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Clinical trials and tribulations at home push companies abroad

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As securing approvals for clinical trials becomes time-consuming under the New Drug Advisory Committee (NDAC), pharmaceutical companies are increasingly considering shifting clinical trials abroad to expedite the process.

The Indian Pharmaceutical Alliance (IPA), which represents leading domestic pharma companies, expressed concern over the slowdown in decisions related to trials in India. "We have noted with mounting concern the increasing reluctance in the Central Drugs Standard Control Organisation (CDSCO) to grant approvals for new drugs, even if these are approved in developed countries, and allow clinical trials or bio-studies for exports. This is evident from the significant decline in the grant of drug approvals in the recent period," it said.

CDSCO data show new drug approvals dropped from 264 in 2008 to 98 in 2011 and just 15 in 2012 (till May). Industry sources said in 2013, just five-seven new drugs were approved.

While Biocon recently indicated it was forced to move some trials abroad, Lupin had also moved some trials to the US and EU. Cadila Healthcare (Zydus Cadila) is considering shifting some of its trials to the US. Sources in Zydus said while the cost of conducting trials was higher abroad, one couldn't jeopardise investments in developing a drug due to inordinate delays.

Dhananjay Bakhle, executive vice-president, medical research (novel drug discovery and development), Lupin, said, "The regulatory environment and volatility therein and the high degree of uncertainty over the last two years had already discouraged us from conducting clinical trials in India. We started conducting our clinical trials in other geographies such as Europe about one and half years ago."

Sources in Alembic, which has conducted a few of its bio-equivalence studies outside India (to meet regulatory requirements related to gene pool variance or trials to be conducted in certain geographies), said there was a lag in the process, the requirement to conduct trials outside India was growing.

A Torrent Pharma spokesperson said, "We have faced difficulties on uncertainties in the requirements and the time to clear study permissions. However, we have not moved our ongoing studies out of India. Our first-in-man studies have generally been carried out outside India to ensure we have regulatory consent from relevant countries...We do not believe we need to deviate from this strategy in general."

Sun Pharma, Glenmark, Cadila Pharmaceuticals and Dr. Reddy's Laboratories did not respond to queries till the time of going to press. Sources indicated Sun Pharma had conducted a few trials outside India.

Clinical research organisations have taken a hit due to the slowdown in clinical trials in India. Apurva Shah, group managing director, Veeda Clinical Research, said, "Due to the lack of transparency and certainly in the regulatory process, not only have global clinical trials stopped coming to India, but local pharma companies have also started looking elsewhere to execute their trials in a timely manner. The delays have cost us millions of dollars in lost revenue, hundreds of jobs for the educated and smart professionals and disappointment for our dreams to discover and develop our own drugs in India."

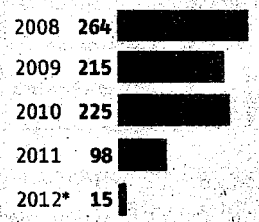
A few organisations are already taking steps to increase focus on other geographies. For instance, Veeda has already set up a phase-I unit in Malaysia, while Lambda Therapeutic Research has opened its first centre in Thailand, following a request from the Thai government.

In the long run, India may lose its cost-competitiveness vis-a-vis Southeast Asian economies as a clinical trial destination. Shah said, "If things do not work in the stipulated time, the costs go up significantly. While India is indeed a cheaper destination to conduct clinical trials compared to many countries, on a case-to-case basis, costs here, at times, catch up with US or EU levels."

Bakhle said, "Indian companies are conducting clinical trials for developing new products, and this is bound to have an adverse impact on the number of new drugs being introduced in India. Similarly, if global companies are discouraged in carrying out trials in India, their interest in bringing new drugs to India will also fall. The net result is reduced treatment options for patients in India."

Inputs from Gireesh Babu in Chennai

DRUG APPROVALS BY CDSCO



*Up to May; CDSCO: Central Drugs Standard Control Organisation
Source: www.cdsco.nic.in

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