



HEALTHCARE & PHARMA

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Swine flu vaccine data "promising," says EU agency

By Ben Hirschler, Kate Kelland



LONDON (Reuters) - Early clinical trial results show swine flu vaccines now being rushed through development produce a strong immune response, suggesting they should work well, the head of Europe's drugs watchdog said on Thursday.



Governments in Europe have started to take delivery of shots against pandemic H1N1 swine flu but are awaiting a license from European authorities before they can start mass vaccinations.

"It seems to be quite promising," Thomas Lonngren, executive director of the European Medicines Agency (EMA), told a news briefing.

"The immune response to all these vaccines is a very high response, whatever type of vaccine it is, whether it is adjuvanted or non-adjuvanted," he added.

Adjuvants are immune-stimulating compounds added to vaccines to boost their effectiveness.

The strength of the immune response is important in determining not just that the vaccines work but how many doses people will need.

Because swine flu is a new strain, many infectious disease experts have been expecting people will need two doses to get full immunity against the virus.

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However, Novartis said last week that a single dose of one of its experimental vaccines appeared to protect against the virus, raising hopes that potentially tight supplies could go further when mass immunization gets under way.

Lonngren said the finding from Novartis was encouraging and preliminary results from other companies in recent days painted a similar picture of a strong immunogenicity with a range of different types of shot.

ONE SHOT OR TWO?

The issue of whether one or two doses is needed will be evaluated in the light of the clinical trial data that are still coming in, he added.

The EMEA's expert committee on new medicines will consider the first three H1N1 swine flu vaccines from GlaxoSmithKline, Novartis and Baxter -- called Pandemrix, Focetria and Celvapan -- its next meeting on September 21 to 24.

If all goes well, the first swine flu vaccines could be licensed in Europe early in October.

"It will be up to the committee to discuss whether we know enough that we could recommend one or two doses, and of course the most difficult thing for the committee to discuss will be recommendation or non-recommendation for pregnant women and children," Lonngren said.



So far, swine flu vaccines have only be tested in healthy adult volunteers. But many healthcare experts believe children and pregnant should get priority immunization.

Following a recommendation from the EMEA, the shots will still have to get a green light from the European Commission, a process that is expected to take 10 to 20 days under the accelerated approval system for pandemic vaccines.

Editing by Karen Foster

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