International Journal of Academic Research and Development
ISSN: 2455-4197, Impact Factor: RJIF 5.22
www.academicsjournal.com
Volume 2; Issue 4; July 2017; Page No. 401-405

A review on prosperous and growth of generic medicines in India

[1] Dr. P Raja Babu, [2] Gowsya SK

[1] Associate Professor & Alternate HoD, Department of MBA, KLU Business School, KL University, Vaddeswaram, Guntur, Andhra Pradesh, India

[2] Research Scholar, Department of MBA, KLU Business School, KL University, Vaddeswaram, Guntur, Andhra Pradesh, India

Abstract
India is one of the life line country for all developing country for supplying of generic medicines (Shrank WH, 2011). Since, India has been exporting generic medicine more than 200 countries. These are 28% to America, 18% to Europe and 17% to Africa. In India branded medicines have occupied dominant role in the pharma market. It is might be the reason of lack of drug pricing control laws. Present the generic medicine has been exporting 80% whereas branded and patent drugs are 20% occupation in domestic drug market. It is estimated that the generic products has to be increased up to 90% in the next year 2017-18 and it is higher than 80% in the previous year. This study presents to analyse the growth of generic medicine in India, to understand the mechanism for approval process of generic products, to analyse the future challenges for Indian generic products and to give appropriate suggestions for promoting generic products in order to reducing health expenditure in India.

Keywords: pharmaceutical industry, branded drugs, growth of generic medicine, health expenditure

Introduction
India enjoys an important position in the global pharmaceuticals sector. The country also has a large pool of scientists and engineers who have the potential to steer the industry ahead to an even higher level. Presently over 80 per cent of the antiretroviral drugs used globally to combat AIDS (Acquired Immuno Deficiency Syndrome) are supplied by Indian pharmaceutical firms. After independence the Indian pharmaceutical industry has been providing prominent healthcare products to the domestic as well as global market. India is present global leader in the pharmaceutical industry. According to the market value Indian pharma industry occupied 3rd rank in the volume and 14th rank in the market value. The Indian generic products plays a important role and it has crossed 100 billion dollars in the past and it is estimated growth rate is three times in future.

Meaning
The English dictionary defines the word generic as: "Not protected by trademark registration; Nonproprietary or any product, as a food, drug, or cosmetic that can be sold without a brand name." Briefly, it pertains to the salt name or active ingredient of a drug delivery form.

According to World Health Organization (WHO), "A generic drug is a pharmaceutical product, usually intended to be interchangeable with an innovator product that is manufactured without a license from the innovator company and marketed after the expiry date of the patent or other exclusive rights."

An individual or a company invention of new drug the inventor is having intellectual property. No one can produce the same product up to expiry of their patent (usually 20 years unless specified). After expiry any one can produce the same product without permission. These products are called generic while those who are invention companies or individual is called branded.

Pharmaceutical industry in India
There is a intensity of the competition and complexity of the pharma market in India have made the country is a hub for manufacture of generic medicine (Kapczynski A. 2013) [5]. Certain flexibilities have also given by Trade Related Aspects of Intellectual Property Rights (TRIPS) and Indian companies are agreement with World Trade Organization. All are being forward step for enlargement of generic medicines in India (Lancet Oncol. 2013) [6].

As per Indian scenario, there are three categories of generic drugs. These are Innovator Brands (IB), Most Selling Generics (MSG) and Least Price Generics (LPG). The IB will be at the highest price followed by next categories (Bhargava A, 2013). The IV category of drug was also introduced viz., unbranded generics (UG). These drugs are manufactures by non-government organizations (NGOs) (Amit G, 2004) [7]. Drug regulations are including manufacture, sale and distribution is primarily under the control of state authorities while the central government is the responsible for approval of new drug based on standards and quality. At central level all drug related issue under the control of central drugs standard control organization under ministry of health and family welfare. This organization deals with all new drug approvals, review of new safety information regarding approved drugs, medical devices and implant (Mohamed Naeem Devla, Sanjeev R. Acharya, Niyati S. Acharya, Vimal Kumar, 2011) [12]. For testing of drugs are located at Central and regional levels. These laboratories are testing quality of medicines.

