White Paper on

DRUGS AND PHARMACEUTICALS SECTOR

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SECTION 1 - INTRODUCTION

1.1 Introduction to Ease of Doing Business

The "Ease of doing business" is a World Bank index which is widely used to rank 189 countries for their present business laws and regulation environment every year. The index however does not take into account general conditions like macroeconomic indicators, market proximity, infrastructure etc. Further, "Ease of doing Business" ranking is characterised by the average of 11 sub-indices like starting a business, getting credit, electricity, registering property etc. A higher ranking indicates efficient and simpler regulations for business and strong protection of property rights. This index not only identifies the source of the obstacle for doing business in a country, but also serves as the basis for policymakers to compare the regulatory environment for business across countries and design more compelling regulatory reforms for future.

India is one of the fastest growing economies in the world and has become one of the most attractive investment destinations in the world. On analysing "Ease of doing business" index for 2016, we observe that India has moved up its ranking to 130, up by 4 units as compared to the previous year. The improvement in ranking is mainly because of the ongoing reforms and the 2 major drivers are, "Distance to frontier" sub-index where India outperformed all the South Asian countries since 2004. The biggest improvement came from "Getting Electricity" sub index where the ranking jumped to 70 in 2016 from 137 in 2015. In order to complement its economic growth, India has to set major reforms to improve its "Ease of doing business" ranking and attract more investors.

While the Government of India (GOI) is constantly encouraging investments, the Department of Industrial Policy and Promotion (DIPP) is complementing the government's initiative by taking several initiatives to ease doing business in India. The future reforms taken by GOI must ensure that India is on equal footing amongst other countries in terms of flexible, favourable, efficient and a transparent business environment.

With this in view, the British High Commission (BHC) has initiated a study called "Breaking Business Barriers" for various sectors in India, which focuses on stakeholder engagement and arriving at insights around business barriers. Specific recommendations have been identified for each of these sectors. The main objective of this report is to emphasize on the retail sector and the various barriers faced by businesses. We hope that the findings of this report would help bring the issues of retail sectors to the forefront and also serve as a reference point for the imminent need to pursue reforms in business policies and processes.

1.2 Introduction to Breaking Business Barriers

Centre for Public Policy Research (CPPR) in association with the British High Commission (BHC) has taken up an initiative '**Breaking Business Barriers**' aiming to curtail the regulatory barriers in

setting up, operating and exiting a business in the states of Karnataka, Kerala and Tamil Nadu. The initiative focuses on easing the business in seven sectors – Drugs and Pharmaceuticals, Education, Energy, Information Technology (Hardware & Software), Infrastructure, Retail and Manufacturing.

The initiative intends to enhance the development of a business-friendly environment in these states, by removing the regulatory barriers in doing business. The collaboration with the stakeholders has helped to identify the issues and challenges faced by them in operating the business and work towards finding a solution. In this regard, CPPR organized round table meetings with the Government representatives and business community in order to understand all relevant information regarding policies, taxation regimes, rules and other general information for doing business.

The website EasyBiz (easybizindia.com) India is created for the purpose of giving insights into the policy framework in the three states and measure state competitiveness. The website offers an interactive portal for the entrepreneurs to flag the issue faced by them in operating the business and work with one another to resolve the issue. The portal also has a clear process flowchart of the steps involved in starting a business (licenses, NOC, certificates) in the three states.

SECTION 2 - SECTOR OVERVIEW

2.1 Definition of the sector

As per THE DRUGS AND COSMETICS RULES, 1945 (as corrected up to the 30th April, 2003) the term "drug" includes - (i) all medicines for internal or external use of human beings or animals and all substances intended to be used for or in the diagnosis, treatment, mitigation or prevention of any disease or disorder in human beings or animals, including preparations applied on human body for the purpose of repelling insects like mosquitoes; (ii) such substances (other than food) intended to affect the structure or any function of human body or intended to be used for the destruction of 6 (vermin) or insects which cause disease in human beings or animals, as may be specified from time to time by the Central Government by notification in the Official Gazette;] 2 [(iii) all substances intended for use as components of a drug including empty gelatine capsules; and (iv) such devices intended for internal or external use in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals, as may be specified from time to time by the Central Government by notification in the Official Gazette, after consultation with the Board.

