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Pharmaceutical Industry- Studious or spurious? - An Indian Context.

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ABSTRACT

Indian pharmaceutical sector accounts for about 1.4 per cent of the global pharmaceutical industry in value terms and 10 per cent in volume terms. India accounts for 20 per cent of global exports in generics. The country's pharmaceutical industry is expected to expand at a CAGR of 14.5 per cent over 2009–20 to reach USD55 billion. Indian healthcare sector, one of the fastest growing sectors, is expected to advance at a CAGR of 17 per cent to reach USD280 billion over 2011–20. The generics market is expected to grow to USD26.1 billion by 2016 from USD11.3 billion in 2011 and India's generics market has immense potential for growth. This case study discusses the overview of the present growth prospects of Indian pharmaceuticals and the value drivers in rural market. It highlights on the other face of the pharma market i.e. spurious drugs market and its consequences in India. Finally, it also provides the India's stand on anti-spurious drugs and its remedies for the safe life of Indian consumers.

Keywords: Indian Pharmaceutical industry, Indian Pharma case study, Pharma rural market, spurious drugs

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INTRODUCTION

Pharmaceutical Industry- Indian Scenario

India is among the top six global pharmaceutical producers in the world. Indian vaccines are exported to 150 countries. India produces 40-70 per cent of the WHO demand for DPT & BCG and 90 per cent of measles vaccine. Approximately 70 per cent of the patients in developing countries receive Indian medicines through NGOs like The Clinton Foundation, Bill & Melinda Gates Foundation, Doctors without Borders, the UNCTAD etc. Presently there are 10,500 manufacturing units and over 3,000 pharma companies in India, growing at an exceptional rate. India has about 1,400 WHO GMP approved manufacturing units. India has been accredited with approximately 1,105 CEPs, more than 950 TGA approvals and 584 sites approved by the USFDA. Globally more than 90 per cent of formulations approvals for Anti-retroviral (ARVs), Anti-tubercular & Anti-malarial (WHO pre-qualified) has been granted to India. Manufacturing costs in India are approximately 35-40 per cent of those in the US due to low installation and manufacturing costs. India ranks amongst the top global generic formulation exporters in volume terms. India's pharma exports stood at US$ 15 billion in 2013-14.[1]

The Ministry of Commerce targets to export USD25 billion worth of pharmaceuticals in 2016. Indian drugs are exported to more than 200 countries in the world, with the US as the key market. (Exhibit1). India exports all forms of pharmaceuticals from APIs to formulations, both in modern medicine and traditional Indian medicines (Exhibit 2).The country's pharmaceutical industry accounts for about 1.4 per cent of the global pharmaceutical industry in value terms and 10 per cent in volume terms. The Government of India has announced a host of measures to create a facilitating environment for the Indian pharmaceutical industry. The policies of the Government of India are aimed at building more hospitals, boosting local access to healthcare, improving the quality of pharmaceuticals and improving the quality of medical training. The Government of India is committed to setting up robust healthcare and delivery mechanisms. India's pharma sales are expected to reach US$ 27 billion by 2016. India is well placed to become one of the major drivers in providing healthcare to all while controlling the ever-increasing healthcare spend of both developed and developing nations[2](exhibit 3).The Indian pharmaceuticals market increased at a CAGR of 9.4 per cent in 2013 from USD6 billion in 2005, and is expected to expand at a CAGR of 23.9 per cent to USD55 billion by 2020.By 2020, India is likely to be among the top three pharmaceutical markets by incremental growth and sixth largest market globally in absolute size (exhibit 4). With 72 per cent of market share (in terms of revenues), generic drugs form the largest segment of the Indian pharmaceutical sector India's generic drugs account for 20 per cent of global exports in terms of volume, making the country the largest provider of generic medicines globally and expected to expand even further in coming years Over the Counter (OTC) medicines and patented drugs constitute 19 per cent and 9 per cent, respectively, of total market revenues[3] (exhibit 5).

