Regulating the Drug Industry

Why in news?

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- Indian government may bring in a legal framework under which doctors will have to prescribe generic medicines.
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- It is the Government’s responsibility that everyone should get health services at minimal price.
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What is the importance of the issue?

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- It is a noble intention and indeed the responsibility of the government to make healthcare accessible and affordable to all.
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- A landmark act introduced in the US in 1984, “the Drug Price Competition and Patent Term Restoration Act” transformed the drug market in that country by allowing a generic medicine.
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- The generic drug would not have to undergo a complete clinical trial to be proved equivalent.
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- Subsequently, this model has been followed in other countries and today most OECD and other developing countries accept the substitution of a branded medicine with a generic equivalent.
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What is the need for a regulator in Drug industry?

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- The argument is that the need for a muscular drug regulatory authority (DRA) is far more urgent.
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- The DRA should serve the dual purpose of making the rules simpler yet stricter, while having the required resources to enforce them effectively.
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- Every drug manufacturer should publish details of its manufacturing facilities, specifications, capacity, certifications, all subsequent inspection reports to a central portal.
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- Products should be approved as generics based on whether they are pharmaceutically equivalent, bio-available, and bio-equivalent.
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- All new products or new combinations of existing products should be subjected to a more extensive clinical study to prove safety as well as effectiveness.
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- Facilities which do not comply with GMP (Good manufacturing Practice) should be immediately barred from production until such compliances are in place and products made in such a facility should be immediately recalled.
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- All products should be tagged with a unique RFID, barcode or such similar identification to ensure traceability from manufacture to consumption.
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- Generics should be labelled and sold as such in order to prevent a brand to brand substitution rather than a brand to generic substitution at the retail level.
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What are the steps taken by the government?

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- The Ministry of Health and Family Welfare proposed the setting up of an e-portal to track and regulate the sale of drugs across the retail chain.
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- The aim was to prevent the sale of fake and substandard drugs, which are estimated to account for a substantial share of India’s drug market.
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- The Ministry’s proposal to bring both traditional and e-pharmacies under the

ambit of the e-portal to track drugs is a welcome move.
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- It has mandated that e-pharmacies must set up a “licensed brick and mortar facility” as part of their operations to comply with the new regulations.
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What is the way forward?

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- The risks associated with e-pharmacies, especially when it comes to the dispensation of prescription drugs without the necessary checks, cannot be taken lightly.
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- The Ministry’s plan on regulating e-pharmacies is a rather outdated one.
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- This seems like an indirect way of delegitimising the business model of e-pharmacies, rather than a regulation that aims to improve their transparency and regulation.
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- The huge potential for e-commerce in the retail drugs industry is enough reason to avoid such unreasonably stringent standards.
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- Enforced with punitive fines for non-compliance, the new measures will not only make medicines affordable to all, but also give the customers the choice without fear of compromising the quality of their care.
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Source: Business Line

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