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Indian ruling harms health of clinical trials

PHARMACEUTICALS

News analysis

Liability regulations have brought drugs testing to a halt, write **Amy Kazmin** and **Andrew Jack**

For nearly a decade, Biocon, a Bangalore-based pharmaceutical company, has been working to develop an insulin pill – the "holy grail" of diabetes treatment – that could revolutionise the lives of millions of diabetics who every day inject themselves with the hormone.

It is a market, potentially worth $18bn year, also being chased by Denmark's Novo Nordisk, the world's largest insulin product producer, and Israel's Oramed Pharmaceuticals.

But Biocon, which has an agreement with Bristol-Myers Squibb for developing its oral insulin treatment, this year hit an unexpected roadblock: Indian regulatory turmoil that has brought clinical drug trials in the country to a virtual standstill.

In response to a public interest lawsuit by activists complaining of global drug companies using Indians as "human guinea pigs", New Delhi this year laid out tough rules that make companies liable for any drug trial subject's injury or death – whether caused by the study or not.

The Supreme Court suspended 157 previously approved clinical trials, pending review by new committees. Approvals for new drug trials have slowed dramatically, due to the newly created multi-level approval process, and bureaucrats' fears of giving go-aheads for trials that may later prove controversial.

As a result of the ruling, western and Indian drug companies have been forced to cancel or suspend hundreds of clinical trials – including some backed by India's National Institute of Health.

Industry executives say the rules have cut Indian patients' access to new therapies, and are threatening the competitiveness of local drug companies, including their efforts at original research.

"If India wants to be the pharmacy of the world, you have to have clinical research," says Kiran Mazumdar-Shaw, Biocon's chairman and managing director. "Just because a few companies may not have followed the norms, they have taken this drastic action against all companies. This is a knee-jerk reaction."

Mahima Datla, managing director of Hyderabad-based vaccine producer Biological E, which has had several clinical trials delayed, says the action "will kill drug development in India. Companies will do their studies elsewhere and it is the Indian consumer who will suffer."

India carried out about $450m worth of clinical drug trials in 2010-11, and the total was expected to grow to $1bn by 2016. Growth was fuelled partly by global drugmakers seeking low-cost centres to test new medicine, while many Indian pharmaceutical companies set up units to facilitate studies by foreign groups.

But drug trials were also increasing because of the rising international ambitions of India's own domestic pharmaceutical industry, which last year exported $13bn of medicines.

Most Indian drug exports are low-cost generic versions of patented medicines already widely used in the west, but their makers must also carry out clinical trials to prove that their drugs are as safe and efficacious as the original before selling in western markets.

Indian drugmakers such as Biocon, Zydus Cadilla, Glenmark and Sun Pharma, are also pushing into innovative drug research and development, hoping to create globally groundbreaking new medicines – aspirations that could be set back by ponderous restrictions on clinical trials.

On paper, industry executives say, India's rules for clinical drug trials were already consistent with international standards. But the severely understaffed regulating agency failed to monitor trials on the ground adequately.

Amulya Nidhi, an activist with the Swasthya Adhikar Manch (Health Rights Forum), the group that filed the public interest lawsuit against clinical tests, says many drug trials in India have exploited the desperation of poor patients, who cannot afford to buy proven medicines and are instead offered free drugs under a study – without realising the medicine is still being tested.

"They enrol and they are not even given consent forms," Mr Nidhi says.

Indian health officials told the Supreme Court that 2,500 Indian drug trial participants died between 2005 and 2012, but said just 80 of the deaths were linked to the tests. However, activists say that many deaths were never properly investigated. Mr Nidhi also said most Indians who suffered injury as a result of the drug trials were not compensated, or received only tiny sums of money.

DG Shah, head of the Indian Pharmaceutical Alliance, which represents India's leading drug companies, says that clinical trials in India have not always met international standards, but adds that the new rules are threatening to stifle such tests.

"Certain excesses were committed which did not take care of patient interests," he says. "This is a backlash against that. But the pendulum has swung to an extreme."

Quintiles, a US-based clinical research organisation that carries out drug tests for the global pharmaceutical industry, says it has scaled back its Indian operations, while GlaxoSmithKline says it is "pausing patient enrolment" into clinical trials. Local generics companies are switching studies to countries including Bangladesh, Malaysia and the Philippines.

But with the industry in an uproar, New Delhi is re-examining the new rules to ensure that they do not stifle the prospects of domestic drug companies. Suresh Jadhav, executive director of the Serum Institute of India, has called the new rules "ridiculous", but says changes and clarifications in response to industry concerns are expected in the next few months.

Mrs Mazumdar-Shaw says she is optimistic that the issue will be resolved, though Biocon is relocating the Indian portions of its oral insulin trial elsewhere, in spite of higher costs.

Global interest in India as a stage for clinical drug trials may remain muted, however. New Delhi has indicated that foreign companies testing new drugs in India must ensure the medicines will subsequently be made accessible to Indian patients – linking clinical trials to the fraught issue of the high prices of patented drugs.

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