International Research Journal of Management and Commerce
Vol. 4, Issue 2, February 2017 Impact Factor- 5.564
ISSN: (2348-9766)
© Associated Asia Research Foundation (AARF)
Website: www.aarf.asia Email : editor@aarf.asia , editoraarf@gmail.com

MARKETING OF GENERIC MEDICINES IN INDIA

B. Poovazhahi
Assistant Professor in Commerce
Sengamala Thayaar Educational Trust Women's College.
Mannargudi, Thiruvarur (Dt), Tamil Nadu, India.

ABSTRACT

A generic medicine is a pharmaceutical drug that is equivalent to a brand-name product in dosage, strength, route of administration, quality, performance, and intended use. The term may also refer to any drug marketed under its chemical name without advertising, or to the chemical makeup of a drug rather than the brand name under which the drug is sold.

An example of a generic drug, one used for diabetes, is metformin. A brand name for metformin is Glucophage. (Brand names are usually capitalized while generic names are not.) A generic drug, one used for hypertension, is metoprolol, whereas a brand name for the same drug is Lopressor.

Generic drugs are usually sold for significantly lower prices than their branded equivalents and at lower profit margins. One reason for this is that competition increases among producers when a drug is no longer protected by patents.Generic companies incur fewer costs in creating generic drugs—only the cost of manufacturing, without the costs of drug discovery and drug development—and are therefore able to maintain profitability at a lower price.The prices are often low enough for users in less-prosperous countries to afford them. For example, Thailand has imported millions of doses of a generic version of the blood-thinning drug Plavix (used to help prevent heart attacks) from India, the leading manufacturer of generic drugs, at a cost two indian rupees per dose.

Keywords: Gentric medicines, new schemes, marketing of gentric drugs, price controls.

INTRODUCTION

The Indian Pharmaceutical Industry has witnessed a robust growth over the past few years moving on from a turnover of approx. US $ 1 billion in 1990 to over US $30 billion in 2015 of which the export turnover is approximately US $ 15 billion. The country now ranks 3rd world wide by volume of production and 14th by value, thereby accounting for around 10% of world's production by volume and 1.5% by value. Globally, it ranks 4th in terms of generic production and 17th in terms of export value of bulk actives and dosage forms. Indian exports are destined to more than 200 countries around the globe including highly regulated markets of US, West Europe, Japan and Australia. It has shown tremendous progress in terms of infrastructure development, technology base creation and a wide range of products. It has established its resence and determination to flourish in the changing environment. The industry now produces bulk drugs belonging to all major therapeutic groups requiring complicated manufacturing technologies. Formulations in various dosage forms are being produced in GMP compliant facilities. Strong scientific and technical manpower and pioneering work done in process development have made this possible.

Recognizing the potential for growth, the Government of India took up the initiative of developing the Indian Pharmaceuticals sector by creating a separate Department in July 2008. The Department is entrusted with the responsibility of policy, pIanning, development and regulation of Pharmaceutical Industries.

An assessment of the Indian Pharmaceutical Industry's strength reveals the following key features:

- Strong export market- India exported drugs worth US$ 15 billion to more than 200 countries including highly regulated markets in the US, Europe, Japan and Australia. Large Indian pharma companies have emerged as among the most competitive in the evolving generic space in North America and have created an unmatched platform in this space. Indian companies are also making their presence felt in the emerging markets around the world, particularly with a strong portfolio in anti-infective and antiretroviral.

- Large domestic pharma companies have continued to grow, assuming leadership position in many therapies and segments in the Indian market as well as creating a strong international exports back-bone.

- Competitive market with the emergence of a number of second tier Indian companies with new and innovative business modules.

- Indian players have also developed expertise in significant biologics capabilities.

- Biologic portfolios while still nascent in India are being built with an eye on the future.

- Multinational companies have continued to invest significantly in India and are making their presence felt across most segments of the Indian pharma market. Companies have also begun to invest in increasing their presence in tier II cities and rural areas and making medical care more accessible to a large section of the Indian population.

- Low cost of production.

- Low R&D costs.

- Innovative Scientific manpower.

- Excellent and world-class national laboratories specializing in process development and development of cost effective technologies.

- Increasing balance of trade in Pharma sector.

