Review Article

Hurdles in Mandatory Generic Medicine Prescription

Verinder Jit Singh Virdi, Money Gupta[1], Rohit Gupta[2]

Departments of Pediatrics and [1]Surgery, Gian Sagar Medical College, Patiala, Punjab, India, [2]Phd Student, Public Affairs Program, Woodrow Wilson School, Princeton University, USA

Abstract

Coronavirus pandemic has brought forth the urgency of providing affordable health care to everyone. Generic medicines are often one-fourth to one-tenth of the cost of the branded drugs, and so offer a remarkable opportunity to significantly lower the health-care expenditure. However, the argument for promoting generic medicines is indisputable, we have to think about the other enabling conditions which are necessary for a successful health policy on encouraging generics without causing unintended adverse repercussions. This paper attempts to answer such questions by considering the motivations of the various stakeholders of the broader health services ecosystem in India and undertaking a systematic analysis of the winners and losers from such a policy. We argue that generic prescription will not be successful without prior improvement in the state capacity for quality control of drug manufacturing; rise in awareness among the doctors, patients, and pharmacists; improved trust in the medical systems; and innovative demand-side interventions.

Keywords: Branded medicines, generic medicines, health policy, prescription

Introduction

India's National Health Policy, 2017 sets down the worthy goal of making health care affordable to all. Research has suggested that the out-of-pocket expenditure accounts for 69% of health care spending in India, and 70% of this expenditure is borne on medicines.[1] An estimated 94 million people are pushed below poverty line due to health-care expenditure every year.[2] Coronavirus pandemic has furthermore highlighted the urgency of providing affordable health care to everyone. Generic medicines are often one-fourth to one-tenth of the cost of the branded drugs,[3] and so offer an important opportunity to significantly lower the health-care expenditure.[4] The usage of generic medicines has been increasing globally. Prescription audits show that in countries such as the USA and Canada, more than 80% of drugs sold over the counter are generic drugs. In contrast, in India, <40% of medications are prescribed by generic names. Paradoxically, at the same time, India exports quality generic medicines to more than 215 countries of the world.[2] By mandating doctors to prescribe only generic medicines, it is hoped that health care can be made more affordable to patients.

Indeed, the Prime Minister of India has revealed the intentions of the Union Government to make generic prescription compulsory. We need to identify the enabling conditions that are needed to create such a policy. This paper attempts to answer such questions by considering the motivations of the various stakeholders of the broader health services ecosystem in India and undertaking a systematic analysis of the winners and losers from mandatory generic prescription policy.

Definitions

According to the Food and Drug Administration (FDA), generic medicine is understood to be "identical to an innovator or product brand name in dosage, form, strength, route of administration, quality, performance, characteristics and intended use."[5,6] There are four different kinds of drugs: branded drugs, branded generic, nominally branded generics, and pharmacological generic.[7,8]

A drug that is marketed under a trade name by the manufacturer that first brought the drug to the market is known as branded drugs. New medicines are considered intellectual property of firms and strict patent regimen exist to help companies recover

Address for correspondence: Money Gupta, House No, 29, Sector 70, Mohali, Punjab, India.
E-mail: drmoney_surgeon@yahoo.com

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costs spent on development of drugs. In most countries, patents are granted for 15–20 years.[6] Branded drugs are vigorously promoted by the pharmaceutical companies. A drug that is marketed under a separate trade name than the one under which the drug was first brought to the market is known as branded generic. Such marketing happens after the patent of the originator company has expired, and manufacturing can be done by other firms also.

Nominally branded generics can be thought of equivalent to branded generics, except that these are sold by companies directly to retailers and are not promoted by companies to the medical practitioners. Generic generics are drugs that are marketed under the pharmacological name. This market is dominated by small, domestic firms in India.

Evidence in Favor of Encouraging Generic Medicine Usage

Governments across the globe have been struggling to devise an efficient market structure which offers a fair deal to the consumers. There are very few economically efficient mechanisms to control supply chain margins of pharmaceuticals. On the demand side, one major part of the problem is that it is the doctor and not the end-consumer who decides which product will be consumed in the pharmaceutical industry.[9] Hence, the "relative attractiveness" of a drug is a function of price and clinical attributes of the drug, and the promotional expenditure of the pharmaceutical firm.[9] A higher promotional expenditure on drugs can make them more attractive to the doctor, leading to an increase in prescriptions of such drugs and resulting in higher sales and profits for the manufacturing firm. This can set off a reinforcing cycle of increased demand driven by promotions, leading to higher prices of drugs and exploitation of the consumers. Mandatory generic prescription can break down this vicious cycle.[10]

It has been argued that the social benefits of generic medicines go far beyond the immediate reduction in health-care costs. A critically reviewed study in the USA found that fee-for-service Medicare beneficiaries in the USA were significantly more likely to adhere to antidepressant treatment regimen if they were prescribed generic drugs rather than branded drugs.[11] The study found that aged and disabled patients were particularly most affected, and branded therapy had 35% more probability of disruption in treatment compared to generic drugs. With the help of reduced costs of generic medicines, pharmacotherapy can be introduced earlier in the treatment algorithm.[12] For example, introduction of generic atorvastatin in European member states in 2012 led to significant cost-effective treatment of cardiovascular diseases.[13] Moreover, with the help of generic medicines, previously untreated patients can also be brought under treatment.

