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India ready to battle swine flu

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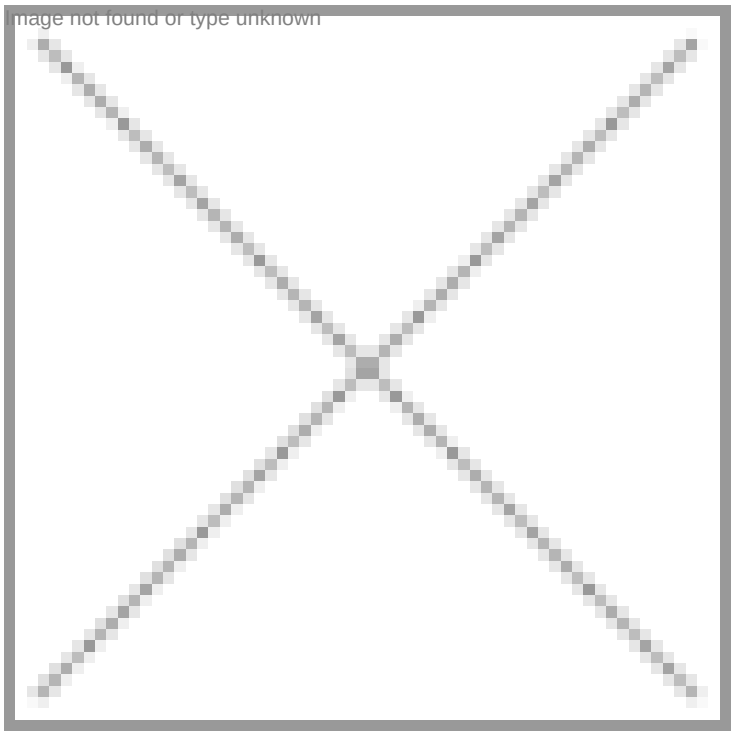

India ready to battle swine flu

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swine flu

The battle against swine flu is getting intensified with the fruitful results of the clinical trials for developing H1N1 vaccines and diagnostic kits by both domestic and international pharmaceutical and diagnostic companies.

The rapid pace at which H1N1 spreads has created panic among people from all across the world. The surge is expected to continue for more than a year from now. Understanding the gravity of the situation, the Indian government has been taking various initiatives to procure vaccines from international pharmaceutical companies to curb the spread of the pandemic and to enhance the development of indigenous diagnostic kits and vaccines for H1N1.

Swine flu vaccine scenario

In August 2009, the Indian government approached four international pharmaceutical companies that are 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 have also got the approvals to conduct clinical trials. The process will take at least a couple of months to complete.

While commenting on the current status of GSK's H1N1 vaccine, a spokesperson of the company says, "We are in talks with the government on the procurement and supply of H1N1 vaccines and are not in a position to further comment on the said matter."

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

Meanwhile, during a Parliament briefing in November 2009 on the development of swine flu vaccine, Ghulam Nabi Azad, health minister of India, said that India would be able to indigenously develop swine flu vaccine by June 2010.

According to Azad, three Indian companies — Serum Institute of India, Bharat Biotech, and Panacea Biotec — are working towards developing indigenous vaccine for the swine flu and the clinical trials would start in January 2010.

To cover the interim period, the government is importing pandemic vaccine to vaccinate the high risk group. So far, the government has procured 40 million capsules and 400,000 bottles of Oseltamivir, the drug used to treat swine flu.

Approvals and partnerships

On the clinical trial front, the animal trials for the much-awaited H1N1 vaccine have been completed by the Pune-based Serum Institute of India (SII). The company has also started its human clinical trials. On the other hand, Ahmedabad-based vaccine maker, Zydus Cadila has filed the first clinical trial protocol with the Drug Controller General of India (DCGI) and has entered the race to launch H1N1 swine flu vaccine in India.

Two multinational drug makers — GSK and Baxter International Pharmaceuticals has formed a joint venture with Novavax, a US-based clinical- stage biotechnology company, to develop, manufacture and market vaccines, pharmaceuticals and diagnostic products in India. The joint venture will develop and commercialize Novavax's seasonal influenza virus-like-particle (VLP)-based vaccine candidate and Cadila's therapeutic vaccine candidates against cancer as well as its adjuvants, biogeneric and biological diagnostic products for the Indian market.