The Indian contexts branded generies are also generies with a brand name plus the quality assurance. These drugs are releasing well known companies like Cipla, Sun

or Dr. Reddy's. Branded drugs are not the expensive. These drugs are promoted or publicised. If a doctor prescribe quality branded drug sometimes the chemist will dispense it with another brand. In the absence of an international standard drug regulatory mechanism like the USFDA, Indian doctors have to rely on the reputation companies like Cipla, Sun and hundred of other who have demonstrated their commitment to quality over time and become trusted names in the eyes of doctors and patents.

In India branded generic companies have been innovative they are introducing novel drug delivery system i.e., the drug to improve absorption, reduce side effects, thereby increasing the efficiency of the drug. For the institutional safeguard the Indian government has enhancement of good manufacturing practices (GMP) to meet the global standards with global regulations for better quality of pharmaceutical products.

Problem of the study

As per the report of World Health Organization (WHO, 2015) [10] about 30% of the world population is lack of access to essential drugs while this was increased up to 50% in some countries viz., Africa and Asia. The cost of medicines and the world-wide healthcare budget has been increasing it varies between 20%-60% (Daemmrich A & Mohanty A, 2014) [2]. The growth of Indian pharmaceutical market share is also increasing year by year. As a result, the government has to concentrate on durg research for universal access.

Since the developing country like India has been spending expenditure is more than that of other developped countries (Cameron, 2009) [1]. It is about 1.2% of GDP in 2012. The expenditure for generic medicine has been incurred 20%-60% in developing and transitional countries (WHO, 2004) and it is 18% in countries of the organization for economy co-operative and development (OECD, 2007). In developing countries 90% of the population to meet these expenditure through out-of-pocket (WHO, 2004). This expenditure has to give the priority after food. The per capita spending expenditure on healthcare is 160 USD. Due to these reasons the researcher has taken up this study in order to find out the growth and future challenges of generic products in India.

Objective of the study

The main objective of generic medicine is to provide at a low cost to the developed world. Indian generic market is playing a major role in growth of Indian Economy. Indian Pharmaceutical companies are getting approval from U.S. and it has been growing day-by-day for exporting generic medicines especially cardiovascular, anti-biotics and other groups. The main objectives of the study are:

1. To understand the mechanism for approval process of generic products
2. To analyse the future challenges for Indian generic products
3. To analyse the growth of generic medicine in India
4. To give appropriate suggestions for promoting generic products in order to reducing health expenditure in India.

Generic drug and its approval process

After expiry of patent of drug any one can produce and marketed its same drug. Before marketing the durg, generic manufacture need to obtain from regulatory body of the respective state. First, any drug manufactured should follow good manufacturing practices and also to obtain certification from drug related regulatory authorities (Schedule M. Drugs and Cosmeties Act of India, 1940) [11]**.** In the second step, there is a requirement of bio-availability and bio-equivalence (BA-BE) testing of new brand which compares with other active pharmaceutical ingredient and its reference standards. It is satisfactory then only approved for marketing. The Indian generic products will get the approval from United States Food and Drug Administration (USFDA) and approval of ANDA (Abbreviated New Drug Applications) will stand benefitted. Present the global share in generic products is 35% and major export is U.S. A set of rules, regulations and a detailed description is required for exporting to the developed nations. The ANDAs review process is more important for promoting generic medicine. After thorough reviews on branded drug its microbiology, chemistry and labelling of product finally approvals given by respective Food and Drug Administration (FDA). The FDA has approved generic products only after met regourous study from the point view of indentity, strength, quality, purity and potency.

Future challenges for Indian generic manufactures

The strength of Indian generic products are involving in research and discovery of drug changing dynamics. But their future is sustainable growth depends on understanding competitive markets of developed world. The major challenges are strengthening the existing regulatory system and need of universal classification for generic and branded generics. Apart from that allocation of high cost for R&D and investment in research is also a major stumbling block in this direction.

