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NAVIGATING CHINA: LOCKING IN SUSTAINABLE GROWTH IN THE PHARMACEUTICAL SECTOR

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ABSTRACT: China pharmaceutical industry is one of the fastest growing pharmaceutical industry. Due to the presence of various factors such as the growth of economy, large population, rising health care, increase in the health spending the industry is growing. There is a presence of both domestic and international players in the market. The paper also focuses on the SWOT (Strength, Weaknesses, Opportunities and Threats) analysis of the chinese pharmaceutical market. There are various laws and regulations in the pharmaceutical industry These laws and regulations covers things such as clinical trials, drug manufacturing, generic drugs, imported drugs etc. These drugs are first classified into various categories.

Keywords: Pharmaceutical, SWOT, players, generic, economy, clinical.

I. INTRODUCTION

The Chinese pharmaceutical industry has been growing at an average annual rate of 16.72% over the last few decades.[1] It is growing at an increasing rate. Investment conditions in China have improved due to the vast consumer demand for pharmaceuticals, the lower labor costs and the changes resulting from economic reform. Changes to the patenting laws in full compliance with the requirement of the Agreement on Trade-Related Aspects of Intellectual Property Rights (or "TRIPS Agreement") and the lack of Chinese pharmaceutical R&D have also left gaps in the market.[1]

NET WORTH	YEAR	SOURCE
105 billion USD	2014	https://globenewswire.com/news-release/2015/07/21/753676/0/en/Pharmaceutical-Industry-in-China-2015-2020.html
200 billion USD	2020	https://globenewswire.com/news-release/2015/07/21/753676/0/en/Pharmaceutical-Industry-in-China-2015-2020.html
GROWTH RATE	16.72%	WIKIPEDIA

II. KEY TRENDS OR GROWTH TRENDS

Key drivers of market expansion are the

- rising health care awareness and needs
- The economy is growing at an increasing rate
- Very large population
- Increase in health spending
- Rapid Economic Growth in terms of GDP and disposable income

III. KEY PLAYERS

Region	Fraction of Market	Main Distributors
East	44	Shanghai Pharma, Sinopharm, Nanjing Pharma, Huadong Medicine, Anhui Huayuan
North	20	Beijing Pharma (China Resources Medication Group, Sinopharm, Pacific Group, Tianjin Pharma
Central-south	20	Accord Pharmaceutical (Sinopharm, Guangzhou Pharma, Sinopharm, Jointown Pharma, Changsha Double-Crane Medicine
South-	8	Chongqing

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west		Medicines, Chongqing TongJunGe, Yunnan Pharma
North-east	5	Sinopharm, Harbin Pharma
North-west	3	Xinjiang Pharma, Lanzhou Pharma, Qinghai Pharma

Source: Ministry of Commerce of PRC, Booz & Company

IV. SWOT(STRENGTH, WEAKNESSES OPPORTUNITIES AND THREATS) ANALYSIS

SWOT analysis is a method that evaluates the four elements: strength, weaknesses, opportunities and threats of anything. The SWOT analysis can be done for company, industry, person or anything. The meaning of various terms in the SWOT analysis means:

- Strength: Distinguishing features of the project on whom the analysis is being done and how those features give it an edge over the others
- Weaknesses: The features that give the project a disadvantage over the others
- Opportunities: Elements elements that the business or project could exploit to its advantage[3]
- Threats: elements in the environment that could cause trouble for the business or project [3]

V. SWOT ANALYSIS OF THE CHINESE PHARMACEUTICAL INDUSTRY

5.1. Strengths:

- Chinese drug makers do not share the development costs, liability costs and quality assurance costs of global players; moreover, they are able to offer drugs produced on a completely different and intensely competitive cost base.[4]
- Cheap labour is one of the key strength of the chinese pharmaceutical industry. Also, the working hours are subject to change which further adds to the strengths.
- Raw materials available in china are often cheaper in comparison to the other countries.

