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Clinical trials: pharma firms, labs told to justify benefits for India

Regulator issues new parameters to protect rights of patients subjected to drug tests

AESHA DATTA
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Pharmaceutical companies, research labs and others looking to conduct clinical trials will now have to justify the research. India is seen as a cheap destination for clinical trials and companies often test products meant for overseas markets here.

A new order issued by the Central Drugs Standard Control Organisation makes it compulsory for these entities to prove why the research needs to be conducted in India.

Parameters set

The order has made it mandatory for them (companies/research labs) to furnish details on three new parameters while filing applications. They are: assessment of risks versus benefits to patients; details on innovation *vis-à-vis* existing therapeutic options; and details on unmet medical needs in the country.

In 2013, only 17 applications for global clinical trials received approval in India, against 55 in 2012. The number has been falling following controversies.

The new requirements come almost a year after the Supreme Court passed an order, in October 2013, asking the Government to assess clinical trial applications on these parameters.

The parameters have been set to protect the rights of Indian patients, said Suresh Menon, executive committee member of the Indian Society for Clinical Research, speaking to *BusinessLine*. "In practice, these parameters are being looked at for about a year now, but now sponsors will have to justify their applications at the onset," he said.

While the first two requirements – on risk assessment and innovation – are factors that every trial should take into consideration, even if not required by law, the last one – furnishing details on how they will address unmet medical needs – could be a challenge.

"This could be a grey zone, which remains open to interpretation," said Menon.

Dhananjay Bakhle, Executive Vice-President (Medical Research), Lupin, said the assessment on these parameters needs to be done by the Government itself as the companies are interested parties.

"What the Supreme Court had told the Government was that each application should be assessed for these three parameters. These were guidelines given to the Government, why are they being passed on to the industry?" he asked. The order needs to clarify whether details need to be furnished for all trials (existing as well as new chemical entities) or just for new drugs, he added.

"This will create further confusion in the industry and could disincentivise companies from conducting clinical trials in India. We need clarity," he said.

Protecting patients

Amit Sengupta, Associate Coordinator, People's Health Movement, said the move would protect the rights of those subjected to clinical trials. "In many trials done in India by foreign companies, the benefits to Indian patients were not very clear. This should bring that to the fore."

However, Sengupta said clarity is needed on whether generic drugs and existing drug molecules would be exempted from these parameters as they do not fulfil "unmet medical needs" and could face hurdle.

Getting tough

- Supreme Court halts all clinical trials in October 2013
- Asks Govt to furnish details on the approval process
- Between 2005 and 2012, over 2,600 people died during clinical trials; 80 deaths were directly due to the trials
- Debate on patient safety has been on since 2005
- New parameters will mean focus on Indian healthcare needs

clinical trials