

EU drug agency: License 2 swine flu vaccines

September 25 2009, By MARIA CHENG , AP Medical Writer



State Health Lab technician Heather Bickley tests samples for H1N1 flu Thursday, Sept 17, 2009 at the Arizona State Health Lab in Phoenix. With Arizona among at least 11 states where swine flu is already widespread, state health officials are casting a surveillance net wider than normal to detect cases of illness and deaths as they try to learn how the outbreak is spreading. (AP Photo/Matt York)

(AP) -- The European Union's drug regulator recommended Friday that two swine flu vaccines be licensed in the 27-nation bloc to ensure their availability before the start of the normal flu season.

The European Medicines Agency called for the vaccines made by [Novartis](#) AG and [GlaxoSmithKline](#) PLC to be granted a marketing authorization. The agency issues advice on whether to license for medicines across Europe, and their decisions are generally accepted by the European Commission and individual countries.

The decision to recommend the vaccines be licensed was made earlier than usual, because tests for both vaccines are ongoing. But authorities wanted to ensure the vaccines would be available before the usual flu season, when a spike in swine flu is expected.

Despite early data showing that one dose of both swine flu vaccines might work in most adults, the European Medicines Agency is recommending a two-dose regimen. Authorities expect further data from ongoing studies and said these recommendations might be updated later.

Other swine flu vaccines are being made by Sanofi-Aventis SA and Baxter International, but have not yet been approved by European authorities.

Novartis' Focetria and GlaxoSmithKline's Pandemrix vaccines both use adjuvants, chemical compounds used to boost the immune system and stretch the vaccine's active ingredient. The adjuvant used by Novartis has been used in flu vaccines since 1997 in more than 45 million doses, while GlaxoSmithKline's adjuvant has only been tested in clinical trials involving several thousand people.

The European Medicines Agency also said [pregnant women](#) and children older than six months should get two doses. There is limited information on how safe vaccines with adjuvants are in both these groups, thought to be particularly vulnerable in a pandemic. Some countries, such as Canada, are buying vaccines without adjuvants for pregnant women.

Novartis said it had already begun shipping the first batches of swine flu vaccine to countries across Europe. It also expects its swine flu vaccine for the U.S., which does not contain an adjuvant, to be shipped to the U.S. by early October.

Glaxo had not yet begun shipping its vaccine. Dozens of countries

worldwide have placed orders with the company for 291 million doses. Glaxo shares were up 0.2 percent in late-morning trading on the London stock exchange.

Many European countries, including Britain, Denmark, France, Spain and Italy, have planned massive swine flu immunization campaigns for the fall.

In a news conference Thursday, the World Health Organization predicted drug makers could produce 3 billion pandemic doses a year. Most of that will go to rich countries who have pre-ordered the vaccine, though nine countries have offered to donate 10 percent of their supplies for the developing world.

This week, China became the first country to begin using the swine [flu vaccine](#): about 44,000 people have so far been vaccinated. WHO said they had received reports of 14 side effects possibly linked to the Chinese-made vaccine, including headaches and dizziness.

WHO officials said any rare and potentially dangerous side effects would likely not be spotted until millions of people start getting [swine flu](#) shots.

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