However, concerns have been expressed in medical literature about the efficacy of generic medicines for certain diseases. For example, generic substitution for chronic diseases such as epilepsy is contested strongly by doctors.[14] Similar concerns have also been expressed for high-risk patients (such as extreme age groups, pregnant women, and patients with multiple disorders being treated with several drugs) or other high-risk diseases.[15-17]

Impact Of Mandatory Generic Prescription on Stakeholders in Indian Health-care System

Table 1 shows how various stakeholders in the health ecosystem in India will be impacted by mandatory generic prescription. These are pharmaceuticals, physicians, pharmacists, and patients.

Pharmaceuticals

Indian pharmaceutical sector was valued at USD 33 billion in 2017 and it is the world's leading manufacturer and supplier of generic medicines. India's pharmaceutical sector is very complex, multilayered and a plethora of agencies regulate it. The line between retailer/pharmacist and medical practitioner is blurred. In many parts of countryside and in small towns, pharmacists routinely make diagnosis and dispense medicines (without involvement of a medical practitioner). Likewise, many medical practitioners dispense the medicines they prescribe.[18]

Given the high level of exposure to foreign market, a large section of Indian pharmaceutical industry is placed in a peculiar position where its processes and procedures are negotiated globally. Sometimes, efforts of foreign regulatory agencies to establish trust in their own domestic constituents can create negative perception among Indian citizens regarding their drug suppliers.[18] For example, in 2005, EU commission reported that 75% of counterfeit medicines confiscated at EU border were from India. However, this was found out to be false later on. Similarly, India has the largest number of production faculties approved by the US FDA beyond USA boundaries. Reeling under domestic pressure after counterfeit medicines (heparin) from China caused deaths in the USA, FDA indicted Ranbaxy (a leading Indian pharmaceutical) for poor management of records and procedures in 2009.

Physicians

A key difference between the developed countries (where generic drugs are prescribed routinely) and India is the attitude of doctors toward generic medicines. In the UK, for instance, there is a high percentage of doctors who voluntarily prescribe medicines in international nonproprietary name (INN).[19] Doctors may have a bias toward branded drugs, either under the influence of better marketing strategies of branded manufacturers or because of less confidence in the quality and efficacy of generic medicines.

Doctors may also resist mandatory generic prescription because it constrains their therapeutic freedom. Perceptions about generic medicines among physicians tend to vary due to other factors. Older physicians have significantly poorer view of generic medicines than younger doctors. As noted earlier, serious diseases such as epilepsy need to be tackled

Table 1: Stakeholders in the health ecosystem in India impacted by mandatory generic prescription

Stakeholders	Potential loss	Potential benefits	Challenges	Issues
Pharmaceuticals	Big pharmaceutical companies who have invested in developing branded medicines will lose	Smaller domestic companies can gain ground	Maintaining quality of generic medicines, especially of smaller players	Regulating a complex market
Doctors	Lose control over prescriptions	No need to remember brand names of pharmaceutical compound Free from influence of pharmaceuticals	Educating/disciplining doctors and changing perception of generics	Therapeutic freedom
Pharmacists	Depending upon the definition of generic, they may be held for accountable for side effects	Will certainly benefit financially, size of benefit will depend on definition of generic	Educating pharmacists	Proper definition of generic
Patients	May get substandard medicines	Cheaper availability of drugs	Raising awareness	Low trust in the system

with cautiously. Similarly, branded drugs belonging to specific drug classes, such as those with narrow therapeutic index, are more likely to be favored by physicians as compared to generic brands.[20]

Pharmacists

Since 70%–80% of pharmaceutical sales are accounted by retailers (remainders are sold directly by hospital pharmacies),[18] pharmacists can play a very important role in encouraging the use of generics. The education and awareness level of pharmacists regarding generic medicines can be critical for their widespread use. Even in developed countries, the knowledge of pharmacists regarding generic substitution is far from perfect. For example, a survey in New Zealand revealed that more than 65% of pharmacists believed branded medicines are of better quality than generic versions. Similarly, only 42.5% of French chemists encouraged generic substitution[21] owing to their beliefs. While similar evidence for Indian pharmacists does not exist, one can presume that the situation could only be worse due to lower levels of education and training. Further, pharmacists can have very different incentives for promoting branded drugs. While a lot of countries target pharmacists for generic substitution (rather than physicians), similar policy in India could backfire because of misaligned financial incentives and lower levels of trust in pharmacists (as compared to physicians).

