Generic Drugs

Published On: 16-08-2023

Why is in news? After the National Medical Commission notified new guidelines on professional conduct recently, doctors have been protesting one of the stipulations — using generic names of medicines on the prescription instead of a particular brand name.

What do the guidelines say?

The guidelines say that **doctors can only write the generic names of the medicine** on the prescription.

For example, a doctor will have to prescribe paracetamol for fever, instead of Dolo or Calpol "Every RMP should prescribe drugs using generic names written legibly," the guidelines say.

This practice can **only be relaxed for medicines with narrow therapeutic index** (drugs where a small difference in dosage may lead to adverse outcomes), biosimilars (a different version of biologic products that are manufactured in living systems), and "similar other exceptional cases."

The guideline says that generic medicines, on average, are **30% to 80% cheaper than the branded versions**, and are hence likely to bring down healthcare costs.

About the generic drugs:

It is a medication that has **exactly the same active ingredient as the brand-name drug** and yields the same therapeutic effect.

It is the **same in dosing, safety, strength, quality, the way it works, the way it is taken, and the way it should be used**.

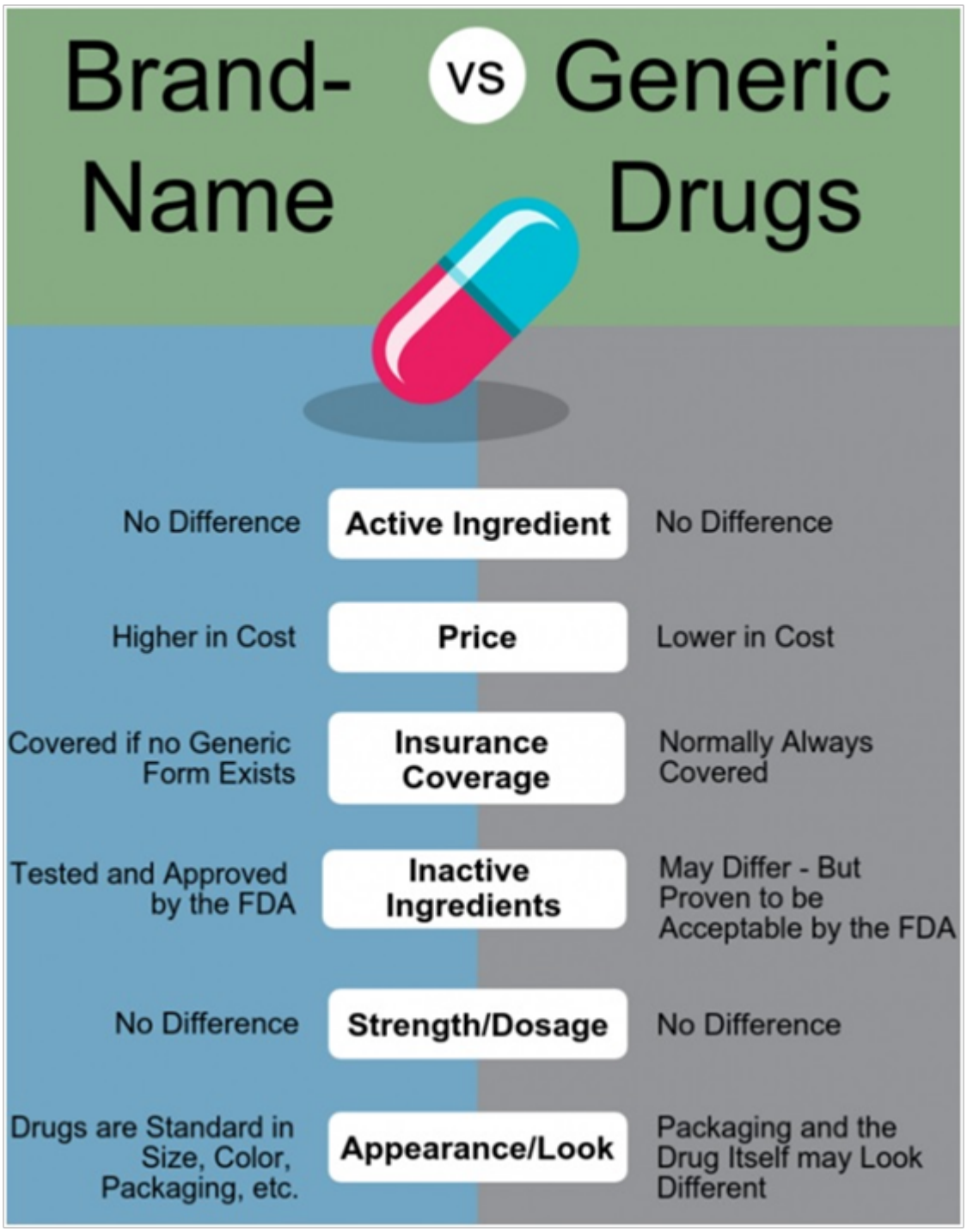
These similarities help to demonstrate bioequivalence, which means that a generic medicine works in the same way and provides the same clinical benefit as the brand-name medicine.