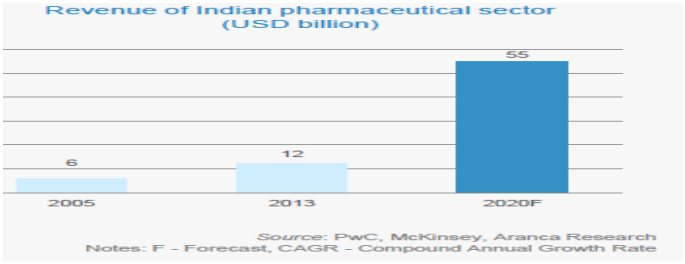

Exhibit 1: Revenue of Indian Pharmaceutical sector (USD billion)

Exhibit 2: Pharmaceutical Industry - Segments

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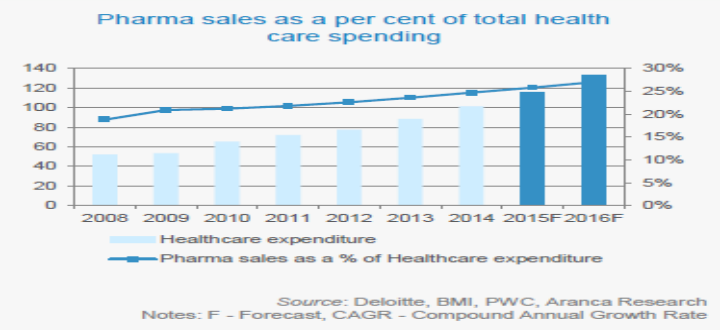

Exhibit 3: Pharma Sales as a percent of total health care spending

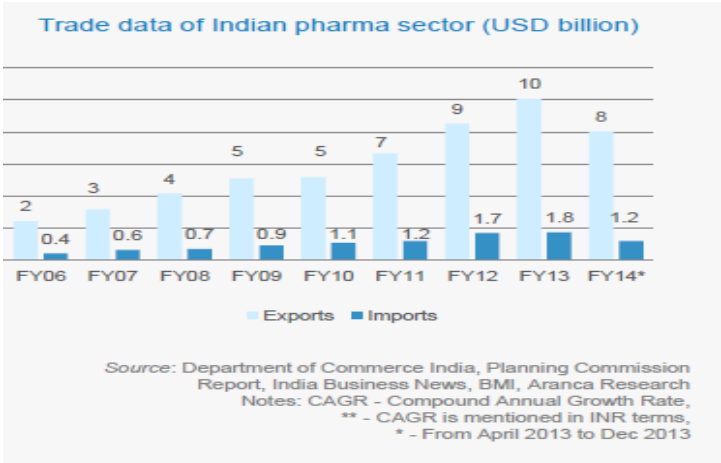

Exhibit 4: Trade date of Indian Pharma sector(USD billion)

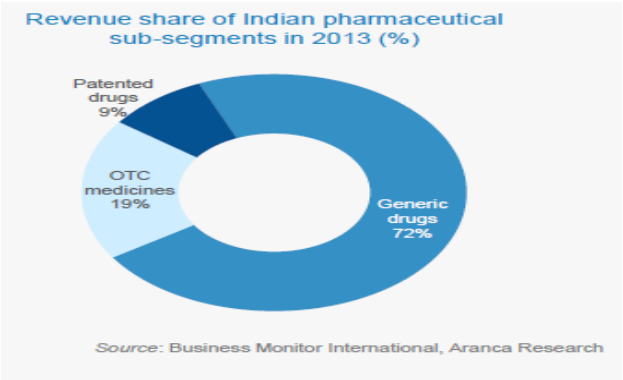

Exhibit 5: Revenue share of Indian Pharmaceutical sub-segments in 2013 (%)

Studious Opportunities in India:

The Indian pharmaceuticals market has unique characteristics. First, branded generics dominate, making up for 70 to 80 per cent of the retail market. Second, local players have enjoyed a dominant position driven by formulation development capabilities and early investments. Third, price levels are low, driven by intense competition. While India ranks tenth globally in terms of value, it is ranked third in volumes. These characteristics present their own opportunities and challenges. In our earlier report, India Pharma 2015 – Unlocking the Potential of the Indian Pharmaceutical Market, we projected that the market would grow at a compounded annual growth rate of 12 to 14 per cent to become a USD 20 billion to USD 24 billion market by 2015. This growth would be driven primarily by rising incomes, and be supported by five other factors: enhanced medical infrastructure; rise in the prevalence and treatment of chronic diseases; greater health

insurance coverage; launches of patented products; and new market creation in existing white spaces. From a market size of USD 12.6 billion in 2009, the Indian pharmaceutical market will grow to USD 55 billion by 2020, with the potential to reach USD 70 billion in an aggressive growth scenario[4].

