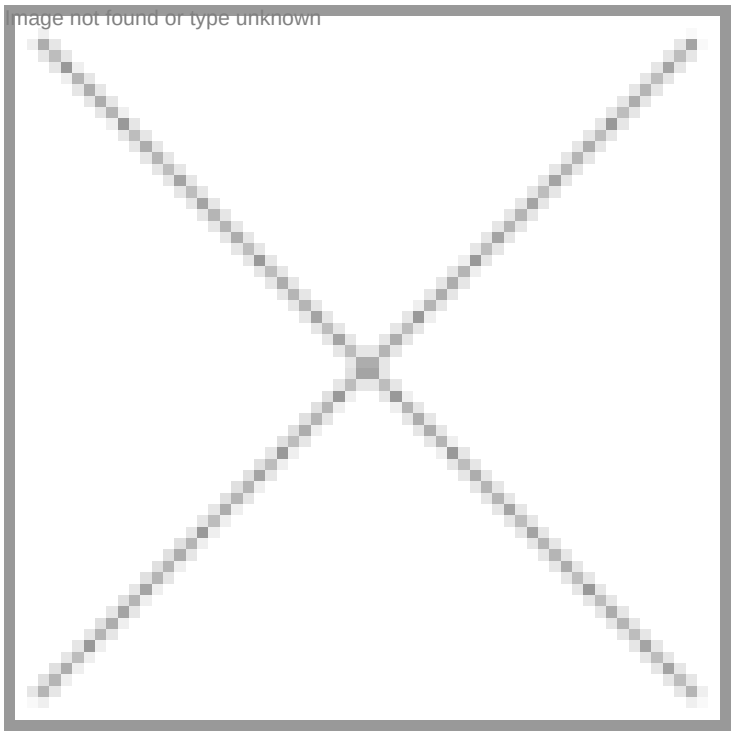
BioSpectrum
the business of Bio & Health Sciences

Serum leads India's Swine Flu Vaccine Race

05 August 2009 | News

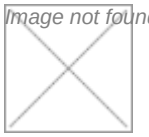
Image not found or type unknown



Serum leads India’s Swine Flu Vaccine Race

India’s largest biotech company and also one of the world’s top pediatric vaccine makers, Serum Institute of India, based in Pune, is lead player from the country in the global race to develop an effective vaccine against the “unstoppable” spread of the swine flu virus. Two other companies—Panacea Biotec and Bharat Biotech— too have joined the race. A Special Report.

Image not found or type unknown



It is a quiet corner of the sprawling campus of Serum Institute of India in the western Indian city of Pune, a crack team of 16 scientists has been running a battle against time. This team, chosen specifically by the senior management of India’s largest biotechnology company, has no time to relax, as they are part of the global race to develop a vaccine against the swine flu.

The crack team now works out of BioSafety Level 2 (BSL 2) facility, enhanced with various facilities as per current global standards. The facility suitable for work involving agents of moderate potential hazard to personnel and the environment. It includes various bacteria and viruses that cause only mild disease to humans, or are difficult to contract via aerosol in a lab setting, such as Hepatitis A, B, and C, influenza A, Salmonella, mumps, etc.

The team was put together just a few weeks after the first Influenza A infection, caused by a new, virulent strain H1N1 was first detected on April 12, in a small village near Veracruz in Mexico. It was transmitted from pigs to a five-year-old son of a worker in a pig farm. And it was quickly named, the “swine flu” virus. The summer in the Northern Hemisphere is the time when influenza viruses normally lie low, waiting for their turn to strike as the winter set in around October-November.

However, this H1N1 strain has had other ideas and aided by air travel, it has traveled to the farthest corners of the world within weeks. And the global health agency, the World Health Organization (WHO) of the United Nation has now termed it

“unstoppable.” Normally, it takes about 25 weeks for a new influenza virus to cover the planet. But H1N1 reached all continents within nine weeks and WHO was forced to term it a pandemic, the term used to describe a viral infection present widely in all the continents on Earth. And it triggered a global response to find a solution to secure people in the years to come in the shortest possible time.

“The flu transmission didn’t stop even after the increase in summer temperatures. And studies have indicated that people born after 1975 were more vulnerable due to the inability of their immune system to recognize this H1N1 virus strain,” said Dr Suresh S Jadhav, executive director, Serum Institute, and coordinator of the company’s swine flu vaccine initiative.

WHO has decided to take the H1N1 challenge head on and hence roped in as many companies as possible with expertise in manufacturing vaccines to develop a vaccine against the H1N1 influenza strain. Though Serum Institute is not a manufacturer of seasonal influenza vaccine, Serum was chosen from India by WHO to lead the challenge. Technical and other inputs to Serum followed.

WHO has roped in 21 current manufacturers of influenza, located mainly in the US, Europe, Japan and Australia for the global efforts. Serum Institute and five other companies—Birmax, Mexico, Bio Farm (Indonesia), Government Pharmaceutical Organization (GPO), Thailand, Vabiotech (Vietnam) and Butantan, Brazil—were chosen by WHO to join the global swine flu vaccine production efforts.

Gearing Up

Developing a vaccine against the H1N1 virus strain is complex and time-consuming process. Serum Institute’s team is very much aware of the complex process, informed Dr Rajeev M Dhere, senior director, handling the effort at the Pune company.

