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MANDATORY GENERIC PRESCRIBING AND GENERIC SUBSTITUTION FOR BRAND-NAME MEDICINES IN INDIA - A CROSS-SECTIONAL SURVEY

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ABSTRACT

Background: India is considered as the pharmacy of the world, being the largest provider, supplying 18% by volume in the world's generic drugs market, exporting US$20.0 billion worth of drugs in the 2019–20. It is ironical that India has very low domestic consumption of the generics, being dominated by branded medicines. It's matter of huge burden to public health funding of the Government as well as the patient's huge out-of-pocket expenditure. **Aim & Objectives:** The primary objective of the study is to conduct a systematic review and critical appraisal of perception among various stakeholders on (i) mandatory prescribing with a generic name and (ii) generic substitution for brand-name medicines. **Methodology:** A cross-sectional survey was undertaken in the form of systematic interviews with various stake holders (N= 426) comprising physicians (96), representatives of the industry (20) and regulatory bodies (10), pharmacists (110) and patients (190) which is followed up with a self-administered questionnaire using Google Forms. **Results & Discussion:** Verbal interviews with physicians, pharmacists & patients revealed a lot of misconceptions with lack of trust on the quality, stability and extent of regulatory control of generic medicines. Out of 426 respondents, 234 (55%) were found to have basic understanding on quality, safety, efficacy, cost & applicable regulatory controls on generics and the majority of this fraction (90%) voted for mandatory prescribing of medicines using generic names, while there was a mixed response on the right to generic substitution by the pharmacist. **Conclusions:** The study revealed the need for continued education and improving the perception of generics among all stakeholders through effective regulatory system, supply-chain management and enforcement of anti-counterfeiting policies. The study has perceived a strong resistance from the physicians for mandatory generic prescribing while the industry & pharmacists are not inclined to the right for generic substitution by pharmacists.

INTRODUCTION: Internationally, the generic medicines have been increasingly favoured due to substantially low prices Without compromising on quality, economic pressure on public health care budgets, and the expiry of patents on widely used medicines.

Especially the Governments in the high-income regions of the world such as the United States and Europe, generic medicines are supported through their drug policies [1]. Though India has become a global hub of generic drug manufacturing, the Indian pharma market is dominated by branded generics whose price is substantially higher than the true or unbranded generics. The Indian pharmaceutical industry through generic medicine exports, has significantly reduced the burden on the US public health system to tune of $292.6 billion (USD) in 2018, according to the *AAM Access & Savings Report* [2]. According to an Indian Brand Equity Foundation report, the Indian pharmaceutical sector meets 60% of vaccines demand globally, 40% of generics demand in the United States, 50% of generics in the United Kingdom, and 25% of all medicines in the United Kingdom. It is ironical that these generics do not find a place in our domestic market (less than 15%). In fact, Indian pharmaceutical companies are now also becoming a key source of medicine for the rest of the developing world. Of note, they are playing a pivotal role in bringing down the price of lifesaving, antiretroviral drugs that have helped contain the AIDS epidemic. The global demand for medication from India will continue to go up. India's share of the US generic market is growing rapidly, and the number of companies and manufacturing facilities supplying to the US market is growing fast. The focus on growing regulatory requirements, improved healthcare infrastructure, and surge in research and development spend bodes well for the pharma industry. Multiple studies have proven that saving through substitution of originator brands by cheaper generic medicines, savings in the range of 10-90% can be achieved [1]. Most national governments have been encouraging the use of generic medicines worldwide and many healthcare systems have policies of substituting expensive branded original medications with generic medicines [1]. In the United States, generic substitution is an accepted practice which has resulted in a substantial reduction in public health care costs and significant savings to the economy [1]. In the United Kingdom, generic substitution is now a standard practice in hospitals operated by the National Health Service (NHS) and medical schools have included generic prescribing as a part of their medical training [1]. In India, branded generics are portrayed to be superior to unbranded generics via advertising and promotion. Medical professionals have added to this confusion by indicating they trust drugs made by reputed companies. The Indian Medical Council (Professional conduct, Etiquette and Ethics) Regulations, 2002 was already amended in 2016 to mandate that drugs be prescribed by generic names only by registered medical practitioners [1]. As much debate still surrounds the topic of usage of generic drugs – it is important to understand the opinions held by stakeholders in relation to these generics. Hence, a need is perceived for the cross-sectional survey to understand the perception of stakeholders - in specific- mandatory prescribing of generic names & generic substitution for brand-name medicines by the pharmacists.

