Use of Generic Medicines: Challenges and Benefits

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Abstract

The government is committed to make healthcare affordable as stated in the National Health Policy 2017. An estimated 94 million people in India are pushed into poverty due to expenditure on healthcare. About two thirds of the expenditure is incurred on medicines. Generic medicines are as effective as branded medicines. The initiative of the government and Medical Council of India by making it mandatory for doctors to write generic medicines has raised many concerns related to generic drugs availability and quality. Experience in the USA and Canada support the argument in favor of generic medicine. India is the main supplier of the generic medicines to the USA. There is a need to curtail inducement by pharmaceutical companies to promote their branded drugs as is being done in the USA. The government needs to make generic drugs easily available, strengthen quality control and educate doctors on benefits of using generic drugs.

Keywords

Generic drugs, branded drugs, Challenges for generic drugs, fixed drugs combinations, affordable healthcare, healthcare expenditure

The Indian government is committed to make affordable quality healthcare available to its citizens. Its recent initiative to increase access to generic medicines by making it mandatory for doctors to write only generic medicines is being widely discussed in India. While all stakeholders agree that it is a well-meaning step, there are many concerns that need to be addressed. The major concerns include quality of generic medicines and their availability. Here, we present the scientific aspects and implementation challenges of this initiative.

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What Is a Generic Medicine?

All pharmaceutical medicines are branded when first introduced. Pharmaceutical companies spend a large amount of money in research and development (R&D) of new medicines. In order to recover these costs (average US$1.2 billion for each medicine), these medicines are patented by the companies who developed it, to prevent anyone else from manufacturing and selling the medicine so that they recover R&D cost. These patents last for a defined period of time (average 10–15 years). After this period is over, the patent expires allowing other companies to make and sell this medicine, consequently known as a generic medicine. In the USA, there have been instances of pharmaceutical companies prolonging their exclusive rights to maximize profits by paying generic manufacturers to keep generic versions of the medicine off the market, ('pay to delay'), litigation (Swain, Dey, Patra & Rao, 2014) or 'evergreening', a practice in which a minor change is done in the medicine molecule to extend the patent. In India there are about 10,000 medicine manufacturing units and 800,000 outlets but about 100 companies manufacture 95 per cent of the medicines mostly through contract manufacturing (Rao, 2017). The medicine control and regulatory mechanism in India is fragmented between centre, states and ministries of health and department of pharmaceuticals under ministry of chemicals and fertilizers. Generic medicines may be prescribed in two ways, that is, as generic-generic (only generic name) or generic-brand (the generic medicine with manufacturer's name in bracket). Generic medicines are not inferior; it is the same as brand medicine only at a later stage in the market cycle of a medicine. A generic medicine is made and sold by a company other than the one who invented it and may have different colour, packaging and inactive ingredients, but the active ingredient is the same. The differences between branded and generic medicines are shown in Table 1.

Governments All Over the World Favour Generic Medicines to Decrease Healthcare Expenditure

Approximately 95 million people were estimated to get pushed below the poverty line in India in 2014 due to healthcare expenditure (Garg, C. et al., unpublished). About two-thirds of this expenditure is on

Table 1. Differences in Branded and Generic Medicines

	Branded Medicine	Generic Medicine
Property	Same	Different
Government Regulatory Mechanism#	✓	
Effectiveness	✓	
Purity	✓	
Safety	✓	
Strength	✓	
Active Ingredient	✓	
Colour		✓
Packing		✓
Inactive ingredient		✓
Price		✓ (much cheaper)

Source: Adapted from Razmaria (2016).

The Rise of Generic Antiretrovirals

The story of antiretroviral medicines (ARVs) is worth mentioning in the generic vs. branded debate. Due to the prohibitive costs of ARVs at the time, thousands were dying in Africa in the 1990s, neglected by the major pharmaceutical companies that held the patent for these medicines. In 2001, generic players like Indian pharmaceutical major Cipla began supplying generic versions of ARVs at 1 USD/day to the African market. Patent litigations followed in Indian and international trade courts accusing Indian pharmaceutical companies of stealing intellectual property. Doctors were discouraged from prescribing generic medicines with unsubstantiated claims of poor quality. However the courts ruled in favour of Indian companies who now hold 90% of the worldwide market share of ARV medicines.

