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National Pharmaceuticals Pricing Policy: A Review

Abstract

Like many other developing and a few developed countries, India also partly depends on pharmaceutical companies for its economic growth. Realizing the concept along with the need to provide accessible and affordable essential drugs to the citizens, especially those of economical weaker section, many drugs or pharmaceutical policies were formulated in India. Such policies ensure continuous availability of safe and effective essential medicines, especially in the public sector and quality, safety and efficacy of human and veterinary drugs inline with internationally acceptable standards while ensuring appropriate regulation and control, latest being the National Pharmaceutical Pricing Policy (NPPA), 2013, the focus of which is to include more drugs under NLEP, decrease in cost of medicines, providing generic medicines, etc. The use of the international non-proprietary name (INN), or generic name, is a recognized strategy to reduce medicine costs and expenditure. The policy though up to certain level provided the relief in the cost of essential medicines but still major areas were still untouched by the policy. This article deals with the drawback of the pharmaceutical policies in our country. Also the major problems being faced by the doctors who are part of government healthcare system and a vision of how to deal with it or what more can be added in such policies to provide the smooth and effective basic healthcare to the community.

Introduction

Globally, India is the third-largest producer of medicines. The Indian pharmaceutical industry, driven by knowledge, skills, low production costs and international quality of products has witnessed a robust growth from the production turnover of about Rs. 5000 crore in 1990 to over Rs. 1 lakh crore in 2009-10.[1] By 2020, the country is expected to be within the top three pharmaceutical markets by incremental growth and sixth-largest market globally in absolute size. The Government of India unveiled *Pharma Vision 2020* aimed at making India a global leader in end-to-end drug manufacture. Approval time for new facilities has been reduced to boost investments. Further, the government introduced mechanisms such as the Drug Price Control Order and the National Pharmaceutical Pricing Authority to deal with the issue of affordability and availability of medicines. First ever Drug Policy 1986 was passed with the objective of ensuring abundant availability, at reasonable prices, indigenous capability for production of drugs.[2] With the system of quality control over drugs and to encourage cost-effective production with economic sizes and to introduce new technologies and new drugs, in which all the points were laid down regarding guidelines for registration, standardization, monitoring of adverse effects, use of generic names, etc. It also laid down the central and state infrastructural facilities for quality control and line to establish the first National Drug & Pharmaceutical Authority at the central level, with a permanent secretariat.

Equally prices of drugs were the main focus; also it was in conformity with the principle of selectivity commended by the Hathi Committee. There was a uniform norm for all bulk drugs falling in the controlled category I and II and the manufacturers were given the following three options: 14% post tax return on net worth; or 22% return on capital employed; or long-term marginal costing with 12% internal rate of return in the case of

new plants.

A Drug Price Equalization Account (DPEA) was set up essentially to encourage domestic production of bulk drugs through a system of retention pricing.

Since the first drug policy, where the price list and generic drugs prescription, etc., were mentioned many new policies came such as Modification in Drug Policy 1986, Drugs (Price control) Order 1995, Pharmaceutical Policy 2002, National Pharmaceutical Pricing Policy 2012, which is the recent one was approved by the Cabinet and notified in 2012. Based on this policy, a new Drugs Price Control Order was notified in May, 2013. A list of several drugs will come within the ambit of price control called the National List of Essential Medicines (NLEM).

For the new pricing policy Drugs (Price Control) Order 2013, the main objective was to put in place a regulatory framework to ensure the availability of essential drugs listed in the NLEM at affordable prices.[4] Healthcare access in India is affected with 70:70 paradox; 70% of healthcare expenses are incurred by people from their pockets (out of pocket expenditure), of which 70 percent is spent on medicines alone, leading to impoverishment and indebtedness.[5] The incidence of catastrophic healthcare expenditure (CHE) is growing and is now estimated to be one of the major contributors to poverty. Healthcare costs are more impoverishing than ever before and almost all hospitalizations, even in public hospitals, leads to CHE and over 63 million people are facing poverty every year due to healthcare costs alone.[6] The policy was also oriented to decrease this OPP and reduce the burden on health service consumers. Other measures such as encouraging the growth of the pharmaceutical industry and the development of new medicines were part of the framework of the policy.[7] With this policy, many essential drugs became more accessible to common man; however, the situation is reverse for pharma companies. At one end of the policy, the drugs have become easily and cheaply available for procurement of common man, at other end it is not much supportive to the foreign pharma companies, which ultimately will have a detrimental effect. It varies with the prescription of the drugs by the practitioners increase the cost of the drugs. In both developed and developing countries, prescription of medication is one of the most important factors in the rising costs of health services.

