

Ban on clinical trials for Wyeth vaccine lifted

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Mumbai: The drug controller general of India (DCGI) earlier this week lifted a temporary ban on clinical trials for a vaccine by US drug maker Wyeth Inc., allowing the drug company and the Hyderabad-based clinical research organization GVK Biosciences Pvt. Ltd to go ahead with the trials.



The ban had been imposed following the death of a baby that was less than a year old due to lapses in standard operating procedures while conducting clinical trials for the vaccine in St John's Hospital, Bangalore, in November. However, the ban on trials has been removed only for 11 of the 12 hospitals where they were being carried out. It stays in St John's, said Surinder Singh, drug controller general.

Singh, who heads India's Central Drugs Standard Control Organization, also said that the hospitals, GVK and Wyeth have been asked to comply with the necessary rules and regulations, and re-train the people involved in the trials.

An earlier audit by the regulator had found the trial had violated protocols, standard operating procedures and norms on good clinical practices listed in the country's drugs law. DCGI had issued warning letters to the violators asking for an explanation before suspending the trials.

"The hold (on the trials) was lifted as DCGI is satisfied with the systems and protocols in place for conduct of the trial as per GCP (good clinical practices) norms. Wyeth has now strengthened the processes and supervisions at trial sites," said a Wyeth spokesman.

Mint had reported last November that DCGI's audit findings had proved that Wyeth's trials violated the GCP norms as the child subjected to the vaccine test had a pre-existing cardiac disorder. Indian drug rules prohibit testing on human subjects with such conditions without the prior approval of DCGI.

The problem in cases such as this, says an expert, is the lack of clarity on the penal action against violations that are caused by negligence and result in a loss of life.

"Currently, the scope of penal action against violation of clinical trials ends at suspension of trials, as there is no enabling provision in the Drugs and Cosmetics Act for the drug control department to proceed against the violators—neither in terms of fines nor any other form of punishment," said India's former drug controller general M. Venkateswarlu.

And a law seeking to allow the regulator to take penal action against offenders is yet to be passed by India's Parliament.

The regulator is now considering a way to address the issue.

"The enabling penal provisions are at present in the Central Drugs Authority (CDA) Bill (2007). We are thinking, and this is only something we are thinking of right now, is that we take out the provisions for clinical trials, including penal provisions, and medical equipments from the CDA Bill and make a separate amendment in the Drugs and Cosmetics Act, because that way the amendments can be fast-tracked," said Singh.

The proposal to do so, Singh added, is being considered by the department and may be submitted to the health ministry by June. Earlier, an expert committee set up by the government to look into regulatory issues had recommended that violation of clinical trial norms be treated as cognizable and non-bailable offences that attract fines and prison sentences.

That may change the complexion of clinical trials regulation in a country where inadequate laws have meant that there hasn't been a single instance of such a case being prosecuted, despite at least a dozen instances where the violations resulted in the death of subjects.

Apart from this, Singh said, the department is already collaborating with the US Food and Drug Administration to train drug inspectors and clinical trial auditors to strengthen the clinical trials watch in the country.