2.2 Drugs & Pharmaceutical Sector in India

India enjoys a significant global position in pharmaceutical sector. According to a sector analysis by Equite Master Indian Pharmaceutical industry, the Indian Pharmaceuticals market is the 3rd largest volume wise (10 per cent) and the13th largest (1.4 per cent) value wise globally. India is the largest exporter of generic drugs globally which account to 20 per cent. Of the total export of drugs, 55 per

cent constitutes formulation and 45 per cent constitute bulk drugs. The total retail medicine market in India is worth anywhere between Rs 45,000 and Rs 50,000-Cr (The New India Express, 2014). The Government of India has allowed 100 per cent FDI through automatic route. According to data released by the Department of Industrial Policy and Promotion (DIPP), the drugs and pharmaceuticals sector attracted cumulative FDI inflows worth US$ 13.32 billion between April 2000 and September 2015. The sector which is currently growing at 15 per cent is expected to double by 2020. According to McKinsey report on Pharma 2020 the Indian India's pharmaceutical sector is poised to grow to $ 55 billion by 2020 (McKinsey, 2015). According to the report, the Indian Pharma Industry will be comparable to all development markets other than US, China and Japan.

India has the maximum US Food and Drugs Administration registered manufacturing units which stood at 523 by March 2014. This has given a competitive edge for the Indian pharmaceutical sector globally. This will also help Indian which is currently eyeing to capture Japanese market which has currently opened up the import of medicine to cater to its ageing population and higher cost of health care. The per capita consumption of drugs in India, stands at US$3, is amongst the lowest in the world, as compared to Japan- US$412, Germany- US$222 and USA- US$191. Apparently, this huge gap indicates the underlying opportunities (McKinsy, 2015).

The Indian Pharmaceutical Industry is one of fastest emerging international Center for Contract Research and Manufacturing services (CRAMS). The main factors for the growth of the CRAMS is due to the international standard quality and low cost. The estimated value of the CRAMS market in 2006 was $ 895 million (Business Maps of India, 2015)

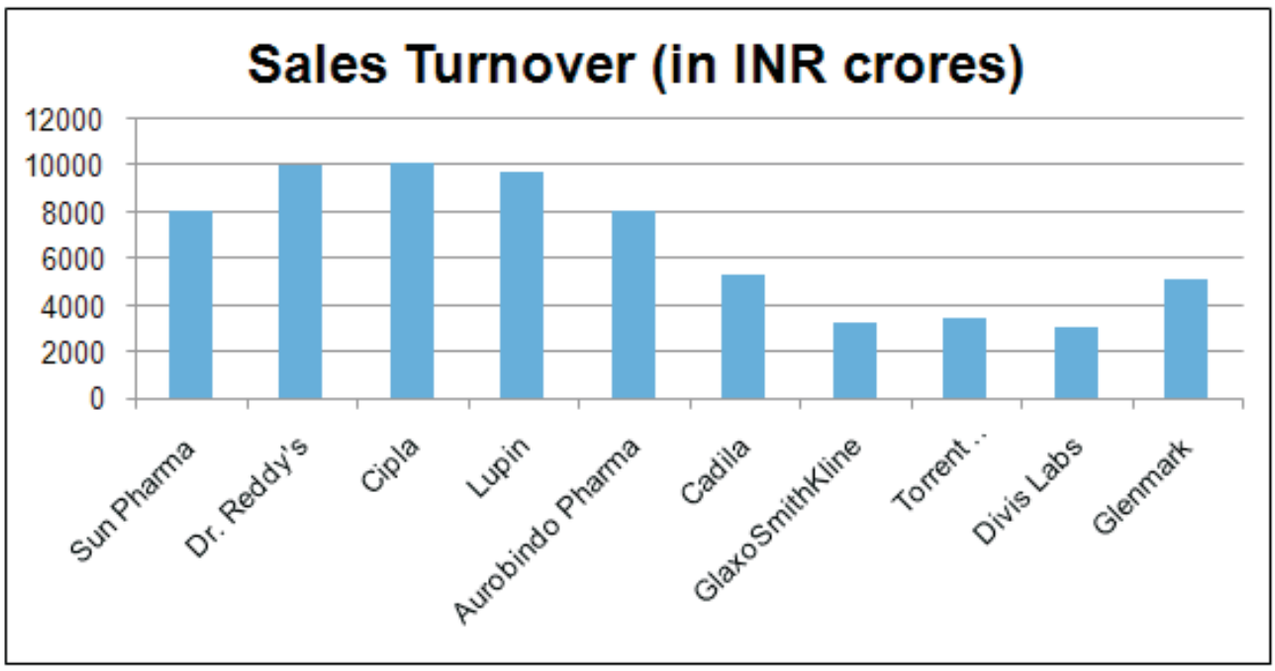
The Indian sector is estimated at Rs 1 Lac crore per year including import & export. It employs around 42 Lac (4.2 million) people in pharmaceutical manufacturing and ancillary sectors. The Indian Pharmaceutical Market is valued at Rs 860 billion for the year ending March 2015.

