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FACTS ON GENERIC DRUGS TO MEET OUT WORLDWIDE CHALLENGES FOR IMPLEMENTING GENERIC MEDICINE RELATED POLICIES OF HEALTH SCHEMES

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ABSTRACT: Global market of generic drug has been propelled by new government initiatives to produce generic drugs and to promote the use of generic drugs; thus the use of generic pharmaceutical products represents over half of the total volume of pharmaceutical products used worldwide. India is the world's largest exporter of cost effective generic medicines and leading Indian generic companies are generating more than fifty percent revenue from the export business of generic drugs. After the expiry of patent or marketing rights of the patented drug, generic drugs can be marketed. Generic drugs are available at affordable prices with assured quality and therapeutic value. The decision on drug approval is taken only after being assured of its pharmaceutically equivalent and bioequivalent properties. According to an estimate from the World Health Organization (WHO), the percentage of population without adequate access to essential medicines is less than 1% in high-income countries, 24% in middle-income countries, and 39% in low-income countries, due to their high cost. Recently Govt. of India has launched a campaign '*Pradhan Mantri Bhartiya Janaushadhi Pariyojana* (PMBJP)' to promote the availability of generic drugs at affordable prices for all. It has also been decided to create a database of generic equivalents of branded medicine, paving the way for mandatory prescription of generic drugs along with brand names, to bring down the healthcare budget of every citizen of India. Branded versus generic medicines is an ongoing topic of debate and discussions among physicians, pharmacists, drug users, drug regulators, and policy makers across the world. Considering this aspect, the present article is an attempt to produce facts on generic drugs and focusing on the worldwide challenges through the major stakeholders of generic medicine.

INTRODUCTION: Generic medicine related policies are important for any health care system, primarily to reduce the costs on pharmaceutical products and secondly to improve access to drugs. Treatment of many patients, and in particular of those in developing countries, is now possible because of low-cost generic drugs [1, 2].

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An important goal for any national health schemes on generic is to reduce national expenses on medicine. The generic drugs increase the competition among pharmaceutical companies and reduce the cost of treatment. However, the general population has difficulty in accepting specific generic medicines, whereas there appears to be a widespread myth among doctors and patients that branded medicines are better in terms of quality and safety than generic forms [2]. A brand name or reference drug can only be substituted by a generic drug when the latter contains the same active ingredient and strength as the reference drug, and is administered in the same dosage form.

Further, challenge for patients and healthcare personnel is the existence of several generic alternatives to a branded drug. The switch from a brand name to a generic drug may prove more of a challenge for chronic patient and polypharmacy users who can easily become confused, especially since the new product can be morphologically differ [1].

It has been estimated that switching procurement from branded drugs to the lowest-priced generic equivalents in the private sector in 17 developing countries could result in an average of 60% cost savings [3], the generic substitution is mandatory in many European countries like Sweden, Germany, Norway, France, Finland, Spain, and permissive in others like Portugal, Denmark, Italy, Poland, Czech Republic, The Netherlands, Hungary, Poland, Latvia [4], while in USA, generic substitution is a common practice with pharmacists substituting up to 84% of brand drug prescriptions [5]. After, the UK, Finland, Greek and other governments introduced generic prescribing, Govt. of India also recently launched a campaign '*Pradhan Mantri Bhartiya Janaushadhi Pariyojana*' (PMBJP) to provide generic drugs at affordable prices for all, particularly the poor and disadvantaged, and to bring down the healthcare budget of every citizen of India. The World Health Organisation certification will be empanelled to supply generic drugs, specially manufactured and packed for the PMBJP [6].

This campaign of seventh largest country in the world may further give rise to discrepancies about branded versus generic drugs among the stakeholders actively involve in it. So, this article is an effort to make an efficient awareness about generics to approve readers' attitudes toward generics with a belief that generic drugs may provide a pathway for strengthening generic drug related policies of nations like India.

Generic drugs and Branded drugs: Reductions in national drug spending of more than 40 % have been estimated if generic penetration reached a maximum in each country of the world. In the USA, generic medications cost less than one-third of their branded counterparts. The WHO defines a generic product as "a pharmaceutical product, usually intended to be interchangeable with an innovator product that is manufactured without a license from the innovator company and marketed after the expiry date of the patent or other exclusive rights".