There are some perceived disadvantages of drug policy and regulations. On the one hand, regulations curb costs and thus potentially improve the welfare of the current generation. However, some argue that pharmaceutical regulations might also have negative consequences for consumers. For example, price regulation can lead to less competition in markets for generic drugs,[8] delay launch of new drugs,[9] and limit the availability of new drugs.[10] In addition, such regulations might reduce the pace of innovation, by limiting pharmaceutical revenues and the profitability of investing in research and development.[11]

The available drugs due to high uncontrolled cost were not able to reach the needy who were deprived of all the essential medicines. Cost was one of the factors associated with it. To limit the drugs cost-based mechanism was used which proved to be an inefficient mechanism to calculate the price.

Major Recommendations[4]

- The weighted average price of all brands, having greater than 1% market share formula will result in over 40–70% price reduction in 60% of the National List of Essential Medicines (NLEM). The WAP mechanism to control the price of essential medicines will achieve twin objectives of public health and industrial growth.
- 348 *essential* drugs, including cancer and HIV medicines will come under the purview of the pricing policy.
- The policy would not only prove to be miracle of reduced price ranging from 40 to 77% but it would also bring hope to thousands of poor and needy ones who unfortunately are usually deprived of the basic healthcare as the government has assured of continued availability of these medicines even after the price reduction after the implementation of the policy.
- Under the current cost-base formula of determining the price of the drugs, the expenditure on research & development on export market development was not being considered at all. However, the mechanism suggested in the policy to determine the price of drugs would reflect the cost.

However, one important drawback of this policy was that it was unable to put some lifesaving patent drugs under the policy. This further is detrimental as some drugs such as ARV drugs used for treatment of PLHA/HIV were beyond the coverage of this policy, hence still upto this time also they are out of reach of the common and needy people, resulting in increased purchasing of drugs privately, i.e., out of the pocket expenditure (79%).[12]

WAP-based system: This is the recommended method in the current policy to determine the price of the drug in which price is calculated in simple average of all drugs with 1% market share cut-off.

Apart from working in other outputs, one of the novelties in this policy is that it is aiming to place a framework to regulate the pricing of the drugs so that the drugs will be available at minimal price to the citizens.

Current Situation

1. Many companies exist but in spite of that the prices of drugs have not come down.
2. Same drug is sold in different prices by the same company under different brands.
3. Lack of awareness that price is not necessarily a denominator of quality, hence brand leader is often also the price leader, resulting in selling of costliest drug more and competition does not automatically bring down the prices. In fact it seems more.
4. It has also been seen that the interaction between doctors and pharmacy companies influences the prices.

Implications of NPP 2013

- The pharmaceutical industry plays a vital role in the world's economy, as well as in ensuring the welfare of its citizens.[13] The Indian pharmacy industry, which is expected to grow over 15% per annum between 2015 and 2020, will outperform the global pharmacy industry, which is set to grow at an annual rate of 5% between the same periods. With this rate of growth, the country's GDP will also grow. Not only it will impact the economy but also being the largest producers of generic medicine, the manpower required in setting up industries will also grow. For example, growth in the pharmacy retail market nearly halved from nearly 15% witnessed during 2012's first quarter (Jan–Mar) to single digit 8% during the first quarter (Jan–Mar) 2013 year. Sequentially, growth (GDP) slipped to 11.6% in 2012's Q2, remained static over two consecutive quarters at 10.4% in the third quarter ended September, and the fourth quarter (Oct–Dec) last year.
- **Decrease in essential medicine costs:** Since many drugs are being brought under NLEP, the cost of these drugs decreased automatically. Also the production of many branded drugs into some simpler generic drugs also started. These will further decrease the per unit cost of medicines. The regulation of prices of drugs is on the basis of essentiality of drugs as specified under National List of Essential Medicines (NLEM)-2011, on the basis of regulating the prices of formulations and on the basis of fixing the ceiling price of formulations through market-based pricing (MBP). As per the provisions of NPPP-2012, all the manufacturers/importers manufacturing/importing the medicines as specified under NLEM-2011 shall be under the purview of price control. Such medicines shall have an MRP equal to or lower than the ceiling price (plus local taxes as applicable) as notified by the government for respective medicines.

