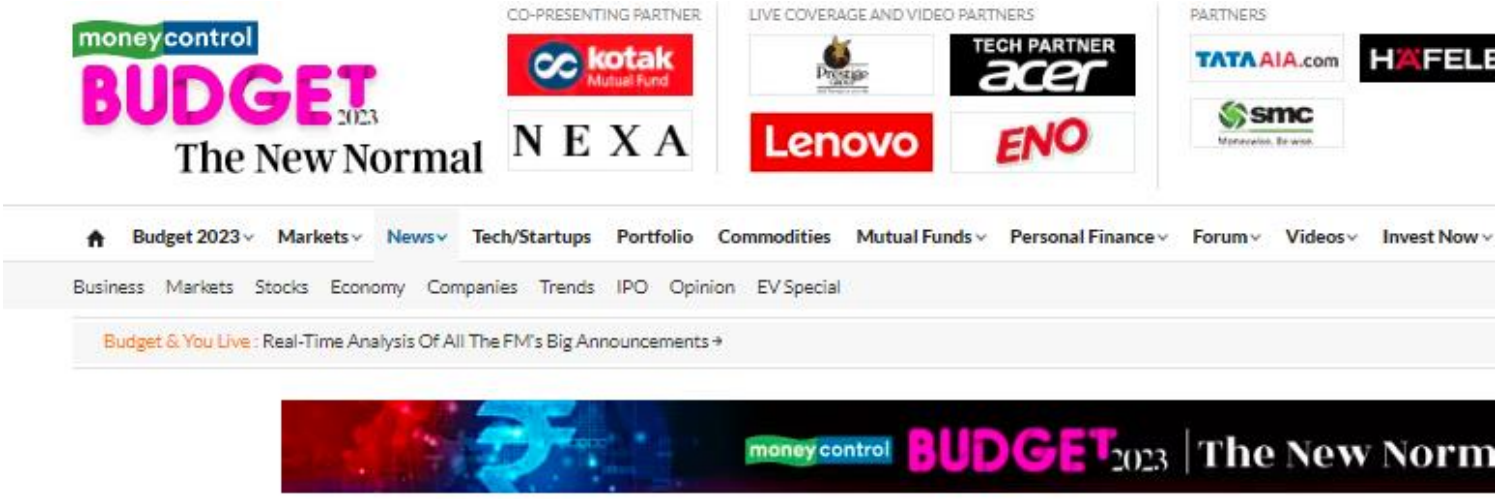
Link: https://www.moneycontrol.com/news/trends/health/budget-2023-foreign-pharma-firms-push-for-fast-tracking-of-new-drug-approvals-ease-of-doing-business-9879471.html




Home > News > Trends > HEALTH

# Budget 2023: Foreign pharma firms push for fast-tracking of new drug approvals, ease of doing business

*Multinational drugmakers are seeking relaxation of norms that govern the launch of new medicines and clinical trials of drugs in India.*

SUMI SUKANYA DUTTA | JANUARY 17, 2023 / 12:55 PM IST

Vivek Sehgal said the industry expects the Budget 2023 to usher in a policy direction t investment.

Vivek Sehgal said the industry exp

Vivek Sehgal said the industry expects the Budget 2023 to usher in a policy direction that facilitates more investment.

Multinational pharmaceutical companies in India have reached out to the government for fast-tracking regulatory clearances of new drugs and clinical trials saying this is crucial to facilitate more investment into the sector.

In an exclusive interaction with *Moneycontrol*, Vivek Sehgal, director general of the Organisation of Pharmaceutical Producers of India, a body of MNC pharma companies, said that the association is also in talks with the government on the establishment of a "meaningful and effective" intellectual property (IP) regime. The senior OPPI executive said the industry expects the **Budget 2023** to usher in a policy direction that facilitates more investment.
"There are a lot of fence sitters who want to see a more enabled ecosystem to bring in investments," Sehgal stressed.

The OPPI over the past several months has been asking the government to implement rule 101 of the New Drugs and Clinical Trials Rules, 2019. This allows the Drugs Controller General of India (DCGI) to specify certain countries for considering waiver of local clinical trials for approval of new drugs but the list of the new countries is yet to be prepared.

**Reducing time of product launch**

The pharma association has been pointing out that the high-powered committees that framed the rules said that if a molecule is approved in other countries, particularly countries like the US, Europe or Japan, it can be fast-tracked in India without a phase-three study here.

***Also read | Budget 2023: Will health sector get the due it deserves?***

The association reasons that during the global studies, normally all population groups such as Caucasian, Mongoloid and Asiatic origin, among others, are covered.

If the pharma companies are permitted to do just post-marketing studies in those cases, says OPPI, the lag between the launch of a product in the US or Europe and India will come down significantly.

The other suggestion by the OPPI includes streamlining the pre-grant opposition process.

“Our suggestions have been to streamline the pre-grant opposition process, protection of confidential business information related to working of patents and doing away with the burdensome disclosure requirements where information is otherwise digitally available,” said Sehgal.

“We also want a stable and predictable pricing policy and easing of conditions in the case of brownfield pharma projects,” he said, adding that OPPI has had several meetings with the Department for Promotion of Industry and Internal Trade (DPIIT).

According to the OPPI DG, the Union government is open to discussion and has been inviting the pharma bodies for consultations on various issues.

**Focus on research**

Sehgal said the MNC pharma companies operating in India are completely in sync with Prime Minister Narendra Modi's vision of bringing innovation and research to the country.

"We see ourselves as a key contributor and a stakeholder in those discussions, especially when it comes to pharma," he said, adding that the association hopes the government's push for innovation and research will be reflected in Budget 2023.

As the OPPI head now has a seat in the National Institute of Pharmaceutical Education and Research (NIPER), said Sehgal, the association can positively influence the curricula of some of the institutes, aid the capacity and faculty and help produce human resources who are better prepared for the industry.