For the generic products Market Exclusivity Period (MEP) is longer. On an average 7-20 years after launching the brand. 9% of generic products were launched in 1995 and 80% of products were introduced in 2012. It will be continued minimum period 7 years after getting approval from FDA. Amendment of pharma regulations for generic products and getting approval from FDA for change generic product. Some of the companies are to reduce R&D expenditure after expire of their patent either duplicate or without patent extention of the same drug. Brand name drug is very expensive these drugs are given by researcher and it has first time introduced into the market. After expiry of patent period other companies launch as genries of the innovator drug. Only the difference is the price.

Controlling the generic durg prices

In India most of the essential medicines availability is lower and the cost is very higher in the public sector. Due to limited control mechanism the retail price of drug is very higher than procurement price and also the branded drug is more than 20 times higher than generic medicine

(Kotwani A, 2007) [4]. Controlling the drug prices by the government of India revised as National Pharmaceutical Pricing Policy in 2012. Most of the pharma companies the Market Based Pricing (MBP) has been taken into consideration for fixing of ceiling price. In case of non-schedule medicines which are not included in schedule of the DPCO, 2013, the manufactures are free to fix the launch prices. But, they can't fix more than 10% on MRP of the preceeding 12 months.

Now, the government has been giving more priority for generic drug due to sold these drugs are not more than 1% in our country. Experts are saying only doctors prescribe them then only the sales has to be increased. Hence, the role of doctors and chemist will give the most appropriate durg to the patient. In the US, the Food and Drug Administration noted that the cost of generic drug is 80% to 85% lower than the branded product whereas in India fixation of generic product price as per the direction of National List of Essential Medicines included in the order of First Schedule of the Drugs order, 2013. These prices are applicable all branded and generic products. And also these schedule drugs to comply the prices of drugs fixed by the National Pharmeutical Pricing Authority from the date of Notification.

A Cameron, MEwen, D Ross-Degnan, D Bal, R Laing are expressed in their article Medicine prices, availability and affordability in 36 developing and middle-in-come countries: A secondary analysis said that the overall public and private sector prices for originator and generic medicines and its cost depends on purchasing and distribution were efficient and mark-up is reasonable policy options like promoting generic products concentrate on increasing availability, reduce prices and improve affordability.

Growth of generic medicine in India

The domestic pharma market was valued at $15.4 billion in 2014 and is expected to expand at a CAGR of 13.3 per cent to $32.7 billion by 2020. Driven by favourable demographics including growing aging population, increasing lifestyle diseases, steep growth in disposable incomes, and increasing penetration of Indian drug players in the global market. India is likely to be among the top three pharmaceutical markets by incremental growth and sixth largest market globally in absolute size. According to a joint study by the Associated Chambers of Commerce and Industry of India (Assocham) the domestic generic drug market is expected to cross $27.9 billion from the current level of $13.1 billion registering compound annual growth rate (CAGR) of about 16.3 per cent. It is expected that the Generics would account for 85 per cent share in the domestic by 2020 and Generic drugs account for 75 per cent of the domestic pharmaceutical market by value. These druges are used for Cholesterol control, pain management, anti-coagulant, respiratory, liver disorders, depression and lipid regulators are highly prevalent in the global market.

Table 1: Global drug market

Particulars	2012-13	2016-17	%Growth
Global pharma market (in $ bn)	962	1200	24.7%
Global generic market (in $ bn)	274	432	57.7%
Global generic market (in $ bn)	28.5%	36%	
	2012-13	2014-15	%Growth
Indian pharma generic drug exports (in $ bn)	15	25	66.7%

Indian pharmaceutical industry's exports comprise mainly of generic drugs and accounted for nearly $ 15 billion in the FY 2012-2013 as per data available from a strategy paper from the Commerce Ministry of India. According to a report by the ministry, Indian pharmaceutical exports were expected to achieve a target of $ 25 billion set for 2014-15.

Trends in Indian pharma exports during 2008-2013 (in $ bn): The percentage contribution of the generic pharmaceutical market to the world is expected to increase from 28.5 percent in 2012-2013 to 36 percent in 2016-2017. Indian pharmaceutical export medicines contribute to nearly 5 percent of the total world's consumption of generic drug medicines in the current scenario. The year on year growth has taken a promising growth since 2008 with an incremental increase in the range of $ 1-1.5 billion each year. The US is the largest consumer of Indian pharmaceutical exported medicines followed by the UK. Many of the top 50 domestic Indian pharmaceutical companies contribute to this growth both in value and volume.

