

# Panel rejects clinical trial plea by some drug makers

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New Delhi, 31 March

Proposals from leading pharmaceutical companies such as Novo Nordisk, Cadila Pharmaceuticals, Wockhardt, Novartis, Roche and Reliance Life Sciences for conducting clinical trials were recently rejected by a regulatory committee, formed following the Supreme Court's directions to supervise tests of new medicines on human beings.

The committee, headed by Health Secretary Lov Verma, evaluated a total of 47 fresh proposals, seeking permission to conduct clinical trials in India. The panel cleared 28 applications, also recommended by a technical committee.

"The committee deliberated on the details of the proposal and agreed with the recommendations of the technical committee," the minutes of the apex committee's meeting noted last month. *Business Standard* has reviewed the minutes of the meeting. The rejected proposals include clinical trials of new drugs, fixed dose combinations, medical devices and global trials.

Some of these proposals were earlier recommended by the new drug advisory committee. However, they were elimi-

## CRITICAL DIAGNOSIS

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nated by the technical committee, keeping in view the "risk versus benefit to the patients, innovation vis-a-vis existing therapeutic option and unmet medical need in the country".

The technical committee, whose recommendations are finally accepted by the apex

committee, also pointed that many of the rejected proposals lacked an opinion from a pharmacologist. The government as well as the central drug regulatory agency have become cautious while approving any

clinical trial or even new drugs in the country after the Supreme Court's strict instructions to ensure safety of patients participating in clinical trials.

Central Drugs Standard Control Organization data show new drug approvals dropped from 264 in 2008 to 98 in 2011 and only 15 in 2012 (till May).

Industry sources said in 2013, only five-seven new drugs were approved. Several clinical trials which were allowed permission

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by the regulator in 2012, were also barred by the apex court last year. The court has asked the government to wait for its nod while the cases are being re-examined under the new regulatory regime, which was framed following earlier directives from the apex court.

The Indian clinical trial industry is pegged at \$550 million and is growing at 12 per cent a year. It is predicted to pass the \$1-billion mark in 2016.

Regulatory