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New clinical trial rules to be final in two months

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New rules drafted by Indiaâ??s Central Drug Standard Control Organisation will reduce the approval time for review of applications to between 30 and 60 days.



India’s drug regulator plans to finalize new rules for clinical trials in a couple of months that would shorten the review time, reported Reuters, aiming to boost clinical research in the country after interest in recent years waned.

The country’s 1.2 billion people and large burden of diseases make for an attractive patient pool for global pharmaceutical companies looking to test new drugs, but stringent rules in the last few years have caused some companies to move their research work to other countries.

New rules drafted by India’s Central Drug Standard Control Organization (CDSCO) aim to change that, reducing the approval time for review of applications to between 30 and 60 days, Ranga Chandrashekhar, a deputy drugs controller at the CDSCO said on the sidelines of a pharmaceutical conference in Mumbai.

“We have already received comment from stakeholders on our draft, and it should be finalised in about two months,” Chandrashekhar said.

The draft was uploaded on the agency’s website in February. If finalised, it would go to the country’s health ministry for approval before being published, he added.

The agency tightened rules for clinical research a few years ago after cases emerged of some patients being enrolled into trials without informed consent, and not being adequately compensated.

The new rules would let the ‘ethics committees’ – groups of medical experts – that oversee clinical trials decide on the level of compensation for patients who suffer adverse events, Chandrashekhar said.

Tougher compensation rules could turn the industry away from conducting trials at a time when companies have been gradually looking back to India for clinical work, warned D.G. Shah, secretary general of the Indian Pharmaceutical Alliance, which represents large Indian drugmakers.

“There has been some revival (of clinical research) based on some assurances given by the government and simplifications (of rules),” Shah said. But if compensation rules are adopted as mentioned in the draft released by the CDSCO, companies “will run away from here,” he said.

“This is not conducive to doing innovation and research in India,” Shah said.

As part of overhauling drug regulations in the country, the CDSCO is also planning to bring in new rules for the sale of over-the-counter drugs, and e-pharmacies in the coming months, Chandrashekhar said.