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Generic Drug Distribution in India-Issues and Challenges

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Abstract

Indian Pharmaceutical industry is worldwide famous for its export of generic pharma products. India is one of the major generic distributors all across the world. There are many famous pharmaceutical companies which contribute in the production of generic drugs such as sunpharma, cipla, Dr. Reddy, Lupin etc. After China, India is the second largest producer of generic drugs. We have good production of them but still there are so many issues and challenges due to which Indian population is still struggling to find out the generic medication easily accessible to them. Even doctors are not prescribing generic drugs. There are few government regulatory bodies which take care of the availability of the generic medicines and try to make them available to the Indian population especially to the ones who are below poverty line.

Keywords: Indian pharma Industry; Generic drug distribution; Pradhan mantri jan aushadhi yojana; Drug distribution in India

Introduction

The pharmaceutical industry is known for discovering, inventing, producing and marketing pharmaceutical drugs intended to be used for medicinal purpose or others [1]. These drugs come in variant of generic as well as brand medications. Pharmaceutical industry comprises of various pharmaceutical companies that deal in these drugs and variety of medical devices that are used in health sector. These are governed by various rules and regulations that govern the patenting, testing, safety, efficacy and marketing of drugs prior to the launch of these products in the market [2].

India is a significant player and one of the largest suppliers of generic drugs in the international market [3]. More than 50 per cent of the global demand for various vaccines is met by the Indian pharmaceutical industry. In addition, the industry also satisfies nearly 40 per cent of generic drug demand of US and 25 per cent of all medicines imported by UK. Currently the supply of over 80 per cent of the antiretroviral drugs, that are being used globally to combat AIDS (Acquired Immuno Deficiency Syndrome) is made by Indian pharmaceutical firms.

The premier position that India enjoys in the international pharmaceutical market is a result of the talent pool that the country possesses. It has a deep talent pool of scientists and engineers who have the potential to steer the industry to greater glories.

In this study we explore the pharmaceutical drug distribution in India, the various issues and challenges relating to drug distribution in the country and discuss the initiatives taken by the Government of Indiawith specific reference to the Pradhan Mantri Bharatiya Jan Aushadi Pariyojana (PMBJP).

The Indian pharmaceutical industry

On the basis of type, the Active Pharmaceutical Industry (APIs) hold the largest market segment. As of 2016, India is the third largest global generic API merchant market with a 7.2 percent market share. The Indian pharmaceutical industry accounts for the second largest number of Abbreviated New Drug Applications (ANDAs) and is the world's leader in Drug Master Files (DMFs) applications with the US. This is supported by the fact that Indian companies has received 304 Abbreviated New Drug Application (ANDA) approvals from the US Food and Drug Administration (USFDA) in 2017. The country accounts for around 30 per cent (by volume) and about 10 per cent (value) in the US$ 70-80 billion US generics market [4].

Major contributors

The major players in the Indian pharmaceutical market are Sun Pharma, Dr. Reddy's, Lupin, Cipla, Aurobindo, Candila. Glenmark, Torrent Pharma, Alkem Lab, Divis Lab, Piramal Enter, Ipca Lab, Glaxo SmithKline, Abbott India, Biocon, Jubilant life, Sanofi India, Wockhardt, Pfizer, Dr Lal Path Lab, Merck, Hikal, Novartis India and Eris Life.

In 2017, the pharmaceutical sector in India was valued at US$ 33 billion [5]. But, it is expected that in the upcoming years the country's pharmaceutical industry will expand at a CAGR of 11.3 per cent. It is expected to reach US$ 55 billion by 20. India's pharmaceutical exports stood at US$ 17.27 billion in 2017-18 and is expected to rise to US$ 20 billion by 2020 [6].

Looking at India's biotechnology industry which comprises of bio-pharmaceuticals, bio-services, bio-agriculture, bio-industry and bioinformatics – this too is expected to grow at a rate of 30 per cent annually and reach US$ 100 billion by 2025. Biopharma, comprising vaccines, therapeutics and diagnostics, is the largest sub-sector of Indian Pharmaceutical Industry which contributes to nearly 62 per cent of the total revenues at Rs 12,600 crore (US$ 1.89 billion) (Figure 1).

- The Indian pharmaceuticals market increasing from US$ 20.95 billion in FY11 to US$ 27.57 billion in FY16 i.e. witnessing growth during FY11-16 at a CAGR of 5.64 per cent. The industry's revenues are estimated to have grown by 7.4 per cent in FY17 making it upto US$ 29.61 billion.