In the USA, the Food and Drug Administration (FDA) has stated that, "A generic drug is identical or bioequivalent to a brand name drug in dosage form, safety, strength, route of administration, quality, performance characteristics and intended use". Finally, the European Medicines Agency (EMA), the main regulatory body for pharmaceutical products in the EU, defines a generic medicinal product as a "product which has the same qualitative and quantitative composition in active substances and the same pharmaceutical form as the reference medicinal product, and whose bioequivalence with the reference medicinal product has been demonstrated by appropriate bioavailability studies". Nevertheless, the fact that many pharmaceutical companies decide not to file patents in every country allows for generic pharmaceutical products to emerge in those countries despite the product being under patent in other countries [7].

When a pharmaceutical company first markets a drug, it is usually under a patent. When it expires, the company cannot exclude other companies from manufacturing its generic version. In most countries, patents give 20 years of protection. Pharmaceutical companies that develop new drugs generally only invest in drug candidates with strong patent protection as a strategy to recoup their costs to develop the drug which generally includes the costs of the drug candidates that fail and to make a profit. The average cost to a brand-name company of discovering, testing, and obtaining regulatory approval for a new drug was estimated to be as much as $2.6 billion in 2014. For as long as a drug patent lasts, a brand-name company enjoys monopoly, in which the company is able to set the price of the drug at a level that maximizes profit [8]. This profit often greatly exceeds the development and production costs of the drug, allowing the company to offset the cost of research and development of other drugs that are not profitable. It is only after the patent expires; other companies can produce and market the generic form of the drugs after following the regulatory procedures which are usually subject to government

regulations in the respective countries. Thus, the prices of generic drugs are often low enough for users in less-prosperous countries to afford them, and are labelled with the name of the manufacturer and a generic non-proprietary name such as the United States Adopted Name or international non-proprietary name of the drug. A generic drug must contain the same active ingredients as the original brand-name formulation [9].

The U.S. Food and Drug Administration requires that generics be identical to, or within an acceptable bioequivalent range of their brand-name counterparts with respect to pharmacokinetic and pharmacodynamic properties.

Bioequivalence does not mean generic drugs must be exactly the same as the brand-name product (pharmaceutical equivalent). Chemical differences may exist but the therapeutic effect of the drug must be the same (pharmaceutical alternative). Most small molecule drugs are accepted as bioequivalent if their pharmacokinetic parameters of area under the curve (AUC) and maximum concentration (C_{max}) are within a 90% confidence interval of 80 - 125%; most approved generics are well within this limit [10].

Before a company can market a generic drug, it needs to file an Abbreviated New Drug Application (ANDA) with the Food and Drug Administration, seeking to demonstrate therapeutic equivalence to a previously approved "reference-listed drug" and proving that it can manufacture the drug safely and consistently. For an ANDA to be approved, the FDA requires the bioequivalence of a generic drug to be between 80% and 125% of the innovator product. These products cannot be entirely identical because of batch-to-batch variability and their biological nature, and they are subject to extra rules. When an application is approved, the FDA adds the generic drug to its Approved Drug Products. The FDA also recognizes drugs that use the same ingredients with different bioavailability, and divides them into therapeutic equivalence groups.

Physicians' Perceptions towards Generic Drugs: On the basis of literature, the major outcome of physicians' choice was found to be as follows:

In Malaysia physicians reported that the factors mostly affecting their prescribing decisions included their own experiences, evidence from the literature, their patients' ability to afford the medication, and hospital policy. There were misconceptions about the meaning of 'bioequivalence', 'efficacy', 'safety', and 'manufacturing quality standards'. It appeared that, although the Malaysian physicians were largely prescribing generics, they still had concerns regarding the reliability and quality of such products. It was also revealed that the choice of drug depends upon advertising, product incentives/ bonuses offered by pharmaceutical companies, patient's socioeconomic background, and the credibility of manufacturers [11, 12].

In Australia, there was mixed attitude of physician towards generic prescribing, some viewed generics as equally effective as the innovator brand, further, they mentioned that they were concerned about patient confusion following substitution, and some felt that their role as a prescriber was threatened when pharmacists dispensed the generic drug [13].

In Jamaica, approximately half of physicians participated in study, claimed that they prescribed generic drugs when cost was a significant factor for the patient and felt that bioequivalent generics were therapeutically equivalent to branded drugs. It was concluded that more emphasis should be placed on improving physician confidence in the therapeutic equivalence of generics [14].

