Introduction

Due to the changing lifestyles of the Chinese population, there has been a rapid increase in diseases such as diabetes, obesity, eating disorders, hypertension, cerebrovascular disease, arthritis, and heart disease in recent years. The increasing incidence of these diseases has led to greater demand for medicines used in their prevention and treatment. Driven by strong economic growth, increased coverage of healthcare insurance and an aging population, pharmaceutical sales in China reached 97.9 billion USD in 2012, after growing an average 20% over the past five years.[1] Pharmaceutical sales are expected to continue strong but more modest growth from 2012 through 2016, at a CAGR of 15 to 18 percent.[2] This growth has been felt at each level along the pharma value chain.

Figure 1 - Pharma Value Chain

1. Raw material manufacturer
   i. Raw material
   ii. Intermediates
   iii. Active Pharmaceutical Ingredients (API)

2. Pharmaceutical company
   i. Active Pharmaceutical Ingredients (API)
   ii. Pharmaceutical

3. Drug distribution company
   i. Traditional distributors - 85%
   ii. Special types distributors - 10%
   iii. Others: direct marketing, etc. - 5%

4. Medical service provider
   i. Hospitals (Public/army/private) 85%
   ii. Special types distributors 10%
   iii. Others: Direct marketing, etc. 5%

5. Drug stores (Chain/individual) 20%

6. Healthcare buyer
   i. Government-subsidised insurance programme (three BMI) 94%
   ii. Commercial healthcare insurance programme N/A
In China, there are four types of drugs: chemical prescription (Rx) drugs, OTC (over the counter) drugs, biopharmaceuticals (vaccine, etc.), and a special category of Traditional Chinese Medicine (TCM). Due to China’s system of combining hospitals and pharmacies, 56% of drugs, especially Rx drugs, are sold through hospital pharmacies (23,170 hospitals in China in 2012). While retail pharmacies and community health institutions are the two main sales channels for TCM, chemical OTCs, and dietary supplements, they account for only 17% of drug sales respectively.[3] It is noteworthy that China’s healthcare reform plan includes reform of public hospitals, which will separate a hospital’s operation and management functions, and separate the pharmacy from the hospital. Furthermore, China’s Central Government is determined to reduce patients’ expenses by removing the hospital’s mark-ups on drug prices (announced in 2012) and will look at additional avenues to continue reducing drug prices. These factors cast some uncertainty over the growth of China’s Rx drug market.

China’s Rx Drug market had an estimated sales value of USD 50 billion in 2011[4] while the OTC market is expected to grow to an estimated USD 30 billion by 2014.[5] China has more than 4,000 pharmaceutical manufacturers – about 98 percent of which produce generic drugs.[6] Generic drugs (branded generics) dominate China’s pharmaceutical market, and will likely continue to do so for the foreseeable future. From 2007 to 2010, the sales of generic drug accounted for over 85% of prescription sales and over 90% of total pharmaceutical sales. While the government encourages and relies upon innovation to meet industry targets, China will probably continue to rely upon widespread prescription of generics in the public insurance plan to hold down overall healthcare expenditures. Current domestic R&D capabilities also limit the possibility of launching domestic patented drugs in the near term.[7]

According to diseases prevalence and the trends of an aging society, it is projected that drugs in the areas of cardiovascular, diabetic, anti-tumor, anti-Hepatitis B, anti-HIV, nerve system, digestive, metabolic, and hypertension control will be the most needed in the China market.
- Anti-infection drugs: 17%
- Cardiovascular drugs: 13%
- Hematological drugs: 11%
- Anti-tumor drugs: 10%
- Digestive system drugs: 8%
- Nervous system drugs: 8%
- Immune adjusting reagents: 7%
- Endocrine and metabolic drugs: 6%
- Biotech drugs: 3%
- Respiratory drugs: 3%
- Musculoskeletal medicine: 2%
- Mental disorders drugs: 2%
- Anesthetic and adjuvant: 2%
- Others: 8%

Source: *PDB sample hospitals in 22 Chinese cities, 2012*

**China's OTC Sales by Sector, 2008**
Multi-National Corporation Activity

Adding to more than 4,000 domestic pharmaceutical manufacturers, China’s promising pharmaceutical market has attracted worldwide multi-national corporations (MNCs) into the market. By 2006, there were over 1,500 foreign owned (WOFE) or joint venture (JV) pharmaceutical manufacturers in China. These foreign WOFEs and JVs control about 27% of the market share of the overall pharmaceutical sales in China today. However, in large urban cities like Beijing and Shanghai, foreign branded drugs control approximately 60%-65% market share and have a dominant position especially with popular, top-selling drugs including those treating i.e. diabetes, anti-clotting, and blood pressure control.\(^8\)

Besides investing in China for localized manufacturing, MNCs are also setting up R&D centers in China. Following Novonordisk, the first company to set up an R&D Center in China back in 2002, Roche, Bayer Schering, Novartis, Merck, Pfizer, AstraZeneca, GlaxoSmithKline, and Eli Lilly have all done so. In 2005 the “China Association of Enterprises with Foreign Investment R&D based Pharmaceutical Association Committee” (RDPAC) was founded. It now has 37 members representing MNCs doing R&D in China.