They also **have the same risks and benefits** as their brand-name counterparts.

Generic drugs **do not need to contain the same inactive ingredients** as the brand-name product.

A generic drug can **only be marketed after the brand name drug's patent has expired**.

Generic drugs are **usually much less expensive** than brand-name drugs.



Need for Generic Medicine in India:

Affordability: In a country like India where high drug prices pose a barrier to accessing healthcare, generic medicines play a crucial role in making essential medications accessible to a larger population.

According to a survey by **National Pharmaceutical Pricing Authority** a major portion of hospital bills – 55% – is payments for medicines and other consumables in India.

According to the **National Health Accounts Estimates** 2019-20, out-of-pocket expenditure (OOPE) constituted 47 % of the Total Health Expenditure.

In India, about 55 million people are annually pushed below the poverty line due to healthcare payments.

Accessibility: Generic medicines play a crucial role in India's diverse and remote areas by bridging the healthcare access gap.

Disease burden: The high prevalence of disease burden in India is directly related to the lack of affordable healthcare. Generic medicines can help in reducing the financial burden, thereby improving healthcare outcomes.

Challenges:

One of the primary challenges is the **perception and awareness of generic drugs among patients** and healthcare professionals. Some patients may still have reservations about the quality and efficacy of generic drugs compared to brand-name drugs. Lack of awareness and understanding about bioequivalence and regulatory standards can contribute to this perception.

Illegitimate drugs have been a challenging issue for India over quite a period of time. In 2018, the Central Drug Standard Control Organization (CDSCO) identified nearly 4.5 per cent of all generic drugs circulated in the domestic market to be substandard. Meanwhile, the issue begins with **the lack of quality testing facilities** across the country.

In the US, there is a **stringent quality control procedure and periodic quality check facilities** in place, but India has a different story to tell as widespread corruption makes it a sidewalk to obtain a drug license through bureaucratic or political connections.

Additionally, **drug control procedures in India** suffer from the lack of fund, resources and manpower and hence makes matters worse.

Another issue is with the **counterfeit medicines sellers** who operate at the retail level and procure the substandard medicines from dubious suppliers.

Also, **many fraud chemist shops sell the counterfeit drugs illegally** using the name of a pharmaceutical company that remains completely unaware of the incident.

While fighting this issue is beyond the scope of a pharma company, it is very important that it is stopped immediately since it ruins the reputation of that particular pharma company.

Trust plays a crucial role in the adoption of generic drugs. In some cases, instances of substandard or counterfeit generic drugs have eroded public trust. Additionally, misinformation or rumors about the quality or effectiveness of generic drugs can further hinder their acceptance and adoption.

Intellectual property rights and patent-related issues can create challenges for the availability of certain generic drugs. Patents granted to brand-name drugs may limit the immediate entry of generic versions into the market.

Although compulsory licensing provisions exist in India, the complexity of patent laws and litigation processes can impact timely access to affordable generic alternatives.

Way forward:

There is a **need to have in place stringent criteria for government agencies** to ensure that there is no difference in the dose, efficacy, potency and side-effects between generics and the branded ones.

The government should **ensure that all pharmacies have qualified pharmacists** and that basic quality is maintained for all generics produced in India.

In short, there should be a **sort of star-rating for quality certification**, helping people to understand the quality of the generic.

The government’s intention to promote generics will reach its goal only if these **three important factors** (clarity in definition, safe quality and standardised quality certifications along with qualification of pharmacists) are considered.