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Drugs and Substitutes in Medical Store

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ABSTRACT

A very large part of India's population fulfils its healthcare needs from government run healthcare delivery system which is free, contributory or highly subsidised. Use of medicines forms a large part of healthcare facility. As the number of medicines and brands are ever increasing in today's market, it is usual for pharmacy to substitute a generic instead of the prescribed brand or a different brand if the prescribed brand is not available. Depending on the type of substitute, it could fall under 'generic' or 'therapeutic' substitution. For any condition, there may be numerous medicines existing, some of which probably got introduced more recently, may be more expensive and erroneously perceived to act better than the earlier known medications for the same ailment. Also, due to very high number of medicines that are approved and available for use in the market, it is impossible to stock all the medicines in any pharmacy. Generic and therapeutic substitutions should be formalised and implemented by institutions, with the consent and cooperation of all the stake holders as guided by World Health Organisation. The advantages and limitations of medicines substitutions are discussed in the review.

Keywords : Brand Names, Generic, Therapeutic.

I. INTRODUCTION

A large part of India's population fulfils its healthcare needs from government healthcare delivery system such as Central Government Health Scheme, Armed Forces Medical Services, Employees State Insurance Corporation, State Medical Services etc. Use of medicines forms a large part of healthcare facility. For any condition, there may be numerous medicines existing, some of which probably got introduced more recently, may be more expensive and erroneously perceived to act better than the earlier known medications for the same ailment [1]. Even though more expensive, the newer medicine of the same drug class may not offer any distinct advantage in terms of the treatment outcomes. Also prescribers, many times choose to prescribe by the brand name whereas prescribing through the generic name may facilitate the dispensing as well as it turns out to be cheaper. What a physician prescribes to a patient for his/her

ailment is largely a decision based on the patient's clinical condition and physician's personal choice for that condition based on his knowledge and experience. In free healthcare delivery systems, ideally a medicine that is not available in the medical store or dispensary should be avoided as far as possible by the treating physicians. Due to ready availability of large number of products and addition of many more almost every day to it, is impractical for any dispensary to stock all the possible options. Due to the large number of patients that the public healthcare system handles, there is a perpetual shortage of funds for procurement of medicines and other medical devices for patients [2,3]. In this situation of fund constraint, provisioning of medicines with an ever expanding list of 'me too' drugs, is an unmet challenge. Inadequate funding and inappropriate selection of medicines is one of the important reasons for non-availability of medicines in government hospitals [4]. Due to the reasons of non-availability, some of the prescribed medicines may have to be substituted on the spot with alternatives at the dispensary to avoid wastage of time and harassment to patients. Such substitution could fall into one of the two categories generic or therapeutic. As per World Health Organisation (WHO) guidelines, generic substitution is defined as 'the dispensing of a product that is generically equivalent to the prescribed product, with the same active ingredients in the same dosage form, and identical in strength, concentration and route of administration' Therapeutic substitution or interchange is 'the substitution of one medicine with another that differs in composition but is considered to have similar pharmacological activity (including side-effects) and therapeutic outcomes' [5].

II. RELATED WORK

Search strategy:

A systematic literature search with a computer-assisted literature search for relevant studies was performed using Science Direct, Google scholar, SpringerLink, BioMed Central and Elsevier. The following nine countries were reviewed: Australia, Canada, Czech Republic, Ireland, Japan, Switzerland, Indonesia, the United States and the United Kingdom. The analysis involved reviewing the journals on generics substitution policy. From 27 journal articles that were reviewed, only 14 were selected based on the fulfilled criteria.

Inclusion and exclusion criteria

The selection of studies for this systematic review focused on the generic substitution or drug policy in countries that implemented a generic substitution policy. The study was selected if it was written in English language only. In addition to that, reviews on generic substitution guidelines designed worldwide were also included. Countries that did not implement generic substitution policy were excluded.

III. PROPOSED SYSTEM

I. Pharmacists and patients should always communicate to know the safety and suitability of the alternate brands for patients before using the generic drugs to minimize the patient's misunderstanding and confusion about the drugs and improve patient acceptability of a generic product. Acceptability of the patients might stimulate the motivation, behaviour, and knowledge about the generic products of the practitioner.

