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SPARE THE ROD AND CHANGE THE LAW

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People gather at a pharmacy to buy supplies. | Photo Credit: AFP

The Director General of Health Services (DGHS) issued yet another order on May 12 reiterating directions that doctors in Central government hospitals prescribe only generic medicines instead of branded drugs.

The driving force behind these office orders is the standard trope that doctors are in cahoots with the pharmaceutical industry wherein the doctor receives a kickback for each prescription of a particular company's drug. Thus, by forcing them to write only the generic names of medicines, the hope is that the pharmacist will provide the patient with the cheapest available generic drug and thus save them the cost of the more expensive branded drugs. This policy objective obviously rests on the assumption that the pharmacist is a benevolent individual who does not have his own incentives to sell the patient more expensive branded drugs. Such orders have been passed earlier and the most recent order does not hide its irritation at having to repeat previous orders; it threatens government doctors with unspecified "further action" for failing to comply with these directions.

But before threatening its doctors, perhaps the Directorate should conduct a survey among government doctors asking them to explain their reluctance to write prescriptions with just the generic names. It is no secret that many Indian doctors in both the public and private sector simply do not trust the quality of all generic medicines in the Indian market. They have a valid reason for this: India has lagged behind countries like the U.S. in creating the appropriate legal and scientific standards that provide guarantees to doctors on the interchangeability of generic medicines with each other and the innovator drug.

The U.S. created this environment of trust by mandating as far back as in 1977 that most, but not all, generic drugs be tested on human volunteers in order to measure the rate at which the drug is bioavailable; i.e. the rate at which the drug dissolves in the bloodstream. Such testing is required because generic manufacturers may use different excipients like binders, coating and punching machines which directly affect the ability of the drug to dissolve in the blood. If the dissolution profile of the generic drug is same or similar to that of the innovator drug over a time period, it is declared to be "bio-equivalent" and hence therapeutically interchangeable with the innovator drug.

India mandated such bio-equivalence testing only in 2017. Even then, the regulations were vague. But the far more worrying aspect from a public health perspective is the fact that a

recommendation by the Drugs Technical Advisory Board (DTAB) to ensure that existing generic drugs, approved prior to 2017, also be tested for bio-equivalence, was ignored by the government. This means that a vast majority of drugs in the Indian market have never been tested for bio-equivalence. Hence, the government cannot provide doctors with a legal guarantee that all generic medicines in the Indian market are, in fact, interchangeable with the innovator drug.

If the government cannot provide such a legal guarantee, it should not be barring doctors against prescribing their preferred brands. Many doctors have developed faith in particular brands, not because they receive bribes but because patient feedback has taught them that other brands do not work as effectively.

The lack of bio-equivalence testing is just one of the issues with generic medicines in India. The other massive problem is the issue of stability testing. The key challenge to manufacturing any drug is to ensure that it remains stable through a stressed supply chain in differing conditions of heat and humidity. An unstable drug will start decomposing, possibly reducing its efficacy. Sometimes a tablet will just crumble into powder when removed from its packaging. In other instances, the tablet will be visibly discoloured or if it is a liquid, particulate matter may be visible. Many of these problems can be checked if the law prescribed mandatory stability testing prior to providing marketing approval and also while the drug is in the market. This common requirement across the world became mandatory in India only in 2018, after the government managed to overcome immense opposition from the pharmaceutical industry. But once again, the new regulations not only lacked scientific rigour, but also did not apply retrospectively to generic drugs approved prior to 2018. This means that many generic medicines in the Indian market have not been subjected to mandatory stability testing. This could be an additional reason contributing to quality issues that undermines the trust of governmnent doctors in generic drugs.

Given these issues related to the quality of generic drugs, it is not appropriate for the DGHS to force doctors to prescribe drugs by generic names. Rather, the DGHS must work towards resolving the genuine concerns being raised by doctors. A starting point would be to ask for regulations which require pharma companies to identify on their packaging whether a drug has been tested for bio-equivalence and stability as required by the law. Building the confidence of doctors in generic medicine serves public interest better than threatening them with punitive action for failing to comply with directives on mandatory prescription of drugs by their generic names.

***Dinesh Thakur was the whistleblower in the Ranbaxy case and author of* The Truth Pill*; Prashant Reddy T. is a lawyer and the author of* The Truth Pill**

logging into their accounts on Vuukle.

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