

Govt eases norms to test, launch drugs

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New Delhi: In an attempt to ease norms for testing and introduction of new medicines in the country, the government has taken steps to fast-track approvals for clinical trials as well as launch of drugs already approved in other countries.

Pharmaceutical companies planning to launch new drugs already approved outside India after conducting pre-clinical or toxicological studies on animals will not be required to repeat such studies in India for importing or manufacturing them here unless some specific concerns are raised, the Drugs Controller General of India, under the health ministry, said.

The drug regulator has also given more freedom and responsibility to the Ethics Committee — that monitors clinical trials for new medicines. As per the new norms, the Ethics Committee is expected to cut timelines for launch of new medicines, including biologics.

Ethics Committee has also been allowed to add trial sites



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and investigators without the need to obtain a no objection certificate from the DCGI. However, companies will have to inform any changes to the DCGI.

The move comes in the wake of concerns raised by the industry which complained of repeat tests and data submissions to different authorities.

Of late, the regulator has also been cautious on approving new drug trials after the Supreme Court's directive asking the government to ensure patient safety while approving clinical trials.

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