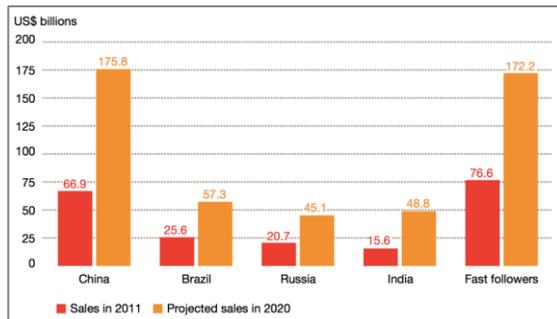


Figure 1: China is the most promising emerging market by 2020

Source: PwC (2012)

Emerging countries will be the main market driving force, not only because the natural demand are rising but also the governments of the growth economies are improving access to healthcare, such as Brazil's introducing mobile clinics for rural communities, China's on track with a US\$200 billion programme to extend health insurance cover to 100% of the population and India's National Rural Health Mission. Basically, BRIC will still be the first tier emerging market and show very strong growing power; especially China is expected to be the world's second largest pharmaceutical market after the US in 2016, with high growth rate and sales quantity. (See Figure 2)

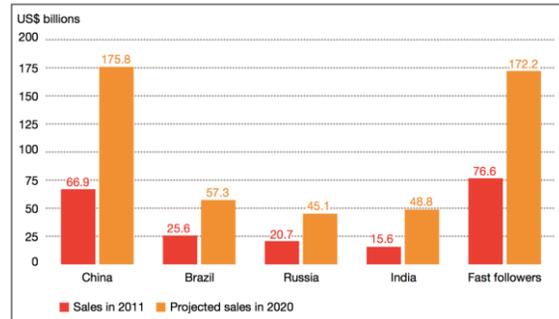


Figure 2: China is the most promising emerging market by 2020

Source: PwC (2012)

In term of pharmaceutical supply chain, not only the new business model will drive it updated but also the integration of pharmaceuticals, healthcare, and medical device industry to end user will restructure the supply chain system. That is, more innovations and various emerging technologies will help manufacture and distribute its products more efficiently. Some of these technologies will enable it to build quality into its manufacturing processes, while others will enhance its throughput or facilitate collaboration to realize economies of scale. (See Figure 3)

Research Approach

To provide a helicopter view and the updated analysis of the pharmaceutical cold chain in emerging economics, narrative literature review would be the main approach to structure this research, and China was selected to be the case study. The research steps include performing a preliminary search of the literatures, glancing over the contents of selected materials to refine the questions need to be explored, synthesizing the contents, and making conclusion. The final output of the review analysis would be the results of analysis, the overview of pharmaceutical cold chain in China and the challenges/opportunities of pharmaceutical cold chain in China.

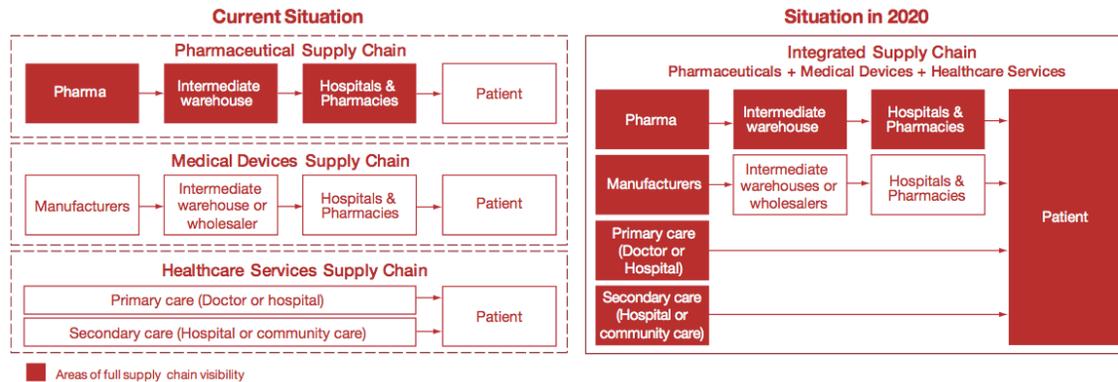


Figure 3: By 2020, the healthcare supply chains would be fully integrated

Source: PwC (2011)

Issues of pharmaceutical cold chain

A well-developed cold chain systems ensure that adequate amounts of pharmaceuticals, mostly biologics medicine like vaccine, can be procured, stored, and distributed in a manner that minimizes waste, avoids stock outs and maintains proper temperature control to prevent damage. The issues of pharmaceutical cold chain nowadays include:

