



PERCEPTIONS AND ATTITUDE TOWARDS THE USE OF GENERIC DRUGS BY ONCOLOGISTS FROM EMERGING MARKETS: A MULTINATIONAL CROSS SECTIONAL SURVEY

Medical Science

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ABSTRACT

Introduction Generic drugs provide same therapeutic effect as an originator, at more affordable price. Still, they are not best adopted. We conducted a survey to understand oncologist's perceptions and attitudes towards generic drugs and understand factors that influence their prescribing behavior.

Methods Oncologists from 15 countries were invited for this cross-sectional survey. Assessment was completed using a series of structured, closed qualitative questions to which participants could select from predefined answers.

Results Fifty three oncologists participated in the. About 70% oncologists acknowledged high-cost of originator drugs often limits providing guidelines based therapy to patients. Most of the participants (86%) opined that quality of generic drugs depends on the manufacturing company. More than 90% respondents agreed that good generic companies often match the quality of originator drugs. A majority (67.5%) of the oncologists believed that side effects caused by generics were similar to those caused by originator drugs.

Conclusions Our finding suggest that educational programs highlighting the benefits of generic drugs should be imparted to the key stakeholder including patients.

KEYWORDS

Access, High-quality generic drugs, generic adoption

INTRODUCTION

Generic medicines have been available for many years and are routinely used to treat a wide range of acute and chronic disease. A generic drug is defined as a medication that is produced after expiry of the patent protecting the originator product, necessarily being similar to the reference drug in pharmaceutical equivalence and bioequivalence in order to obtain the same therapeutic effect at an economical price.(1,2) Most of the world's population encounters difficulties in accessing medications, due to high prices, specifically in the developing countries.(3) Generic medicines are 20% to 90% cheaper than the originator medicine, and their utilization represents a well-established strategy for controlling health care expenditures. (4,5,6) Consequently, generic drugs are an alternative to originator drugs in many countries all over the world.

Globally, generics account for more than 65% of the pharmaceutical market share (7). In 2009, 66% of prescriptions in the USA (United States of America) were for generic drugs that contributed to only 13% of total prescription expenditure (7). In Brazil, the introduction of generic drugs resulted in a drop in prices between 40% and 62%. (8) However, their sales in Brazil accounted for only 27.1% of the pharmaceutical market (8). Therefore, an emphasis is presently being placed on usage of generic medicines. A national study conducted in the USA reported that switching prescriptions from originator medications to identical generics could lead to an 11% reduction in overall drug costs. (9,10) In addition to reducing the overall cost of health care, use of generics can reduce patients' out-of-pocket costs and has been shown to improve adherence.(9,10) Studies evaluating the clinical equivalence of generic medications have been reassuring (11) yet overall generics remain underused.

Despite the advantages offered by generic drugs, their market penetration is far from uniform in most countries for a series of reasons; among them are lack of coherent policies, variations in reimbursement systems, in addition to the negative perceptions about generics among physicians, patients, and pharmacists. Many doctors resist prescribing generic medications (12, 13) on the perceived grounds of quality and equivalence of generic medicines (14) believing to be inferior to their originator counterparts. Furthermore, some of the other commonly reported resistance factors in terms of their adoption are: limited availability of generic drugs in pharmacies, limited knowledge and negative beliefs among consumers.(15) In fact, physicians' attitudes towards generics have been a major concern to researchers and policy

makers since they directly predict the outcomes of any generic-promoting policy.(16-21) In a country like India, known to be a global hub for generic drug manufacturing; results of a recent online opinion poll on generic drugs among 5,673 physicians reported that 73% physicians were against the decision to prescribe generic drugs expressing various concerns ranging from the quality of generic drugs to educational qualification of chemists.(22)

Cancer is one of the leading causes of morbidity and mortality with about 14.1 million new cancer cases, 8.2 million deaths and 32.6 million people living with cancer.(23) Access to medications in general—and cancer treatments in particular—is one of the major challenges faced by health care practitioners and patients today. A cost comparison study between the generic and originator chemotherapy drugs in India revealed significant cost savings per cycle and per patient ranging from INR 11,000 to > INR 90,000 (\$170-\$1,400) and from ~INR 50,000 to > INR 240,000 (\$770-\$3700) respectively.(24) However, even with such cost savings, in a survey of 839 oncologists, nearly a quarter reported negative perception for the efficacy and 50% for the quality of generic medicines.(13) Therefore, we conducted a survey to understand oncologist perceptions towards generic drugs and the factors that influence their prescribing behavior.