- An efficient and cost effective source for procuring generic drugs, especially the drugs going off patent in the next few years.

- An exce|lent centre for clinical trials in view of the diversity in population.

Low cost of manufacture

India is capable of manufacturing low cost generic alternatives due to a number of economic factors favouring the industry. Some of these include the competitive land rates, the

cheap labour available, low resource costs like water, electricity etc., lower cost of production machinery. Importantly, the various drugs like, Intermediates, APIs and Formulation companies are seamlessly integrated while following international regulations of safety.

Bureau of Pharma PSUs of India

A Bureau of Pharma PSUs of India (BPPI) has been established on the 1st of December 2008 comprising all the Pharma CPSUs under the Department of Pharmaceuticals. The Bureau will bring about effective collaboration and cooperation in furthering the working and resources of these organizations. More specifically it would:

- Co-ordinate marketing of the generic drugs through the Jan Aushadhi stores.
- Co-ordinate supply of medicines in the State from their own plants, other Pharma PSUs of Central & State Governments and Private Sector.
- Coordinate with Hospitals in preparation of formulary.
- Monitor proper running of Jan Aushadhi stores with the help of other CPSUs.
- Provide medicines as per rates decided in the joint Forum/Core Committee.
- Monitor activities of the Jan Aushadhi stores in the areas allocated to them.

To begin with the Bureau has started working as separate and independent unincorporated entity from its office at IDPL , Gurgaon with an independent administration, operation and accounting system for its receipts and expenses. The Central Government would suitably assist the Bureau both financially and technically till the Bureau sustains by itself through its own operations. Other Central and State Pharma PSUs would also be given the opportunity to join the Bureau. The Bureau has been registered as an independent society under the Societies Registration Act, 1860 as a separate legal entity in April, 2010. BPPI follows the provisions of GFR, 2005 as amended from time to time, the CVC guidelines, and instructions from the Department of Pharmaceuticals. Under the mandate, BPPI is required to coordinate with States to open stores, monitor functioning of the stores, fixing Maximum Retail Prices (including fixing common prices, in consultation with NPPA for the medicines manufactured by the CPSUs for Jan Aushadhi supply) and also suggest/approve common super stockiest to ensure a proper supply chain mechanism.

JAN AUSHADHI CAMPAIGN – A NEW BUSINESS PLAN

1. Background

Over the years, India has developed strong capability in manufacturing generic medicines in almost every therapeutic category. The Pharmaceutical industry has evolved from merely Rs.1500 crores in 1980 to more than Rs.1,19,000crores by 2012. Medicines in almost every therapeutic category are sold primarily as branded drugs, at disproportionately very high prices.

There is still a large section of the population which finds it difficult to afford these high-priced medicines. According to World Health Organization estimates (2008), 65% of India's population does not have access to modern health care. Since 80% of out-patient care and 60% of inhospital care occurs at private facilities in India, households are exposed to a private-sector market to buy drugs (Public Health Foundation of India, 2012). According to NSO estimates, upto 79% of health care expenses in rural areas are due to the cost of medicines.

This problem gets aggravated further as almost 80% of expenditure on health care is out-ofpocket to the patients. Thus, access to low-priced generic drugs is very critical in ensuring health care at affordable prices.

'Ensuring availability of quality medicines at affordable prices to all' has been a key objective of the Department of Pharmaceuticals, Government of India. Some important regulatory steps that have been taken to keep the prices of drugs reasonable include:

i. Price control of Scheduled Drugs through the National Pharmaceutical Pricing Authority (NPPA): Under the Drug Price Control Order, 1995, NPPA has been given the mandate to control and fix maximum retail prices (MRP) of a number of scheduled drugs and their formulations, in accordance with well-defined criteria.

ii. Price regulation of Non-Scheduled Drugs: Apart from the scheduled drugs under DPCO, 1995, the NPPA also monitors prices of other non-scheduled medicines in a way that price increase is never more than 10% per annum, on a moving period basis.

To supplement the above regulatory measures, and particularly to improve access to medicines at affordable prices to all (especially to the poor masses) the Department has decided

to launch a nation-wide campaign i.e. the Jan Aushadhi Scheme, as a direct market intervention strategy for promoting use of generic drugs

A key initiative under the campaign involves opening of 'Jan Aushadhi Stores' where high quality generic medicines would be sold at low prices. Such medicines would be equivalent in potency and efficacy to expensive branded drugs.