- **Regulation:** Pharmaceutical industry is highly regulated by law globally. Certainly, pharmaceutical supply chain has various global regulatory requirements, such as Good Storage and Distribution Practices, to meet while handling, storing, and distributing environmentally sensitive products.
- **Network of pharmaceutical cold chain transport logistics:** Pharmaceuticals cold chain logistics is a series of whole refrigerated scheme, special logistics network and supply chain system to maintain the quality of pharmaceuticals by keeping the constant state of low temperature from production to consumption process.
- **New technology:** Innovation is leading to better insulation products, the ability to maintain a specific

temperature range for longer time periods and in-transit monitoring that doesn't require the package to be opened, thereby lessening the risk of counterfeiting and diversion. The innovations are highly in need in cold chain, such as phase-change materials (PCMs), insulating materials, environmental data loggers, software for monitoring and tracking shipment conditions, three-dimensional modeling software to optimize package design, integration of temperature protection/monitoring by logistics providers and temperature-controlled bulk containers to protect larger shipments.

- **Prevent cold chain break:** Cold chain breaks can, and do, happen at any time. Preventing the cold chain break has been one of the important issues in pharmaceutical cold chain management. To improve this situation, more management system and technology such as cumulative heat monitoring devices should be implemented to cold chain management system

China's pharmaceutical market

- The healthcare reform programme triggered the market demand. China is going to be the second large pharmaceutical market by sales in the world, but the status is arguably due to the size of its population, as the market is not yet mature. The combined forces of economic and demographic development, government stimulus, enhanced health awareness among the public, market consolidation, and improving R&D capability may help the country to grow into a more sophisticated market within the next decade. Key drivers of market expansion are the rising health care awareness and needs fueled by economic growth, large and aging population, increasing total and per capita health spending, and the ongoing healthcare reform and 12th Five-Year Plan supportive measures. According to BMI, the China's pharmaceutical market sales could reach 132 billion USD in 2017 with 9 % annual growth rate.
- Biologics has been targeted as a key development sector by Chinese government. Although biologics only account for 10 percent of the total pharmaceuticals market in China, their recent annual growth rate of 32.2

percent has been quite impressive.

The Five-Year Plan provisions specifically related to biotechnology applications in the life sciences industry are expected to take effect shortly. It has been reported that China's government will invest RMB10 billion to support major new drug innovation, with RMB5–10 million in funding for each project on average from 2011 through 2015. The investment on biologics will also trigger the demand of cold chain service.

- The major issue to China's pharmaceutical industry: building a more efficient ecosystem, from regulation authority to supply chain, from dispersed industry structure to integrated value chain. In China, the pharmaceutical distribution system is too dispersive, large amount of distributor levels made the end price unstable and the end price was stacked up as well. To relieve the pain of high pharmaceutical product end price, Chinese government has released policy to refine the pharmaceutical procurement process of public hospitals (more than 80% of hospitals in China are government owned) and to restructure the pharmaceutical distribution system.

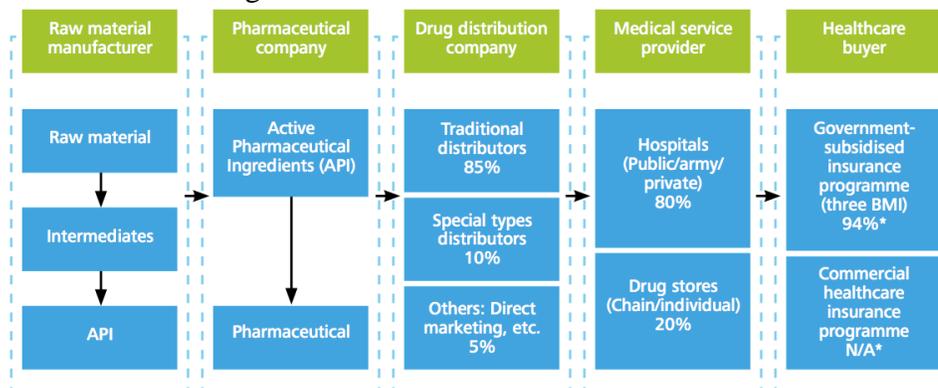


Figure 4: Chinese pharmaceutical industry value chain

Source: Deloitte (2011)