As per IBEF, Indian Biotechnology industry, which is the largest sub-sector, is also expected to grow at an average growth rate of around 30 per cent a year to reach US$100 billion by 2025 (IBEF 2016). The annual turnover of the Indian Pharmaceutical Industry is estimated to be about Rs. 128044.291 Crores during the year 2013-14. The share of export of Drugs, Pharmaceuticals and Fine Chemicals is Rs. 63293.912 Crores (Annual Report 2014-15 Department of Pharmaceutical, GOI). India as a total of 24,000 pharmaceutical companies, out of which only 250 are organised. This 250 organised companies control 70 per cent of the Indian market.

2.3 Major Players

As of 2014 India has a total of 24,000 pharmaceutical companies, of which around 250 fall under the organised category. These 250 organised units control nearly 70 per cent of the market. About 8,000 small scale units together form the core of the pharmaceutical industry in India, including 5 Central Public Sector Units. About 75 per cent of the top 20 pharma companies are Indian owned.

Figure 1: Sales Turnover of top 10 pharmaceutical companies as of 2014



2.4 SMEs in Pharmaceutical Sector

SMEs play crucial roles in Indian pharmaceutical company. According to India Micro, Small and Medium Enterprise Report 2013 the Indian pharmaceutical industry is highly fragmented and estimated to have 9,456 units in the SME segment, which account for around 87 per cent in production by volume and 40 per cent by value."

In India, SMEs are mainly focus on manufacturing and niche marketing like Contract Research and Manufacturing (CRAMs) and Bio-pharma. A report by Asia Net India states that it is recognised that the MSME units can effectively meet the two major public expectations viz. cost effective and affordable medicines of given framework of excellent manufacturing process, technology, regulatory compliance, distribution system and prices (Asia Net India SMEs likely to plan important role in Pharma growth story.

2.5 Foreign direct investment in Pharmaceutical Sector

Foreign Direct Investment (FDI) up to 100 per cent has been in operation in Pharmaceutical Sector since 2001. However, after the acquisitions of some of the major Indian Pharma Companies like Ranbaxy and Piramal, Department of Industrial Policy & Promotion in November, 2011 revised the FDI Policy. At present 100 per cent FDI in pharmaceutical sector is allowed through automatic route for greenfield investment. In brownfield investment FDI is permissible Government approval route. Further in brownfield investment 'noncompete' clause is not allowed except in special circumstances with the approval of the Foreign Investment Promotion Board (FIPB). Also, FDI up to 100 per cent through automatic route for manufacturing of medical devices has been allowed.

Table 1: Regulatory Bodies guiding Pharmaceutical Sector in India

STAGE	CLINICAL TRIALS	NEW DRUG APPROVALS	MANUFACTURING	DISTRIBUTION AND SALE	POST MARKETING SURVEILLANCE
Regulatory Functions	Applications online in the Clinical Trials Registry - India (CTRI) Approval of applications · Good Clinical Practices · Inspections · Registration of Ethics Committee · Serious Adverse Events (SAE)	· 12 Subject Expert Committees (SECs) for deliberation on new drug applications for grant of marketing licence · Import of new drugs (Registration of foreign manufacturers and grant of licence to import)	Application for Licence to manufacture (Generics and those with marketing licence) · Inspection of Good Manufacturing Practices (WHOGMP/Schedule M) · Grant of Licence to Manufacture · Collection of Samples, testing and prosecution for Non-Compliance	· Application for Licence to distribute and sell · Inspection of Good Distribution Practices (GDP) and sale premises · Grant of Licence to distribute and sell · Prosecution for Non-Compliance	· Periodic Safety Update Reports (PSURs) required to be submitted (Schedule Y of the Drugs and Cosmetics Rules) for new drugs granted marketing licence · Banning of Drugs considered harmful or subtherapeutic under Sec. 26A of the DCA · Pharmacovigilance Programme of India (PvPI) is the national coordinating centre for collecting Adverse Drug Reaction Reports from Adverse DrugM