The assessment of Saudi Arabia physicians revealed that majority of them had adequate knowledge of the therapeutic value of the generic drugs, they prescribed and they were positive towards the government's role in enforcing physicians to prescribe generic drugs. Primary care physicians were significantly more likely to prescribe generically than hospital and private physicians. The physicians reported that representatives from generic drug companies were less likely to visit them than representatives from brand drug companies, and that they received significantly more drug samples from the brand name drug companies [15]. The majority of Greek physicians claimed that they were not affected by the sales representatives from drug companies and that Greek patients do not interfere with their

prescribing, but often complains about the drug cost. When asked about quality, half of the respondents characterized the quality of generics as high or very high and claimed that implementation of an International Non-proprietary name system was necessary. However, only one fourth were found prescribing generic drugs in Greece, while more than double of physicians in Cyprus were prescribing generics [16, 17].

In USA, physicians older than 55 years of age were more than three times as negative to generics as younger doctors. The youngest physicians (under the age of 35) were significantly less likely to hold negative views regarding the quality and more likely to report a personal preference for generics or to recommend them to their family [18].

In a nationwide web based survey conducted in Italy, the majority believed that the efficacy of generic medicines was sufficient or good, and most of them have a fair knowledge of generic medicines. The major issues preventing generic prescribing were reliability of bioequivalence tests and the safety of switching from branded to generic equivalents, more information regarding generic drugs was felt to be required [19].

In Norway, it is obligatory for the pharmacist to perform generic substitution, while the majority of doctors were positive toward the generic system despite complaining that it was time consuming. A key reason for brand name prescribing was their memory of the brand name and the confidence that the pharmacist would take care of the substitution [20].

Scenario of Indian physicians: The recent directive of Medical Council of India under code of medical ethics 1.5 which states "Every physician should as far as possible, prescribe drugs with generic names and he/she shall ensure that there is a rational prescription and use of drugs" creates confusion between terms "generic drugs" and "generic names." This directive/ guidance is questioned by Dhamija *et al*. in their article entitled "Only generics (drugs/names): Is India ready?" [21]. By default, most drugs sold in India are generic. While other studies identified a clear gap between the knowledge and perception of generic versus original drugs, as majority were reported to have a considerable amount of knowledge regarding generic drugs, but this was not translated into their percentage of prescribing generic medicines, thus exposing a cliff between knowledge with attitude and practices.

Indian physicians are also doubtful about the efficacy of the generic drugs, which in turn shows the lack of confidence for the use of such drugs and lack of knowledge regarding generic drugs. Health-care providers also doubted the efficacy of the quality of generic drugs although they thought it was cheaper. Evidence suggest that medical representatives are a good source of information and pharmaceutical industries and their representatives do have direct and indirect effects on prescribing outcomes. Majority believed that generics testing should be more vigorous and generic drug companies need to carry out clinical study to prove equivalence to original drugs. Maximum accomplices believed that switching to generics would alter the course of treatment and they prescribed more of branded drugs, because their names were easy to memorize [22, 23].

Pharmacists' Behaviour towards Generic Drugs: In France, since 1999, the pharmacists have the right to switch from branded to generic medicines unless the prescriber has specified otherwise, which was found to be 'a good thing' in a mail oriented study and felt that the substitution system improved pharmacists' influence within the healthcare system, but at the same time, it is stated that substitution was difficult to implement thus training was necessary, but had positive attitudes towards generic prescribing [24].

In a comparative study between Finland, Australia and Italy, the generic substitution is generally accepted in Finland, the pharmacists were concerned about customer confusion following substitution. The Australian pharmacists reported that it took time to instruct 'resistant customers', like polypharmacy users. The Italian and Australian pharmacists experienced frustration when the customer did not believe that the generic was equivalent to the branded medicine. The respondents also reported that physicians act as a significant barrier. In general, pharmacists in all three countries felt that it was a professional challenge to educate customers about the generic

substitution system [25]. Further in an exclusive Australian based study, it was recommended that patients' acceptance required further improvement in implementation of generic medicine related policies [26].

In New Zealand, more than half of pharmacist believed that original brand products were of better quality, and majority were worried about a 'reduced profit' on dispensing generic drugs [27].

In Malaysia, it was reported that customers showed a high degree of mistrust when the manufacturer was unknown and deemed it difficult to explain that a drug with a different shape and colour can have the same efficacy as the drug previously used [28]. While in a Swedish study pharmacists felt that a reason for the mistrust could be that generics might have different tablet coating, lack calendar packaging, and not always be packed in ''the same exclusive way'' as the brand products [29].