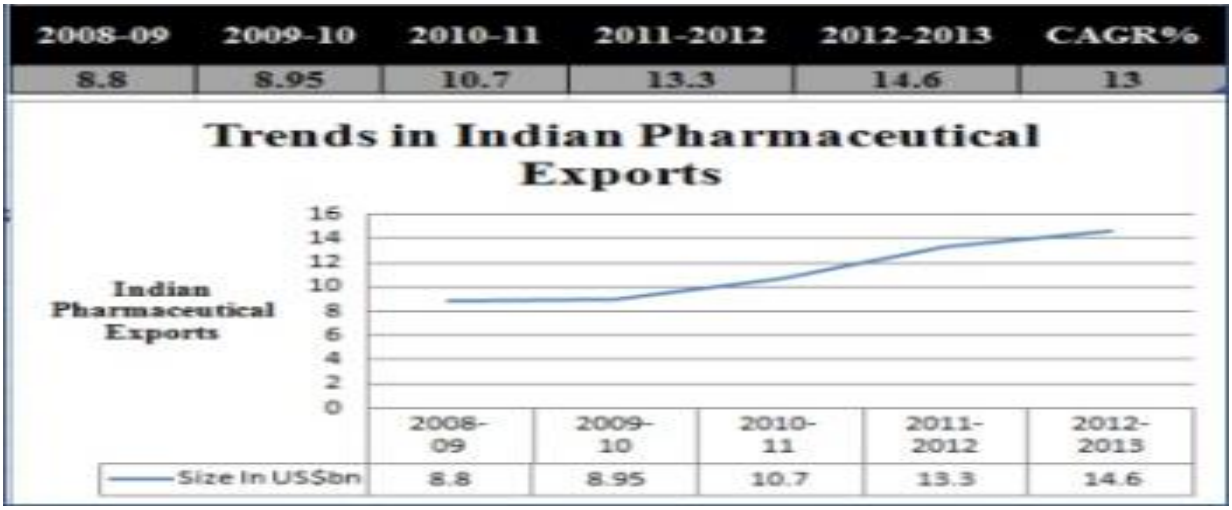

Fig 1

Market Size

The Indian pharma industry, which is expected to grow over 15 per cent per annum between 2015 and 2020, will outperform the global pharma industry, which is set to grow at an annual rate of 5 per cent between the same period. The market is expected to grow to US$ 55 billion by 2020, thereby emerging as the sixth largest pharmaceutical market globally by absolute size, as stated by Mr Arun Singh, Indian Ambassador to the US. Branded generics dominate the pharmaceuticals market, constituting nearly 80 per cent of the market share (in terms of revenues).

India has also maintained its lead over China in pharmaceutical exports with a year-on-year growth of 11.44 per cent to US$ 12.91 billion in FY 2015-16, according to data from the Ministry of Commerce and Industry. In addition, Indian pharmaceutical exports are poised to grow between 8-10 per cent in FY 2016-17. Imports of pharmaceutical products rose marginally by 0.80 per cent year-on-year to US$ 1,641.15 million.

