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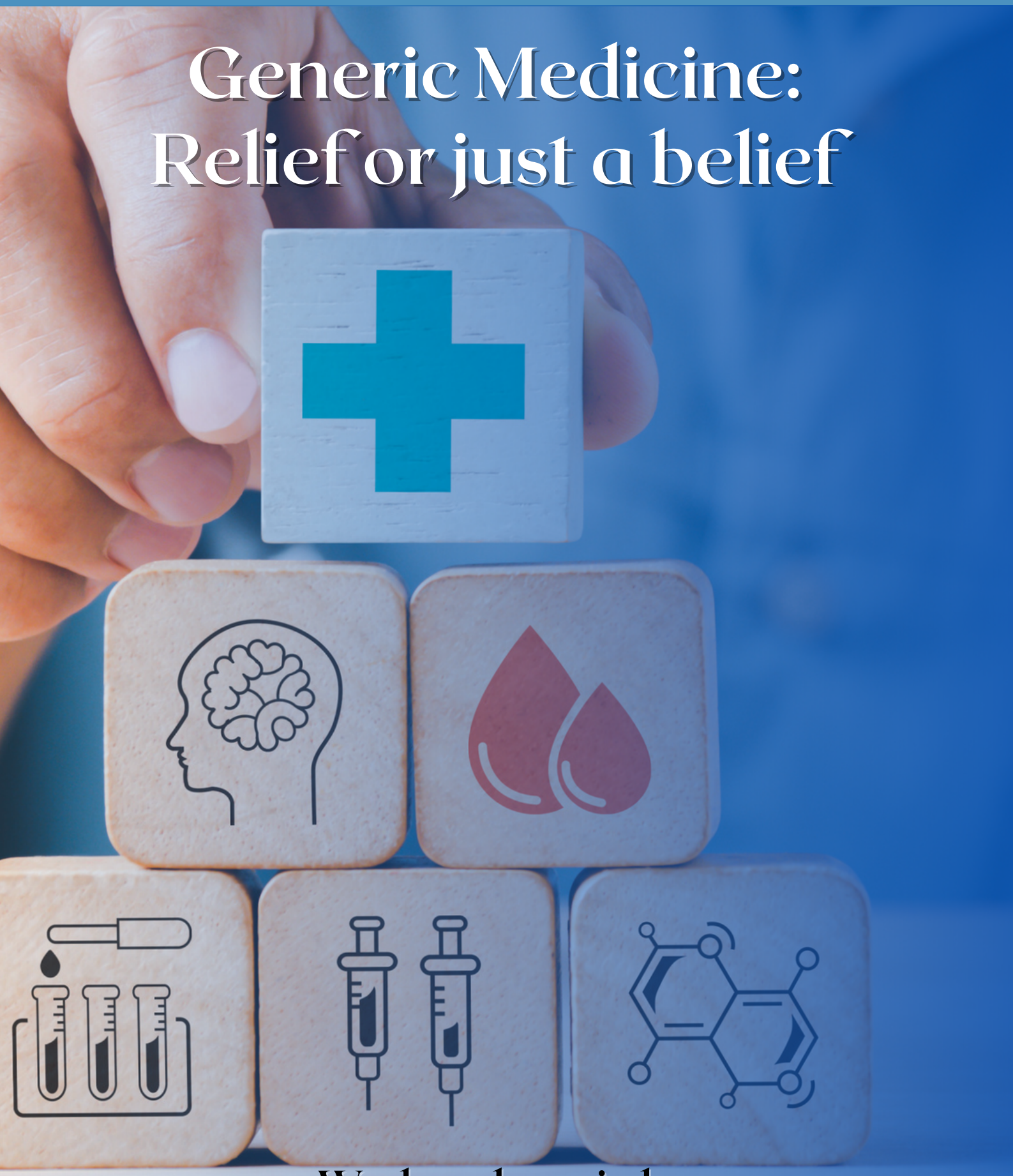
# Generic Medicine: Relief or just a belief



