

Human trials for H1N1 vaccine start in India

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In a positive step towards the approval of H1N1 vaccine, Sanofi Pasteur has started the first ever human trials of a swine flu/H1N1 vaccine for Indians on January 20, 2010, at three places. The vaccine will be tested on about 100 Indians for three

weeks at three hospitals in Pune, New Delhi and Chandigarh.

Sanofi Pasteur has received the approval for conducting human trials from the Drug Controller General of India (DCGI). Sanofi's vaccine was developed in France and has been tested on Europeans. However, the DCGI wants to make sure Indians respond well to the vaccine before giving approval for the sale of this vaccine.

Sanofi Pasteur had acquired a majority stake in Hyderabad-based vaccine maker Shantha Biotechnics in mid 2009. After three weeks of trials, the DCGI will wait for another six weeks to check whether or not there were any side effects on all the 100 people who were part of this trial exercise.

Three Indian companies—Pune's Serum Institute, Ahmadabad-based Cadila and Hyderabad-based Bharat Biotech have been contracted to develop swine flu vaccine and their research is in various testing phases. Meanwhile, Bharat Biotech has commenced phase I clinical evaluation of HN-VAC, its cell culture-based H1N1 vaccine candidate. The company has received the nod from DCGI to conduct the phase I clinical trials.

In August 2009, the Indian government approached four international pharmaceutical companies that were manufacturing H1N1 vaccine, but no pre-bookings were made. The government said the booking would be made only after conducting the clinical trials to ensure the safety and efficacy of the vaccine in the country.

In the first week of December 2009, GlaxoSmithKline (GSK) got the approval to start its clinical trials in India. Two other pharmaceutical companies, Baxter and Novartis also got the approvals to conduct clinical trials.

French drug company, Sanofi Aventis' vaccines division, Sanofi Pasteur, is one of the international companies that are expected to join hands with the government in the fight against swine flu.

Speaking to BioSpectrum, Dr Vishwa Mohan Katoch, director general, Indian Council of Medical Research (ICMR), says, "The government is very cautious in its approach and would not like to take any action in a hurry as the matter is directly linked to people's health. Proper trials are a must so that all the safety issues are addressed before the release of vaccine in the market. First time in India, all precautions have been taken and the maximum safety needs have been addressed in this regard."

Dr Katoch, also the secretary of the Department of Health Research, Ministry of Health and Family Welfare, says, "Increase in the number of positive swine flu cases, has put a lot of pressure on the government to look for an early vaccine trial and making it available in the market."

"There is an ethical committee in every company and the volunteers of 2-200 per group have been used to check the bridge effect and the adverse effect. Primarily, the health workers are being targeted for the trials as they are at the higher risk and later on other segments of population will be involved," adds Dr Katoch.