METHODS

To obtain an understanding of oncologists' attitude towards generics and the factors that influence prescribing of generic medications versus originator products in cancer treatment in emerging markets, invitation letters were sent to a total of 53 oncologists from 15 countries in emerging markets to participate in the cross-sectional survey conducted at International Hemato-Onco Conclave, held in Hyderabad on the 24th September, 2017. The list of countries from where the participants were invited is presented in Table I.

TABLE I: List of participating countries

Sr. No	Country
1	Algeria
2	Belarus
3	Brazil
4	Colombia
5	India
6	Kazakhstan
7	Myanmar

8	Romania
9	Russia
10	Sri Lanka
11	Tunisia
12	Turkey
13	Ukraine
14	Uzbekistan
15	Vietnam

Purposeful sampling of participants, based on geographical location, was used in order to ensure geographical spread of participants. Assessment of opinions was completed using a series of structured, closed qualitative questions to which participants could select from predefined answers. A number of factors covering physicians' perceptions on the generics were summarized and written as interview questions. The study questionnaire used during the interview is presented in Table II. Participants provided their consent to participate and were free to provide additional commentary on each and at the end of the survey session. The study instrument was based on published data in the scientific domain regarding the global usage of generic medications by physicians and patients specifically in emerging markets for optimal usage of health care budget.

TABLE II. : Summary of questions and Oncologist's response outcomes

Sr. No	Questions	Oncologist's response
Cost of Generics		
1	Do you think high-cost of drugs limits providing guidelines based therapy to patients?	Often: 75% Sometimes: 22.7% Rarely: 4.5% Don't know: 2.3%
2	What in your opinion is the price of the generic drug compared to original drug?	Less than original drug: 93.9% Same as original drug: 4.1% More than the original drug: 0.0% Don't know: 2.0%
3	Would you choose a generic drug over an originator drug because of lesser price?	Yes: 81.3% No: 6.3% May be: 12.5% Don't know: 0.0%
4	What is your estimate on the generic product price in comparison to the originator?	Same as originator: 0.0% Lower than originator by 10-20%: 6.3% Lower than originator by 21-30%: 53.1% Lower than originator by 31-50%: 40.6%
5	Why do you think generic drugs are of lower price?	Lower quality: 0.0% Less spend in R&D: 74.4% Less clinical data: 23.1% Don't know: 2.6%
Quality, Effectiveness and Safety of Generics		
6	Compared to the originator drug, do you think that the effect of the generic drug is?	More: 0.0% Less: 9.5% Don't know: 4.8% Depends on company: 85.7%
7	Compared to the originator drug, what do you think that the generic drugs side effects are?	Similar: 67.5% Fewer: 5% More: 5% Don't know: 22.5%
8	Do you think generic companies have a Pharmacovigilance programs to monitor the safety of the generic drugs?	Yes: 74.5% No: 0.0% May be: 21.3% Don't know: 4.3%
9	Do you think the adverse events for generic drugs are adequately reported?	Yes: 48.9% No: 14.9% May be: 21.3% Don't know: 14.9%
10	Generic drug represents pharmaceutical product identical or bioequivalent to originator drug	Always: 61.2% Sometimes: 32.7% Never: 2.0% Don't know: 4.1%

11	Do you think a product from a good generic company can match the quality of an originator?	Yes: 91.9% No: 8.1%
12	Do you think generics produced by different companies varies in quality?	Yes: 74.4% No: 0.0% May be: 23.1% Don't know: 2.6%
13	Would you be interested in generating clinical data with generic products?	Yes: 94.7% No: 5.3%