As per the India Brand Equity foundation report, based on the 'Pharma Vision 2020', the Government of India aims to make India a global leader in end-to-end drug manufacturing. Manufacturing costs in India are approximately 35-40 per cent of those in the US due to low installation and manufacturing costs. Pharmaceutical exports from India have grown at a CAGR of 21 per cent over the last decade. Indian vaccines are exported to 150 countries. The projected human resource requirement in the Indian pharma sector is estimated to be about 21, 50,000 by 2020.India is home to 10,500 manufacturing units and over 3,000 pharma companies. India accounts for 36.9 per cent (3,411) of the 9,296 Drug Master Files (DMFs) filed with the USA, which is the highest outside of the USA (as on December 31, 2013). Higher spending on R&D, owing to products patents has made India a major destination for generic drug manufacturing. India has been accredited with approximately 1,105 CEPs, more than 950 TGA approvals and 584 sites registered by the USFDA. Following the introduction of product patents, several multinational companies are expected to launch patented drugs in India. The Government of India is committed to setting up robust healthcare and delivery mechanisms. Due to increasing population and income levels, demand for high-end drugs in India is expected to reach US$ 8 billion by 2015. Expenditure on pharmaceuticals is likely to increase to over 40 per cent of the total spending on healthcare by households by 2015. With 70 per cent of India's population residing in rural markets, various pharma companies are investing in the distribution network in rural[5].reas.

Pharma in Tier-II and rural markets:

The government plans heavy investments in medical infrastructure during the next decade. A majority of this spending will go towards upgrading infrastructure in primary and secondary care centres, i.e., district hospitals, PHCs and CHCs. Executed well; these investments will create real options for the poorer underserved segments to access quality healthcare. During the last 5 years, metro and Tier-I markets have grown at an estimated rate of 14 to 15 per cent, in line with the overall market and this segment to become a USD 33 billion market by 2020. Indian pharma market is regarded as one of the fastest growing pharma markets in the world. It is expected that although driven by a huge patient base, increasing incomes, improving healthcare infrastructure and strong penetration of health insurance in the rural areas of India, the pharma market in villages and small towns will double in size in the next five years. Growth in metro and Tier-I markets will be driven by three factors. First, rapid urbanisation will lead to 250 million people moving from rural areas to urban centres during the next two decades, with a majority of them moving to the top 70 cities. Second, medical infrastructure will expand in terms of scale and scope. Corporate hospital chains will extend their hospital network in the top 70 cities; innovative formats will plug gaps in healthcare delivery in Tier-I markets; and hub and spoke delivery models providing access to higher secondary care procedures will rise within the top 200 to 250 towns. Third, compliance has the potential to rise sharply driven by organised initiatives. While diagnosis and treatment levels in metros and Tier-I markets are 30 to 40 per cent higher than in rural areas, compliance levels remain similar. Driven by income growth and greater penetration, rural markets have grown a few percentage points above the overall market. Going forward, the share of rural markets will move up to 25 per cent by 2020, up from the estimated 20 per cent currently. Tier-II markets, in contrast, will get marginally squeezed out. Affordability increases will be the single largest driver of growth. More than 28 million households, nearly 20 per cent of all households in rural areas, will climb out of the deprived income class in rural areas during the next decade. In addition, health coverage through RSBY will further enhance the affordability for healthcare, and enable rural patients to be treated for serious illnesses and higher cost procedures. These markets could grow further if the shortage of doctors and other care delivery points is addressed. There are 0.33 allopathic physicians per thousand people in rural areas which is half the national average. While the government has announced plans of upgrading infrastructure at primary health centres (PHCs) and community health centres (CHCs), the shortage of manpower continues to be a bottleneck[6].