China's pharmaceuticals distribution system

- China's drug distribution environment is fragment and complex. China's pharmaceutical distribution base is extremely fragmented. Before 2009, there are more than 13,000 distributors, most providing access to only a local market or even just one or two hospitals. The fierce competition has led to widespread discounting. As a result, many distributors are lossmaking. Many newly established distributors are reported to be unregistered, and it has been a critical safety issue in pharmaceutical supply chain
- Consolidation and integration is the top priority. To fixed the high drug price and inefficient distribution system, China's Ministry of Commerce (MOFCOM) has outlined its plans for the development of the pharmaceutical sector from 2011 to 2015, focusing on the distribution of drugs

New regulation-GSP, will restore the cold chain management

On January 22, 2013, the newly revised Good Supply Practice (GSP) for Pharmaceutical Products was adopted at the executive meeting of the China's Ministry of Health and officially issued, and has been formally implemented on June 1, 2013. The new GSP revision constitutes a major adjustment of China's policy for supervision of drug distribution, which greatly raised the threshold of qualification requirements and standards for engaging in drug distribution practice. To enhance the cold chain guidelines, on October 23, 2013, CFDA issued five GSP appendices (2013 No. 38) as GSP supporting documents, including the Management of storage and transportation

for drugs needed to be retriggered or frozen, Management of Computer systems for drug suppliers, Management of Automatic temperature and humidity monitoring, Drug delivery and acceptance/Validation management. The new guideline will help the cold chain industry to develop a higher qualified ecosystem and may generate new business opportunities such as 3PL (third-party logistics provider) in the future.

Biologics medicine: the driving force of pharmaceutical cold chain

The dramatic shift in pharmaceutical industry from small molecule drugs to high value biologics drugs is not only happening in US and Europe market but also in China, even with higher growth tare, increasing the need to focus on cold chain management.

Conclusion

- Consistent with the 12th FYP for drug safety, the new GSP reflects government efforts on improving drug quality by raising standards for the whole healthcare industry, which could accelerate industry consolidation. After implementing the new GSP in June 2013, the government declared 5 cold-chain relevant guidelines under new GSP close behind, pushing process of industry restricting. The impact would be the same for big or small distributors, but big distributors can more easily assume the costs for compliance with the regulations, while small companies are much less flexible. Since all the service providers need to follow the new regulation by the end of 2016, more M&A activities will happen and more qualified cold chain service

- providers should appear in the near future.
- Before implementing new GSP, most of the big pharmaceutical companies build up their own cold chain facilities, including storage and logistics, to ensure the quality and safety and prevent the product from degrading caused by break-up cold chain. However, the model is not economics efficient and not easy to optimize the operation. In the near future, the status may not change too much, and the cold chain logistic will still rely on the pharmaceutical companies' self-built logistics center. However, the high quality pharmaceutical cold chain system would steadily set up under the new regulations, and the current ecosystem should change in the mid-term, such as more integrated cold chain, new supply model and 3 PL service.
 - Although the new GSP has made the regulation on cold chain management, however the operational standards and best practice still need to be clarified and set up. By the end of 2013, the China Association of Pharmaceutical Commerce united Sinopharm Group Co, Jointown Pharmaceutical group, China Resources Pharmaceutical Group Limited and Harbin Pharmaceutical Group Co., etc., nine major pharmaceutical cold chain distribution enterprises to establish drug distribution security laboratory. The main mission of the lab is to formulate the standard and best practice which align with key players and government. Thus, the practical standards of cold chain management may be well set up in the couple years.
 - Due to the healthcare reforms, 12th 5-YP and the increasing aging population, the demand of biologics could keep steep growing in the near future, but the current poorly structured cold chain system may force the pharmaceutical company to invest more on cold chain management. Besides the promising market may attract more service provider to join this market, including foreign players, the ecosystem of pharmaceutical cold chain will dynamically change to adapt the fast changing market demand and regulations.

Key takeaways

Under the fast changing industry environment, many new challenges are waiting to be explored. According to the literatures review result in this research, some opportunities ahead can be pointed out include:

- 3PL will play a role in China's pharmaceutical cold chain in long-term. The current cold chain logistic is mostly self-build by big pharmaceutical company because it's hard to find a trustable and qualified 3PL currently, therefore the pharmaceutical enterprises can only build up their own infrastructure even the cost is extreme high. However, once the new regulation completely implemented in the future and also the industry standards are practiced well, 3PL could be an solution to the industry, not only for big pharmaceutical companies but small and medium enterprises.
- In the near future, new technology and equipment will be highly in need to build a modern cold chain system. The new GSP requires IT-based management and automatic

monitoring of storage temperature and humidity, and introduced new management philosophies and methods for quality risk management, system internal evaluation and equipment validation. Regarding infrastructure, the newly revised GSP calls for the comprehensive implementation of IT-based management and specified requirements on the facilities, network environment, database and functions of applied software; required retail and wholesale enterprises to adopt automatic temperature and humidity monitoring system for drug warehouse to conduct continuous and effective real-time monitoring of warehouse

environment; and provide special facilities and equipment for the storage and transportation of drugs stored in a refrigerator or freezer. The China's future pharmaceutical cold chain will need more technology solutions to complete a modern cold chain.