2. The Jan Aushadhi Scheme – agenesis

It is a well-known fact that branded medicines are sold at significantly higher prices than their un-branded generic equivalents, which are just as good in the therapeutic value they provide. A sample comparison of prices of similar branded/ unbranded generic drugs is given below

Name of salt	**Dosage**	**Pack**	**Price of branded drugs (Rs.)**	**Price of Generic drugs (Rs.)**	**Difference**
Antibiotic: Ciprofloxacin	250 mg	10	55.00	11.10	5 times higher
Pain Killer: Diclofenac	100 mg	10	36.70	3.50	10 times higher
Common Cold: Cetrizine	10 mg	10	20.00	2.75	7 times higher
Fever: Paracetamol	500mg	10	10.00	2.45	4 times higher
Pain & Fever Nimesulide	100	10	25.00	2.70	9 times higher
Cough Syrup		110 ml bottle	33.00	13.30	2.5 times higher

Therefore, if reasonably priced quality generic medicines are made easily accessible and available in the market, everyone would benefit. With this objective, the Pharma Advisory Forum in its meeting held on 23rd April, 2008, decided to launch the Jan Aushadhi Campaign.

To fulfill the aforesaid objective, a Task Force comprising senior officers of the Department of Pharmaceuticals, Chief Executive Officers of Pharmaceutical Central Public Sector Undertakings (CPSUs), representatives of the Pharmaceutical industry, NGOs/charitable organizations and State Governments, and most importantly, doctors from reputed national institutions like the All India Institute of Medical Sciences, Maulana Azad Medical College and

Ram Manohar Lohia Hospital, was constituted.. Senior representatives of the World Health Organization were also invited to these deliberations. The Task Force held extensive discussions and unanimously recommended launching the Jan Aushadhi Campaign, starting with the sale of generic medicines through dedicated sales outlets in various districts of the country. It was proposed that the campaign be launched in association with the Central Pharma Public Sector Undertakings (CPSUs) viz, Indian Drugs and Pharmaceuticals Limited (IDPL), Rajasthan Drugs and Pharmaceuticals Limited (RDPL), Hindustan Antibiotics Limited (HAL), Karnataka Antibiotics Limited (KAPL) and Bengal Chemicals and Pharmaceuticals Limited (BCPL) as part of their Corporate Social Responsibilities agenda.

It was proposed that the Jan Aushadhi Campaign be implemented initially for the period of 11th Five Year Plan starting from 2008-09. The Department proposed to open at least one JAS in each of the 630 districts of the country so that the benefit of "quality medicines at affordable prices" is available to at least one place in each district of the country. If successful, depending on the cooperation of all stake-holders, the scheme was proposed to be extended to subdivisional levels as well as major towns and village centers by 2012.

It was envisaged that the Scheme would run on a self-sustaining business model, and not be dependent on government subsidies or assistance beyond the initial support. It was to be run on the principle of "No Profit, No loss".

2.1 Key objectives;

*The key objectives of Jan Aushadhi Scheme are to;

* make quality the hallmark of medicines by ensuring supplies from the CPSUs and also through other PSUs and GMP compliant manufacturers in the private sector.

*extend coverage of quality generic medicines, which would reduce and thereby redefine the unit cost of treatment per person.

* provide access to any prescription drug or Over The Counter (OTC) drug in all therapeutic categories as generic equivalents.

* not be restricted to the beneficiaries of Public Health System but also to serve others.

* create awareness through education and publicity that quality is not synonymous with high price

*create a demand for generic medicines “By All for All” by improving access to better healthcare through low treatment costs.

*also involve State governments, Central Government, Public Sector Enterprises, Private Sector, NGOs, Cooperative bodies and other institutions, being a public welfare programme.

*develop a model which can be replicated in other countries of the world, in pursuit of their common goal of achieving affordable quality health care.

The Jan Aushadhi Scheme was accordingly formulated and approved in the Standing Finance Committee Meeting of 01/02/2010 in consultation with the Planning Commission. The Planning Commission approved Rs. 24.25 crores for the 11th Plan Period of the Scheme for opening 626 Jan Aushadhi Stores (JASs) in the first phase.