CRO Activity

MNCs have been outsourcing some of their R&D to professional Contract Research Organization (CRO)s in China, which has driven quick development of the local CRO market. Cost saving is only one of the benefits of conducting R&D in China, some others include:

- large pools of talent in drug R&D;
- increasing number of high quality CROs, i.e. Wuxi AppTec, PPD, Sundia, etc.
large patient pool;
Chinese government’s support for new drug R&D.

A market survey by JTMed Inc. indicated there are 250 professional service providers, 50 multinational service providers, 150 traditional Chinese pharmaceutical companies, and 20 Chinese biotechnology companies operating in the CRO industry. Local CRO alliances have also been set up to promote the industry such as the Alliance of Bio-Box Outsourcing (ABO) in Beijing and Contract Research Organization Service Alliance (CROSA) in Shanghai. In 2009, the ABO had over 20,000 transactions with a value of USD 700 million. The CRO industry is growing rapidly in China and is attracting international CROs to join the local alliances or set up their own presence in China such as PPD, MDSPharma, and Covance.

Reimbursement for Pharmaceuticals/Drugs

The National Reimbursement Drug List (NRDL) lists those drugs that are reimbursed by the country’s three basic national health insurance schemes (Urban Employee Basic Medical Insurance, Urban Resident Basic Medical Insurance, and New Rural Cooperative Medical System). The Essential Drug List (EDL) is a list of drugs that are used in China’s primary healthcare facilities, and encouraged to use in Class II/III hospitals. All the therapeutic drugs listed on ELD 2009 edition are included in the NRDL 2009 edition as Tier A drugs, which are fully reimbursable. While the Tier B drugs in NRDL receive certain reimbursement ratios. Drugs not listed in NRDL are at patient’s own expense. Health departments at the provincial level have the right to adjust up to 15% of the Tier B drug combination of NRDL, and local health authorities define the reimbursement rate of Tier B drugs based on their local needs and financial resources.

Division of Regulatory Responsibility

The Ministry of Human Resources and Social Security (MOHRSS) draws up and publishes the NRDL and oversees the budgets of the Urban Employee Basic Medical Insurance and Urban Resident Basic Medical Insurance. The National Development and Reform Commission (NDRC) controls the prices of the listed drugs. The Ministry of Health (MoH) ensures the implementation of the NRDL developed by the MOHRSS and manages the budget of the New Rural Cooperative Medical System. The China Food and Drug Administration (CFDA) ensures the efficacy and safety of drugs, while the Ministry of Finance (MoF) ensures that sound accounting principles are applied to public medical care funding.

Policy Updates

The 2012 revision of EDL was released by MoH in March 2013, whose drug number increased to 520, including 317 chemical and biological drugs, and 203 traditional Chinese medicines (TCMs). MoH has indicated that it will increase the usage of EDL drugs in Class II/III hospitals. Guangdong is considered as the weathercock for China’s pharmaceutical market trends and health policy, and its government has specified in its “Initiatives for deepening the medical & health system reform, 2013” in August, 2013 that Class II hospitals’ EDL drugs usage and sales volume must reach 40-50% of the total, while the EDL drugs percentage for Class III must reach 25-30%. In related to EDL, the new revision of NRDL(2009 edition) is reported to be published by MOHRSS within 2013, and the industry has predicted it would be no surprise that drugs listed in the new NRDL would be required to lower the price again. In China, drugs are divided into four categories: patented drugs, generics, originators (i.e. off-patent branded drugs) and independently priced drugs (i.e. drugs which are priced externally
to their respective molecule classes). In previous rounds of price cuts, most MNCs’ originators and independently priced drugs were little impacted. However, now the NDRC has clearly pointed out that the winner drugs with pricing privileges in EDL tenders must also abide by retail price ceiling for their respective molecule classes.