Authority Responsible	CDSCO (appointed by the MOHFW, Central Government.) has the sole responsibility –relies on expert committees.	CDSCO has the sole responsibility	SDRA (appointed by the Department of Health, State Government) has primary responsibility Exceptions (CDSCO competence) - CDSCO acts as SDRA in Union Territories (e.g. Delhi) - WHO-GMP Inspections - High Risk Products (IV Fluids, Large volume parenterals, Vaccine and Sera, Blood and Blood Products, r-DNA products (CDSCO may include new products in this list via notification)	SDRA has the sole responsibility	CDSCO has sole responsibility for PSURs and Indian Pharmacopoeia Commission (IPC) is in charge of co-ordinating Adverse Drug Reports (ADRs)

2.6 Government Initiatives:

Some of the major initiatives taken by the government to promote the pharmaceutical sector in India are as follows:

- The Government of India plans to incentivise bulk drug manufacturers through 'Make in India' programme and reduce dependence on imports of active pharmaceutical ingredients (API), nearly 85 per cent of which come from China.
- The Department of Pharmaceuticals has set up an inter-ministerial co-ordination committee, to conduct periodically review, coordinate and facilitate the resolution of the issues and constraints faced by the Indian pharmaceutical companies.
- The Department of Pharmaceuticals has planned to launch a venture capital fund of Rs 1,000 crore (US$ 154 million) to support start-ups in the research and development in the pharmaceutical and biotech industry.
- Indian and global companies have expressed 175 investment intentions worth Rs 1,000 crore (US$ 150 million) in the pharmaceutical sector of Gujarat. The memorandums of understanding (MoUs) would be signed during the Vibrant Gujarat Summit.
- Telangana has proposed to set up India's largest integrated pharmaceutical city spread over 11,000 acres near Hyderabad, complete with effluent treatment plants and a township for employees, in a bid to attract investment of Rs 30,000 crore (US$ 4.5 billion) in phases. Hyderabad, which is known as the bulk drug capital of India, accounts for nearly a fifth of India's exports of drugs, which stood at Rs 95,000 crore (US$ 14.3 billion) in 2014-15.
- At the launch of Cluster Development Programme of pharmaceutical sector, Ananth Kumar, Minister of Fertiliser and Chemicals, announced that six pharmaceutical parks will be approved and established this year which will have sufficient infrastructure and facilities for testing and treatment of drugs and also for imparting training to industry professionals.

2.7 Overview of Pharmaceutical Industry in the states

Karnataka

Karnataka has emerged as a centre for generics, medical devices, biotech and drug discovery. The industry is growing at 17.82 percent. In 2006-07 it accounted for 55 per cent of the total Biotech companies in India (Financial Express). The state pharmaceutical industry constitutes 1000 pharmaceutical manufacturing units in Karnataka, out of which only a handful of units are under organised. The sector provides around 25,000 direct employments and generates Rs. 12,000 crore worth revenues. Total export revenue constitutes to Rs. 5,000 crore is from exports. It is. It is also

expecting the clearance for the formation of the Karnataka Pharmaceutical Development Council (KPDC) with a budgetary provision of Rs. 1 crore and the Vision Group on Pharmaceuticals with an Rs.25 lakh allocation, which are two monitoring agencies for the development of the sector.

Tamil Nadu

Tamil Nadu Drugs & Pharma sector is estimated at Rs 1500 crores per year including exports and domestic. It consumes about 8 per cent of the domestic drug consumption of total Indian market which is approximately Rs 4800 crores per year. Though there is a huge domestic market in the state, the industry is only able to produce Rs. 1200 crores worth drugs.