Jan Aushadhi Campagin

New Business Plan The Standing Committee, in its 32nd report, has recommended (recommendation no. 9) that more Jan Aushadhi Stores should be opened on a mission mode. It further recommended the possibility of opening stores through a Public-Private Partnership, and partnering with individual 10 entrepreneurs. This remains to be explored. Public Health Foundation of India, which assessed the performance of Jan Aushadhi Scheme, has also advocated converting Jan Aushadhi stores into a low cost pharmacy chain at different levels in States.

Accordingly, a revised Business Plan has been worked out. It aims to extend the geographical coverage of the scheme, by opening more than 3000 stores during the 12th Plan Period. It is proposed to channelize efforts to popularize the scheme in a few selected states and ensure availability of the complete basket of medicines at affordable prices. The new Business Plan takes care of major bottlenecks in implementation of the scheme so far. The proposed changes in the scheme under the New Business Plan are listed below:-

1. Relaxation of eligibility conditions for Operating entities

Over-dependence on support from State Governments to provide space within premises of hospitals, and to identify operating agencies, has slowed down momentum of the campaign. This is evident from the fact that only 149 JASs have been opened so far since inception of the scheme. The State Governments regularly identified entities like RogiKalyanSamitis, Red Cross Societies and cooperative societies. Moreover, a few stores have been closed due to change in policy of the State Governments in favor of free supply of drugs through public health institutions. Therefore, it has been decided that the Jan Aushadhi Stores may be opened outside the premises of hospitals also. Moreover, any NGO/ charitable society/ institution/ Self Help group with experience of minimum 3 years of successful operations in welfare activities, supported by three years audited accounts, will be eligible for applying for opening of drug store.

As far as individuals are concerned, unemployed pharmacists/ doctors/ registered medical practitioners would be given preference for running the stores. These changes have been made with a view to make the scheme sustainable and marketable in a competitive market. The applicants have to approach BPPI with a complete application along with the following particulars;

i. Own space or hired space duly supported by proper lease agreement

ii. Minimum required space conforming to standards as approved by the BPPI.

iii. Sale license from competent authority.

iv. Proof of securing a pharmacist.

v. Financial capacity to run the store (bank statements/ audited accounts for the last three years/ a sanction letter from bank for extending loan).

2. Coverage of the Scheme

In the consolidation phase, it is proposed to establish a complete supply chain in the States where Jan Aushadhi Scheme has a substantial presence. Efforts would be made to open as many stores as possible in these States such as Punjab, Haryana, Delhi, Uttarakhand, Jharkhand, Himachal Pradesh and Odisha. North Eastern States would be 11 given special attention to

popularize the scheme. Later, the scheme will be extended to other States depending on the response from them. It is proposed to start a minimum of 3000 stores over a period of four years.

3. Review of existing list of medicines

At present, 319 medicines are listed for sale at the Jan Aushadhi stores. There was a need to review this list to provide maximum coverage to the newer molecules in demand, and also products under the NLEM. With this in view, a revised list of 361 medicines has been prepared, covering almost all therapeutic categories of drugs.

4. Supply Chain Management

As BPPI considers increasing the basket of medicines to meet the growing demand of the patients, more suppliers of medicines have to be roped in from other Public Sector Undertakings (PSUs) as well as private manufacturers. Procurement of drugs from private manufacturers is also necessitated by the fact that CPSUs have in-house capacity to manufacture only 138 products. Special focus is to be given to the availability of medicines, surgical and consumables, etc. In order to avoid any stock-outs, BPPI has to supplement supply by direct purchase of medicines from other PSUs and private sector companies through open tender process, as per the guidelines issued by Central Vigilance Commission. An IT based Management Information System is proposed to ascertain availability of medicines in stores on a real time basis, and accordingly trigger supply of medicines through a transparent procurement process and supply chain, patterned almost on the model of Tamil Nadu Medical Services Corporation (TNMSC).

5. Sourcing of drugs

As mentioned earlier, the list of products (138 Nos), reserved for CPSUs, has been finalized in consultation with them based on their in-house manufacturing capability. In respect of these drugs, CPSUs shall have the first claim to supply. The remaining products will be sourced through the private sector, following due process. As and when infrastructure for in-house manufacture of drugs is created in CPSUs, the private sector will be gradually phased out. Even in respect of drugs reserved for CPSUs, these drugs may be procured from private sector or other PSUs in case the respective CPSU fails to supply medicines on time. It is to be kept in mind that stock-out situations for any drug should be avoided at any cost.

