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India to increase supply of free generic medicines: some key issues

Recent reports indicate that the Indian government plans to increase manifold its spending on procurement of generic medicines for supply free to patients. This is welcome news. However, it is important to ensure future supply of generic medicines by addressing the present problems facing the Indian drug industry.

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By Nirmalya Syam

Recent news reports suggest that India is proposing to substantially increase government spending on public procurement of generic medicines in order to distribute them freely to patients through government hospitals and clinics. A recent article in the Wall Street Journal reports that India wants to spend up to 300 billion rupees (5.4 billion USD) to this end by 2017, increasing its expenditure substantially from the current level of 60 billion rupees (1.1 billion USD). Other news reports in the global and Indian media also suggest a move in this direction with the objective of providing universal healthcare.

Thus, it seems that the government is actively pursuing a policy of promoting universal access to healthcare with access to affordable medicines forming an integral part of this schema. Such a move is indeed laudable and much desired in view of the fact that almost 80 per cent of the spending on healthcare in India comprises out of pocket expenditure and this is one of the contributory factors for poverty in India.

The proposal by India is based on the recommendations of a High Level Expert Group on Universal Health Coverage (HLEG-UHC) constituted by the Planning Commission of India. The report of the Group which was submitted to the Planning Commission in November 2011 proposed that every citizen of India should be entitled to primary, secondary and tertiary healthcare services to be guaranteed by the Central Government.

The report contains recommendations regarding the architecture of the Universal Health Care (UHC). A key recommendation is recommendation 3.1.2 to "Ensure availability of *free* essential medicines by *increasing public spending on drug procurement*" (emphasis added). This recommendation constitutes the basis for the current proposals from the Government of India. While making this recommendation, the HLEG report explains that "Low public spending on drugs and non-availability of free medicines in government healthcare facilities are major factors discouraging people from accessing public sector health facilities. Addressing this deficiency by ensuring adequate supplies of free essential drugs is vital to the success of the proposed UHC system." To this end, the report recommends a two-pronged approach: 1) increasing government spending on public procurement of medicines from 0.1 per cent of the GDP to 0.5 per cent of the GDP; and 2) introducing a pooled procurement system to ensure adequate supplies and rational prescription of quality generic drugs by the public health system.

Introduction of free medicines in the public health care system is not a novel phenomenon and is certainly not confined to India. In some developed countries there is a preference for free supply of medicines to patients. For example, in Spain patients get medicines at no cost from pharmacies which are then

reimbursed by the government. By law pharmacies are compelled to provide the cheapest generic alternative to the patient even if the prescription states another brand. A recent report in the French magazine *La Nouvelle Observateur* states that the new French government is of the view that the national social security system cannot afford the pharmaceutical bill of the patients unless reimbursements are restricted to only generic medicines.

The supply of free medicines is not a novelty even in India. Chapter 3 of the HLEG report itself shows that in the mid-1980s, approximately one-third of the drugs prescribed during hospitalization were supplied for free in India, but since then the supply of free medicines has progressively fallen. The report also shows that this fall in the supply of free medicines has been accompanied by a simultaneous and dramatic increase in out of pocket expenditure by patients.

With regard to the procurement of medicines for free distribution through government-run hospitals and clinics as a part of the UHC system, the report of the High Level Expert Group stresses on the need for establishing a system of pooled procurement of generic medicines. The report points out the current situation of diverse systems of medicines procurement in different states of India, which suffers from serious deficiencies and leads to wasteful expenditure, unnecessary purchases and stock outs. However, the report also draws lessons from one successful model of medicines procurement from the state of Tamil Nadu which is being replicated in other states like Kerala, Bihar, Madhya Pradesh and Odisha. The success of the "Tamil Nadu model" has encouraged the government to contemplate adopting the model at a national scale to serve as the pooled procurement mechanism for distribution of free medicines.

According to officials of the Ministry of Health and Family Welfare, Tamil Nadu and Rajasthan are already distributing free drugs. Free drugs are also being given to pregnant women under the National Rural Health Mission (NRHM). Thus, it will be pertinent to look at the "Tamil Nadu model" in somewhat greater detail.