## Wednesday wisdom
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In the world of healthcare, soaring medicine costs present a significant hurdle to effective treatment globally. Enters generic medicine, a transformative influence silently reshaping healthcare accessibility and affordability. It is deeply impacting the intricate network of pharmaceuticals, patents, and pricing. Generic medicines emerge as a beacon of hope, providing a budget-friendly alternative without sacrificing on quality.[1]

As we are experiencing the new India, the healthcare facilities can be seen exploring new realms where invention and promotion of healthcare benefits are a priority. In order to provide better health benefits, the Government of India has taken various initiatives and schemes such as Ayushman Bharat Pradhan Mantri Jan Arogya Yojana, Pradhan Mantri Swasthya Suraksha Yojana and other facilities and schemes implemented nationwide by the Government.

In light of this, recently the Government of India under the National Medical Commission, Ethics and Registration Board issued a notification dated August 2, 2023, called “National Medical Commission Registered Medical Practitioner (Professional Conduct) Regulations, 2023” (“the Regulation”) wherein the guidelines with respect to prescribing only the generic medicines were issued to the Registered Medical Practitioners (RMP).

The Government has always been keen on emphasizing the importance of prescribing generic medicines. The Government has established Jan Aushadhi Kendra in various areas to make sure that generic medicines are easily available to the citizens. Considering the nature of the generic medicines, its affordability attracts the citizens. The rates of these generic medicines are cheaper than the branded generic medicines.
The guidelines were issued considering the economic reach of the people wherein such generic medicines were made affordable so as to make them available to the citizens.

[1]The article reflects the general work of the authors and the views expressed are personal. No reader should act on any statement contained herein without seeking detailed professional advice.

## WHAT DOES THE GUIDELINE SAY?

Section 8 of the Regulation mandated RMPs to prescribe drugs using generic names written legibly and prescribe drugs rationally, avoiding unnecessary medications and irrational fixed-dose combination tablets. The regulation stated that RMP can prescribe or supply drugs, remedies, or appliances as long as there is no exploitation of the patients. Drugs prescribed by RMP or bought from the pharmacy for a patient should explicitly state the generic name of the drug.[2] In the said regulation, very specific and distinct guidelines were issued with respect to how the generic medicine shall be prescribed keeping in mind India's population spending more money on branded drugs/ medicines. The guidelines stated "India's out-of-pocket spending on medications accounts for a major proportion of public spending on health care. Further, generic medicines are 30 to 80 % cheaper than branded drugs. Hence, prescribing generic medicines may overtly bring down health care cost and improve access to quality care."[3]

It is pertinent to note the difference between a branded generic drug and a generic medicine.

## LISTED PRODUCT:

A "Listed Product in Dosage" is essentially a specific medication with precise details about its form and potency. For instance, take "Relief Tablets 500mg."

"Relief" is the brand or product name.

"Tablets" indicate the dosage form, suggesting that it comes in tablet form.

"500mg" is the strength, specifying the amount of the active ingredient in each tablet.

## WHAT IS A GENERIC DRUG/ MEDICINE?

A generic drug is defined as a "drug product that is comparable to brand/reference Listed Product in dosage in dosage form, strength, route of administration, quality and performance characteristics, and intended use".[4]

[2]Section 12 (B) National Medical Commission Registered Medical Practitioner (Professional Conduct) Regulations, 2023
[3]Guidelines – 1, Generic Medicines and Prescription Guidelines - Preamble
[4]Guidelines – 1, Generic Medicines and Prescription Guidelines

## WHAT IS A BRANDED GENERIC DRUG?

A branded generic drug is one which has come off patent and is manufactured by drug companies and sold under different companies' brand names. These drugs may be less costly than the branded patent version but costlier than the bulk manufactured generic version of the drug. There is less regulatory control over the prices of these “branded” generic drugs.[5]

For the purpose of better understanding, the following are the Branded Generic Drug Names and Generic Drug Names of some commonly used medications.

| Sr No. | Branded Generic medication | Generic medication |
|---|---|---|
| 1. | Crocin | Paracetamol, Calpol, Dolo |
| 2. | Combiflam | Ibuprofen, Acetaminophen |
| 3. | Aspirin | Ecospirin |
| 4. | Pan D | Panfast , Pantop |
| 5. | Bi-quinol | Clop- 75 |

[5]Guidelines – 1, Generic Medicines and Prescription Guidelines

## THE CONTROVERSY

As soon as the regulation was published by the Government, the mandate of prescribing only generic medicines and not branded medicines has resulted into certain controversies.