6. Quality Control

12 BPPI would ensure that only quality drugs are supplied through the Jan Aushadhi stores. To ensure this, it is essential that manufacturers of drugs are selected carefully and after due inspection of their facilities to ensure that they conform to required standards i.e. WHO-GMP compliance. Further, samples should be sent for testing on a regular basis. Any failure on the part of suppliers to comply with quality standards should trigger initiation of stringent actions, in addition to blacklisting the firms against future contracts. Though BPPI would ensure quality control through its own channels, the ultimate responsibility to ensure quality of medicines would rest with the manufacturers.

7. Pricing of Drugs

Out of the proposed list of 361 medicines, MRPs for 138 medicines, manufactured and supplied by the CPSUs, have already been fixed in consultation with NPPA. In respect of medicines procured from private manufacturers or other PSUs, MRP will be fixed on the basis of rates arrived through tender process plus trade margins and other incidental costs (including excise duty, if any, and VAT component).

As mentioned earlier, MRPs of the medicines will be decided by BPPI after taking into consideration the wholesalers' margin of 8% and retailers' margin (Jan Aushadhi stores) of 16% for medicines under DPCO'95 and 10% for wholesalers and 20% for retailers for the non-DPCO medicines. Similarly, MRPs of surgical and consumables will be worked out based on the procurement rates including distribution costs.

Beyond the 12th Plan period, an additional margin not exceeding 2% will also be collected to meet administrative expenses of BPPI. As the BPPI has to be run on 'no profit no loss' basis, the exact percentage would be worked out based on the volume of turnover at that time.

8. Working Capital

There was also no provision for financial support to establish a supply chain in the original scheme. In the new business plan, it is proposed to provide a working capital of Rs. 65 croresto BPPI. Besides supporting CPSUs by extending advances as part payment against firm orders, this working capital will also be utilized to meet costs of exigencies such as inventories in supply

chain. For the first time, an amount of Rs.4.5 crore was allocated in the year 2012-13 to BPPI for the purpose, with the approval of Planning Commission.

9. Losses due to expiry of medicines

In the initial period of Jan Aushadhi Scheme operations, neither CPSUs nor BPPI had experience of handling retail operations of medicines. Initially, medicines covered under the Preferential Purchase Policy (PPP), and also other medicines manufactured by CPSUs for the institutions, were supplied to the Jan Aushadhi Stores in much larger quantities than what the stores actually required in the retail outlets.

The demand for several of these PPP items like anti-TB drugs at the retail outlets is generally insignificant, as these drugs are given free of cost to the patients under the TB Control programme of the Government of India. This resulted in expiry of such medicines because the stores were not able to sell within the specified period.

The expiry of 2% of medicines is permissible, as per the Pharma industry norms. In the case of Jan Aushadhi, it could be somewhat higher as the consumption of medicines depends upon the extent to which the generic medicines are prescribed by the Government doctors. Normally, the loss arising from expiry of medicines is to be borne by super stockiest and supplying agencies including CPSUs. It is also proposed to establish a supply chain management system, which would ensure supply of drugs only in tune with demand, thereby bringing down the expiry of drugs to reasonable limits.

10. Non-prescription of Generic Medicines

With respect to non-prescription of generic medicines by the Government doctors, BPPI has requested State Governments several times to issue necessary guidelines to government doctors. BPPI will continue pursuing this matter with concerned authorities. It is also proposed to organize workshops for promotion of Jan Aushadhi in States where in Government doctors, officials and other stake-holders would be invited. Besides, directions from Medical Council of India to the medical fraternity to prescribe generic medicines will also go a long way in promoting the Jan Aushadhi.

11. Health Policies of Central/State Governments

Several State Governments such as Haryana, Rajasthan and Tamil Nadu, as per their health policies, provide free medicines to all patients visiting Government hospitals. It is learn that even the Ministry of Health and Family welfare, Govt. of India, is contemplating a scheme to provide free medicines to all.