Findings

The following findings are including

1. In 2012 the UPA government issued "Statutory direction" to state governments under sections of the drugs and cosmetics Act, 1940 to grant licence for manufacturers for sale of generic medicines only. This was intended that wider usage of generic medicines. The doctors will have responsibility to prescribe generic medicines for patients so that the patient need not to buy any other medicine. And also the UPA government issued circulars to all the state and central government health scheme (CGHS) dispensaries to "prescribe generic medicines" to the maximum extent possible.
2. As per the directions of Hon'ble Prime Minister Narendra Modi with intention to make health care affordable in the country and he has given priority for generic medicines. In that line he said that doctors must prescribe only generic medicine to controlling the health expenditure in the country. In view of the directions of Prime Minister Narendra Modi to facilitate these drugs in various hospitals under the scheme of 'Jan Aushadi Kendra'. The government has to take initiative to introduce first in its government hospitals**.**
3. For promoting generic products the government has enforcing in warfoot manner interact with various stakeholders to discuss the issue and roll-out a plan for successfully promoting generic drug in India.
4. Under the Prime Minister Bharatiya Jan Aushadhi Pariyojana Kedras were started. Total 861 kendras are functional in 28 states. Out of which 99 are private manufacturing companies. This was certified by WHO. The Pradan Mantri Bharatiya Jan Aushadhi Pariyojana (PMBJP) the main aim is to provide cheaper medical drugs to the people. As per clause 1.5 of the Indian Medical Council Regulations, 2002 "Every Physician should prescribe drugs with generic names legibly in capital letters and he/she shall ensure that there is a rational prescription and use of drugs."
5. The government is encouraging generic medicines even our Prime Minister Narendra Modi strictly given instruction to all the doctors to write prescription on generic medicine**.** In the U.S. also it is standard practice in hospitals operated by the National Health Services Medical Schools have included generic medicine. In US generic substitute is an accepted practice and at the end of 2012. Almost 80% of the prescriptions were of generic medicines. It is the result of reducing healthcare expenditure and significant saving to the economy (Hoffman JM, 2012) [3].

Conclusion

It may be concluded that the main aim of generic medicine is reducing health expenditure about 10-90% can be achieved. The Indian Pharma's vast supply chain of 8 lac wholesalers and retailors doing their business profitable with high margin. Their role is very important to promote the generic product between doctors and patients. Sometime they are selling unbranded generics at margin as high as 1000%. Expecting these 8 lac retailers to suddenly transform and become charitable dispensers of low generics like Jan Aushadhi shows a complete lack of understanding how the system work. There is a chance of chemists to take advantage sell the medicines that suit

him the best for generating revenue. Due to this very first to understand chemists perception for selling generic products in India. The government also to take initiative for compulsorily prescription generic medicine to the public by the doctors as a result reducing the healthcare expenditure and significant saving to the economy.

References

1. Cameron A, Ewen M, Ross-Degnan D, Ball D, Laing R. Medicine Prices, availability, and affordability in 36 developing and middle-income countries: A secondary analysis. Lancet. 2009; 373:240-9.
2. Daemmrich A, Mohanty A. Healthcare reform in the United States and China: Pharmaceutical market implications. J Pharm Policy Pract. 2014; 7:9.
3. Hoffman JM, Li E, Doloresco F, Matusiak L, Hunkler RJ, Shah ND *et al*. Projecting future drug expenditures-2012. Am J Health Syst Pharm. 2012; 69:405-21.
4. Kotwani A, Ewen M, Dey D, Iyer S, Lakshmi PK, Patel A *et al*. Prices and availability of common medicines at six sites in India Using a standard methodology. Indian J Med Res. 2007; 125:645-54.
5. Kapczynski A. Engineered in India-patent law 2.0. N Engl J Med. 2013; 369:497-9.
6. Lancet Oncology. Is India ready to lead the battle for fair access to medicines? Lancet Oncol. 2013; 14:437.
7. Amit G, Rosen A, Wagshal AB, Bonneh DY, Liss T, Grosbard A *et al*. Efficacy of substituting innovator propafenone for its generic formulation in patients with atrial fibrillation. Am J Cardiol, 2004; 93:1558-60.
8. Shrank WH, Chowdhry NK, Liberman JN, Brennan TA. The use of generic drugs in prevention of chronic disease is far more cost-effective than thought, and may save money. Health Aff (Millwood). 2011; 30:1351-7.
9. World Health Organization, 2015.
10. WHO. The World Medicines Situation. Geneva: World Health Organization, 2015.
11. Schedule Drugs M. Cosmeties Act of India, 1940.
12. Mohamed Naeem Devla, Sanjeev Acharya R, Niyati Acharya S, Vimal Kumar. Dietary supplements: Alegal status in India and in foreign countries, Indian J Pharm Pharm Sci. 2011: 3(3):7-12.