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SAFETY ISSUES

Clinical drug trials on humans set to become more stringent

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NEW DELHI

The regulation of clinical trials of drugs on humans is set to become more stringent in the new year as the government tries to make the process safer and more transparent.

The drugs regulator, the Central Drugs Standard Control Organisation (CDSCO), plans to make the registration of clinical research organisations (CROs) mandatory and introduce two new provisions in the Drugs and Cosmetics Act relating to the inspection of such trials.

Deaths of some subjects have been reported from clinical trials in the last two years. Recently, two girls enrolled in a study for an HPV vaccine, which can prevent cervical cancer, in Andhra Pradesh died. A panel set up to investigate their deaths has submitted its report to the health ministry.

The clinical trial market in India is valued at $300 million (₹1,353 crore) with a compounded annual growth rate of 30%, according to a report by consulting firm Ernst and Young and the lobby group Federation of Indian Chambers of Commerce and Industry. Registration of clinical trials with the Indian Council of Medical Research was made mandatory in June 2009.

> The regulator has identified six trials that it plans to inspect, which include those of Sanofi-Aventis and Bayer CropScience

The proposal for registration of CROs under a separate schedule in the Act has been approved by all stakeholders and is now awaiting the health ministry's notification.

"CRO registration is just pending short of notification. Once the final notification by the ministry is done, all CROs will have to register with the drug controller general of India," said a senior health ministry official on condition of anonymity.

"The registration of all stakeholders in clinical trials with the government will make the system more transparent. It will create a minimum standard, a benchmark that has to be followed by all. This uniformity will remove the fly-by-night operators and make space for people who are serious," said the official.

Alongside, CDSCO has prepared two new schedules to be introduced in the Act. While Schedule Y2 will cover all aspects of clinical trial inspections by the organisation, Schedule Y3 will be for registration of ethics committees that oversee clinical trials at various trial sites. CDSCO has identified six clinical trials that it plans to inspect. These include trials of Spectrum Clinical Research, **Sanofi-Aventis SA** and **Bayer CropScience Ltd**.

"The schedule for clinical trial inspections will look into the causes of adverse events in any given trial. We will choose these trials based upon the serious adverse events and number of deaths. So, we will check if there is a problem in the trial conduction or if it's just because of the disease condition. In most cases, death rate is high because the subjects enrolled in the trial are terminally ill or suffering from a chronic disease," said a CDSCO official. He did not want to be identified as he is not allowed to speak to the media.

"These are remarkable steps being taken by the government," said Swati Piramal, director, strategic alliances and communications, **Piramal Healthcare Ltd**. "But the biggest challenge is still the time taken for regulatory approvals. That's a huge bottleneck. Usually the ethics committees have no experience in microdosing and phase II trials, so they take a long time to approve the trial."

She said that while it normally takes 28 days to get a clinical trial approval in some other countries, in India it can take up to six months. "That's a big loss of time because the patent clock is already ticking for your product. Nonetheless, these regulations will certainly weed out all those who don't conduct trials properly."

Clinical trials