The Indian Medical Association (IMA), representing approximately 400,000 doctors, expressed concern, stating that this directly impacts patients' care and safety. They argued that if the Government genuinely wanted to implement generic drugs, it should not license branded drugs and simultaneously ensure the quality of generic drugs.[6]

However, there are different views on mandating the generic medicines wherein the doctors are protesting stating that prescribing generic medicines only may increase the risk of exposure to substandard drugs which can be harmful to the health of the patients.

## CONNECTION OF GENERIC MEDICINES WITH INTELLECTUAL PROPERTY RIGHTS

Another aspect involved in the manufacturing and use of generic medicines is its patentability and the intellectual property rights connected to it. Considering this, the concept of Compulsory Licensing needs to be taken into account. Compulsory Licensing in simpler terms means that when a drug is manufactured which is lifesaving, such drug needs to be compulsorily licensed considering its nature and use, so that such drug can be made available to public use to treat a disease on a major level. The Government can disclose the components and formulas of such a drug to an individual or company in order to manufacture such life saving drug in large quantity[7]. India's one and only compulsory license was granted by the Patent Office in the year 2012 to Natco Pharma Ltd for producing generic version of a drug called "Nexavar" which was already being produced by Bayer Corporation. The drug of Nexavar is a lifesaving drug in the treatment of liver and kidney cancer. The said Nexavar drug was earlier being priced over Rs. 2.8 Lakhs for a 120-capsule pack for a month's therapy, however, the cost reduced to Rs. 8,880 when the same was manufactured and sold by Natco Pharma Ltd. [8]

[6]https://www.business-standard.com/industry/news/generic-prescription-controversy-nmc-regulations-for-docs-held-back-123082400960_1.html
[7] Section 92 of the Patent Act, 1970
[8]Guidelines – 1, Generic Medicines and Prescription Guidelines

Further, according to 161st report published by Parliament of India on Review of Intellectual Property Rights Regime of India dated July 2021, the concepts of Compulsory licensing being linked to production of generic medicines has been simplified. The aspect of availability of generic medicines was considered important as during the time of national emergencies like Covid 19, the inadequacy of medicines led to a high death toll during Covid-19. Therefore, it was recommended by the committee in the said report that the Government should delve into the prospect of temporarily waving patents rights and issuing Compulsory Licensing to tackle the inadequacy in availability and accessibility of Covid-19 vaccines and drugs during an emergency like situation induced by the pandemic[9].

**CONCLUSION:**

In conclusion, it's suggested that patients choose generic medicines instead of expensive branded options. This recommendation aims to make healthcare more accessible and affordable while maintaining good medical results. Generic medicines are just as effective and safe as branded ones, providing a practical way to save money on medication without sacrificing quality or effectiveness. Choosing generics can lead to significant cost savings for patients.

Generic medicines not only benefit individual patients but also help the entire healthcare system by promoting a sustainable and inclusive approach to medical care. The cost savings from using generic medications can enhance medication adherence, leading to better health outcomes. When financial barriers are reduced, patients are more likely to stick to their prescribed treatment plans.

However, it's important for patients to know enough about their medications. When patients are well-informed, they can make choices that suit their health and budget. Healthcare providers are key in educating patients about the safety, effectiveness, and cost-effectiveness of generic medicines, supporting a collaborative and informed decision-making process.

Patients should be encouraged to engage in open and transparent discussions with their healthcare providers, seeking clarification on any concerns or queries they may have about generic medications.

[9] 161st report on Review of Intellectual Property Rights Regime of India dated July 2021

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