The "Tamil Nadu Model"

Under the "Tamil Nadu model", the procurement, storage and distribution of all drugs as well as surgical and suture items to all government hospitals and public health centres (PHCs) is conducted by a government company. In the state of Tamil Nadu, procurement has been undertaken by the Tamil Nadu Medical Services Corporation (TNMSC) since 1994. The TNMSC has been lauded for following a very clear and transparent tender process. It procures about 268 drugs in bulk directly from the manufacturers based on an Essential Drugs List (EDL) which is reviewed and updated periodically. These drugs are packaged with a special "TG" (Tamil Nadu Government) logo to prevent unauthorized sale outside hospital dispensaries. Each and every batch of drugs supplied by suppliers are subjected to quality tests by laboratories empanelled through an open bidding process.

The drugs procured are stored in TNMSC warehouses in each district from where they are distributed to government hospitals and PHCs in the district. Every government hospital and PHC is issued a passbook with which it can approach the nearest warehouse to procure a drug. The entry in the passbook serves as the basis of an inventory system which helps to prevent stock outs. The passbooks are issued based on the budget allocation for each hospital or PHC. 90 per cent of the allocated budget amount is deposited in a special account from which the TNMSC purchases the drugs each time an indent is made from the hospital or PHC. 10 per cent of the budget allocation is provided to the respective hospitals and PHCs for local purchases.

The TNMSC system has been very successful in substantially reducing the cost of procurement. It has also been very successful in ensuring through strict quality control mechanisms in the procurement process that medicines of high quality are made available for free to patients through the government hospitals and PHCs. According to a World Bank report, the TNMSC system has been highly successful in significantly increasing the number of patients using government hospitals and PHCs.

While the proposal to distribute free drugs through a scheme of central procurement and distribution of generic medicines is indeed a significant advancement towards ensuring universal access to medicines in India, there are many other factors impeding access to medicines that need to be addressed in order to draw maximum benefit from these proposed schemes. The report of the High Level Expert Group itself points out to these factors:

1) High drug prices – the report recommends applying price control on formulations in the Essential Drugs List.

2) Widespread use of irrational medicines – the report points to the need to promote the rational use of drugs through prescriber, patient and public education.

3) Lack of regulation of drugs and diagnostics – the report recommends strengthening central and state regulatory agencies to effectively perform quality and price control functions.

4) Barriers arising from product patents on medicines – the report stresses on the need to protect the safeguards under India's patent laws and the TRIPS Agreement against the country's ability to produce essential drugs.

5) Insufficient focus on research and development.

The Need to Strengthen India's Generic Drug Industry

A very critical challenge towards effectively implementing the proposal for procurement of generic medicines and free distribution of the same in government hospitals and clinics is the need to ensure a sustainable supply of affordable and quality generic medicines. However, while India is blessed with a very strong generic industry that acts as the source for affordable generic medicines across the developing world, the industry itself faces significant existential threats. The most important of the various challenges confronting the Indian pharmaceutical industry is the increasing control of the industry by multinational companies (MNCs) and the abuse of patent rights to restrain generic competition.

Since 2001 India has been allowing 100 per cent foreign direct investment (FDI) without any need for prior approval (automatic route) in pharmaceutical manufacturing, except in sectors using recombinant DNA technology. However, the FDI that has been attracted has been largely brownfield investments focused on acquisition of Indian generic companies, rather than greenfield investments focused on setting up new pharmaceutical manufacturing facilities. There has been a spate of high profile acquisitions of Indian companies by MNCs, sometimes offering purchase prices that were significantly higher than the sales turnover of the Indian company.

For example, Abbott Laboratories acquired Piramal Healthcare for $3.7 billion though the sales turnover of the company was about $400 million. A study by Prof. Sudip Chaudhuri (2011) points out that through this acquisition, Abbott Laboratories became the largest company in India with a market share of 6.2 per cent in 2010, from its position as the 30th largest company in 2008 with a market share of 1.1 per cent. According to Chaudhuri, "If a few major Indian companies such as Cipla …, Sun …, Cadila Healthcare …, Mankind …, Alkem …, Lupin … are taken over, the MNC share will exceed 50% immediately."

