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H1N1 flu vaccine to hit market soon

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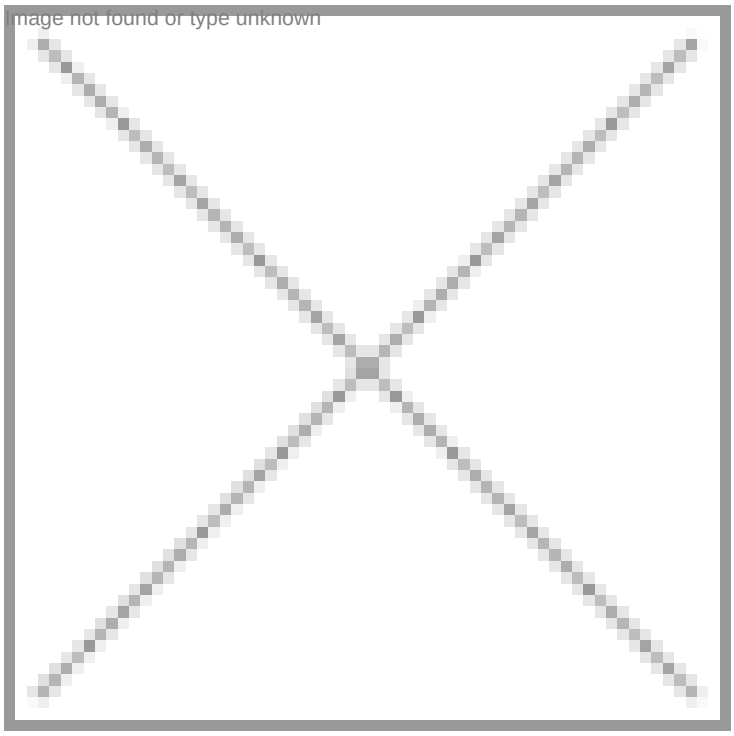

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Increase in the number of positive swine flu cases, has put a lot of pressure on the government to look for an early vaccine trials and making it available in the market. And we are ready. Well, almost!

Indian fast bowler S Sreesanth was tested positive for swine flu, showing that the flu is still hovering in some parts of the country. The global outbreak of H1N1/09 virus popularly known as 'swine flu', was first detected in April 2009, in Veracruz, Mexico, with an evidence that there had been an ongoing epidemic for several months before it was officially recognized. In India, the first case of the flu was detected in the first week of August 2009 when a girl from Pune succumbed to the virus. Followed by a staggering number of deaths caused by swine flu virus, the country came into the grip of this pandemic outbreak. By September 2009, India's position was at its edge. The country had to deal both with dueling outbreaks of swine flu and related panic.

Recently, around 175 fresh cases have been reported, and the death toll has touched a record high of 700, and over 21,000 people have been affected in the country. Maharashtra tops the list in terms of the casualty figure, the number in this state has jumped to 240. Death toll in Gujarat so far shows 57 and 94 in Rajasthan. After Maharashtra, Karnataka with 123 deaths

is second in terms of death toll from the pandemic H1N1 influenza.

Speaking to BioSpectrum, Dr Vishwa Mohan Katoch, director general, Indian Council of Medical Research (ICMR) says, “We have always encouraged the Indian companies to take the initiative as an indigenously developed vaccine may be safe and suitable for the Indian population. 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 trials and making it available in the market.”

As the origin of the outbreak was traced in Mexico where nearly 200 people died in 1968, the World Health Organization (WHO) made loud campaigns that resonated at every nook and corner of the globe, compelling governments to launch surveillance and preventive measures. And India, which started working on a vaccine from April 2009 soon after the pandemic spread abroad, is among the first few countries to get into the fast-track to develop the indigenous swine flu vaccine.

In order to avoid repetition of past experiences which indicated that during global epidemic, countries where these vaccine manufacturing units were located would lay the first claim on the products, WHO selected six companies — Serum Institute of India (SII) (India), Birmex (Mexico), Bio Farma (Indonesia), Government Pharmaceutical Organization (Thailand), Vabiotech (Vietnam) and Butantan (Brazil)— to equip them with the expertise, technical assistance and production capability to develop and manufacture any new pandemic influenza vaccine. WHO’s preparations came handy in the current situation. The seed virus of H1N1, isolated from the first set of patients in Mexico and California were quickly sent to the newly identified companies worldwide.

Drug Controller General of India has approved the four stains made available by WHO. Based on these stains, the H1N1 vaccine is being developed at Serum Institute, Panacea and Bharat Biotech. Out of the three, India’s largest biotech company and also one of the world’s top pediatric vaccine makers, the 42-year-old Serum Institute is the lead player from the country in the global race to develop an effective vaccine against the swine flu virus. The government this time got actively engaged to deal with the situation, and is learning the ways to deal with such pandemic issue. It is for the first time that the Indian government and the industry worked in tandem to tackle the pandemic flu.

