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Swine flu and biosimilars

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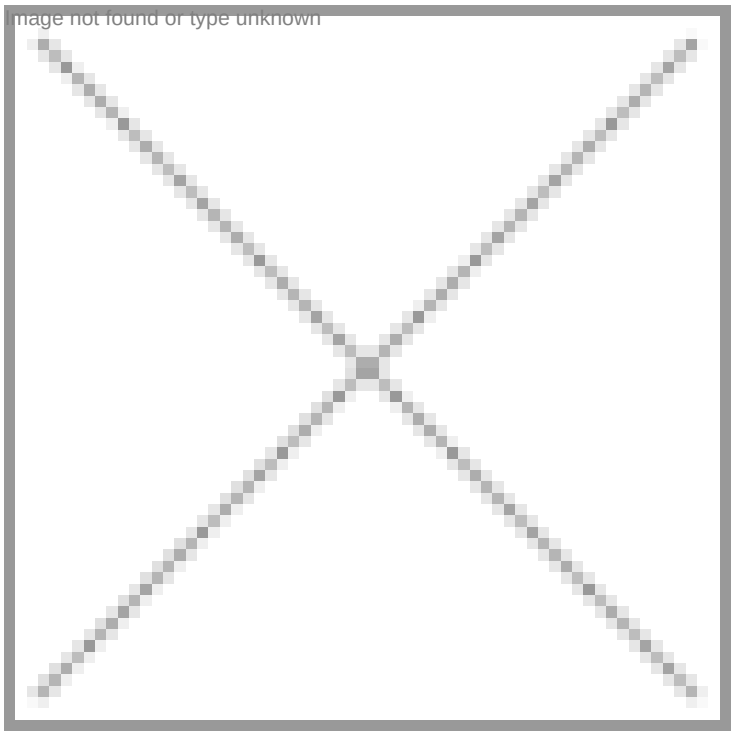

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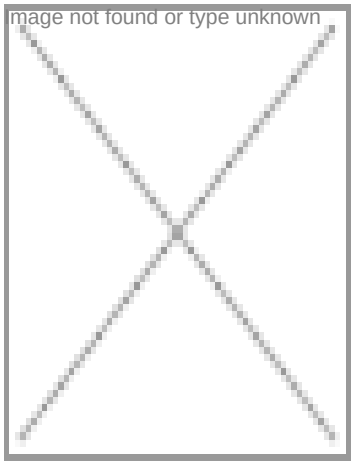

After a gap of few years, yet another virus scare has threatened to engulf the world. The latest outbreak has been caused by the H1N1 virus, a relatively new strain of the influenza virus. It belongs to the same family of H1N5 virus, or the bird flu and the SARS virus that wreaked havoc in some parts of the world in the last five years.

Of course, the world is better prepared this time to handle the crisis. The global attention is also more because the H1N1 virus has infected people in the US, Canada, Germany which are some of the world's most affluent countries. The origin of the outbreak has been traced to Mexico where nearly 200 people have died. Because of the high profile of the countries affected, the World Health Organization (WHO) has drummed up a high pitched campaign and governments around the world have launched surveillance and preventive measures.

The SARS and bird flu outbreaks were also touted to engulf the world. But they were contained quickly even though the most affected countries were China and her Asian neighbors. The lessons learnt from these two earlier outbreaks will come in handy to contain the swine flu which has been renamed by WHO as H1N1 influenza, to prevent any damage to the powerful pork industry in the US. Leading governments have cranked up the production of only known cure against the virus, Oseltamivir, known by its popular brand name, Tamiflu.

More importantly, the innovator of Tamiflu, Roche had licensed Hetero Drugs in Hyderabad, India and few other companiesin Africa to boost production capacity and increase stockpiles with health care agencies around the world. Generics companies like India's Ranbaxy and Cipla too have their own versions of Tamiflu and have offered to produce large quantities of the drug to meet any global emergency.

Clearly, the frequent global scares created by the influenza virus has helped to soften the opposition to generics drug

manufacturers. In fact, these periodic episodes have brought more respectability to generics drug makers as any distressed society will be appreciative of the cure providers even if they are generics drug makers.

May be the time is right for the entry of biosimilar drugs in the world's largest market, the US, which had resisted it so far. The world's largest biopharmaceuticals market is being slowly prised open for the entry of generic versions of expensive biotechnology drugs. Europe set the tone few years back by granting regulatory approval to a biosimilar version of somatropin, Omnitope in 2006. Now the push has come from President Barack Obama's campaign promise to open the US market too gradually for biosimilars.

A legislative attempt to allow the US regulator, FDA, to permit biosimilars fell through during the Bush administration in 2008. With President Obama as a passionate supporter, votaries of biosimilar drugs have unleashed an array of legislative proposals in March to give push for the efforts to lower prices of biotech drugs.

The most notable effort has come from Senators Orrin Hatch and Charles Schumer, representing both spectra of political opinion, who have pitched for providing discretionary powers to FDA to allow follow on biologicals of patented biotech drugs. In fact, their proposal which will be a companion legislation to the path-breaking Drug Price Competition and Patent Term Restoration Act of 1984 or popularly called the Hatch-Waxman Act, seeks an encore. They have proposed reduction in patent exclusivity period from 14 to 5 years. America's top biotech companies are strongly opposed to the new legislative proposals. For the 1984 Act, allowed the emergence of a strong generics pharma industry in countries like India, China and even in Europe to challenge the might of the Big Pharma. Biotech majors fear a similar repeat act by Asia's biotech companies.

With President Obama's support, most experts expect the legislation to sail through and biosimilars would become a realityin the US market by end of 2010.

Asia's biogenerics players have been preparing for this global opportunity. Now they are on the threshold of seeing the long term plans to get a slice of the US market become a reality. However, it will not be cake walk. Asia's biotech companies will have to invest heavily in improving quality and increasing manufacturing capacities. They will also have to build their marketing muscle in the US to make an impact in the shortest possible time. All these steps will require enormous resources and so the companies will have to gear for the new opportunity in the next two years.

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