Generic Medicines

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Why in news?

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The Medical Council of India (MCI) issued a circular on April 21, 2017 drawing attention to clause 1.5 of its regulations regarding the professional conduct of doctors.

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What is the issue?

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- It noted that every physician should prescribe drugs with generic names legibly and preferably in capital letters and he/she shall ensure that there is a rational prescription of drugs.
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- The circular also added that, “For any doctor found violating clause 1.5 of Ethics Regulation, suitable disciplinary action would be taken by the concerned SMC/MCI.”
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- This has caused considerable unease among medical professionals.
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- This move is done **to break the unholy doctor-pharma nexus** results in a symbiotic relationship leading to unnecessary, expensive prescriptions.
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Why is the new rule a major concern?

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- The circular simply shifts the focus of promotional activities of generics to the pharmacists.
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- It is well known that different companies offer different trade margins.
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- There is the moral hazard that **pharmacists will dispense the brand which offers them the biggest margin.**
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- Thus the current diktat by the MCI therefore will not reduce prices for the consumer.
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- The most effective way to maintain quality is to have periodic testing and stringent disincentives for poor quality. The best insurance for good quality is good regulation.
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- Some argue that **bioavailability and bioequivalence (**BA and BE) of generics may not be equal to the original brand.
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- Bioavailability refers to the rate and extent to which the active ingredient of the drug present becomes available at the site of action of the drug.
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- In order for a new generic drug to be licensed, it has to be bioequivalent to the reference drug. It means that BA of the generic drug is similar to that of the reference drug.
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- Of the approximately 800 useful drugs known to modern medicine, bioequivalence is really only important for a few drugs with low solubility and high or low permeability, so the debate about BA and BE is somewhat misinformed.
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What could be done?

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- Quality is the major issue with generic drugs. Thus the need of the hour is **resolving the chronic shortage of drug inspectors** who look after the quality control at manufacturing and the dispensing sites of medicines.
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- A logical step would have been to **institute better quality control** in the manufacture of generic drugs first, test their bioequivalence, build doctor and patient confidence on the product and then, push for a change in

prescription behaviour of physicians.
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- The current method of price control legitimises **margins of up to 4000% over the cost of the product.**
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- The core issues are affordable access to medicines and their rational prescription and use.
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- These objectives require an enlarged list of essential and life-saving medicines under price control, elimination of all irrational FDCs, no brands for drugs off patent, and briefer officially approved names to make it easier for doctors to prescribe generics including the rational FDCs.
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- Bringing in a **National Medicine Pricing Policy** would be a simple but very effective way in controlling drug prices, without taking away the choice of prescription from doctors.
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- This could be easily done through the government's National Pharmaceutical Pricing Authority.
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- Prescription pattern monitoring rules need to be implemented stringently to dent the doctor-pharma nexus.
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- Increasing drug manufacturing units and investing heavily in drug research and development will effectively make India "drug self-sufficient" with a wider and cost-effective "drug reach".
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- Better control of branded generics and patent generics are also measures the government should work on.
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Source: The Hindu, Indian Express

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