Patients

Some surveys have estimated that more than 60% of the patients believe that generic medicines are inferior to branded drugs in India.[5] This is in sharp contrast to other countries where generic medicine penetration has been more successful. Even though people in these countries have persistent concerns about poor efficacy of generic medicines, the percentage of such people is considerably less, for example, Finland (19%) or Germany (30%).[5]

Indian consumers are apathetic to generic medicines. There can be multiple reasons for it. Some concerns are related to general level of mistrust in the system and antigeneric attitude of the physicians. If patients do not trust their government and regulators, they might perceive that prescription of generic medicines is for the benefit of someone else. Some elements of generic substitution problem are related to the packaging and labeling of the medicines themselves. A study done in Belgium found that more than half of the respondents got confused between generic and branded medicines because of packaging and labeling.[22]

Moreover, it is a human tendency to believe that costly things are of better quality. Branded names generally provide a positive association with the diseases. For example, *A brand name such as Theraflu clearly implies that it is meant to alleviate flu symptoms; however, the generic name acetaminophen does not have such an advantage.*[6] The attitude toward generic medicines is also shaped by the severity of the diseases: patients with minor illnesses are more willing to accept generic medicines than patients with major illnesses.[22]

The patients today behave as an active participant in health care and critical person with independent views about authority of science and medicine.[22] As a result, consumer acceptance is a prerequisite for success of any generic substitution policy. If patients are not taken into confidence, they might migrate away from government hospitals toward private sector. They might not want pharmacists to change to generic drugs. As a more serious consequence, it has been shown that in the absence of education, many consumers make mistakes with generic medicines, such as taking the same medicine twice.[22] A mid-treatment shift from branded to generic medicine may also have a negative impact on medication adherence, as the act of substitution may lead to confusion and insecurity about intervention, and patients may not take the medicine at all.[23]

Issue with State Capacity and Need for Multiple Policies

If mandatory drug prescription for doctors has to be effective, it puts a strong onus on state capacity for the following reasons:

- Educating and regulating doctors so that they indeed prescribe generic medicines (and punishing violators)
- Better quality control on generic medicine manufacturers

- Educating the pharmacists so that they dispense medicines keeping in mind the interests of patients
- Creating awareness among patients about quality of generic medicines, dispelling any myths about their efficacy, and empowering them so that they can put pressure on doctors and pharmacists to prescribe or dispense generics
- Creating an appropriate legal environment (Definition of generic drugs, their uniform packaging and labeling rules).

All the nations which have been successful in promoting generic medicines have deployed multiple demand-side policies. Such multiple policies can be broadly divided in the following four categories:[24]

- Educational activities include organizing sessions in which general practitioners discuss their prescribing patterns, in the presence or absence of pharmacists. For educating patients, media and information campaigns about efficacy of generic medicines and making price comparisons between branded and generic medicines easy to comprehend have been shown to be effective[21]
- Managerial interventions by government such as instructing physicians to prescribe generic drugs , or providing generic medicines through government stores (such as in India)
- Economic interventions providing fixed budgets to hospitals and encouraging them to save money through generics, or financial incentives to physicians and other stakeholders. For example, in a pilot project in Austria, patients were charged lower prescription fees if they obtained a generic instead of branded medication. Coupled with the positive attitude of doctors and pharmacists, the pilot project was able to successfully increase the share of generics[25]
- Enforcement mandatory generic substitution at the level of pharmacist or compulsory INN prescribing. Several countries have imposed (e.g., Abu Dhabi, France, Lithuania, Portugal, and Spain) or encouraged (e.g. Belgium, Germany, The Netherlands, and the UK) prescribing by INN. However, it should be noted that this policy in itself does not stimulate generics use, unless it is accompanied by regulation for pharmacists to dispense a generic medicine in the case of an INN prescription or by a generic dispensing incentive system that aligns with pharmacists financial interests[21]
- Federal government in the USA has created an online public database which keeps tracks of emoluments received by doctors under multiple categories (such as travel, meals, speaking, and consulting), research, ownership, etc.[2] ("Open Payments Data–CMS," n.d.). A similar transparency mechanism can go down a long way in bringing down the influence of pharma companies over physicians in India.

Conclusion

It is a good idea to target doctors (rather than pharmacists) for generic drug prescription for India. Doctors have better training and enjoy higher confidence of patients, whereas pharmacists and chemists are very unorganized with lower levels of education and training. However, making generic prescription compulsory for doctors without making fundamental changes in the health ecosystem is a flawed step. It might create confusion in the minds of patients leading to lower adherence to treatment regimen, increase mistrust about the intentions of government, and even push patients away from the formal public health system. Secondly and more importantly, state capacity for quality control of drugs has to be substantially enhanced before any such policy is implemented. Thirdly, multiple demand-side interventions will be needed concurrently for effective results. Finally, it is important to establish trust in the medical system simultaneously so that people believe that government acts in public interest and they do not shift to alternate forms of treatment or become dissatisfied. It is also important to include physicians in the whole process, so that their therapeutic freedom for serious diseases (where generic substitution is not desirable medically) is not restricted.

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Conflicts of interest

There are no conflicts of interest.

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