- If we talk about the CY2017 the Indian pharmaceutical market grew 5.5 percent in terms of moving annual turnover. Currently

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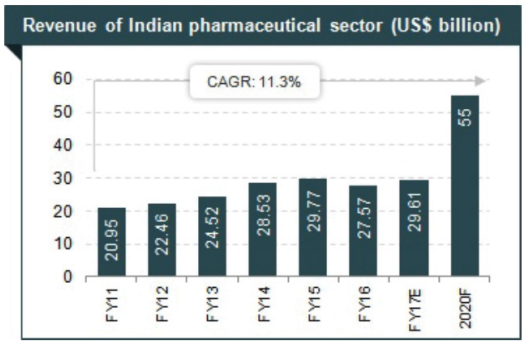

F: Forecast; CAGR: Compound Annual Growth Rate; CY: Calendar Year; E: Estimated (**Source:** Department of Pharmaceuticals, PwC, McKinsey, AIOCD AWACS).

Figure 1: Revenue of India pharmaceutical sector.

In March 2018, the market grew at 9.5 per cent year-on-year with sales of Rs 10,029 crore (US$ 1.56 billion).

Thus from an overall perspective, given the pace at which the market is growing, India will be most likely be among the top three pharmaceutical markets by 2020 in terms of value and 6th largest in terms of absolute size.

With the advent of the awareness about health in the masses, domination and penetration of health insurance schemes countrywide coupled with the improvement in the medical technology and infrastructure, the growth in the pharmaceutical sector especially in the field of generic drugs is inevitable in days to come.

Despite this phenomenal growth and the bright prospects facing the industry, the generic drug distribution in India continues to experience some serious challenges. This paper discusses these challenges and the steps taken by the Government of India to address this challenge [5].

Drug distribution in India

Post the manufacturing stage, the pharma products - drugs, surgical items, serums, vaccines and the like are forwarded to the respective manufacturer's clearing and forwarding agents (CFA) [3]. The following are the critical players in the chain of generic drug distribution across the country.

- **CFAs:** The CFA's are the primary stockists. On request from the stockist, the CFA's are responsible for forwarding the finished products in appropriate Stock Keeping Units (SKUs). Most companies require and deal with 1 to 3 CFAs per Indian state. On an average, a company may work with 25-35 CFAs across the country. The companies pay the CFAs on quarterly, half-yearly or annual basis on the total turnover [7].
- **Stockist:** The stockist at any point in time may simultaneously deals with 5-15 companies depending on the territory covered. Occasionally this number can go up to 30-50 different manufacturers or companies. The stockist pays for the products directly to the pharmaceutical company after a period of 30 to 45 days.
- The stockists or their sub-stockists supply the products to the retail pharmacies through whom the products reach the end consumers (patients) (Figure 2) [8].

Issues and challenges

There are several issues and challenges related to the distribution of generic drugs in India which results in lower level of adoption of pharmacy products drugs in the country. Some of the issues and challenges are discussed here [9].

Most generic drugs sold in the retail pharmaceutical stores are branded, which come at a premium. But it should be noted that unbranded generic drugs are comparable to the branded drugs in the market. The quality depends on research, processing and manufacturing of the molecule. These generic drugs are as effective in treating the patients as the branded medicine, provided the necessary care is taken at the manufacturing stage to take care of product quality. If good quality manufacturing (GMP) practices is adhered to this could result in better affordability of pharmaceutical drugs to the common man.

A second challenge relates to the code of ethics issued by the Medical Council of India (MCI). In 2002 the MCI released guidelines to physicians to prescribe drugs to patient by their generic names only and to avoid mention of branded names in the prescription (A study on generic prescripti, 2014). The medical community is asked to follow MCI's 2016 notification in which it had amended clause 1.5 of the Indian Medical Council (Professional).

Conduct, Etiquette and Ethics) Regulations, 2002, in this regard. It states that every physician should prescribe drugs with their generic names only. Those found violating this clause, suitable disciplinary action by MCI would be undertaken against that individual.

All the registered medical practitioners under the IMC Act are directed to comply with the aforesaid provisions of the regulations without fail," said the MCI circular as quoted by PTI.

But for various vested reasons this is rarely followed in practice. Doctors continue to prescribe branded medicines to the patients without any second thought. This turns the table towards the emerging upliftment of fake and deleterious drugs in the market. Doctors

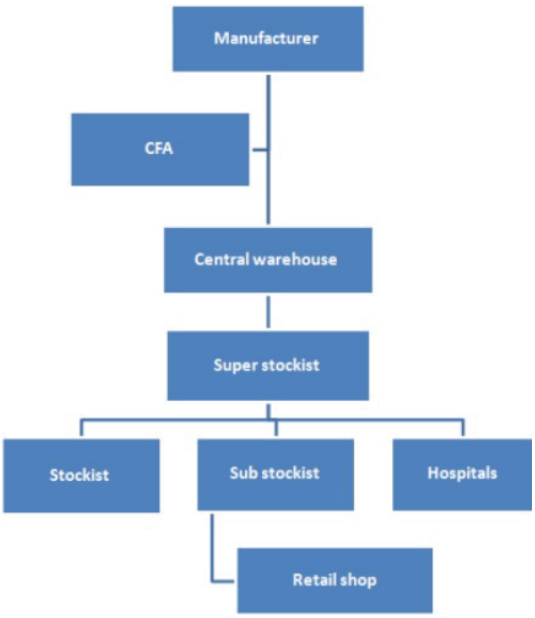

Figure 2: Indian_Pharma_Industry, Dolcera, public wiki.

prescribe it to improve their business and to maintain their tie-up with these brand holders [10].