Ahmedabad-based Intas Pharmaceuticals (Intas) has entered into a strategic partnership with US biotechnology company, Amarillo Biosciences, Inc (ABI), whereby Intas will sponsor clinical trials of ABI's orally administered interferon-alpha lozenges for influenza, which could also be used in combating the H1N1 virus.

When asked about the prospects of Intas Pharmaceuticals-Amarillo Biosciences partnership, Dr Samir Sangitrao, assistant general manager - regulatory affairs, Intas Biopharmaceuticals,says, "Intas has submitted the required documents to DCGI for approval of its clinical trial in India. We are expecting the approval very soon. After getting the approval, Intas is planning to conduct a therapeutic clinical trial covering 500 patients with Amarillo Biosciences' patented orally administered interferon-alfa lozenges. Amarillo has already completed animal studies including toxicity studies as well as several other clinical trials in the US and rest of the world."

"Intas is developing a natural interferon-based therapeutic solution for influenza in general (which will also cover swine flu). Oral interferon will be used to prevent influenza, and, as a treatment, it will also be used to reduce the severity of symptoms. The flu virus does not mutate to evade the effects of interferon. Oral interferon will have no interactions with influenza vaccines," he adds.

He further says that the ongoing flu clinical trial in Australia, which is preventive in nature, is well-timed to help Intas deal with the next wave of swine flu or any other viral respiratory infections efficiently. Report of this preventive study is expected in a few months from now. This will further enhance the usability of orally administered interferon-alfa lozenges for preventing influenza and decrease the morbidity caused due to influenza.

Diagnostic kits

The Defense Research and Development Organization (DRDO), a premier defense laboratory in India, has developed a swine flu detection kit and the process for transferring the technology for commercialization is yet to be initiated.

This development was informed by AK Antony, defense minister of India, in a written reply to the Lok Sabha in the last week of November 2009. DRDO's diagnostic kit is a rapid and cost-effective swine flu virus specific isothermal gene amplification

assay for reliable and early clinical diagnosis of H1N1 in human patients.

The defense minister also emphasized that the kit works on a single-tube method as compared to WHO approved Center for Disease Control (CDC) recommended real-time reverse transcriptase polymerase chain reaction test system. The assay is based on the principle of the isothermal gene amplification protocol. No expensive real-time PCR equipment is required as the result can be monitored by the naked eye.

The DRDO developed method gives results in an hour as compared to the three-four hours required for the WHO-approved CDC-recommended kit. The DRDO kit has been validated at the National Center for Disease Control, New Delhi; Post Graduate Institute, Chandigarh and the National Institute of Mental Health & Neurosciences, Bangalore.

Bangalore-based Bhat Biotech, is also in the process of developing a H1N1 detection kit. Dr Shama Bhat, managing director, Bhat Biotech India, says, “We have been developing diagnostic kits for H1N1 virus detection for the past four months. We are planning to have both quantitative PCR (qPCR) and rapid protein-based kits.”

“Bhat Biotech is collaborating with a German company for developing qPCR-based kits. Within a month, soon after the validation, the kits will be available in the market. For the past three months, we are also working on the protein-based kits. Due to the lack of positive samples, it is very difficult to test the kits. To overcome this obstacle, we will be collaborating with some institutions, where this test can be conducted,” adds Dr Bhat.

The way ahead

One of the challenges posed by the H1N1 virus is the mutation of its strain. Though there were not much mutations identified in India, Indian vaccine manufacturers have to take additional measures to tackle this pressing need.

“Since swine flu virus is expected to mutate a lot, developing a vaccine will not be a permanent solution. Vaccine efficacy varies yearly due to antigenic drift. Anti-viral drugs lead to viral resistance,” says Dr Samir Sangitrao.

The mutation of the swine flu virus is one of the major areas of concern but with the kind of domestic and international expertise, India can overcome the obstacle.

Pradeep Kumar in Bangalore