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Curbs on clinical trials leading to drug shortage: Pharma cos

ADITI TANDON
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Pharma companies are blaming curbs on clinical trials for "a drought of new and generic drugs in the country," depriving thousands of consumers of low-cost medicines.

The All India Drug Action Network had filed a PIL in the Supreme Court to seek guidelines for the protection of subjects participating in clinical trials in 2011. Since then, the process of granting approvals to new and generic medicines by the Drug Controller General of India has hit a roadblock with data showing that merely 24 drug approvals were granted this year, says Indian Pharmaceutical Association.

The number was 250 in 2011 before the matter went to the court. The result – new medicines introduced in world markets are not being approved for introduction in India and even generic medicines being marketed abroad but sought to be introduced by local manufacturers for the first time are not being approved for trials. The Indian Pharmaceutical Association has taken up the issue with the Ministry of Health and urged Health Minister Harsh Vardhan to address the crisis by acting as an intervener between the pharma sector and the civil society activists who are pushing for safeguards for subjects who participate in clinical trials.

Talking to The Tribune on the sidelines of the fourth National Health Writers and Editors Conference organised by HEAL Foundation here, IPA general secretary DG Shah said, "We have seen a decline in clinical trial approvals not only for new drugs being developed abroad but also for the versions of generic medicines already introduced abroad. The entire drug approval process has hit a roadblock. The PIL was filed in the apex court three years and we have not reached anywhere. We appreciate the concerns of NGOs and have requested the Health Minister to help us talk to these groups to reach a solution."

The IPA has in its memorandum to Harsh Vardhan given details of how the country is facing a drug drought due to slackness of the Central Drugs Standards Control Organisation (an apex drug regulator) to approve new drugs for introduction in India or to approve trials on generic versions of drugs introduced outside India.

"People are being denied access to new and affordable drugs. While the rich ones can import what they want on a personal licence, the poor are being put to a disadvantage. Suppose a patent on a certain drug is over and our manufacturers want to apply for the drug's clinical trial to produce evidence that they can manufacture a drug that's close to the original, even that is not happening today," says Shah.

PIL's side-effects

- A PIL was filed in the Supreme Court to seek guidelines for the protection of subjects participating in clinical trials in 2011. Since then, the process of granting approvals to new and generic medicines by the Drug Controller General of India has hit a roadblock, says Indian pharmaceutical association
- The IPA has told Health Minister Harsh Vardhan that the country was facing a drug drought due to slackness of the Central Drugs Standards Control Organisation (an apex drug regulator)
- New medicines introduced in world markets were not being approved for introduction in India. Even generic medicines being marketed abroad but sought to be introduced by local manufacturers for the first time were not being approved for trials, leaving poor at a disadvantage.

Dinesh Shah.