In **India**, it was found that a higher level of education had a significant correlation with knowledge of generic medicines and, the majority were against generic substitution even if the branded drug was not available [30]. Though there is need for prescribing generic drugs preferably but due to many prevailing myths the physicians are hesitant in writing prescription by generic name. Here we discuss following myths and their truths regarding the generic drugs.

Myths and Facts of Generic Drugs: Therefore, to meet out the above challenges of prescriber, dispenser and users, it was felt by the authors that there is a great need to counter major myths and truths about the generic drugs to the readers and researchers [31], which are as follows:

Myth 1: The branded and generic drugs have different active ingredients and all branded are available as generic Fact: The branded and generic drugs have same active ingredients and generic forms are available in market only after the patent of branded drugs gets expired.

Myth 2: All generic drugs are OTC drugs and need not to take approval from the regulatory bodies Fact: All generic medicines are not OTC drugs, thus they need prescription like branded one and generics have to pass approval processes from the regulatory bodies before arriving in market.

Myth 3: Switching to generic drugs can worsen your medical condition or may lead to treatment failure. Cheaper pills bring forth more side effects than branded ones Fact: Any type of medicine can potentially cause side effects regardless if it is branded or generic. The occurrence of such is dependent on a person's clinical condition and predisposition to allergic reactions toward particular chemicals found in the medicine, and not because it does not possess a brand name. But precaution need to be taken when patient shifts in case of drugs having narrow therapeutic index.

Myth 4: Generic drugs are cheaper because they are inferior versions of branded medicine Fact: Generic medicines are just as effective as their branded cousins. The difference in price has nothing to do with the main active ingredients used. In producing branded medicine, pharmaceutical companies invest on marketing, branding, advertising, research, and development, all of which heavily influence the cost.

Myth 5: Branded drugs are safer than generic ones or vice versa Fact: Both branded and generic medicine utilize the same set of active ingredients, with the preservatives and flavouring agents used coming as the only differences in the formulation. Generic drugs are safe. The Food and Drug Administration (FDA) and other regulatory bodies would not permit the sale of unsafe medicines to the general public.

Myth 6: Generic drugs are poor copies of branded medicine, which is why they appear late on the market Fact: This is far from the truth. Branded medicines appear in drugstores earlier because their development is funded by drug manufacturers, with which the formulations are patented. Once the patent expires, generic drugs can be produced and then released in drugstores. As previously stated, the same active ingredients are used, bearing the same production process. The potency and effectiveness of both branded and generic drugs are identical provided they must pass through strict quality control.

Myth 7: Doctors prescribe branded medicine, so they should be more effective Fact: While it is true that doctors often prescribe branded medicine, it does not mean that generic drugs are any less effective. In fact, patients can very well ask their doctors if the prescribed medicine has a generic alternative.

Myth 8: Generic drugs have to be taken in higher doses or for more times than branded ones for them to be effective Fact: Don't ever take drugs beyond their recommended dosage. Consultancy with the doctor is necessary, if one is not sure on how often patient should take his medicine. Branded and generic medicines carry the same dosage and duration

Myth 9: Other than the brand name, there is no difference between branded and generic drugs *i.e.* both are exactly same Fact: Branded and generic drugs may have the same active ingredients, but they have a plethora of differences, like some extent in bioequivalence. However, none of them have anything to do with the medicine's effectiveness. Apart from the selling price, the typical dissimilarities are the colour, shape, packaging, taste, preservatives used, inactive ingredients, and the expiration dates. Trademark laws state that the appearance of branded and generic medicine should not be identical.

Myth 10: Branded drugs are made in world-class facilities, while generic ones are produced in shoddy laboratories Fact: In line with the FDA's regulations about drugs, all medicines sold in drugstores should be safe, with the manufacturers abiding by the health standards surrounding production and development. The FDA ensures that generic drugs are safely produced at well-equipped facilities.

Myth 11: It is not elegant to buy generic drugs because they are "cheap" Fact: It is more practical to purchase generic drugs compared to their branded counterparts, since buyers receive the same value at cheaper rates. Unbranded pills and syrups are as safe and effective as branded medication sans the stiff prices. With the number of generic drugstores continually increasing, more people will have no trouble securing treatments for various medical conditions.

Myth 12: Generic drugs are not manufactured by multinational pharmaceutical companies and are sold loose Fact: Multinational pharmaceutical companies do manufacture generic drugs and are available as packaged products like branded one. So, generic drugs are as good as other branded drugs.

