Government waives clinical trial requirement for several drugs approved in select countries

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The costs of conducting local clinical trials will be reduced for pharmaceutical firms, therefore passing on these savings to patients. (Representational image)

The government has waived the requirement for clinical trials of certain categories of drugs in India if they are approved in the US, the UK, Japan, Australia, Canada and the European Union.

The waiver only covers five categories — orphan drugs for rare diseases, gene and cellular therapy products, new drugs used in pandemic situations, new drugs used for special defence purposes and new drugs having significant therapeutic advances over the current standard care.

This waiver would ensure expeditious availability of the latest medicines for treating diseases like cancers, rare diseases like Spinal Muscular Atrophy (SMA) and Duchenne Muscular Dystrophy (DMA), and autoimmune conditions in India. “As per Rule 101 of New Drugs and Clinical Trials Rules, 2019, the Central Licensing Authority, with the approval of the Central Government, may specify, by an order, the name of the countries, from time to time, for considering waiver of local clinical trial for approval of new drugs under Chapter X and for grant of permission for

conduct of clinical trial under Chapter V of the said rules," the Drugs Controller General of India (DGCI) said in an order issued on August 7.

"In exercise of the powers conferred under Rule 101 of the said rules with th approval of the Central Government, the countries namely USA, UK, Japan, Australia, Canada and EU are hereby specified for following categories of ne drugs," it said.

Presently, several medicines already approved by other regulatory authorities in the US, the UK and the EU are not immediately available for Indian patients because of certain regulatory requirements under the Drugs and Cosmetics Act and rules made thereunder. These include the requirement of conducting a local clinical trial and generating safety and efficacy data before marketing authorisation in India, an official explained.

However, Rule 101 of the New Drugs and Clinical Trials, 2019, allows the DCGI to specify certain countries for considering waiver of local clinical trials for approval of new drugs.

"The advantages of operationalising this rule are that the latest medicines to treat diseases like cancers, rare diseases like SMA and DMA, and autoimmune conditions will become available expeditiously in India. "Presently, the delay in launching a new or novel medicine in India is anywhere between 5-20 years when compared to western markets. With the waiver of Rule 101, the scope of parallel launches of medicines in India along with the West will be opened up," the official explained.

Besides, there will be a considerable reduction in the cost of various advanced medicines.

Also, there will be a substantial reduction in the public procurement costs o central and state governments under various schemes like the Central Gove Health Scheme (CGHS) and Ayushman Bharat.

Another advantage is that the resources which would have gone into approving the Indian clinical trials could now be utilised productively elsewhere, the official said.

The costs of conducting local clinical trials will be reduced for pharmaceutical firms, therefore passing on these savings to patients. This is especially true for cases of rare diseases where firms have logistical difficulties in finding participants.

The change will promote further research in these areas as there will be access to patient data in the Indian context much earlier, ultimately promoting indigenous innovation and shift from volume to value, the government's mission for the pharmaceutical industry, the official said.

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