Maintaining that the progress in the making of the vaccine is going head-on, Rajeev Dhere, senior director of SII, says, “The present status of the vaccine is that animal toxicity studies have been completed. We will be going for human trials, hopefully this month.” SII is making two vaccines: Live attenuated vaccine to be given intra-nasally and an Inactivated vaccine to be given by injection. The vaccine is ready. Live attenuated vaccine has been sent to the National Control Laboratory for testing. Likewise, Bharat Biotech too has submitted the animal trials report to the regulator and government. “We are waiting for the government’s nod to undertake human trials,” says Dr Krishna M Ella, chairman and MD, Bharat Biotech.

According to Dr Katoch, “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.”

“We are highly optimistic about the early success of the trials. We are hopeful that all the trials would be concluded by the end of December 2009 and the vaccine would be ready for market entry in January this year,” he adds.

However, it wasn’t a cakewalk for these companies. Initially, the major challenges for these companies were import of stain and reagents at a short notice. But government’s help at every stage was a sigh-of-relief for these companies, especially in a situation when the panic button had been pushed too hard. Dr Dhere adds, “Every day is a challenge but this one was ‘race against time’, for which we required co-ordination from all agencies both internal and external. It was a joint effort, and over 10 agencies were roped in for the manufacture of the vaccine. Besides the organization, we got ample support from the government, WHO, ICMR, DCGI National Control Laboratory, Kasauli and National Institute of Virology.”

Nearly 40 to 50 people are involved in the development process of the vaccine. The budget allocated for the purpose runs in crores. Dr Ella says, “We have already invested Rs 15 crore in the project. The total investment is expected to be Rs 70 crore.” However, SII refused to reveal its investment.

Understanding the severity of the issue, the companies involved left no stones unturned in providing state-of-the-art facilities for vaccine research and development. At SII, the biosafety level (BSL) facilities have been provided for working purpose.

The company's manufacturing unit for the vaccine spreads over a sprawling area of over 15,000 sq ft of land.

Despite the complex and time consuming processes, Indian companies went head on. Bharat Biotech, began by growing seed strains of the virus. "To make the virus grow in cell-culture is also a challenge. It was equally important to maintain the highest level quality control and production capability," says Dr Ella. While Dr Dhere opines that putting both scale of abilities and the R&D division, could handle the process. "And of course, the support from the senior management committee was fast tracked," he adds.

But the steps taken for the manufacture and development of the vaccine were different. SII went for an egg-based vaccine development, while Panacea and Bharat Biotech adopted the cell-culture based vaccine. Dr Dhere says, "Yield of the vaccine is more in the egg-based than in cellline vaccine. Considering the type of stain that we received, if we had gone for the cell-line vaccine then it would have taken a longer time." However, Bharat Biotech which has the facility to produce one million doses of vaccine per year, is of the opinion that egg-based manufacturing process is highly labor intensive, and during flu pandemic, lack in the supply of eggs may arise. To avoid such issues, the Hyderabad-based biotech company chose to develop cell-culture vaccine.

"Cell-culture based vaccines give us the ability to control all aspects of the manufacturing process from start to finish in a single facility using close systems without the requirement of manual handling during the manufacturing process. Cell-culture based vaccines are not dependent upon any external supplies for the manufacturing process that could hinder the supply of the vaccine," says Dr Ella.

The cell-culture substrates available at Bharat Biotech have been tested extensively at international laboratories for safety and quality. It also has extensive expertise in using cell-culture to manufacture other vaccines such as INDIRAB (rabies vaccine) and is also developing cell-culture vaccines for rotavirus, Japanese encephalitis and chikungunya.

Besides these three companies in India, Ahmedabad-based Zydus Cadilla has come forward and invested in the vaccine development. "Zydus Cadilla, did not get the seed money from the government, but they have put their own investment in the vaccine development. Recently, they got a nod from the DCGI to carry out human studies of its vaccines. And hopefully, the outcome would be good," says Dr Katoch.

Further, he informed that GlaxoSmithKline and Baxter are two companies among the three international companies with whom the government had been negotiating on the vaccine trials. "Once the vaccines are finalized from one of the international companies, then phase IV trials will be conducted to check the safety and immunogenicity of the foreign made vaccine on the Indian population." Dr Katoch adds, "We are in negotiations on that and will be developing a fast-track protocol for the same."

Although the sign of progress in terms of H1N1 vaccine development is quite satisfactory, but one can't rule out the re-emergence of the killer virus and the technological challenges in increasing the quantity of the H1N1 vaccine once it is approved by the regulators for large scale use. Fresh positive cases being reported almost every week and warning bells ringing loud against the impending danger indicate that the time is running out for India, we need to be prepared.

Anjana Pradhan in Bangalore & Rahul Koul in New Delhi