The current wave of acquisitions of Indian companies is also accompanied by a simultaneous change in the business models of Indian generic companies. Increasingly, many Indian companies are entering into strategic alliances with MNCs for undertaking contract research and manufacturing (CRAMS) for MNCs. CRAMS essentially involves outsourcing the manufacturing of active pharmaceutical ingredients and formulations, research for new drug compounds and clinical and pre-clinical trials. In this context, a discussion paper by the Research and Information System for Developing Countries (RIS) points out that Indian pharmaceutical firms have become an integral part of the global R&D and production network of MNCs.

Alarmingly, the discussion paper points to instances where the attraction of the western pharmaceutical markets has led to the abandonment of drug research programmes for diseases that affect significant sections of India's population. For example, Lupin – the only Indian company engaged in the development of TB drugs, expressed its desire to end the TB research programme and focus on diabetes and anti-inflammatory research. This was in spite of the fact that Lupin was successful in identifying a candidate for a new TB therapy for the first time in the last 40 years globally (Joseph, 2011). A recent study from the National Institute of Science, Technology and Development Studies (NISTADS) – *Globalization of the Indian Pharmaceutical Industry: Implications for Innovation* (Dinesh Abrol, Pramod Prajapati and Nidhi Singh, 2011) states that "… in India the in-house industrial pharmaceutical R&D is largely directed to the needs of western markets and much less to the undertaking of Type III R&D meant for neglected diseases of the poor in developing countries."

Analysing the acquisitions and takeovers of Indian generic companies by MNCs, Gopakumar and Santhosh (2011) observes that "… the MNCs are mainly targeting Indian companies with a high level of technological capability." According to the authors, this can lead to the following consequences:

(1) The R&D priorities of the Indian companies will be determined by the demand in western markets where increasingly there is a preference for generic medicines. This can increase India's dependency on the MNCs for the supply of essential medicines necessary to address the diseases that predominantly affect the patients in India.

(2) Through such takeovers, MNCs can get access to the marketing and distribution networks of Indian companies through which low-cost medicines can be substituted for higher priced and patented medicines of the MNCs. The MNCs can also substantially increase the price of existing products. For example, according to the Indian Pharmaceutical Alliance (IPA), after the acquisition of Piramal Healthcare, Abbott Laboratories increased the price of medicines sold by Piramal Healthcare. Two specific examples can be cited – i) the price of Haemaccel, a medicine for prevention or treatment of shock, was increased from Rs.99.02 in May 2009 to Rs.215 in May 2011 (an increase of 117% in two years); ii) the price of an epilepsy drug sold by Piramal – Gardenal – was increased by about 121% from 2009 to 2011.

(3) Another important issue is that the takeover of Indian firms by MNCs can significantly undermine India's ability to use the flexibilities under India's patent laws and the WTO TRIPS Agreement to the fullest extent. Critical patent flexibilities such as compulsory licenses depend substantially on the availability of generic companies to make use of the compulsory licenses. The recent grant of a compulsory license by India on a cancer drug soratinib tosylate (Nexavar) over which Bayer held a patent, reflects India's willingness to issue compulsory licenses even for non-communicable diseases (NCDs) like cancer. The existence of generic companies to make use of such compulsory licenses will be critical in this regard. It is important to note that MNCs enjoy a patent monopoly and charge very high prices for many NCDs like cancer, cardiac, diabetes and neurological conditions (Chaudhuri, 2011). In the context of the proposed scheme of procurement of generic medicines and their free distribution, the ability to use patent law flexibilities to make generic versions available at affordable costs will be critical.

Expert Group's Proposals on Drug Industry

In respect of the concerns arising from take-over and strategic alliances in the Indian pharmaceutical industry, the Report of the High Level Expert Group proposes the following options for the government's consideration:

(a) Public Sector Units (PSUs) which have drug manufacturing capability should be strengthened by infusion of capital into PSUs such as the Indian Drugs and Pharmaceuticals Ltd. (IDPL), the Hindustan Antibiotics Ltd. (HAL), and state owned enterprises, and also confer these PSUs with autonomous status. This can ensure the production of the required volumes of drugs for use in primary and secondary health care facilities, help in "benchmarking" procurement costs, and also enable the use of compulsory licenses where required.