Figure 1. Vignette

Source: Adapted from Rajagopal (2017).

medicines, making it a major reason of poverty in India. Generic medicines are much cheaper than branded medicines, approximately one-fourth to one-tenth of the cost (Rao, 2017); hence their wide use will substantially reduce expenditure on health by both individuals and the government. According to US Food and Drug Administration (FDA) statistics, generic medicines are 80–85 per cent cheaper than brand name medicines (US Food and Drug Administration, 2016). There is no mechanism to control the supply-chain margins. Hence in addition to prescription of generic medicines, the government controls the prices of essential medicines by issuing list of medicines brought under price control. Another undesirable practice in India is wide use of Fixed Medicine Combinations (FMCs). The government bans those FMCs that are irrational, for example in March 2016, the government banned 344 combination medicines based on an expert committee report (Ministry of Health and Family Welfare, 2016). The pharmaceutical companies often go to court against these orders to protect their profit (Singh, 2016) Figure 1.

The world has and is moving towards increased use of generic medicines. Let us take examples of two countries, the USA and Canada. In the USA, generic and over-the-counter medicines account for about 80 per cent of sales of all medicines. India is a major supplier of generic medicines to the USA. In 2009, 40 per cent of generic medicines in the USA were supplied by India and China and this figure is increasing (Webster, 2009). Generic medicines account for more than three-quarters of all prescriptions but only 20 per cent of spending in Canada (Kesselheim, 2011).

Quoting the US FDA (2017):

> Generic medicines are important options that allow greater access to health care for all Americans. They are copies of brand-name medicines and are the same as those brand name medicines in dosage form, safety, strength, route of administration, quality, performance characteristics and intended use. Health care professionals and consumers can be assured that FDA approved generic medicine products have met the same rigid standards as the innovator medicine. All generic medicines approved by FDA have the same high quality, strength, purity and stability as brand-name medicines. And, the generic manufacturing, packaging, and testing sites must pass the same quality standards as those of brand-name medicines.

Generic Medicines in India

The Medical Council of India and the Government of India have recently accelerated efforts to promote generic medicines to decrease cost of healthcare and bring it within reach of India's poor. The government is committed to achieve universal healthcare and move towards the right to health as stated in the recently released 2017 Health Policy. Promotion of generic medicines builds on the rich experience across states, especially Rajasthan and Tamil Nadu who were pioneers in introducing generic medicines in the public health system. These states have strengthened procurement through e-tendering for transparency, quality control and electronic monitoring of medicine stocks to minimize stock-outs and substantially bring down the expenditure on drugs.

India is exporting quality generic medicines to 215 countries and is the 'World's Pharmacy'. India's pharma sector is growing at a pace of 20–21 per cent (Agencies, 2017). In a recent study 47,954 samples of both generic and branded medicines were tested from across the country (Medicine Survey—Core Expert Committee, 2016). Three per cent medicines were not of standard quality and less than 1 per cent were spurious and included both branded and generic drugs (Medicine Survey—Core Expert Committee, 2016). The argument that 'branded medicines are good quality and generic are not' does not hold ground. Quality assurance needs to be ensured for both generic and branded medicines in India.

Who Loses and Who Gains from the Promotion of Generic Medicines?

It is important to understand who gains and who loses from the promotion of generic medicines and to understand the stakeholder positions in the current debate on generic medicines in India. The challenges and benefits from the promotion of generic medicines are summarized in Table 2.

Table 2. Challenges and Benefits from Promotion of Generic Medicines

Issues	Challenges	Benefits
Pharmaceutical companies	Big pharmaceutical companies that invented the medicine will lose business and may be discouraged to develop new medicines. Quality control among smaller manufacturers may not be up to par with larger manufacturers.	Small companies can manufacture medicine as generic.
Doctors	Lose control over which company product to write. Doctors cannot be held accountable if the medicine dispensed by the chemist is substandard.	Doctors do not need to know all brand names of a pharmaceutical compound and are less influenced by promotional activities of some companies.
Chemist	May have lower profit margins in generics as compared to branded medicines.	Freedom to choose different company medicines to dispense.
Patients	May run the risk of getting substandard medicines. Generic medicines are not easily available.	Substantially reduce patients' expenses on medication
The quality of medicines	While India is the largest manufacturer and exporter of generic medicines that meet international standards, quality standards in smaller companies may not be as robust.	With generic medicines, it is easier to regulate the dosage of individual medicines which is not possible in Fixed Medicine Combinations (FDCs) of branded medicines.