Kerala

Kerala has 93 pharmaceutical companies and numerous Ayurvedic medicine manufactures. The retail market of Kerala is projected at Rs. 4,000 to 5,000 crores accounts to 8.8 per cent of the total Indian drug retail market (New India Express 2016).

SECTION 3-WAY FORWARD

Propelled by growth of middle class and increased health consciousness and purchasing power the Indians and demand for low cost quality medicine, the Indian pharmaceutical sector is slated to growth at double digits. However, it is often cited by the industry that the regulatory system in India are very complicated which has been acting as a deterrent to the growth of the industry. To find the issues faced by the industry Centre for Public Policy Research conducted round table discussions with the industry and government representatives in Karnataka, Tamil Nadu and Kerala. This section focuses on the outcome of the deliberation during the round table discussions.

3.1 Entry

Issues

Multiplicity of Ministries

The main issues which was pointed out in all the states' round table discussions was that the apart from the usual issues of usual tedious process of getting licenses for building plan, factory licenses, obtaining NOC from Fire and Safety department, pollution control board, for setting up a company, the Industry is ladened with a plethora of compliances and gamut of regulatory Central and State ministries and department. Centre approves new drugs for the market, clinical trials, blood banks, large volume parenteral, vaccines, Sera, imported drugs, testing of drugs by central drugs labs. State provides licensing for drug manufacturers and sales establishments, approval for drug formulations for manufacturing, inspections.

There are various Ministry & departments both at the Centre and State which regulates and controls the sector. For example, Pharma industry is controlled both by Centre Government and the State government Health Ministry. Drug Controller General of India DCGI reports to Central Health Ministry while the licensing authority of the state reports to State Ministry of Health. There is no coordination between the state and the Centre.

The pharmaceutical department under Chemical and Fertilizer Ministry controls the drugs pricing. However, it does not have any say in the licensing and export of the medicines.

The Export is handled by the Pharmexcil which reports to Ministry of Commerce at the Centre. Though they have plan for export promotion of the sector, but cannot contribute to the SMEs need.

The industry has to go to other Ministry like the Food Ministry for production of Dietary supplementary, obtain permission from Narcotic Department under the Home Ministry as some of the medicines are listed under narcotic. For natural and Sidha medicine the ministries and the departments differ.

The dual regulation of the state and the centre has not helped the pharma industry. At one side the companies are made to run between centre and state and at the other side the industry is inflicted with spurious and non effective medicines. It is because the though the Centre may have rejected a formulation, but the state has the power to clear them. The recent ban of 344 Fixed Dose Combination **(FDC)** medicines with the Supreme Court support reveals this fact.

The Ranjit Roy committee's report which was to review the assigned to formulate Policies and guidelines for approval of New Drugs, Clinical Trials and Banning of Drugs in 2013 also reiterates this fact. This country has a unacceptable number of drug formulation accounting to around 60,000 to 80,000. This is due to the Centre's inability to stop this drugs coming to the market because of the reason stated earlier. Another interesting thing is that if one state rejects the production of a particular formulation another state can give approval for the same. The company can produce and market the medicine in the state which had rejected the formulation. Now all of a sudden there is a chaos in the market. The drug producers are in a fix. They say there would have a single authority to regulated and promote the sector, such a chaos would not have happened.

Land

Apart from the usual hurdles of land availability, registration and conversion of the, during the round table discussion it was found that the SMEs in the sector in Karnataka is facing a major issue in land. The Karnataka government makes it mandatory for them to make upfront payment for the land procured from it. This adds a burden to the small players.

Suggested Reforms

1) Single Regulatory Authority

Most of the leading developed nations have single authority to promote and regulate the pharmaceutical industry. This enables them to monitor and frame policies for the industry. India should also have a Single authority. The ministry of Chemical and Fertilizer has Pharmaceutical department. This should be given more power to give licenses and promote policies for the sector. The states should not have separate power to give licenses. The State Drugs Control Board should come under the Department of Pharmaceutical at the Centre. At state level the entrepreneurs should go through the SDCB for licensing and NOC. The Pharmaceutical Department should coordinate with other ministries at the Centre to facilitate the licensing and permits. The SDCB should coordinate with the department and other state ministries and departments to better facilitation. The entrepreneurs need not go the centre for any licensing. It should be done by the SDCB.