5.2. Weaknesses

- The chinese pharmaceutical company is suffering from domestic overcapacity.
- Most of the biotech products currently manufactured by Chinese domestic companies are generics. Moreover, public research institutes are relatively isolated from the market resulting in poor market orientation and a lack of experience in the commercialisation of research. - R&D spending is commonly only 2% of sales.[4]

5.3. Opportunities

- Improvements in the economic environment.
- Exporting out of China is a strategy that Chinese domestic companies are pursuing. The exporting activities of domestic companies with products at earlier stages of the pharmaceutical value chain will remain strong.[4]

5.4. Threats

- Rapid consolidation as smaller domestic players are taken over by larger companies
- Domestic overcapacity to produce basic, cheap generic products will force local producers to export their products to obtain better returns for their products and to survive.[4]

VI. DISTRIBUTION SYSTEM:

China has a three tier distribution system through which the drugs reach the patients. At the top of the system are the pharmaceutical companies. The pharmaceutical companies then supply their drugs to the wholesalers. The wholesalers then supply their drugs to either hospitals or pharmacies and then the drugs are delivered to the patients from the hospitals and the pharmacies. There are some problems also associated with the current distribution system. Due to improper infrastructure there has not been proper delivery to the rural areas of the country.

VII. REGULATORY ASPECTS

The Drug Administration Law of the People's Republic of China, the country's first comprehensive legislation regulating the research, production and distribution of drugs was adopted in 1984. This law was revised "to strengthen drug regulation and to ensure drug quality and safety", according to the government, at the 20th Session of

the Standing Committee of the 9th National People's Congress on February 28, 2001, and became effective on December 1, 2001. [6]

VIII. LEGAL ASPECTS

8.1 Drug Registration Policy:

A set of laws and guidelines regulate the pharmaceutical industry in China. These laws and regulations cover things such as clinical trials, drug manufacturing, generic drugs, imported drugs etc. These drugs are first classified into three categories:

1. Chemical Drugs

2. Biological Drugs

3. Natural Drugs

These drug registrations have several classes in them according to which the registration is done.

For chemical drug there are 6 classes:

1. A new drug which has never been marketed in any country. [6]
2. A new drug preparation which changes the administration route1 of the marketed drug, and has not been marketed anywhere in the world in this form. [6]
3. A new drug which is already marketed outside of China, but has not been marketed in China. [6]
4. A new drug which changes the acid or alkali (or metal) radical of a product marketed in China, but does not change the pharmacological effect.[6]
5. A new drug preparation which has a different dosage form from drugs already marketed in China, but does not change the administration route.[6]
6. Drugs that have already established national specifications in China (generics).[6]

For therapeutic biological product registration, there are 15 different classes:

1. A new biological product which not been marketed before in any country. [6]
2. Monoclonal antibody. [6]
3. Gene therapy, somatic cell therapy, and their preparations. [6]
4. Allergen preparation. [6]
5. Multi-component bioactive products extracted from human and/or animal tissues and/or body fluid, or by fermentation. [6]
6. A combination drug preparation which consists of biological products that are already marketed in China. [6]
7. A drug currently marketed outside of China, but has not been marketed in China.[6]
8. Microbial drug preparations which are produced from cell strains that are not yet approved. [6]
9. A drug preparation with a changed structure from an already-marketed product, where this changed new preparation has not been marketed anywhere around the world (changes include chemical modification, amino acid locus mutation or absence, different expression system, etc.) [6]
10. Drug preparation with different manufacturing processes from an already marketed product (different host cells, expression system, etc.)[6]
11. A drug preparation made for the first time with DNA recombination technology.[6]
12. A new drug preparation with a changed administration route from a marketed product, such as non-injection vs. injection or topical vs. systemic administration, where the new preparation is not marketed anywhere in the world. [6]
13. A new drug preparation which has a different dosage form from a drug already marketed in China, but the same administration route.[6]
14. A new preparation with changes in the administration route from a marketed product, but not including cases falling into class 12. [6]
15. Drugs that have already established national specification in China (generics).[6]

8.2 Drug Registration Applications:

There are 5 types of drug applications in China:

Generic Applications: Generic applications are generally used for drugs that are either listed in chinese Pharmacopoeia or have National Standards in China.

Imported Drug Applications: These are generally used for drugs that are manufactured outside China.

Other drug applications are New Drug Application, supplemental applications and licence renewal.

IX. CONCLUSION

The pharmaceutical industry is one of the leading industry all over the world. China is world's most populous country. It has great potential for the pharmaceutical industry to grow. Various growth drivers such as rising population, increasing spending o the health further add to the growth of the pharmaceutical industry pharmaceutical industry of China provides unique opportunities for the emergence of various innovative business models. But there is still a great deal of uncertainties in the industry.

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