(b) The current policy of 100 per cent foreign direct investment (FDI) through the automatic route should be amended and limited to 49 per cent in respect of the pharmaceutical industry, in order to retain the predominance of the Indian pharmaceutical industry and sustain India's self-sufficiency in drug production. Alternatively, the report suggests that the drug industry should be brought under the ambit of the Foreign Investment Promotion Board (FIPB) to scrutinize all proposals of foreign mergers and acquisitions of Indian drug companies. Another alternative suggestion is to distinguish financial ownership from legal ownership and limit the voting rights of foreign shareholders. This is an approach that is followed in the Indian banking sector, where though the cap on foreign direct investment in private banks is 49 per cent, the voting rights are limited to 10 per cent (1 per cent in the case of State owned banks).

Comments on the Proposals

The above recommendations of the high level expert group are very critical for sustaining a generic pharmaceutical industry from where generic medicines can be procured and distributed for free in government hospitals and public health clinics. Indeed, much discussion has been taking place within the government regarding the mergers and acquisitions of Indian pharmaceutical companies by foreign MNCs. In November 2011, the government of India revised the FDI policy for existing drug companies by making it mandatory for them to seek the approval of the Foreign Investment Promotion Board in respect of foreign investment in such companies. However, this was adopted as a transitional arrangement until a definitive policy could be adopted through inter-ministerial discussions. In this context, an Inter-Ministerial Expert Group was established to decide the FDI policy in the pharmaceutical sector. Media reports suggest that the Expert Group is proposing limiting automatic approval for FDI in existing pharmaceutical companies to 49 per cent and requiring FIPB approval for investments above the threshold of 49 per cent.

These developments suggest that the government is intending to regulate FDI in existing Indian pharmaceutical companies in view of the recent spate of mergers and acquisitions in the industry and its implications for India's health security. However, while there is unity regarding the objective, there are some differences between different ministries regarding the approach that would be most appropriate in this regard. While the revised FDI policy since November 2011 requires FIPB approval for all foreign investments in existing drug companies, the proposal for allowing automatic approval up to a cap of 49 per cent may not be an effective solution to the problem. D. G. Shah from the Indian Pharmaceutical Alliance (IPA) has said in this context that even with a cap of 49 per cent, "The acquirers can still gain majority control in a local company by using proxy investors or financial institutions to buy more shares in the entity or through other options (Livemint, July 20, 2012)."

According to some observers, the Ministry of Health and Family Welfare has also made some proposals for introducing strict conditions for approval of FDI in the pharmaceutical sector. (1) Any acquired entity should significantly increase its R&D spending, especially on certain diseases that are predominant in India. The R&D spending must be increased by five percentage points within three years of the FDI approval. (2) The level of generic drugs should not go down below the average of the last five years. (3) FDI approval should not be only on the basis of the balance sheet of the company but also the product profile of the company should be taken into account, including the prices of the products, the implications for access to medicines and health security of the country, etc.

It has also been suggested that even if a proposal for merger or acquisition satisfies all concerns regarding access to medicines and health security, the government could still refuse approval if it involves a company that is of critical national importance. Such a condition would be very relevant for India, where some private generic companies have made an immense contribution towards the supply of affordable generic medicines and have become of critical importance to not only India but also other developing countries.

Conclusion

The proposal for procurement of generic medicines and the free distribution of such medicines through government hospitals and public health centres in India as a part of a Universal Health Care scheme is indeed a very positive and encouraging development. Drawing from the success of procurement models such as the TNMSC at the state level and replicating the same at the national level can indeed be very beneficial towards establishing the foundations for universal health care in India.

However, it will also be necessary to ensure that a sustainable source of procurement of generic medicines is maintained. For that the survival and growth of the Indian generic pharmaceutical industry is critical. It is imperative for the government to take a holistic view in this regard from a health perspective and take appropriate policy decisions that will support and sustain the generic pharmaceutical industry.

India's patent law as well as the foreign investment policy will play a critical role in this regard. While India has made a very conscious effort to retain flexibilities in its amended patent law to safeguard access to medicines, there is need to ensure effective implementation of these flexibilities, particularly in the process of examination and grant of pharmaceutical patents, and in the use of compulsory licenses even for non-communicable diseases.

However, the most significant challenge towards sustaining a generic Indian drug industry that can contribute towards the realization of universal health care is the re-alignment of the industry through strategic alliances, mergers and acquisitions. In this context, it is critical for India to adopt a policy towards FDI in the pharmaceutical sector that appropriately and adequately addresses the concerns regarding the implications of such mergers and takeovers for access to medicines and India's health security in the future.

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