1. MATERIALS AND METHODS

Interviews with the Stake-holders

A cross-sectional survey was undertaken in the form of systematic & extensive interviews with various stake holders (N= 426) comprising physicians (96), representatives of the industry (20) and regulatory bodies (10), pharmacists (110) and patients (190) which is followed up with a self-administered questionnaire, where dissemination is by online method. The online survey was performed using Google Forms, as it appeared to be the most convenient and effective route. Several visits were made to hospitals and community pharmacies located in Hyderabad and the interviews were taken with the Physicians, regulators, people from the industry, patients & practising pharmacists. The interviews are very systematically focused to discuss two issues which are critical for public health care scenario of the country. Reasons for the responses of the stakeholders were recorded.

Questionnaire Development:

The questionnaire used was developed based on a review of the literature investigating generic medicine

utilization. The initial questionnaire developed was pilot tested on 20 experts who included pharmacists as well as physicians.

Questionnaire Development

The questionnaire used was developed based on a review of the literature investigating generic medicine utilization. The initial questionnaire developed was pilot tested on 20 experts who included pharmacists as well as physicians. They were asked for feedback regarding any grey areas on the questionnaire. The questionnaire was also evaluated for its ability to meet the study objectives and adjusted as required. The questionnaire contained closed-ended questions. There were 7 basic questions to evaluate the participants understanding about the generic & brand-name medicines, with reference to their quality, safety, stability, efficacy and the extent of control by regulatory agencies. These basic questions are followed by the three questions (S.No. 8 to 10 of the questionnaire) relate to the following two objectives of the study - Rights for the pharmacists for the generics substitution for the brand-name medicines. Mandatory prescribing of generic name by the physicians. The 10 questions & answer key are given below:

1. What do you know about generic & brand-name medicines
   A. both contain the same active ingredients
   B. same strength and route of administration
   C. Similar rate and extent of absorption in the body
   D. all of the above

2. Your understanding of control of generic & brand-name medicines by the statutory bodies
   A. both require pre-market approval
   B. similar post-marketing surveillance
   C. similar quality control requirements
   D. all of the above

3. Why do generic medicines cost less than brand-name medicines?
   A. competition between the brand-name drug and multiple generic drugs
   B. does not have to repeat animal and clinical studies to prove safety & effectiveness
   C. development of generics takes less time period
   D. all of the above

4. Do you think that the generics cause more side effects & offer less safety?
   A. Yes
   B. No
   C. I don't know.

5. Do generic medicines work as effective as brand-name medicines?
   A. Yes
   B. No
   C. I don't know.

6. Do you think that the brand-name drugs possess better quality & stability than Generics?
   A. Yes
   B. No
   C. I don't know.

7. Do you believe that generic drugs are equally suitable for treating more serious diseases.
   A. Yes
   B. No
   C. I don't know.

8. Do you vote in favor of pharmacists being given the right for generic substitution in place of Brand-name medicines?
   A. Yes
   B. No
   C. Prefer not to say

9. Do you think that strict laws are required to mandate the Doctors to prescribe only generic medicines?
   A. Yes
   B. No
   C. I don't know.

10. Do you accept substitution of generics in place of brand-name medicines.
    A. Yes
    B. No
    C. As advised by the physician.

Answer key: 1-D, 2-D, 3-D, 4-B, 5-A, 6-B, 7-A

Study Design: A cross-sectional survey employing a self-administered questionnaire as the data collection tool was conducted from December, 2019 to March, 2020 among 426 people comprising various stake holders such as Physicians, pharmacists, industry, regulators and the general public. The questionnaire included the provision of participant identification (mandatory E-mail field) and an informed consent form also to be completed mandatorily for the submission of the questionnaire.

Ethical Consideration: As the study is typically a cross-sectional survey, approval for this study was not mandated by the institutional Ethics Committee. However, a mandatory informed consent provision is kept in the online form and the participant is at freedom to quit the survey without submitting any sort of responses whatsoever it may be. The information obtained was treated confidentially. The questionnaire comprehensively evaluates the understanding of generics in relation to their quality, stability, safety, effectiveness, cost & the process of their approval and vigilance by the regulatory body. Even though the questionnaire consisted of multiple choices of answers, enough care was taken to avoid bias - for the generics or brand-name medicines. For example, if the answer to one question is YES, the answer for the subsequent question is not always YES, thus this jumbling improves the quality of appraisal of participant's knowledge.