Spurious drugs struggle in Indian pharma:

The USFDA defines counterfeit drugs as a "drug which, or container or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, or device, or any likeness thereof, of a manufacturer, processor, packer, or distributor other than the person or persons who in fact manufacture, processed, packed, or distributed such drug and which thereby falsely purports or is represented

to be the product, or to have been packed or distributed by, such other drug manufacturer, processor, packer, or distributor." The definition of counterfeit carries the notion of substandard quality, extending to products without the active ingredient, with an insufficient or excessive quantity of the active ingredient, with the wrong active ingredient, or with fake packaging. This applies to branded and generic drugs and to bulk ingredients used to make the drug therapy. This new division considers the problem through the entire lifecycle of a product from drug components through to the finished dosage to the patient. So, the industry has taken this threat to public safety and market integrity to the life of people[7] (exhibit 6).

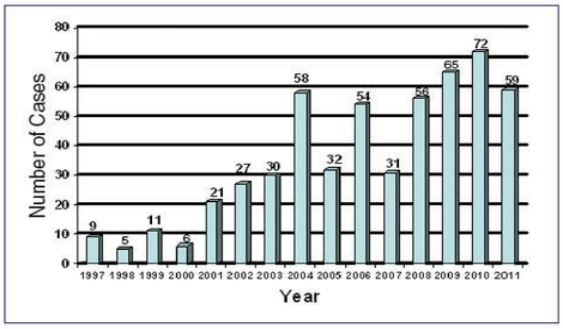

Figure 1. Number of Drug Counterfeit Cases Opened by FDA's Office of Criminal Investigations per Fiscal Year[3]

Exhibit 6: Number of drug counterfeit cases opened by FDA's office of criminal investigations per fiscal year

India's pharmaceutical industry is fourth in the world in terms of production volume, and over 66% of its products are exported to highly regulated markets. Exports are heavily regulated by the importing countries and there is likewise a requirement for continuous monitoring of quality-related aspects within India, including complaints of sub-standard or counterfeit drugs[8]. According to some studies, fake drugs make up 20% of the pharmaceutical market in India. These products are no longer limited to lifestyle drugs, but now also include vital medication like cough syrups, painkillers, and even vitamin supplements. Most cases of fake and spurious drugs in the local market were found in Bihar, West Bengal, Uttar Pradesh and Gujarat[9]. The health ministry estimates that 5% of drugs in India are counterfeit, while 0.3% is spurious. Further, distribution and sale of counterfeit medicines often happen beyond jurisdictional borders, creating greater obstacles to successful anti-counterfeiting enforcement. And though guidelines have been produced by international bodies such as the WHO to help mitigate the flow of illegal medicines, most developing countries in Asia do not have adequate infrastructure or financial resources to implement them. Therefore, combating fake medicines requires increased collaboration at national, regional, and international levels[10].

According to a report of Pharma IQ, 61.5% respondents found that the threat of counterfeit medicines in the next year was more severe than ever and 53.8% admitted that they were planning to increase their budget for investment in the anti-counterfeiting area. Emerging markets from Asia (especially China) were perceived as the major source of the anti-counterfeit drugs (50%). 21.4% and 21% of respondents indicated internet and organised crime respectively as the major threats for the pharmaceutical market. Even though the statistics showed that consciousness of the threat of counterfeit medicines was significant, the vast majority of respondents (84.6%) shared their optimism, claiming that Indian pharma were positive about winning the war on pharmaceutical counterfeits[11].

The Organization for Economic Cooperation and Development (OECD) reckons that 75% of the world's total supply of fake drugs can be traced to India[12]. The World Health Organization (WHO) pegs the figure at 35%. Between 10 and 30% of all pharmaceuticals in developing countries are counterfeit, according to the 2006 WHO figures cited in the OECD report, which estimates that India is the biggest culprit in the spurious drugs market though other countries such as Egypt (7%) and China (6%) contribute to this menace. OECD asserts that counterfeiters include medical professionals such as pharmacists and physicians, organized crime syndicates, bogus pharmaceutical companies, corrupt officials and terrorist organizations. The United Nations Office on Drugs and Crime (UNODC) has released their report on organized crime activities in East Asia. It shows counterfeited/ fraudulent pharmaceuticals are a growing source of profit for criminal gangs, and countries with lax enforcement are the biggest market fraudulent medicines[13] (exhibit 7).