2) Lease/rent of Land:

They were of the opinion that the land in Karnataka should be given as lease or rent. This will help a long way in strengthen the small players which will in turn make them competent and competitive.

3.2 Operate

Issues

1) China dumping cheap and inferior quality raw material

Due to stringent environment laws in India, 90 per cent (as per the data from Industry & Pharmaceutical Export Promotion Council of India) of the raw material is sourced from China. India import antibiotic, penicillin and its derivations, stains, glitazones and solvents and excipients used in all formulation. There is no mechanism to check the quality of the raw material procured from China. Mostly the Chinese suppliers source raw materials from authorised manufactures. This seriously affects the quality of the medicine. US FDA has set up 4 offices in Indian and has posted 19 officials to inspect the manufacturing units that supply medicine to US. The government of India has allocated Rs. 180 crore for setting up offices in China to monitor the quality of raw materials and medical devices. But it is yet to take action.

2) Cumbersome Methanol Licensing in Tamil Nadu

In order to curb the illicit use of Methanol, Tamil Nadu has brought the chemical under prohibition act. However, this has brought unnecessary headaches for the pharmaceutical

companies in the state. For medicine production hardly 10 liters of methanol is used annually by the companies. As per the act the companies have to provide a manned storage place and a register to need to maintained for the chemical.

They have to get special permission from the District Collected to use the chemical. Obtaining permission is not an easy process. The companies have to get NOCs from two offices i.e Excise department and the local police. After they submit the NOCs at the collector's office the Collector or his representatives will visit the companies premise for inspection. Only after they get satisfied will they give the permission to use the chemical. The whole process is tedious and time consuming.

3) Lack of right to procure raw material from the forest

Due to stringent environment laws it is becoming extremely difficult to sourced raw materials from the forest. This issue was especially identified by the drugs manufacturers in Kerala. They are forced to source raw materials from North eastern region of India, which significantly increases the cost of production.

4) Stringent and archaic Labour Law

The labour and shop and establishment act do not allow women to work after 7 pm. This is a serious concern for the industry who often have to continue production after 7 pm. The law compels the companies to provide for conveyance and security for women workers after 7 pm. The pharmaceutical companies' employee medical representatives who call on the doctor which continues even after 7 pm.

Suggested Reforms

1) Quality in Import

The government should set up offices in China for ensuring quality of the raw materials. It should create an inventory of all the suppliers and inspect their facilities and sourcing. It should work with the Chinese government to ensure that the suppliers adhere to certain minimum standards of quality.

2) Exemption for Tamil Nadu Manufactures from Prohibition Act

The pharmaceutical companies could be exempted from the prohibition act. This will ease them off unnecessary time consuming.

3) Right to Collect Raw Material to Manufacturers

Some part of the forest could be allocated for sourcing raw materials. The states' forest dwellers could be made partners to the growth of pharmaceutical industry. They could be assigned and incentivised to grow, preserving and source medicinal plants and raw material required for the Industry.

4) Increase the minimum working hours

The current working hours provisions debar women from gain opportunities similar to their male counterpart. The industry is of the opinion that the working hour should be raised to 9 pm in big cities like Chennai and Bangalore.

3.3 Exit Process

Issue

There is no specified exit process for this sector. It follows the usual course of either merging or acquisitions or bankruptcy or surrendering of licenses which take a long time.

Suggested Reform

There should be a clear and online procedure for this sector's exit policy. There should be proper mechanism for bailing out sick companies before they become a liability for creditor. The bankruptcy bill will if implemented will help the industry to have a defined guideline for companies in case of bankruptcy.

SECTION 4 - CONCLUSION

Pharmaceutical industry has been performing consistency over the few decades. Cost effectiveness and quality have been to two factors which has helped the industry to go a long way. In the rapidly changing global scenario the industry will need to have withstand pressure and continue to growth at double digits. Flexible regulatory framework and monitoring process will add to the strength of the sector.

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The Report on “Breaking Business Barriers (BBB)” has been the culmination of the research conducted by Centre for Public Policy Research on theme of 'Ease of Doing Business' in three southern India states namely; Kerala, Karnataka and Tamil Nadu.The project was executed for a year starting from May, 2015.

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