

## WHO: Swine flu vaccine on track

August 6 2009, By MARIA CHENG, AP Medical Writer

(AP) -- Swine flu vaccine manufacturers are on track to start delivering the first batches of it in September, the World Health Organization said Thursday.

Marie-Paule Kieny, WHO's vaccine director, said several drug makers have started testing <u>swine flu vaccine</u> in humans, and that early safety results should be available next month, clearing the way for its use. Kieny also insisted that speeding the vaccine to the market will not compromise its safety.

WHO has recommended the first recipients of the vaccine be health care workers, perhaps followed by pregnant women and people with underlying health problems.

Kieny said WHO expects to see reports of side effects once the vaccine is given to millions of people, but that deadly side effects will be rare. Vaccines commonly provoke reactions such as nausea, fever, pain from the injection, and diarrhea.

She said the agency would work with country officials to detect any sign the vaccine might cause more worrying side effects, like Guillain Barre syndrome, a temporary paralysis disorder reported by hundreds of people after the U.S.'s disastrous 1976 immunization campaign against another variant of swine flu.

To fight the current pandemic, or global outbreak, half a dozen major pharmaceutical companies located in the United States, Europe and



Australia are developing their own swine flu vaccines, which will have to be approved by drug regulatory authorities in each country where they are used.

It is the first time that companies have rushed to produce a vaccine within months to fight a flu pandemic. Health officials expect swine flu to surge in the fall, with the return of the regular <u>flu season</u>.

On Wednesday, Swiss drug maker Novartis said it had begun testing its swine flu vaccine in Europe, and would begin selling it long before completing its safety tests next year.

Last month, Australian pharmaceutical CSL started trials on its <u>vaccine</u> <u>candidate</u>.

Kieny said ongoing tests in Australia, China, Germany, the United Kingdom and the United States should inform officials how many doses of the vaccine are required. Many experts think people will need two shots to be protected.

Europe and the U.S. both have fast-track approval systems to make the swine flu vaccine available before extensive safety tests are completed.

In a statement on its Web site, WHO said Thursday "the public needs to be reassured" that procedures for approving swine flu vaccines "are rigorous and do not compromise safety or quality controls."

To increase the global supply of swine flu vaccines, WHO recommends that countries use ones containing adjuvants, a component that stretches the vaccine's active ingredient and boosts the body's immune response. Adjuvants are commonly used in flu vaccines in Europe, but there are no licensed flu vaccines with adjuvants in the U.S.



There is little or no information on how safe flu vaccines with adjuvants are in pregnant women and children - two of the groups most at risk in the pandemic.

Kieny dismissed concerns adjuvanted vaccines might not be ideal for groups such as pregnant women. "We see no apparent safety signal," she said. "There is no safety concern with using adjuvanted vaccine."

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