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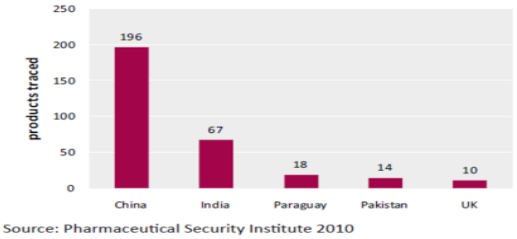
Figure 4: Top five origins of counterfeit medicines detected



Source: Pharmaceutical Security Institute 2010

Exhibit 7: Top five origins of counterfeit medicines detected

India's stand on spurious pharma products:

The Central Drug Standards and Control Organization (CDSCO), located under the aegis of the Ministry of Health and Family Welfare prescribes standards and measures for ensuring the safety, efficacy and quality of drugs, cosmetics, diagnostics and devices in the country; regulates the market authorization of new drugs and clinical trials standards; supervises drug imports and approves licences to manufacture the above-mentioned products[14].

With the conflicting reports keep appearing in the media, especially in the international publications, on the speculated quantum of spurious drugs, the CDSCO is planning to continue its initiative to hold regular surveys to officially assess the extent of spurious and sub-standard drugs in the country. The survey has revealed that only 0.046% samples were spurious. Notwithstanding the efforts by the Indian authorities to check the misinformation and misled propaganda about the quantum of spurious drugs, still reports continued to appear in the Western world projecting India as a major source of spurious drugs. According to a report by the Organization for Economic Cooperation and Development, 75 per cent of fake drugs supplied world over have origins in India followed by 7 per cent from Egypt and 6 per cent from China. India has raised strong concern over the delay in setting up a working group by the World Health Organisation to address the problems of counterfeit and substandard medicines and adopt changes in the policy, instead of leaving the task with controversial International Medical Products Anti-Counterfeiting Taskforce (IMPACT). India took up the matter with the WHO recently after the world agency failed to even set up the working group. India also expressed concerns about the recently completed plurilateral Anti-Counterfeiting Trade Agreement, it's possible impact on the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) [15].

Remedies for evading spurious drugs in India:

Patient safety is being compromised due to counterfeit drugs. Around the world, patients are encountering fake medicines. The packaging seems right, the tablets or capsules look the same—but these fakes are really imitations of government-approved drugs created in unsanitary or unsterile conditions with unsafe manufacturing practices. Counterfeit drugs may be too strong or too weak, missing key ingredients or made with dangerous, even toxic substances. The Partnership for Safe Medicines has developed the following international principles to support quality assurance programs and establish a drug distribution system that is without compromise so people in every corner of the globe can feel secure that the medicines they receive are legitimate, safe pharmaceuticals approved by their country's regulators[16].

Secure and Protect the Supply Chain

- There is strong need for strict, rigorous oversight when pharmaceuticals are transported between countries, including the regulation of its storage throughout the distribution system of imported pharmaceuticals.
- Distribution facilities should be subject to inspection and government agencies should have sufficient funding to inspect all the facilities that manufacture drug products or components of drug products for foreign or domestic use.

- Field offices staffed with both inspectors and criminal investigators should be established to inspect facilities in key exporting areas.
- The public and private sectors should continue to work together to standardize drug pedigrees and documentation.

Regulate Online Drug Sellers

- Online drug sellers and pharmacies should be held to the same rigorous oversight and high standards as traditional pharmacies.
- There should be mandatory Internet accreditation programs created by a country's pharmacy board protect patients from rogue online drug sellers.
- All Internet drug sellers, regardless of which state, territory or country in which they are based, must comply with the pharmaceutical licensing and survey requirements for every area in which they sell pharmaceuticals.
- No one should be able to purchase prescription drugs, including controlled substances, over the Internet without a valid prescription and physician oversight.

Unify the Fight against Counterfeit Drugs

- Counterfeit drugs, tainted medicines, and rogue online drug sellers are global public health problems that require an international solution.
- International cooperation must occur between government agencies, legislatures, law enforcement, and diplomatic corps to prosecute drug counterfeiters.
- Criminal penalties against the manufacturers, sellers, distributors, and purveyors of counterfeit medicines must be increased to reflect the gravity of their offenses.
- Government authorities should be granted the power to destroy unapproved, unlicensed, tainted, and/or counterfeit drugs entering a country's border rather than returning them to the criminals who sent them.

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