Concerns with Generic-Only Model

What is the issue?

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- There is an increased push by the government for generic drugs, for affordable healthcare.
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- But the concerns with quality of the generics call for a relook on this 'generic-only model'.
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What are generics?

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- A generic drug is a copy of drug medication created to be the same as an already marketed brand-name drug.
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- It equals in dosage form, safety, strength, route of administration, quality, performance characteristics, and intended use.
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- Generics do not involve repetition of extensive clinical trials over the years, unlike brands that undergo extensive R&D procedure.
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- Hence, generics' manufacturing cost is less, and so are their prices.
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Why is the emphasis on generics?

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- The government, to cut down on out-of-pocket expenditure and ensure

affordable healthcare, is relying on a generics-only model.
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- In the Indian market, generics hold a whopping 75% share.
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- The push for generics witnessed a boom under Pradhan Mantri Bhartiya Jan Aushadhi Pariyojana (PMBJP).
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- It is a campaign launched by the Department of Pharmaceuticals to provide quality medicines at affordable prices to the masses.
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- PMBJP stores have been set up to provide generic drugs, which are available at lesser prices.
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What are the concerns?

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- India ranks third in the global pharma market (10% in global sales) but the domestic scenario is less encouraging.
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- A 2016 study on Spurious and Not of Standard Quality (NSQ) medicines in the supply chain in India hints at this.
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- More than 10% samples were declared NSQ in the supply chain, of medicines procured by government agencies, compared to the all-India average of 4%.
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- Central Drugs Standard Control Organisation (CDSCO) report shows that a range of commonly consumed generic drugs fall short of standard quality-control criteria.
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- In 2017, five drugs were recalled from Jan Aushadhi stores over quality lapses.
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- Another six drugs were rolled back in the first four months of 2018.
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- Most of India’s generic drugs manufacturers do not follow US Food and Drug Administration (US FDA) guidelines for domestic distribution.
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- India has more than 67,000 drug formulations.
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- But the quality control mechanism of all the Central Drugs Testing

Laboratories can ascertain the quality of only 15,753 drugs annually.
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- But branded generics follow regulatory mechanisms like US FDA and WHO Good Manufacturing Practices, making them more reliable.
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What is the inherent risk?

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- Come 2020, the NCD burden will be responsible for 73% of deaths and 60% of disease burden in India.
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- A low-quality drug delays recovery time, weakens the immune system by a longer duration of dosages, and invites comorbidities.
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- Substandard medicines may promise affordable healthcare in the present, but in the future results could be catastrophic.
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- Thus, relying on generics alone can be counter-productive in the mission to make India disease-free.
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What does it call for?

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- Medicine procurement and distribution should be driven by global best standards, not lowest price.
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- For the goal of universal health coverage by making medication affordable, superior-quality drugs are a prerequisite.
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- The ‘generics-only model’ approach needs a critical reassessment for dealing with India’s disease burden.
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Source: Financial Express

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