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Generic Prescription: Balancing the Benefits and Challenges in Prescribing Practice

Introduction

In an everyday medical practice, there is a pertinent question that haunts physicians and well as the patients: should we use a branded medicine or opt for a generic one?

Globally, there are three types of medicines available: Branded medicines, Branded generics and Generic medicines. After multiple phases of research and development (usually occurring over 10-12 years), the company doing the research introduces the medicine to the market in its own brand name (innovator's product, branded medicine).[1] This product is protected by patent rules and no other company can produce this medicine till the patent exists. Once the patent expires, other companies can manufacture this medicine in their own brand names and are known as branded generics. At this moment, this medicine can also be manufactured without any company-specific brand name, which would then be known as generic medicines. Regulatory-approved generics must demonstrate therapeutic equivalence i.e match the brand in dosage form, strength, quality, stability, effectiveness, safety, and how they are used.[1]

Prescribing medicines in generic name have their own strengths, weaknesses, opportunities and threats, and Here we present a brief discussion on these aspects of generic prescription.

Strengths (Internal Positive Factors)

Implementing generic prescription helps make healthcare more cost-effective for everyone involved, especially patients and healthcare organisations. This enables individual patients to receive medicines at the minimal cost, easing their economic burden, especially if the expenditures are to be borne out-of-pocket by them. It is estimated that generic medicines typically cost 30% to 80% less compared to the branded medicines and branded generics. Similarly, the policy of generic prescription helps in optimal utilization of in-house pharmacy, thereby optimising the net operational cost of the pharmacy service.[2]

Sometimes brand names could create confusion among the prescribers,

dispensers and patients, especially in cases of Look alike, Sound-alike (LASA) drugs.[3] If inadequately regulated, two entirely different medicines could end up having same/similar brand names. This can be devastating if the prescriptions are written in brand names only. Prescribing in generic names could create a safer prescribing habit among the physicians.[3]

Weaknesses (Internal Challenges)

A major challenge is the associated sceptical regarding the quality of medicines available as generic medicines. Though generic medicines are supposed to demonstrate therapeutic equivalence, i.e., have same medical effects on the patients as with branded medicines, this is not always achieved.

One of the major reasons for this discrepancy is the variable manufacturing standards. Though the pharmaceutical companies are WHO-GMP certified (basic requirement for a pharmaceutical company to be registered in most countries), they may still have sourced active pharmaceutical ingredient (powder of active drug) and excipients (inactive ingredients) from different places. This, combined with variation in manufacturing processes and quality assurance/control measures could lead to failure in demonstration of therapeutic equivalence by the generic medicines.[4]

Additionally, generic medicines with poor lipid solubility and/ or permeability (Biopharmaceutical Class System's Class II, III and IV drugs), even after following meticulous formulation processes, may behave differently from branded medicines if they are not bioequivalent.

Medicines that demonstrate narrow therapeutic index should always be prescribed in brand name as there is a substantial risk of change in plasma drug levels, which could lead to subtherapeutic effects or development of adverse effects.

Opportunities (External Positive Factors)

The Government of Nepal promotes generic prescription through The National Drug Policy, aiming at increasing affordability of medicines; and through the policy that requires procurements to be made in generic names.[5]

Similarly, authorities like the Department of Drug Administration (DDA), Nepal Medicine Laboratory (NML) have been working rigorously to promote generic medicines in the country. Regulations like requirement of bioequivalence studies for medicine registration; and activities like market inspections to verify the quality of medicines being circulated in the market are pivotal to promote generic prescription in Nepal.[6]

Effective implementation of regulatory policies increases the public trust in generic medicines.[7]

As generic medicines are cheaper, health insurance policies are more likely to cover the expenses incurred through generic prescriptions only.

Existence of a robust pharmacovigilance system would help detect medicines with quality issues and alert the stakeholders to further evaluate the quality of medicines. The causality assessment of adverse effects due to a questionable medicine can be conducted to generate preliminary data and take necessary steps.

Threats (External Challenges)

Availability of counterfeit (fake) or substandard medicines in the market poses a serious risk. As they can be ineffective or even harmful. When patients encounter such medicines, they may lose confidence in genuine, quality-assured generics and in the treating physician.[8]

Branded generic medicines are priced between innovator's branded medicine and generic medicines. Due to the unhealthy competition between pharmaceutical companies for the market share, they may be influenced to compromise with the quality of medicine being produced.

Absence of infrastructure to evaluate the quality of generic medicine before procurement, or when there is a question regarding medicine's quality increases the risk of procuring counterfeit, substandard and falsified medicines.

If the regulatory authority fails to conduct sufficient regular checks to ensure the quality of generic medicines over time, this would allow medicines with questionable quality to enter the supply chain undetected, creating a direct risk to anyone who uses them and eventually fall in trust on the generic medicines.[9]

Ideal setting for implementing generic prescription[4]

Generic prescription has a decent advantage over the branded prescription in most of the situations. However, to implement this policy effectively, there are several aspects that need to be strengthened.

At the government level, we need to have a supporting policy that is enforced stringently.

Functioning and independent Drug and Therapeutic Committee could assure physicians and patients regarding the quality of the medicines made available through the hospital pharmacies under the generic prescription policy. First and foremost, they can establish a protocol to address the quality concerns regarding the generic prescription at their institute. This trust can further be supported by establishing robust pharmacovigilance services, conducting in-service trainings, developing relevant Information, Education and Communication (IEC) materials, targeting both physicians and patients.

The importance of making generic medicines available for a successful implementation of generic prescription policy can never be over-emphasised. Int the market dominated by branded generics, generic prescription may shift the decision regarding brand selection from prescriber to dispenser.

Conclusion

Generic prescription, even though beneficial, needs to be implemented strategically, with proper preparation so that the adversaries that could occur due to its inherent weakness and threats are balanced by the benefits brought by them.

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Brief Information

Shorter treatment regimen for Tuberculosis

Based on the updated official guideline from the American Thoracic Society, U.S. Centers for Disease Control and Prevention, European Respiratory Society, and Infectious Diseases Society of America, WHO (2025) has issued a conditional recommendation to use a four month regimen of isoniazid (H), rifapentine (P), moxifloxacin (M) and pyrazinamide (Z) for the treatment of drug susceptible pulmonary tuberculosis.

This new regimen consisted of:

- Eight weeks of daily PHZM
- Nine weeks of daily PHM

The regimen showed comparable cure rates, all-cause mortality and adverse events during treatment; and a slight increase in retention on treatment. The evidence was uncertain with regard to acquisition of drug resistance.

However, experts were concerned regarding resource limitation, equity, acceptability and feasibility issues.

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