Due to lack of transparency in the licensing procedures of Drugs, it has resulted in the increased supply of low quality, spurious and substandard drugs. With reference to a WHO study, Mashelkar Committee has declared the data that nearly 30% drugs in Indian market are spurious, substandard, counterfeit drugs. Although there are various bodies present but their actual implementation to maintain the quality of drugs is not sufficient as government is itself coming up with data like there are 8-10% substandard drugs and 0.3 to 0.5% spurious drugs in the Indian market.

However it should be taken note that despite being the third largest pharma market (in terms of volume) in the world the regulatory bodies set up to implement the laws related to drug production are not functioning effectively. If this can be done and all manufacturers comply with GMP/ICH norms, India can ensure that its generic drugs will be of similar quality as the branded drugs. India can borrow from China in implementing such an approach.

The next challenge relates to the fact that even if the doctor does prescribe a generic drug, the pharmacist without regard to the cost impact on the patient, sells only branded medicines, as these are more lucrative. This practice hits at the very root of the aim to make medical care affordable to all strata of the society.

This relates to the fact that prescribing the generic drugs by doctors will merely shift the focus of the pharmaceutical industry's unethical drug promotion to the pharmacist, away from the prescriber. This will again result in the spread of business and false commissions [11].

The next challenge is the unavailability of appropriate generic names equivalents of branded medicines sold in the market. Nearly 90 percent of the Indian pharmaceutical market is faces this issue where more than 1,00,000 crore drugs are there. Add on to this issue, the problem of naming a fixed dose combination (FDC) - when two or more Active Pharmaceutical Ingredients (API) are combined to form a single dosage form or drug, it results in the formation of Fixed-Dose combination (FDC) which is manufactured, dispensed and distributed in the fixed doses. There are many FDC drugs and innumerable brand names for same purpose FDCs. Further complications arise when FDCs have more than two APIs which in some cases goes up to 8 or 9 APIs. To prescribe a generic name for each of the eight or nine ingredients is a very tedious and impractical task.

Efforts by state agencies to address the issues/challenges

To address some of these challenges, the Government of India and some states in India have launched schemes or programs that aims to provide quality medicines at affordable prices to the masses all over country through special centres. In this context we will discuss the Pradhan Mantri Bhartiya Jan Aushadhi PariYojana Kendra (PMBJPK) and the initiative by the Rajasthan Government through the Rajasthan Medical Services Corporation Limited.

Pradhan mantri bhartiya jan aushadhi pariyojna (PMBJP)

The PMBJP is a novel project launched by the Government of India through the Department of Pharmaceuticals, Govt. Of India. It aims to provide quality medicines at affordable prices to the masses all over country through special centres or Kendra's known as Pradhan Mantri Bhartiya Jan Aushadhi Kendra. The PMBJPKhave been set up to provide generic drugs, which are available at lesser prices but are equivalent in quality and efficacy to the expensive branded drugs. These centres are a great benefit to people, especially the poor who cannot afford expensive treatment using branded medicines. The Bureau of Pharma Public Sector Undertakings of India (BPPI) has been established under the Department of Pharmaceuticals, Govt. of India, with the support of all the Central Public Sector Undertakings (CPSUs) for coordinating procurement, supply and marketing of generic drugs through the Pradhan Mantri Bhartiya Jan Aushadhi Yojana which will be dispensed by the kendras set up under the scheme [12].

The first "Jan Aushadhi Medical Store" was opened on 25 November 2008 at Amritsar in Punjab. In September 2015, the 'Jan Aushadhi Scheme' was revamped, modified and introduced as 'Pradhan Mantri Jan Aushadhi Yojana' (PMJAY). Again in November 2016, the scheme was renamed as Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP) (A study on generic prescripti, 2014).

The Jan Aushadhi programme will also be reinforced under which essential medicines will be provided at reasonable rates by the government.

The National List of Essential Medicines, 2015 is also getting revised and updated to include more medicines.