II. In order to give proper guidance on generic substitution, a formulary of interchangeable medicines must be developed. The requirements for marketing authorization of the generic products are:

- The applicant must have a license for manufacturing and marketing.
- The factory must have a license or accreditation for manufacturing the item.
- The name, ingredients, quantity, dosage and indications of the item should be appropriate.
- The items must fulfill the requirement for compliance with the country's GMP.

III. Generic substitution is aimed at cost savings for patients.This leads to the replacement of expensive original pharmaceutics prescribed by the doctor with

cheaper generics having the same active substance or equivalent effect with the original.

IV. The supply chain should be reduced by avoiding unnecessary distribution level between manufacturers and patients to ensure the price offer is affordable to the patients.

V. Strict quality standards should be issued. The generic substitution drugs should be safe and effective, pharmaceutically equivalent, bioequivalent, adequately labeled and manufactured in compliance with current GMP regulation.

VI. The National Pharmaceutical Control Bureau (NPCB) is the regulatory body for approval and registration of the generic drug. It is important for the generic product to meet its crucial criteria such as safety, efficacy and efficiency.

VII. The generic drug products must be manufactured under the FDA's approval under its same standard as good manufacturing practice regulations.

VIII. Education is an important factor. The government and general practitioners are responsible for disseminating the information about the generic drugs to the consumers in order to avoid misunderstanding.

IX. Pharmacists and medical practitioners should have positive perceptions toward generic substitution products as it can affect consumer or patient choice.

X. Labeling of medicine should be based on the international non-proprietary name (INN) as it can help the patients to identify their medication and avoid misunderstanding when substitutions occur (Chua et al., 2010).

XI. Collaboration between general practitioners (GPs) and pharmacists should be established in order to increase the usage of generic drugs by the public (Chua et al., 2010).

XII. Pharmacists should have a system where they can access relevant information about the generic medicines before dispensing them.

XIII. A list of branded products that cannot be substituted with generic drugs should be established, such as non bioequivalent generic products and Narrow Therapeutic index (NTI) medicines in which small variations in bioavailability may be clinically significant. This can help the general practitioners to identify the drugs in the list that cannot be substituted with the generic product.

XIV. The lists can aid the pharmacists to assess the generic equivalence of the products chosen as a substitution for the patients.

XV. If the substituted drugs are included in the lists, pharmacists have the authority to change to the generic drug unless the patient demands the brand name drug. However, if the prescriber puts an initial or sign (e.g. do not substitute), the dispensing pharmacist should dispense according to the prescribed medication. Pharmacist cannot replace it with the generic substituted drug or other brand name drug.

XVI. Reference-pricing system should be implemented.

XVII. Education to increase awareness and confidence towards generic medicines need to be targeted among medical doctors and consumers alike.

IV. CONCLUSION AND FUTURE SCOPE

This article shows that many countries are aware of the advantages of generic substitution especially in reducing cost and increasing patient compliance. However, the fact that generic drugs do not have to undergo large, expensive clinical trials that are required for approval of brand-name drugs give rise to questions about the quality and safety of generics. Furthermore, there is also an issue on the pricing and reimbursement status of generic drugs. It is compulsory for generic drugs to undergo various tests to meet the requirements and to ensure that the authorization procedures of generic drugs are equally efficient, safe and equivalent to the corresponding originator product. It is also important to implement a Reference-pricing system as a solution in the pricing issue (Chua et al., 2010).

This article highlights the importance of educating general practitioners about the generic products

approval system concerning bioequivalence, quality, and safety. Both pharmacists and medical practitioners should have positive perceptions toward generic substitution products since it can affect the choice of the consumers and patients. Good communication between pharmacists and physicians are expected to improve the generic substitution process. Besides, regulatory bodies for approval and registration of the generic drug should play their role to ensure the generic product meets its crucial criteria such as safety, efficacy and efficiency while the government and general practitioners are responsible for disseminating information about the generic drugs to the consumers in order to increase understanding, acceptance and ability to make choices. Lastly, this article is an urgent call for our country to establish a policy regarding generic substitution practice. In addition, several suggestions from the reviewed content can be used to improve the practice of generic substitution in Malaysia.

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