Influenza viruses change frequently and usually a vaccine made against a specific strain is useful only for vaccination during single season. So each year the seasonal influenza vaccine is changed. The seasonal vaccine production for the influenza viruses which were expected to activate in the winter of 2009 is almost fully ready and stocked up in major consumption areas of the world. Experts indicated that the current year’s seasonal influenza vaccine has used three virus strains: A/Brisbane/59/2007 (H1N1), A/ Uruguay/716/2007 (H3N2) and B/Florida/4/2006.

Dr Dhere said experts at the Centers of Disease Control (CDC) in the US have determined the genetic sequence of the new H1N1 influenza virus. The genetic sequence is significantly different to the H1N1 contained in the current seasonal influenza vaccine. So the current seasonal vaccines will not provide any protection against the new H1N1 strain and hence a different vaccine is required.

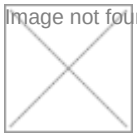
Several strains of the H1N1 viruses have been extracted from the infected people in Mexico and California. The A/Mexico and A/California strains are the basis for the vaccine production.

Dr Dhere explained the process. The first step in the vaccine production is the making of the “seed” virus. Experts at CDC have prepared the “seed” virus from A/Mexico and A/California H1N1 strains. The “seed” virus is a safe form of the influenza virus, stripped of its parts that spread the infection. The live virus is genetically altered to make it safe. This is a time consuming process and takes about three to four weeks.

This “seed” virus is supplied to vaccine manufacturers chosen by the WHO around the world. The “seed” viruses fromvarious strains are then prepared to be ready for vaccine production by a process called “assortment.” These reassorted viruses are then injected into specially prepared pathogen-free, fertile chicken eggs. The safe virus then grows inside the eggs for four to six weeks. The viruses are then extracted from the eggs, purified and inactivated and then formulated into a vaccine.

Serum Institute has got the “seed” viruses. During this period, H1N1 strains have been extracted from infected patients in India and Turkey too. And the viruses are identical indicating that the new vaccine should work against the swine flu which has spread to all these regions effectively.

The normal dosage of influenza vaccine is 15 mg. From each chicken egg, one dose of influenza vaccine is produced. Sometimes, two eggs may be required to produce each dose of standard influenza vaccine.



Tricky Part

Serum’s team is now confronted with another tricky part of the project. That is to source enough chicken eggs to grow the vaccine. Luckily, Venkateshswara Hatcheries, India’s largest poultry maker is situated in the same city. “Currently, the company will supply us about 100,000 pathogen-free eggs. But if there is urgent requirement to step up the vaccine production, they will be able to give us up to 2.5 million eggs a month,” says Suresh Jadhav. There are two other major poultry suppliers near Bangalore. They too will be roped in if the swine flu virus spins out of control in the country. But so far things have been under control with less than 500 H1N1 infections reported in India till July-end.

Under the scheme supported by WHO, Serum Institute is committed to provide at least 10 percent of its swine flu production for use in other countries. “Such an assurance has been guaranteed by the Indian government. This is just to ensure that in the case of a national emergency, the government does not stake claim to the entire production leaving nothing for global use,” explains Serum Institute’s senior director, Dr Satish Ravetkar.

Though the Indian government has given the go ahead for mass scale production of the H1N1 influenza vaccine, it has yet to give firm orders to either Serum Institute or the two other India companies—Panacea Biotec, New Delhi, and Bharat Biotech, Hyderabad—about the quantity requirements.

“We have given approvals to these three companies (Serum Institute, Panacea Biotec and Bharat Biotech) to get seed strains from CDC, Atlanta and the UK-based National Institute for Biological Standards and Control (NIBSC) to start preliminary research,” said Drug Controller General of India (DCGI), Dr Surinder Singh. The companies will now have to go through the other stages of development like pre-clinical trials and clinical tests.

Scientists at Serum expect to have the vaccine ready by September. They are also preparing a limited human trial involving at least 25 volunteers. It will be another six months before the vaccine will be ready for mass use. In the event of an emergency, WHO has clarified that countries could relax some of the stringent provision related to approvals to speed up the vaccine’s availability to fight a raging swine flu pandemic.

Authorities in China have been more proactive and the Beijing city government has already placed the order to supply at least 4 million doses by the end of September to local vaccine maker, Sinovac. This order will be administered to 2 million people in the high risk group. Additional orders are expected beginning in October and, in total, Sinovac expects to supply approximately 10 million doses to the Beijing government. The 10 million doses will be administered to five million people in Beijing.

Serum plans to invest over $30 million (Rs 150 crore) to set up a separate facility to make the swine flu vaccine. “This is part of our commitment to make available affordable vaccine to the people who will need it the most,” asserted Serum’s chairman, Dr Cyrus S Poonawalla. He will be happy if the Indian government makes a firm announcement about its plans to tackle the swine flu which is likely to be around for some more years to come.

India’s citizens are waiting for a similar announcement from their government. Of course, the government is not concerned too much because of the mild form of infection that has surfaced in the country so far. Yet again, the beneficiaries of the technological prowess demonstrated by a company like Serum in developing an influenza vaccine in the shortest possible time could be many global citizens.

Narayanan Suresh in Pune