

Land hurdles could delay govt's plan to set up drug-testing labs

Government has mooted a proposal to set up at least six laboratories across the country to test drugs, medical devices and cosmetics



The proposal is predicated on its acceptance by the states which would provide land, at minimal or no cost in or around accessible areas, to set up the labs. Photo: Bloomberg

New Delhi: The government has mooted a proposal to set up at least six laboratories across the country to test drugs, medical devices and cosmetics, but the plan may face delays as several state governments are yet to respond to requests for land.

The ministry of health and family welfare has identified the states of Delhi, Bihar, Jharkhand, Gujarat, Odisha and Karnataka to set up the labs, according to two ministry officials who spoke on condition of anonymity.

The proposal is predicated on its acceptance by the states which would provide land, at minimal or no cost in or around accessible areas, to set up the labs.

“Only Odisha has responded so far on agreeable terms, with land being offered near Bhubaneswar,” said one of the officials who is directly involved in the process.

According to the proposal, to be implemented over three years, ₹900 crore has been apportioned for strengthening central structures and

₹850 crore for state governments to set up labs.

“The first phase of this project will cost around ₹700 crore. We have sent the proposals to different states and are waiting for their response. We may reach out to more states in case we foresee significant delays, since otherwise it will restrict overall plans to ramp up drug regulation and testing,” said the official quoted above.

The plan involves setting up a diagnostic kit and blood sample testing laboratory in Delhi, drug testing laboratories in Delhi and Karnataka, medical device testing laboratories in Delhi and in either Bihar or Jharkhand or Gujarat, and a cosmetics testing laboratory in Odisha.

Currently, there are seven drug-testing laboratories in the country—in Kolkata, Mumbai, Chennai, Hyderabad, Guwahati, Chandigarh and Kasauli.

The government does not have any dedicated facility to test medical devices and cosmetics or diagnostic kit and blood sample testing labs.

In August 2015, the cabinet committee on economic affairs approved a proposal to strengthen the country's drug regulatory system at an estimated cost of ₹1,750 crore. The proposal envisages setting up testing labs and a training academy for regulatory and drug-testing officials at the central and state levels. It also aims to create additional manpower for regulatory structures.

The training academy is to be set up in New Delhi but land issues have forced delays in execution, said the second official.

“We had originally proposed to set up the institution near the Qutab Institutional Area in Delhi but that did not work out. So now we are looking at setting up the training institute somewhere else in the capital,” said the second official.

Through the proposal, the government plans to enhance quality, safety and efficacy of drugs and other medical products manufactured in the country.

According to a report by legal firm Nishith Desai Associates, the Indian medical device sector is worth about \$5.5 billion and is growing at 15% compound annual growth rate. It is dominated by imported products, which make up around 75% of the total sales.

"With India's drug manufacturing and exports capacity burgeoning at a rapid clip, the demand for a stronger regulatory system is apparent. What India also needs is an ecosystem that harnesses capacity expansion with technical ability of individuals. In order for that to happen, continuous knowledge transfer of global regulatory standards is imperative," said Muralidharan Nair, partner, life sciences, EY.