Making Generic Drugs Compulsory – Part II

Click here for Making Generic Drugs Compulsory Part I

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Why in news?

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PM had recently said that the government is contemplating a law that will make it binding for doctors to prescribe generic medicines.

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What is the difference between generic and brand-name drug?

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- When a company develops a new drug it applies for a patent.
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- The patent prohibits anyone else from making the drug for a fixed period.
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- To recover the cost of research and development, companies usually price their brand-name drugs on the higher side.
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- Once the patent expires, other manufacturers duplicate and market their own versions of the drug called generic drugs.
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- Since the manufacture of generic drugs do not involve a repeat of the extensive clinical trials, they are cheaper.
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- The active ingredient of a drug is the one that cures the patient.
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- The generic drug has the same “active ingredient” as the brand-name drug.
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- The other “inert ingredients”, which give the drug its colour, shape or taste, vary from the brand-name drug to the generics.
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- The compounds in the generic versions have the same molecular structure as the brand-name version and so their quality is essentially the same.
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- U.S FDA notes that the cost of a generic drug is 80% to 85% lower than the brand-name product.
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What is the drug pricing mechanism in India?

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- In India, prices of drugs in the **National List of Essential Medicines (NLEM)** included in the **First Schedule of the Drugs (Prices Control) Order, 2013,** are fixed as per the provisions of the Order.
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- These prices are uniformly applicable to all branded and generic medicines.
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- All manufacturers of scheduled drugs/formulations have to comply with the price fixed by the **National Pharmaceutical Pricing Authority.**
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- In the case of non-scheduled medicines, i.e., medicines not included in the First Schedule of the DPCO, manufacturers are free to fix the launch prices.
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- However, they cannot increase the Maximum Retail Price (MRP) by more than 10% of the MRP of the preceding 12 months.
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What were the previous interventions?

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- **MCI -** In September 2016, Medical Council of India had notified an amendment in Clause 1.5 of the **Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002.**
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- This now mandates that every physician should prescribe drugs with generic names legibly and preferably in capital letters and he should ensure that there is a rational prescription and use of drugs.
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- The words “legibly and preferably in capital letters” were not there originally.
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- **Previous government -** It had also issued circulars regularly to government hospitals and Central Government Health Scheme (CGHS) dispensaries to

"prescribe generic medicines" to the "maximum extent possible".
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- In December 2012, the then government had issued a "statutory direction" to state governments under sections of the **Drugs and Cosmetics Act, 1940** to "grant/renew" licences to manufacture for "sale or for distribution of drugs in proper/generic names only".
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- **Pradhan Mantri Bharatiya Janaushadhi Pariyojana –** It is a countrywide campaign to ensure availability of generic medicines.
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- A total 861 PMBJ Kendras are functional in 28 states — at which 99 private manufacturing companies have been empanelled to supply generic drugs.
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Source: The Indian Express

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