RESULTS AND DISCUSSION: This cross-sectional study performed was more of educating or rather a myth-busting exercise because most of the participants had certain misconception about the equivalence of generic medicines with brand-name medicines with reference to their quality, safety, stability, efficacy and the extent of control by regulatory agencies. The interviews with various speciality physicians revealed that they have a strong preference for branded medicines over generics due to following chief reasons: Lack of trust on the quality, stability, safety, suitability of generics for use in serious diseases. Lack of confidence in generics as physicians are unaware of and lack of clinical experience with generics. Influence of the pharma industry and their medical representatives to prescribe brand-name medicines. Non-availability of generics in the drug stores. In the interaction with various pharmacists, we found that they also have strong preference for branded medicines over generics due to following chief reasons:

1. Patient's lack of understanding of generic medicines and their substitution & switchability for branded medicines. This leads to patient non-compliance and confusion.
2. Lack of knowledge on the quality, stability, safety and interchangeability of generics.
3. More profit margins for selling branded medicines
4. Lack of role in medication and patient's insistence on branded medicines
5. Additional stocking requirements of generics and additional workload.

In the interviews with the representatives of industry, it was found that the industry is rather keen to lead the global generics market especially to USA & Europe. They felt that the market prices are already low with more price control measures of the Government and their profit margins and R&D investments will be severely compromised if strict laws are implemented in India mandating the generic prescribing or empowering the pharmacists with the right to generic substitution. In the interaction with regulatory body representatives, unambiguous statements were given with regard to equivalence of generic medicines in respect of quality, safety, stability, efficacy and the extent of their control without discrimination whether its branded or generic medicine. They felt it’s a policy matter to implement strict laws to mandate generic prescribing or right to generic substitution. We have extensively interacted with patients of various government and private hospitals and clinics in Hyderabad, the capital city of Telangana state. There appears to be a strongly held belief in the patient group, that less expensive equals lower quality and they lack

any knowledge of generic medicines. When informed about the cost benefits without compromise on quality, safety and effectiveness, they were just skeptical. Evidently there is a need to create awareness and needs intervention of the physician to create the confidence. When respondents' views were sought whether they accept the generics substitution personally, 53.2% respondents felt that they would be taking the advice of the Physician while 35.7% respondents were in support of the generics substitution. The responses to the survey questionnaire were critically analyzed, it was found that out of 426 respondents, 234 (55%) possess basic understanding on quality, safety, efficacy, cost & applicable regulatory controls on generics. Among the respondents who demonstrated their understanding on the basic concepts of generic medicines, majority of this fraction (90%), have opined that that "prescribing medicines by generic names should be made mandatory while there is a mixed response on whether the generic substitution by the pharmacist for the brand-name medicines should be allowed or not".

CONCLUSIONS

In India, the majority of the population does not have health insurance and have to pay out-of-pocket for medicines. Indian Government is laying considerable emphasis on promoting generic medicines due to potential economic benefits associated with their use. There almost invariably exists a tension between the promotion of R&D of new medicines and promoting the use of generic medicines and the following conclusions are drawn based on our cross-sectional survey:

Medicines of assured quality- A critical

Component: The study emphasized the need for improving the perception of generics among all stake holders in the business through an effective regulatory system. It is observed that there shall be successful generics policy & mechanism sufficient to provide certainty that generic products are of assured quality.

***I*nfluencing prescribing behavior -** Mandatory Generic Prescribing: As there is a perceived strong opposition for legislation on Mandatory Generic Prescribing, it is advisable to bring a phased introduction of generic prescribing as the most feasible approach, instead of jumping from the first phase into a system of obligatory generic prescribing. It is also necessary to provide incentives for generic prescribing along with steps to curb perverse incentives to prescribe higher-priced branded medicines.

Systems are needed to facilitate market entry of generics - For generics to be used, they must first be available in medicine outlets, public sector health facilities like Jan Aushadi stores. This starts with removing unnecessary barriers to entry for generics. The patients should be encouraged to ask for generic products. Further, the regulatory body has to take a proactive role in promoting generic medicines uptake through the publication of information about generics in particular, information on their quality & price.

Monitoring and evaluating policy changes - It is crucial to actively collect data before and after a change of policy occurs. For example, the new Pradhan Mantri Bhartiya Janaushadhi Kendra (PMBJK) policy mainly faced the problem of supply of generics to the sale outlets. A situation of conflict between doctors and pharmacists (including the fear of doctors about limitation of their "therapeutic freedom") might be a barrier to pro- generics policies, particularly generic substitution. Further, financial incentives for pharmacy stores and their personnel shall be provided to sell generic speciality medicines along with training for patient counseling.

Abbreviations: National Health Service (NHS), Pradhan Mantri Bhartiya Janaushadhi Kendra (PMBJK)

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