

China to approve single-dose swine flu vaccines

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In this photo taken Aug. 28, 2009, lab workers check chicken eggs that are being used to develop H1N1 flu vaccine at Shanghai Institute of Biological Products, in Shanghai, China. China will soon approve domestically developed swine flu vaccines that manufacturers say can protect people against the virus with only one dose, an encouraging development for health officials racing to prepare for an expected spike in cases this winter. (AP Photo)

(AP) -- China is close to approving homegrown swine flu vaccines that manufacturers say can protect people with a single dose, an encouraging development for health officials racing to prepare for an expected spike in cases this winter.

Experts said China's versions could boost global efforts to fight the virus if claims they work with just one dose are proven.

Many health authorities have assumed two doses would be needed to offer complete protection against the new H1N1 virus, so a single-dose vaccine means producers could distribute supplies to more people more quickly.

The World Health Organization said it was encouraged after reviewing details of trials of one of the two Chinese vaccines. However, experts said more test results were needed from other vaccine makers around the world to determine if one dose would be potent enough.

"Everybody is desperately hoping that one will do because then that's much easier to administer," said Jodie McVernon, a vaccine expert at the University of Melbourne who is involved in Australian trials of swine flu vaccines for young children. She said she had not seen the Chinese trial results.

China's State Food and Drug Administration said at least two vaccines are near approval after completing clinical trials last month and passing reviews by panels of about 40 experts this week. Another four vaccines are being reviewed, according to the agency.

The vaccine makers, Sinovac Biotech Ltd. and Hualan Biological Engineering Inc., said the clinical trials show they are effective in single doses when used on people aged 3 to 60 years.

International health experts say swine flu has not been as severe as initially feared. At least 2,185 people have died, but most other cases are mild and require no treatment. Worries remain that a rash of new infections could overwhelm hospitals and health authorities, particularly in poorer countries.

In about two weeks, the U.S. expects to announce initial trial results from its vaccine, which is the same type as China's Sinovac version, said

Dr. Anthony Fauci of the National Institutes of Health, who is overseeing American swine-flu vaccine tests.

"From what I've seen and heard of the data, it looks encouraging," Fauci said of Sinovac's clinical trials. "This is very good news. Let's hope the material that we're using has similar results."

WHO said information provided by Sinovac shows that in trials, the vaccines were tested in three formulations of 15 microgram doses, and all gave antibody responses that satisfied regulatory criteria.

"We have no reason to doubt what Sinovac is reporting," said Melinda Henry, a WHO spokeswoman in Geneva. "Certainly if one dose proves sufficient to produce the desired immune response, this would be very encouraging in terms of augmenting the global supply of vaccine in the near future."

China aims to have enough swine flu vaccines for 5 percent of its population by the end of the year, Health Minister Chen Zhu said at a recent flu symposium in Beijing.

Chen said the government was still deciding who to vaccinate first, but health and public service workers and students are among groups likely to be given priority. Only 20 million people in China, or 1 percent of its population, get seasonal flu vaccinations every year, a small proportion compared to the U.S., where around a quarter of the population receive them.

Beyond meeting domestic needs, China's vaccine makers are eager to supply other countries, some of whom have expressed interest, if production can be ramped up.

"If we still have extra capacity, Sinovac is quite open to discuss the

possible opportunities of H1N1 vaccine exports," the Beijing-based company said in an e-mailed response to questions.

Quality concerns would likely arise if China exports vaccines. Though China is a worldwide manufacturing center for pharmaceuticals, suppliers have been known to substitute cheaper and sometimes lethal ingredients. Tainted cough syrup was linked to several deaths in Central America and blood thinners made with contaminated product are suspected in dozens of deaths in the U.S. in recent years.

Last week, Mexico Health Secretary Jose Angel Cordova said Mexico is considering buying vaccines from China, at a cost that is more than 40 percent cheaper than other vaccines being offered to the government. But Mexico would want a guarantee that China's vaccine is safe and effective, he said.

China has said the two vaccines meet the international standards set by the European Medicines Agency, the EU agency responsible for the protection and promotion of public and animal health. However, data on the clinical trials has not yet been published.

Stockpiling vaccines is China's latest move in its aggressive approach to contain the spread of swine flu in the country of 1.3 billion people with relatively limited medical resources.

Chastised by foreign governments and its own people for initially covering up the 2002-03 outbreak of SARS, the communist government has taken strict measures against swine flu since the virus was first reported on the mainland in May.

These include blanket screening of travelers arriving from abroad at airports and quarantining anyone - including entire foreign school groups and New Orleans Mayor Ray Nagin - suspected of contact with an

infected person.

Temperature checks are required to enter schools and many public buildings. Authorities have ordered schools to quarantine students at home if they come in close contact with swine flu patients. In eastern China, authorities said this week that school officials found responsible for a swine flu outbreak at a high school that led to 109 students being infected will be severely punished for not taking temperatures before classes started.

While criticized by some as excessive, Beijing has defended the measures, saying they've limited infections, with around 3,700 cases of swine flu reported on the mainland - none fatal. In the U.S., more than 8,800 cases requiring hospitalization have been reported, with 556 deaths.

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