China central government has put biopharma industry as one of the seven strategic emerging sectors in the China’s "12th Five-year" Plan and commits 10 billion yuan for new drug innovation during the period of 2010-2015. Adding on the private sector’s counterpart funding to government funded projects, it will make total funding to new drug R&D up to 40 billion yuan. However, when the fund is divided up by hundreds of projects, available funding to each projects is estimated between 5 million to 25 million yuan, which is very modest comparing to the average cost of new drug R&D worldwide. Although reported as the first round of outcomes of “State Key New Drug Development Program” by September 2010, 16 new drug certificates had been issued and 96 drugs were in Phase I and Phase II clinical trials in China, with 36 in Phase III trials, the real achievements of the new drug R&D is a bit suspicious. In 2012, the number of applications accepted for chemical drugs in Class 1.1 reached 78 whereas in 2009 there were only 42 applications. To further increase the productivity and streamline evaluation and approval, on February 28th, 2013 the CFDA published the “Opinions on Deepening Drug Evaluation and Approval Reform and Further Encouraging Drug Innovation”.

On one side Government is supporting the innovation. On the other side, it is trying to streamlining the industry especially on production, distribution and price. A new Chinese GMP was effective on March 1, 2011. The new GMP developed according to EU GMP and WHO GMP sets much higher standards for pharmaceutical productions and CFDA had forecasted that by the deadline of GMP enforcement, 500-1,000 manufacturers would be abandoned from the Chinese market. In March 2009, Government issued policy to require centralized purchase of drugs so as to reduce tiers of distribution between manufacturers and hospitals. Small distribution companies taking about 20% of 12,000 drug wholesalers are likely closed down. At the same time, foreign companies and investors are actively acquiring shares of leading China’s pharmaceutical wholesalers and chain pharmacies. A more consolidated drug distribution market in China is expected to be in place in 2020.

Market Challenges

The pharmaceutical market segment in China is very fragmented, with Pfizer owning the single highest market share at 3%. The country has a complicated, multi-tiered pharmaceutical supply chain that involves more than 12,000 local wholesalers. China’s top three leading national distributors Sinopharm Group Co., Shanghai Pharmaceutical Co. and Jointown Pharmaceutical Co. only have a combined market share of 20%.[9]

On top of the fragmented supply chain, the cumbersome registration and reimbursement process for new therapies makes it difficult for companies to launch new products and for foreign SMEs to enter the market. Registration of new innovative products in China requires local clinical trials (CTs) no matter whether or not CTs have been conducted for the product in its home market. For example, a class III drug for treating a cold, its CT will take about one year and cost 2-3 million yuan, while a class III anti-tumor drug, its CT will take at least 3 years and cost 8-10 million yuan. Eight years of CT and 60 million CT cost is expected for a class I anti-tumor. Further, some herbal medicines which can be registered in Canada as Natural Health Products are considered as TCMs and subject to a strict drug registration process to enter the market.

Processing times have been a traditional problem for the industry. While the United States FDA has
Several thousand staff, the Chinese Center for Drug Evaluation (CDE) only has 120 total staff, of which 3 are assigned to data auditing. According to the 2012 Annual Report for China’s Drug Evaluation issued by CDE, they received 6,919 drug applications in total. Despite the slow pace throughout the whole application process, the waiting time from application to evaluation has been shortened to four months, which is seen by the pharmaceutical industry as a great improvement. The report also says that the majority of evaluations for IND application of chemical drugs in 2012 were completed within 8 months (72%), 45% took 6 to 7 months and 11% took less than 5 months.

<table>
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<th>Classification</th>
<th>New Drugs</th>
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Opportunities for Canadian Companies

- License new drugs in your pipeline to a Chinese pharmaceutical company doing relevant R&D
- License the China market rights of a pharmaceutical product to a Chinese partner
- Provide contract research services to a Chinese company with a product in their pipeline that they are targeting at an overseas market
- Jointly conduct R&D with a Chinese partner for new drugs and therapies
- Perform clinical trials in China
- Source API and manufacturing equipment, and packing materials from China

Reference Information

Useful References

- Life Science and Healthcare in China: Opportunities, Challenges and Implications (Deloitte)
- Investing in China’s Pharmaceutical Industry - 2nd Edition (PWC)

Key Organizations & Associations in China

- China Chamber of Commerce for Medical and Health Products Import and Export
- China National Center for Biotechnology Development
- China Pharmaceutical Industry Research and Development Association (SINO-PhIRDA)
Key Events

Pharmaceuticals & Biotechnology

- **CPHI China**
- **API China** (Semi-annual)
- **PHARMCHINA (China Pharmaceutical Exhibition)**
- **CHINAPHARM (China International Pharmaceutical Exhibition)**
- **BIO China International Conference**

Canadian Government Contacts in China

Are you a Canadian company in the Life Sciences field interested in China and Hong Kong? Our network of Trade Commissioners across China and Hong Kong can help.

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Footnotes


[4] Linkshop, United Business & Information Center - Next year China prescription drug market size is estimated at $50 billion

[5] China News Network - Healthcare companies are "testing the waters" in China’s billion OTC market


[9] Xinhua News