Road Map to Affordable Medicine

What is generic medicine?

Generic medicines and vaccinations are copies of originally researched drugs, but at much lower prices.

- A few years post the launch of a new drug by a pharma company, the patent on it expires.
- That is when copies of the drugs are manufactured and sold by non-original makers at much cheaper rates. For example, Aspirin and Paracetamol are generic drugs that are often sold under brand names like Disprin and Crocin.
- **The dosage, composition, method of intake, benefits, quality, and even side effects of generic medicines are similar to the brand-name version of the drugs.**
- Just because generics have a significantly lower price tag, it does not mean that these medications are less effective.

Why there is need for generic medicine?

In India, high drug prices act as a strong barrier to seeking effective healthcare as people lack purchasing power. The facts mentioned below are direct reasons for high prevalence of disease burden in India and generic medicines play an important role here.

- **Status of health-care India**
  - 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.
  - In 2015-16 the share of household out-of-pocket expenditure including the payment for health insurance constituted 64.7 % of the **Total Health Expenditure (THE)**.
  - **In India, about 55 million people are annually pushed below the poverty line due to healthcare payments.**
- **Regulatory loophole**

Past experiences show that even if the government caps the margins or prices of the consumables, hospitals increase the charges for procedures and other services and refuse to pass on the benefit to the patients.

For instance, in the case of cardiovascular stents, immediately after the prices were capped, hospitals increased the charges for procedures.

The shortcomings in the healthcare system of India

- **Health insurance schemes are not effective**
  - **Instead of directly intervening and regulating healthcare charges, the State and Central governments intervened through insurance schemes to reduce the financial burden of patients. These schemes function as cross-subsidization or by increasing footfalls for the private sector.**
  - Studies have shown that even after insurance schemes like the **Rashtriya Swasthya Bima Yojana (RSBY)** and various state government sponsored insurances schemes, there is no change in the burden of out-of-pocket expenditure.
  - Often hospitals use these schemes to attract patients and charge them heavily by offering services outside the scheme.
- **Regulatory capture**
  - **Regulatory capture is a phenomenon when a regulatory body gets influenced by the economic interests of special interest groups that dominate the industry, rather than those of the general public.**
  - Regulatory capture is a form of government failure, where government agencies fail to perform their duties,for example, even with Drug Price Control Order (DPCO) 2013 , price of anti-diabetic drug Metformin was manipulated.
- **No effective monitoring mechanism**

  Neither the Department of Pharmaceuticals nor the National Pharmaceutical Pricing Authority has the institutional ability to monitor prices of medicines at the state level. Such capacities are key to enforcement of any regulation.

What steps have been taken to promote generic medicine in India?

- In 2017, Central Govt, ordered doctors to prescribe generic formulations of medicines, as opposed to specific brands.
- Medical Council India (MCI) also ordered the medical community to follow its 2016 notification in which the MCI had amended the Clause 1.5 of the Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002 mandating doctors to prescribe medicines by generic names in place of brand names.

Despite this effort, generic medicines are not successful in India - why?

- **Due to profit driven nature of any pharmaceutical product, pharmacies in India are not enthusiastic to sell generic medicine.**
- **A lot of customers aren't happy when low-cost medicines are handed out to them. They feel that the quality of the medicine directly depends on the cost of it.**
- The **Drugs Technical Advisory Board (DTAB)** advisory that retailers should maintain a separate rack/shelf solely for the storage of "generic medicines sold in proper name" is not followed.
- **At least 90% of the Indian domestic pharmaceutical market comprises drugs sold under brand names.** There simply are not enough generic name equivalents of branded medicines sold.
    - About half the market is for fixed-dose combinations (FDCs) of drugs, a further half of them irrational.
    - **Many FDC drugs contain even eight or nine medicines. To write, and remember, the constituent of FDC drugs in generic names is impractical, considering that there would be thousands of FDC brands.**
- Jan Aushadhis, which are pharmacies selling only generic name medicines to the full extent possible, are only about 300 in numbers, thus excluding a significant number of population.

The push towards generics is lauded by many stakeholders, and rightly so. However, Govt policy must move beyond rhetoric—for **in a sector such as health, faulty policy design will directly affect the country's mortality statistics**.

Public health encompasses quality as much as affordability of pharmaceutical drugs. In this context, **it is important to assess and ensure that Indian generic companies are competent enough to take on the task before institutionalizing any policy**.

Areas of concern related to Generic drug

- **The efficacy of generic drugs in India**
    - **Generic drugs have been found to contain less than the required amount of active pharmaceutical ingredient (API), rendering them ineffective.**
    - The FDA's inspection of Avandamet tablets, used to treat type 2 diabetes, found that some tablets lack the proper dosage of rosiglitazone, an active ingredient.
    - A Central Drugs Standard Control Organization's (CDSCO) surveillance report shows that a range of commonly consumed drugs, such as the Cipla-manufactured antibiotic ofloxacin tablets or the Cadila-manufactured Cadilose, fall short of standard quality-control criteria
- **Data-integrity**
    - **Poorly managed documentation practices of Indian generic firms feature as a primary criticism flagged by foreign regulatory authorities.**

    - **The lack of reliable and complete data on the test results of specific drug batches, along with inconsistencies in the records presented meant that inspection and verification of drug quality was extremely difficult.**
    - In fact, in 2013, Ranbaxy pleaded guilty and paid fines amounting to $500 million for fabricating drug-related data in the US.
- **Hygiene Standards**
    - **Individuals suffering from illness are especially susceptible to infections, and inspections of generic drug plants reveal pest infestations and dilapidated infrastructure.**
    - Many a manufacturing unit has become home to stray pigeons and lizards.
    - Gaping holes in building walls and rusted pipes have become sources of infectious parasites, in what ideally should be a sterile environment.

Way Forward

- **Tamil Nadu and Rajasthan governments procure generic medicines at extremely competitive prices** year after year, and crores of drugs are in use in their public health systems due the quality assurance systems in place. **The success of the drug procurement system in these two states should be followed.**
- **Healthcare should be accessible to all,** irrespective of purchasing power.
- The policy of promoting generic drug is a welcome step in this direction, but in doing so the **area of concerns should be taken care of** on an urgent basis, **only then an Ayushman Bharat can be built**.

Drishti Input:

The policy of promoting generic drugs in India is a welcome step but in doing so, all areas of concern should be taken care of. Discuss.

Read up ‘Primary health care’ in the summary of Strategy for New India at 75 report

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