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DCGI's prolonged approval process worries drugmakers

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The Indian Pharmaceutical Alliance (IPA), the industry body representing leading pharma companies, has written a letter to the health minister, Dr Harsh Varadhan, stressing the need for an out-of-court settlement with health activists, fighting for the rights of clinical trial participants. The report mentioned that this was suggested in order to avoid delay in research, and that the ongoing litigation in the Supreme Court is hindering drug development and research work in the country.

"The government's job should be to create enough safeguards and provisions to ensure that the rights and safety of subjects in a clinical trial are not compromised but this does not mean stopping business or development work," the IPA said, adding "what is happening now is hindering access to affordable medicines and this is not in favour of patients either."

"It is, therefore, necessary that the ministry initiate a dialogue with petitioners to allow the Central Drugs Standard Control Organisation (CDSCO) to function normally," it stressed.

Drug makers argue that the research work has almost come to a standstill due to the stringent directives from the apex court asking the government and the Drug Controller General of India (DCGI) to keep a tab on clinical trials and new drug approvals to ensure safety of patients. While the pharma sector is complaining that even genuine trial applications and new drugs are suffering and facing delays, the regulator is being cautious in the light of the court's directive.

As per the DCGI's website, merely 25 clinical trials have been approved by the DCGI in the first five months of 2014, compared with 107 in 2013. The slowdown in clearance is also evident in the case of new drug approvals. While 35 new drugs were approved by the regulator in 2013, only seven new medicines have received a go-ahead so far this year.

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The report also said the health ministry must adopt "a reasoned and hardened position" vis-Ã?Â -vis the apex court to let the executive function.

According to a senior official, around 200 applications seeking permission to conduct clinical trials are pending with the regulator. Officials pointed out that earlier, an approval used to take 12-16 weeks, whereas now there are no clear timelines for a regulatory clearance. This is directly impacting the growth of pharmaceutical companies as well as clinical research organisations.

In the past year, the Rs 80,000 crore domestic pharmaceutical sector has witnessed a significant decline in growth.

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