

Clinical trials no longer needed for approval of international drugs in India

The Drugs Controller of India has waived the need for local clinical trials for several international drugs to make them more accessible and affordable. This decision is expected to expedite the availability of crucial medications in India and reduce costs for public health schemes.

Under a new rule, permission has been granted to countries such as the USA, UK, EU, Japan, Australia and Canada under Rule 101.

In Short

- Drugs Controller of India waives local clinical trial requirement for several international drugs
- New rule allows market authorisation for drugs from the USA, UK, EU, Japan, Australia, and Canada
- The new move aims to expedite the availability of life-saving drugs and reduce costs
- To help make drugs manufactured outside India more accessible and affordable in the local market, the Drugs Controller of India has announced to waive the requirement for clinical trials for several international drugs and medicines.
- These internationally developed drugs can receive market authorisation in India without the need to present local clinical trial data.
- Under a new rule, permission has been granted to countries such as the USA, UK, EU, Japan, Australia and Canada under Rule 101, "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."

"Currently, several medicines already approved from regulatory authorities like the US, UK and EU are not currently available in India due to regulatory requirements under the Drugs and Cosmetics Act. There is a need for conducting a local clinical trial to generate efficacy of data locally before they are given market use authorisation in India," official sources in the Directorate General of Health Services said.

The move comes as the government feels there is a delay in launching many life-saving drugs in the country.

Drugs under the following category have been proposed for waiver of clinical trials in India:

- Orphan drugs for rare diseases
- Gene and cellular therapy products

- New drugs used in pandemic situation
- New drugs used for special defense purpose
- New drugs that have significant therapeutic advantages over current standard care

"The most sought-after and latest medications that would help treat diseases like cancer, rare diseases like SMA and DMA autoimmune conditions will become available expeditiously in India," as per official sources.

These internationally developed drugs can receive market authorisation in India without the need to present local clinical trial data.

"The decision will be helpful in reducing the prices of public procurement for state governments and also under schemes such as DGHS and Ayushman Bharat," they added.

Dr Viranchi Shah, National President, Indian Drug Manufacturers' Association (IDMA), said, "It is a welcome move. It enables approval of new drugs based on results of clinical studies done in certain developed countries, subject to certain due diligence. It will help early approval and launch of such innovative medicines in India."

For example, a drug for breast cancer type 3 which is not available in India could now be available after swift approval of the MUA (market use authorisation).

Official sources also said that final phase four trials for these drugs could be mandatory in certain cases.

A surge in demand among affluent Indians for weight-loss medications has led to a concerning trend: drugs like Ozempic from Denmark's Novo Nordisk and Mounjaro from America's Eli Lilly are illicitly entering Indian pharmacies, sidestepping regulatory checks.

The US Food and Drug Administration (FDA) approved Ozempic for diabetes treatment in 2017, with a higher-dose variant approved in 2021 under the brand Wegovy for obesity treatment.

However, Mounjaro, also approved for diabetes, is often used off-label for weight loss. But both these drugs are not available in India despite being recommended by doctors to treat patients with obesity.

News Source:

<https://www.indiatoday.in/health/story/clinical-trials-no-longer-needed-for-approval-of-international-drugs-in-india-2579193-2024-08-08>