Promotion of Generic Medicines: Laudable Efforts But Must Engage all Stakeholders

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The generic vs. brand name drugs issue has been a hot topic in the medical community recently. All stakeholders agree that it is a good initiative but there are many concerns especially regarding quality of drugs that need to be addressed

1. **What is a generic drug?**

All drugs start as branded drugs. Pharmaceutical companies spend a large amount of money in research and development of new drugs. In order to recover these costs (average USD 1.2 billion for each drug), the drugs are patented by the companies, which developed it, to prevent anyone else from selling the drug for a defined period of time (e.g. 10-15 years). After this patent period is over the patent expires and other companies can make and sell this drug, now called generic. The generic drugs may be prescribed in two ways i.e. as generic (only generic name) or generic brand (the generic drug with manufacturer name in bracket). Generic drugs are in no way inferior, it is the same drug but at a later stage in the life cycle of a drug. A generic drug may to be made and sold by a different company and may have different colour, packaging and inactive ingredients but the active ingredient is the same.

2. **The Governments all over the world promote Generic Drugs to bring down the expenditure on healthcare:**

In India annually, about 32 million people get pushed below the poverty line because of expenditure on medical care. About two-thirds of this expenditure is on medicines, making it a major reason of poverty in India (NHSRC estimates). Generic medicines are cheaper than brand-name drugs, hence will substantially reduce expenditure on health. In the US, the generic drugs that draw a large number of manufacturers average the cost falls to about 20% (US FDA).

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The world has and is moving towards generic drugs. Let us take examples of two countries, US and Canada. In the US, generic and over-the-counter drugs account for about 80 percent of the sale. In 2009, the main suppliers of generic drugs (about 40%) in the US were India and China. (*https://www.scientificamerican.com/article/are-generic-drugs-bad-for-you/ 01 May 2017).* In Canada (2011 *Canadian Medical Association Journal*) generic drugs accounted for more than three-quarters of all prescriptions but accounted for only 20% of spending on pharmaceuticals. The Medical Council of India and the Indian Government have recently accelerated their efforts to promote prescription and the use of generic drugs to bring health care 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. Promoting generic drugs nationally builds on the rich experience across states especially Rajasthan and Tamil Nadu who are pioneers in introducing generic drugs in public health system.

US FDA on their website states,

"Generic drugs are important options that allow greater access to health care for all Americans. They are copies of brand-name drugs and are the same as those brand name drugs 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 drug products have met the same rigid standards as the innovator drug. All generic drugs approved by FDA have the same high quality, strength, purity and stability as brand-name drugs. And, the generic manufacturing, packaging, and testing sites must pass the same quality standards as those of brand-name drugs".

https://www.fda.gov/Drugs/resourcesforyou/consumers/buyingusingmedicinesafely/
Accessed 05 May 2017

In medical colleges, future doctors are taught about pharmacological compounds (generic drugs) only. They later learn about branded drugs from representatives or promotional activities of the pharmaceutical companies.

3. **Who loses and who gains with the promotion of generic drugs?**

It is important to understand who gains and who loses by the promotion of generic medicines and to understand the position being taken by different stakeholders in the current debate on generic drugs in India. The challenges and benefits from the promotion of generic drugs are summarised in the Table below:

Table: Challenges and benefits from promotion of generic drugs

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Issues	Challenges	Benefits
Pharmaceutical companies	Big pharmaceutical companies that invented the drug will lose business Quality control in smaller manufacturers	Small companies can manufacture generic drugs
Doctors	Lose control over which company product to write. Accountability if the drug dispensed by the chemist is substandard	Do not need to know all brand names of a pharmaceutical compound and not influenced by promotional activity of some companies,
Chemist	Decreased profit margins in generics as compared to branded drugs	Get chose different company drugs to dispense (some may be of doubtful quality)
Patients/ Public	May run the risk of getting sub-standard medicines	Reduced patient expenses for medication
The quality of drugs	Quality control standards is the same for all manufacturers. India is the largest manufacturer and exporter of generic drugs which meet international standards. However smaller companies may not be as robust.	With generic drugs, it is easier to regulate the dosage of individual drugs which is not possible in Fixed Drug Combinations (FDCs) of branded drugs. The government also bans many irrational FDCs from time to time.
Inducements and promotional activities	Those who receive inducements (as pharma companies make less money hence cannot offer inducements)	State and Central Governments: Spend less on reimbursement of medical expenditure on their employees entitled to medical care such as CGHS, Railways, Defence, ESI, RSBY etc.
Access to treatment	Market share of big pharma companies shrinks	Access and affordability of medical care increases benefitting especially the poor.

4. **The Government must address the concerns about promotion of generic drugs:**

Despite convincing scientific evidence that generic drugs are equivalent to branded medicines, there remains an undercurrent of fear towards generics in India. Even with very effective quality control in countries like the US, there have been concerns. A study in the US found that of 43 editorials in scientific journals, 53% expressed negative views concerning generic substitutions for branded cardiovascular disease pharmaceuticals (Kesselheim et al 2008 JAMA)mostly due to advertising by brand companies against generic drugs and some generic drug scandals. In India, the main concern raised by professional bodies is that the quality regulatory mechanism is weak. This may adversely impact on health outcomes. Large generic manufacturers which have made India "the pharmacy of the world" meet international standards of quality control, but the manufacturers catering to the domestic market may not. Corruption and inducements that often lead to substandard drugs being sold in the market remain a major concern. Another concern is that the choice of the manufacturer of generic drugs 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 drugs to the public nationally. The pharmaceutical industry needs to encourage all manufacturers to adopt Good Manufacturing Practices, voluntarily or through legal enforcement.

5. **Conclusion**

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The recent decisions by the Medical Council of India and the government to promote generic drugs is welcome and will increase the availability of medicines at an affordable cost and contribute to reducing poverty. The concerns of the Indian Medical Association and other professional bodies regarding the quality of generic drugs need to be seriously addressed by the government. It is important for the professional bodies to collaborate with the government in improving access to affordable quality medical treatment including medicines. There is a need for the government to engage all stakeholders along 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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