Compliance and Education Programs for Generics

14	What do you do if patient cannot afford the complete therapy of an originator drug?	Switch to generic: 78.6% Change the therapy to low price drug: 19.0% Decrease the number of cycles: 2.4%
15	Ability to perform generic substitution will ensure availability of medications to the patient	Agree: 90.2% Neither agree nor disagree: 9.8% Disagree: 0.0% Don't know: 0.0%
16	Do you consider prescribing generic drugs to improve patient compliance?	Always: 19.4% Sometimes: 50.0% Never: 5.6% I only prescribe by molecule: 25.0%
17	Do you think the current company sponsored patient assistance programs adequately covers all patients?	Yes: 46.9% No: 53.1%
18	Do generic companies adequately partner for physician education?	Yes: 53.8% No: 46.2%
19	Current training programs for nurses and hospital pharmacists are	Needs improvement: 56.8% Not available: 32.4% Adequate: 5.4% Not relevant: 5.4%

RESULTS

Fifty three medical and hemato oncologists from 15 countries participated in the survey, with 32 females and 21 males. The median age was 45 years (range, 27-65 years), and the median duration of clinical practice was 13.5 years (range, 2-33 years).

Cost of generics and access to treatment

Oncologists were asked about the importance of cost on their prescribing decision and if they would consider prescribing a generic due to lower price. A high percentage (70%) of oncologists acknowledged that high-cost of originator drugs often limits providing guidelines based therapy to patients (Table II) while astounding 81% oncologists responded that they would consider using a generic over the originator drug due to lower price (Table II). Additionally a majority (92%) of participants believed that generic substitution will ensure increased availability of medications to patients specifically to those who cannot afford high priced drugs (Table II). This was further supported by the fact that majority (94%) of the participating oncologists acknowledged price of generics to be less than originator drugs with more than half the participants (63.1%) estimating the generic product price to be lower than originator by 21%-30%. When asked about the reasons for lower price of generics, approximately three quarters of the participating oncologists responded that lower price of generics was due to less expenditure on research and development. However, it is important to note that none of the oncologists believed that generics are priced lower due to lower quality. Less than one third participants believed limited clinical data on the efficacy and safety of generics to be one of the reasons for lower price. However, a large number (95%) of oncologists were interested in partnering with pharmaceutical companies for generating clinical data for generic products (Table II). Lastly, when asked if oncologists would consider switching to generic drugs in situations where patients cannot afford treatment with an originator drug, majority (79%) of the oncologists agreed to switch while the rest of them either decreased the number of cycles or changed the therapy to another originator low priced drug (Table II). We believe if generic substitution is implemented on a case-by-case basis, it can offer significant cost advantage to the government, insurance companies, and patients.

Quality, effectiveness and safety of generics

When assessing other factors that may influence oncologists' decision when prescribing generics, it was of prime importance to understand their perception of quality, effectiveness and safety of generic drugs. Majority of the oncologists (61%) believed generic drugs were identical or bioequivalent to originator drug (Figure 1a). Furthermore, most of the participants (86%) were of the opinion that the quality of generic drugs depends on the manufacturing company with about 74% of the oncologists claiming variability in quality based on the manufacturing company (Figure 1b). Interestingly, 91.9% respondents agreed that good generic companies often match the quality of originator drugs (Figure 1c). Branded generics were favored as being reputable; relative to other (non-branded) generic preparations.

With respect to safety, a majority (67.5%) of the oncologists believed that side effects caused by generics were similar to those caused by originator drugs. Only 5% of the oncologists believed the side effects caused by generics to be either fewer or more than the originator product (Figure 1d). Furthermore, about half of the participating oncologists agreed that there is adequate reporting of adverse events for generic drugs while only 15% believed that AEs are not adequately reported. Pertaining to pharmacovigilance program, 75% oncologists are of the opinion that generic companies have a pharmacovigilance program for monitoring the safety profile of generic drugs.