Problems Faced by Physicians

1. **Shortage of medicines:** The generic drugs, though according to policy should be available in the hospitals, still in many government hospitals and health centers they are not available resulting in prescribing the medicines from outside. There are various factors involved in unavailability of generic drugs such as excess demand and low supply and lobbying of branded drugs in government stores. In a situation like this, where patients have to go and buy medicines from outside, results in chaos and disorder among patients and attendants.
2. **Ineffective medicines and lack of convincing information on the quality of medicines in the market:** Manufacturing of generic drugs indigenously provides the opportunity to deliver an acceptable level of healthcare at a reasonable cost for populations in the developing world including the ever-growing number of displaced communities, who are left behind in the economic race. Although the manufacture of generic essential drugs offers a practical way of achieving this aim, the quality of these products tends to be jeopardized by overriding considerations of cost. Assuring the quality and safety of essential drugs is paramount to achieving effective implementation of national drug policies, pharmaceutical programs and humanitarian relief operations. For generic drugs, the affectivity of the drugs is still doubtful. The FDA allows different drug formulations and different rates of release and absorption. The FDA accepts generic drugs that are 20% weaker or 25% stronger than the brand name medication. These problems explain why generics are ineffective for some patients, and why generics are too strong and cause drug side effects in others.[14] At times, those medicines which are available in government pharmacy, are not very effective. Even after continuously prescribing the medications, it does

not help in improving the condition of the patients. It has been seen and experienced by many physicians that the same salt of drugs if given from generic drugs available in government setups and those available outside, the affectivity to treat infections and morbid conditions is more with drugs from those available in outside markets. According to a doctor in AIIMS, "there are certain generic medicines that don't work like the branded ones. In AIIMS, certain generic drugs are not prescribed, instead branded ones are preferred." This clearly indicates the lack of quality control in pharmaceutical companies.

3. **Combination medicines:** Combination medicines that are easier to prescribe with good patient compliance are available in the market. In spite of knowing that for medicines such as antibiotics whereas compliance is required the combination medicines work wonders but such medicines are not available in government stores, whereas it is mandatory to prescribe generic medicines; patients are being left out of appropriate treatment
4. **Advanced/ Recent medicines:** Healthcare has become increasingly sophisticated, with rapid development of new drug molecules, drug combinations and other health technologies. Medicines with combination of one or more medicines and medicines where recent developments are also available in markets which are not available in government stores. In such conditions, where a physician knows that the patient can be benefitted by advance medicines but is not able to prescribe it due to unavailability of such medicines, results in losing or no improvement in the condition of the patient, which is ethically wrong.

How to Overcome These Issues

1. Though policies are made but either they are not implemented or those which got implemented did not focus on actual problems or ground realities. Inadequate policy scope, weak governance structures and lack of effective technical oversight of the pharmaceutical sector always persists. One of the solutions is to involve the physician in the making of policy drafts. Those who work directly within the system can only be able to highlight the problems being faced by them pertaining to prescribing drugs and all.
2. In every part of the country, a big economic divide is there. There exists an economically sound section who can afford costly medicines, who comes to government health facility putting in faith on the experience of physician but they were not prescribed the best of available medicines because the pharmaceutical does not permit prescription of medicines other than the generic ones. This is unethical from their point of view that in spite of the need of good and effective drugs which they are willing to buy are not provided such medicines just because our system is not flexible and does not cater to the need of them. This over regulations of the policies should be stopped. Our system should be flexible enough or treating physicians should be given choice to treat the patients subjectively. Or in other words, one standard treatment does not fit every patient. Since it modifies with the patient's condition, the drugs which the physician can prescribe should also be modified and that is not possible just by limited drugs, especially when every other day advanced and best medical care products or medicines are being discovered. If a person can afford more effective medicines, there should be provision for providing them after probably taking written informed consent from them.
3. Create rules and regulations that allow generic substitution in the public, faith-based and private sectors. It will be incumbent upon the pharmacist, before dispensing a prescription, to inform the patient on the benefits of generic substitution and to ensure that such substitution takes place with the full understanding and consent of the patient. Affirm the right of patients to make informed decisions concerning their own health, including a choice for generic medicines.
4. Research and development (R&D) is one of the key features of the global pharmaceutical industry. For development of new drugs and technologies and improvement in the performance of existing products, R&D is required. A current gap is that R&D is virtually lacking for the neglected disease conditions that disproportionately affect poor populations. The Global Strategy and Plan of Action (GSPOA) on Public Health, Innovation and Intellectual Property, negotiated through the World Health Assembly, provides a global framework for better investment in R&D for neglected diseases.[15]
5. In some countries, for example Germany, automatic substitution of the drug is acceptable legally. It simply means after telling the benefits of generic drugs and substituted compound and giving the choice to patients or consumers, the generic drugs can be replaced by other salts or same salts with higher quality. Such amendments in policies can also help in giving health decisions into community hands.

Conflict of Interest: Nil

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