Under such circumstances, it is imperative to assess the viability of opening Jan Aushadhi stores in such States given the demand for generic drugs outside the ambit of Government run health care programs. There is a domestic market of more than Rs 60,000 crores, and the target group for the Jan Aushadhi scheme (the poorer segment of the general population) constitutes a large share of this market. Intuitively it appears that, given the higher percentage of out-of-pocket expenses i.e. 80% on health care, there will always be scope for running this scheme.

The revised Jan Aushadhi scheme proposes to take this campaign not only by extending spatial coverage beyond Government hospitals in order to reach larger sections of the society but also by extending coverage to other NGOs, institutions and individuals (preferably qualified pharmacists/doctors).

12. Media Campaign

Media campaigns would play an important role in educating people about use of generic medicines, and more specifically, on the benefits of the Jan Aushadhi Campaign. In this connection, BPPI would initiate necessary steps, especially in those States where the Jan Aushadhi scheme has already been started, so that people take full advantage of the availability of generic medicines at affordable prices at the Jan Aushadhi stores.

Workshops of government doctors, officials and other stakeholders may also be organized. It is also proposed to utilize the wide reaching SMS facility to make people aware of less costly generic substitutes, which are available at JASs.

13. Administrative expenses of BPPI

With the expansion of the JAS as per new business plan, BPPI will also require qualified manpower to implement the scheme effectively. It is proposed to appoint one Chief Executive Officer, who would lead the team and supervise day-to-day functioning of Jan Aushadhi

Scheme. He/ she would be supported by managers with expertise in supply chain management, marketing, accounting, pharmaceuticals, quality analysts, Management Information System related issues. All these executives would be hired from the open market for a specified period and renewal of their services would depend on their successful performance against the predetermined success indicators. The exact organization structure would depend on the workload and need of the hour. However, it would be kept in mind that the size of the organization remains sleek to handle core activities and most of the peripheral work is outsourced to appropriate agencies.

BPPI is managing its administrative expenses out of financial assistance being provided by the Central Government for the Jan Aushadhi Campaign. It is proposed to continue this arrangement for a further period of four years or till BPPI becomes self-sustainable, whichever is earlier. In order to sustain the activities of BPPI beyond 12th Five Year Plan, it is proposed to make provision for the collection of margin not exceeding 2% by BPPI

be made by the committee to popularize generic drugs.

Expected Outcomes

Given India's position as a major player in the manufacture and supply of generic medicines around the world, the scheme will definitely find its place in domestic market, making medicines widely and easily available at affordable prices.

The following outcomes are expected from the successful implementation of Jan Aushadhi Scheme;

i. Overall availability and access to essential generic drugs would improve dramatically.

ii. Access to healthcare would improve as the cost of treatment comes down substantially.

iii. There will be significant reduction in out-of-pocket expenses, thereby reducing impoverishment to a great extent.

iv. This initiative would provide a secure socio-economically viable mechanism / institutional arrangement for sale of Pharmaceutical CPSU products, thereby improving their viability.

v. Promoting & encouraging private industry, particularly small and medium enterprises, to sell their quality generic products through these retail outlets would provide a space for their products in the domestic market. vi. The patients and doctors would be fully aware of the potential of unbranded generic drugs. This would be achieved by creating consumer awareness involving private and charitable bodies, NGOs etc. It would help in dispelling the myth that quality of medicines is linked to price, and demonstrating that quality medicines with equivalent efficacy and safety can be made available at substantially lesser prices

Conclusion

The Jan Aushadhi Campaign is expected to make a great contribution by way of achieving the socio-economic goal of affordable health, by ensuring availability of quality drugs at affordable prices for all.

The scheme is also expected to reduce expenditure on medicines, thereby extending patient coverage under the public health scheme. Popularization of the use of unbranded generic medicines will bring down actual out-of-pocket expenses on medicines for the common man and thereby make health care affordable and safe.

Jan Aushadhi Scheme will prove to be an effective market intervention strategy to bring down the prohibitively high prices of medicines, and will create market for drugs manufactured in CPSUs, other State PSUs and private sector, particularly small and medium enterprises.

References:

1. http://www.janaushadhi.gov.in

2. . http://www.pharmaceuticals.gov.in

3. . http://en.wikipedia.org/wiki/Generi_drug.