In the financial year 2016-17, Bureau of Pharma PSUs of India (BPPI) has done Rs. 33.00 Crores sales at MRP and in the subsequent financial year 2017-18, BPPI has done Rs. 112.00 Crores sales at MRP till 31.12.2017 and the projected sale shall be more than Rs. 120.00 Crores sales at MRP by end of this financial year, which corresponds to approximately Rs. 600.00 Crores of the branded products. PMBJP ahead: The endeavour of BPPI is to make available at PMBJP Kendra's all the commonly used generic drugs covering all the therapeutic groups. In the coming years, PMBJP shall provide the complete spectrum of Health care products and services, starting from making available all the generic drugs covering all the therapeutic groups.

Initiative by Rajasthan government through the Rajasthan medical services corporation Ltd

In 2011 the state of Rajasthan started supplying free generic drugs to its 68 million people. The goal of this initiative was to provide medicines to the needy free of cost and to eliminate the supply of high price medicines distributed by the private pharmacies [13]. This program also aimed at curtailing the price manipulation indulged in by private pharmacies and manufacturers in coalition with doctors who prescribed expensive medicines to patients. For instance, there are various pharmaceutical laboratories that produce different kinds of medicines with the same chemical ingredients or composition, though not always the same quality. For example, Cipla, produces three kinds of tablets for 'cold', with the same chemical composition. The generic drugs are sold to pharmacies at a wholesale price of about 0.03 US$ per ten-tablets-pack but the branded drugs are sold at for 0.42 US$ per pack. Chemists sell all three drugs for anything between 0.50 to 0.72 US$ as per the printed price.

The above case reflects clearly mis-selling of medicines to patients. Patients with lifelong conditions like diabetes or heart disease face greater difficulties to buy medicines at reasonable prices. For example, a particular brand of medicine used for diabetes costs 2.17 US$, but 10 tablets of the same generic medicine can be bought for 0.036 US$.

This makes the case strong for direct governmental intervention for direct purchase of generic drugs from manufacturers and distribution to the patients through its approved drug distribution centres. This can ensure the availability of essential drugs necessary for treatment to the poor and needy mass of the country.

Currently on an average more than 350 essential generic drugs are being distributed free of cost to over 200,000 people. This has led to the increase in the number of outpatients by 60 percent and inpatient admission is at 30 percent.

The Rajasthan program means to be a pilot for a scheme to be initiated throughout India. Other states in India such as Tamil Nadu and Karnataka have also attempted to launch similar schemes to provide easy and effective access of quality medicines to the needy.

Conclusion

Challenges continue to persist despite government intervention

Although the government has come up with the Jan Aushadi Scheme, the lack of adequate number of outlets plagues this program. Another challenge is that the Drugs Technical Advisory Board (DTAB) initially supported the spread of Jan Aushadhis and gave pharmacists the license to dispense generic drugs against prescription in brand names but later on withdrew this idea stating the point that bioavailability - the proportion of a drug or other substance which enters the circulation when introduced into the body and so is able to have an active effect - of generic drugs may not be as good compared to the bioavailability of branded drugs. This reflects that the country's own advisory body does not have confidence in the quality of the government owned generic drug manufacturers. This also raises questions about the ability of India's drug regulatory agencies to enforce strict quality control measures on government owned generic drug manufacturers [14]. Moreover, India is planning to amend the Drug and Cosmetics act. In fact stringent measures have been taken to ensure that strict quality checks are being done before giving generic manufacturing licenses to drug companies and also ensuring that the bioavailability of the generic drug is equivalent to branded drug. However, strict quality checks to be done on the drugs intended for domestic use as well along with the drugs intended to be exported worldwide. Therefore, for this manufacturers are checked for their GMP/ICH norms compliances time to time.

The other challenge is that while the outpatient and inpatient statistics shows a positive growth post the introduction of government programs for free or concessional generic drug distribution, the overcrowded and understaffed public health facilities raises questions about how easy is it for the people to have access to these benefits.

With the help of the latest interventions done by the government in the field of distribution of generic drugs, undoubtedly it has helped in raising and promoting the sales and use of the generic drugs in our country. The original molecules given to the patients are more efficacious and have higher biological availability to act on the root of the disease. This has been scientifically proven by the clinicians and now has become a part of their global experience. But still, currently the culture of the generic drugs is expanding in India and people are accepting it gradually [15,16].

From a distribution perspective, the Indian regulatory bodies can consider the option of limiting the number of CFA's that the pharma companies deal with. For example the limit can be 1-3 CFA's per state depending upon the size of the state. Another option could be of the Govt ownership of some of the CFA's. This will ensure that the Govt can directly sell the finished product to the end user eliminating the middle man (SKUs).

Another initiative could be that could be focused upon is the MCI (Medical Council of India) can implement the law passed in 2002 that advices physicians to prescribe drugs by their generic names and to avoid mention of branded names in the prescription.

Given the overcrowded and understaffed health infrastructure the Govt. can initiate measures to improve the pharma education sector.

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