Rise of Generic Market and Indian Pharmaceutical Industry: The Indian pharmaceuticals market is the third largest in terms of volume and thirteenth largest in terms of value, as per a report by Equity Master, May - June 2017. The Indian government began encouraging more drug manufacturing by Indian companies in the early 1960s and with the Patents Act in 1970. The Patents Act removed composition patents for foods and drugs, and though it kept process patents, these were shortened to a period of five to seven years. The resulting lack of patent protection created a niche in both the Indian and global markets that Indian companies filled by reverse-engineering new processes for manufacturing low-cost drugs [32].

India is the largest provider of generic drugs globally with the Indian generics accounting for 20 per cent of global exports in terms of volume. Presently over 80 per cent of the antiretroviral drugs used globally to combat AIDS are supplied by Indian pharmaceutical firms. Overall drug approvals given by the US Food and Drug Administration (USFDA) to Indian companies have nearly doubled to 201 in FY 2015 - 16 from 109 in FY 2014 - 15. India has also maintained its lead over China in pharmaceutical exports with a year-on-year growth of 11.44 per cent to US$ 12.91 billion in FY 2015 - 16, according to data from the Indian Ministry of Commerce and Industry. The Indian government has taken many steps to reduce costs and bring down healthcare expenses.

Speedy introduction of generic drugs into the market has remained in focus and is expected to benefit the Indian pharmaceutical companies [33].

In addition to the social benefits, the generics-only policy also makes economic sense. By promoting generic drug consumption, the government safeguards the health of its generic drug manufacturing industry one of the largest suppliers of low-cost medicines in the world.

A significant change in intellectual property protection in India was the 1 January 2005 enactment of an amendment to India's patent law that reinstated product patents for the first time since 1972. The legislation took effect on the deadline set by the WTO's Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement, which mandated patent protection on both products and processes for a period of 20 years. With increasing pressure from the "Big Pharma" companies in developed countries, Indian generic manufacturers must now operate under a markedly restrictive intellectual property rights (IPR) regime. The new policy can ensure that at least in the Indian market generic manufacturers retain an advantage.

CONCLUSION: It is the prescriber or dispenser of the drug who is the final decision maker, therefore, health authorities in any country must establish generic promotional laws and information policies toward the health care professionals, and hold public campaigns in media about the generics' quality, to build confidence among doctors, pharmacists, and consumers. The developed healthcare systems have more reliable public control routines for drugs in general as well as better bioequivalence requirements concerning generics in particular. A study of Aggeliki V. Tsaprantzi *et al.,* 2016, has shown that there is a significant positive association between information and generic prescription practices.

The key lesson of this article is continuous improvement of the generic drug policy and its implementation. And one of a solution to the problem of branded versus generic lies in strengthening the drug regulatory and quality control structure. Further more research in the field of paediatric and geriatric pharmacology is required to increase generic drug prescribing. With special reference to India, having a population 1, 139, 737, 707; spends 4% of its GDP (gross domestic product) as health expenditure, while the Indian pharmaceutical industry's contribution for the growth of the global generics market is very high. On the other hand WHO says 3.2% Indians and such others will fall below the poverty line, because of high medical bills. 39 million Indians are pushed to poverty because of ill health every year. Around 30% in rural India didn't go for any treatment for financial constrains. About 47% rural and 31% urban hospitalizations financed by loans and sale of assets. The world health organization is worried about Indians high out-of-pocket (OOP) expenses to medicines. About 70% Indians are spending their OOP income on medicines and healthcare services in comparison to 30% - 40% in other Asian Countries and are still suffering from infected disease due to lack of best quality drugs and healthcare facilities. WHO stressed the need for effective monitoring system in hospitals of various countries like India Drugs and Therapeutics committee (DTC), and Pharmacy and Therapeutic committee (PTC). These committees can play an effective role to provide patients more efficient and rational use of medicine, generic or branded. As it was felt that basic information on health policy, pharmaceutical policy, essential drug list, innovators and generic medicines, and their availability and affordability should also be provided to health care providers.

Therefore, under *Pradhan Mantri Bharatiya Janaushadhi Pariyojana*, the Indian government has decided to create a database of generic equivalents of branded medicine, paving the way for mandatory prescription of such low-cost drugs along with their costlier versions. The ministry plans to make it compulsorily for Doctors to write name of generic drugs along with brand names by referring to the database, a move that can reduce cost of medicines by more than half.

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