(Table 2 Continued)

(Table 2 Continued)

Issues	Challenges	Benefits
Public declaration of inducements and promotional activities	A system of public declaration of inducements offered by pharma companies to doctors (as started in the USA) may be difficult to operationalize in India.	If operationalized, it will make doctors more conscious of inducements and public to know financial interest of their doctor(s) in the pharmaceutical companies, if any.
Access to generic medicines	Market share of big pharma companies will shrink as has happened in the USA and Canada. Currently the availability of generic medicines is limited. Even in AIIMS, only 230 medicines are available as generic (Press Trust of India, 2017). The number of Jan Aushadhi stores (JAS) is limited and expanding at a very slow pace. Generic medicines should not be confined to only JAS and need to be made available at all chemist shops.	Access to and affordability of medical care increases, benefitting especially the poor. State and central governments spend less on procurement of medicines in public health system and reimbursement of medical expenditure on their employees entitled to medical care such as CGHS, railways, defence, ESI, etc., and government funded insurance for general public under RSBY and its other variants.

Eliminate Conflict of Interest and Promotion of Public Disclosure of Payments from Industry

The medical curriculum teaches only about pharmacological compounds (generic medicines). Doctors learn about branded medicines from representatives or promotional activities of the pharmaceutical companies only upon graduation from medical school. Pharmaceutical companies' medicine promotional activities targeting physicians have been a matter of debate both in India and abroad. It was highlighted by Brennan et al. (2006) which prompted academic and medical centres to implement restrictions on physician and pharmaceutical companies (Brennan et al., 2006; Larkin & Loewenstein, 2017). In the USA, efforts are being made to make it transparent for any user to access data online regarding emoluments received by their treating physician under multiple categories such as general (travel, meals, speaking and consulting), research or ownership (shares, etc.). Before making this data public, it is opened to the physicians for 45 days to provide an opportunity for contest. In 2015, only about 0.13 per cent physicians disputed the payments (Ornstein, 2017). In the USA, between 2009 and 2014, at least 11 pharmaceutical companies settled whistle blower lawsuits contesting illegal marketing and kickbacks (Ornstein, Groeger, Tigas & Grochowski Jones, 2016; Zuger, 2017). India needs to make similar efforts to make data on payments to physicians, hospitals and professional bodies publicly available.

The Government Must Address the Concerns About Promotion of Generic Medicines

Despite convincing scientific evidence that generic medicines are equivalent to branded medicines, there remains an undercurrent of fear towards its quality in India. Even with very effective quality control in countries like the USA, there have been concerns. A study in the USA found that of 43 editorials in

scientific journals, 53 per cent expressed negative views concerning generic substitutions for branded cardiovascular disease pharmaceuticals (Kesselheim et al., 2008), mainly due to advertising by brand companies against generic medicines as well as some generic medicine scandals. In India, the main concern raised by professional bodies is that the quality regulatory mechanism is weak and variable across states. This may have an adverse impact on health outcomes. Large generic manufacturers that have made India 'the pharmacy of the world' have to meet international standards of quality, but other manufacturers catering to the domestic market may not be meeting these quality standards. Corruption and inducements that often lead to substandard medicines being sold in the market remain a major concern. Another concern is that the choice of the manufacturer of generic medicines will shift to the chemist from the doctor which may affect the quality of care if the medicine is substandard. The government needs to strengthen regulatory mechanisms and address corruption and inducements to assure the availability of quality generic medicines to the public in the country. The pharmaceutical industry needs to encourage all manufacturers to adopt 'Good Manufacturing Practices', voluntarily or through legal enforcement.

Conclusion

The recent decisions by the Medical Council of India (2017) and efforts of the government to promote generic medicines are welcome. These will increase the availability of medicines at an affordable cost and contribute to reducing poverty while accelerating progress towards achievement of health goals in the country. The concerns of the Indian Medical Association and other professional bodies regarding the quality of generic medicines need to be taken seriously and addressed by the government. It is important for the professional bodies to collaborate with the government in improving access to quality medical treatment that is affordable, including medicines. There is a need for the government to engage all stakeholders in its noble efforts to improve access, affordability, timeliness of high-quality medical care to reach Universal Health Care and move towards the right to health in the country.

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