

Forcing Drug Trials Outside the Country

Blame lethargy in finalising clinical trial norms

Biocon joins a growing list of Indian drug companies that are now forced to shift their clinical trials to locations outside India, including the EU and the US, where costs are much higher. Uncertainty in India's regulatory regime is the root cause. It is tempting to blame the Supreme Court, which has stayed clinical trials. But then, the court has only stayed trials pending finalisation of norms. It is the delay in finalising norms that is at fault, not the court's concern that trials should take place in a sound regulatory framework. Blame administrative lethargy, not judicial overreach, for a regulatory vacuum that makes India forgo a valuable economic activity and increases the cost of new Indian drugs.

The same fear of taking decisions that had stymied investment in large projects has taken a toll on new drug approvals and taking a call on the regulatory framework for conducting trials. It does not help that finalising the clinical trial norms falls to the health ministry, which



notoriously allowed a contract to procure TB drugs to lapse without creating an alternative mechanism for procuring new dosages for three years and created a disastrous stock-out of TB drugs in many parts of the country, raising the risk of multi-drug-resistant TB.

Drug trials are an emotive issue. Whenever politics interfaces with them, it is to damn trials and demand a ban. This is condemnable populism. The interests of drug companies and of patients taking part in the trials are entirely aligned: both want high standards and foolproof mechanisms. Drug companies stand to suffer damning loss of confidence if their data or trial procedures come under a cloud, after having spent huge amounts of money on drug development. Responsible clinical trial agencies have similar incentives. Drug trials are a valuable economic activity in themselves, creating high-value jobs and benefiting many patients who have little to lose and much to gain from experimental drugs. And for the drug industry, it is a vital part of making India a thriving hub for pharmaceuticals.

Clinical trials.