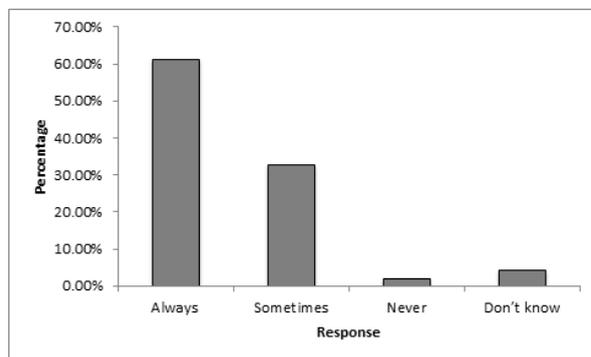


Figure 1a: Response to the statement-Generic drug represents pharmaceutical product identical or bioequivalent to originator drug

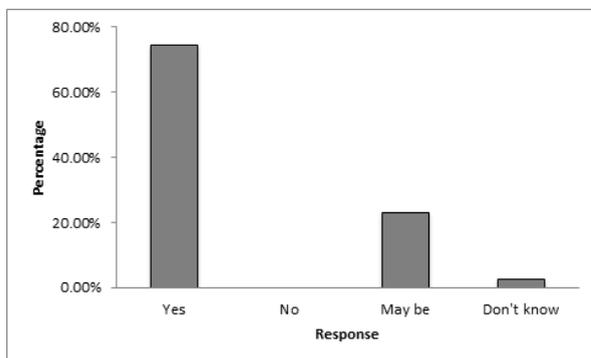


Figure 1b: Response to the question on variation in quality of generics produced by different companies

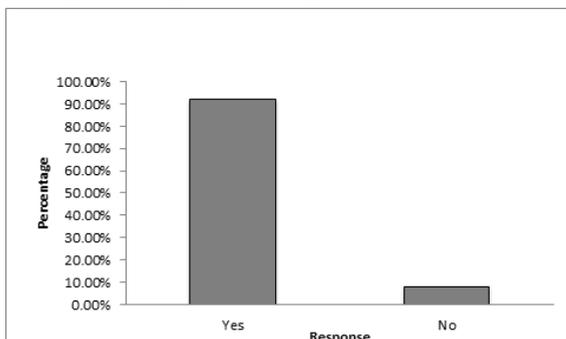


Figure 1c: Opinion of the responders on a good generic company matching the quality of an originator

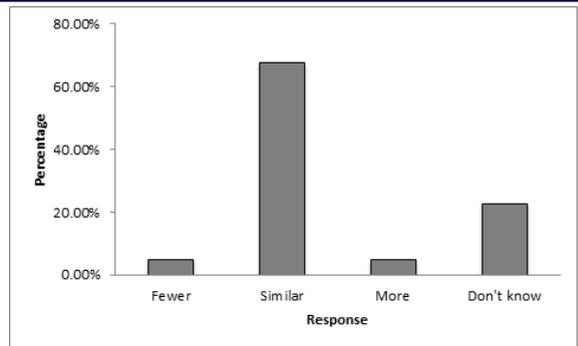


Figure 1d: Opinion of the oncologist on the side effects of generic compared to that of originator

Education programs for generics

The requirement for education for oncologists, pharmacists, other health professionals, and patients, was a recurring theme. That requirement was reinforced by the fact that majority (57%) of the oncologists believed that programs focusing on imparting training to nurses and hospital pharmacist needs improvement while 32% physicians believed that training programs are not available. Surprisingly, only 5.4% physicians believed that the current training programs are adequate. Furthermore, 54% of the participants agreed to have generic companies adequately partnering for physician education. Lastly over half (53%) of the participating oncologists believed that a company sponsored patient assistance program does not cover all patients adequately. Table II summarizes the physician response outcome to the questions asked.

DISCUSSION

Healthcare expenditure is rapidly growing worldwide and cancer is among the most expensive conditions to treat primarily due to high cost of anti-cancer drugs. The cost of anti-cancer drugs plays a major role in utilization especially, in resource poor countries. Generic medicines provide economical alternatives to originator medicines, resulting in considerable savings to healthcare budgets. While there have been numerous publications dealing with generic medicines: their development and market introduction, subsequent use and aspects of acceptance or otherwise; there is relatively limited recent literature regarding the attitudes of oncologists towards these products. This paper is the first published exploration, using semi-structured interviews, of oncologist perceptions and behaviors relating to their use of generic medicines in emerging markets.