- To align with the national healthcare reforms- ensure the people safe and affordable pharmaceutical, a new business model highly link with government could be an opportunity. For instance, a 3PL contracts with government to deliver specific products set with high quality cold chain management to regional hospitals.

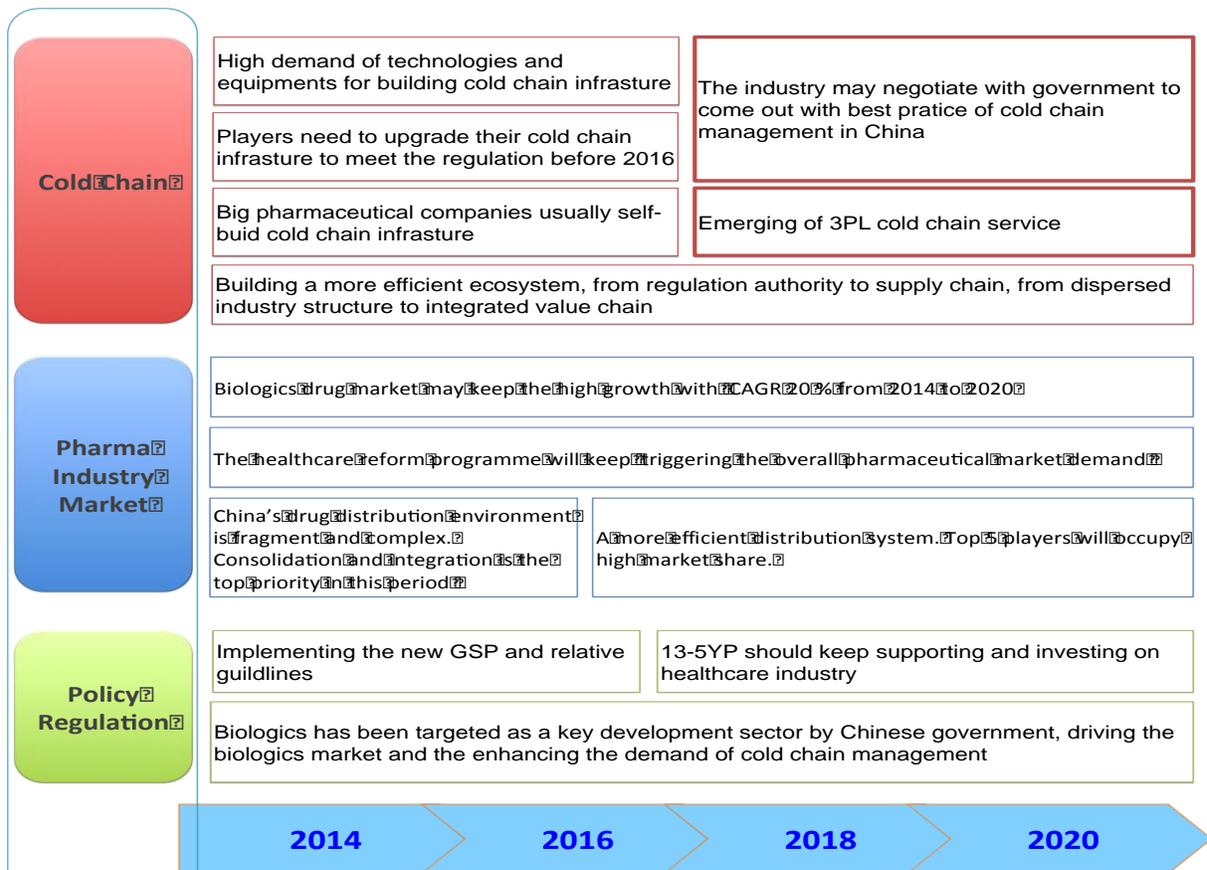


Figure 6: Roadmap of China's Pharmaceutical Cold Chain
Source: Author (2014)