A previously published review highlighted collective views of physicians as: accepting of generic substitution under policy and economic pressures but having concerns regarding generic drugs' overall quality. The review further theorized that these concerns may prevent full adoption of generic drug prescription and substitution by physicians, which could lead to escalation in health care costs for governments, insurers or consumers directly (25). Cognizant of the concerns published in literature, we wanted to determine if attitudes towards generic prescribing have evolved appreciably specifically among physicians treating patients in cost constrained emerging markets. One of the most important findings from this study is that majority of the oncologists were open to considering prescribing generics over originator drugs. Findings from previous studies have reported drug cost as an important factor in physicians prescribing behavior. (26) In a study that was held in America (26), drug cost was an important factor when prescribing especially for uninsured patients. In this study, the views of physicians were consistent with findings from previous studies where over half the participants believed that generics were priced considerably lower than the originator drugs and that they would consider switching to generics specifically for patients who cannot afford high cost drug therapy. As reported in literature, physicians are often more concerned about the effectiveness of a drug rather than its price when making prescribing decisions.(27) Largely, most of the participants believed that quality and safety of generics was similar to the originator drug and did not express grave concerns regarding this aspect. Though not covered in our study, previous studies have demonstrated a strong association between physician's acceptability for generic substitution and their employment sector with physicians in public sector favoring generic medications.(28) This needs to be evaluated further in our research endeavors.

To enable successful generic adoption a series of prerequisites are required; among them is the understanding of the physicians' attitudes. This is important because prescribers' perceptions impact policy measures and prevent potential conflicts between care providers and the authorities. Physicians play a key role in prescribing and dispensing generic drugs and thus their perception towards the same play an important role in generic switch. Although, the use of generics have become widespread there is evidence that many physicians and pharmacists hold negative thoughts of generics and resist prescribing generic medicines. This may be due to the perception of generic drugs being inferior in quality. However, this is not necessarily true. Regulatory guidelines for generic drug approval are stringent. For the review and potential approval of generic drug, the applicants must follow stringent regulatory guidelines with respect to quality parameters of the product along with plant inspection, labeling and packaging requirements. In order to get approved by the regulatory bodies, though the generic drug applicants are generally exempted from pre-clinical and clinical data establishment for safety and effectiveness, they must demonstrate pharmaceutical equivalence and bioequivalence to the originator drug to show no significant difference in the rate and extent of absorption of the active pharmaceutical ingredient. Though the present study reflects a general positive attitude of oncologists towards generics, there a need gap for information among physicians regarding quality, effectiveness and safety of generics. There is a need for interventions aimed at health professionals to overcome misperceptions of inferior quality, safety and effectiveness—as well as to explain the reasons why generic medicines are cheaper than originators, the meaning of bioequivalence, and the testing and regulatory processes involved in approving a generic medicine for general use. Overall generic drug applicants spend less on research and development and clinical trials which in turn leads to a perception that generic drugs are inferior in quality than the originator. However as generic drugs are for the most part exempted from conducting multi-phase pre-clinical and clinical trials, their cost tends to be lower than that of the originator drug without compromising the quality and effectiveness of the drug. Recently, the US FDA has initiated generic drug education/awareness program for physicians and patients using generic drugs facts handout, prescriber advertisement, public service announcement, social media posts, animated GIFs and information cards and infographics to highlight safety, effectiveness, quality, looks, cost, strength and benefits of the generic drugs. These initiatives should be coupled with the development and adoption of standard guidance on generic substitution process for healthcare professionals. This can be further supported by introducing legislation for compulsory generic substitution wherever appropriate to encourage the use of generics and maintain accessibility and affordability of medicines.

CONCLUSIONS

Our finding suggest that participating oncologists were aware about generics drugs and that they would choose generic drug over originator drug given the quality, safety, effectiveness of generic drug are similar to the originator drug. Educational programs highlighting the benefits of generic drugs should be imparted to the key stakeholder including patients. Generic drug policies may help in boosting generic drug prescription by physician and optimize pharmaceutical public expenditure however, a framework to identify high quality generics will be useful for adoption of generics in resource constraint countries.

DISCLOSURES

Amit Garg, Anupama Rao Singh, Shyamal Sahadevan Kadukkatt, Suhas S Khandarkar are employees of Dr Reddy's Laboratories Ltd, Hyderabad, India.

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