



INFLUENZA A/H1N1 (2009) VACCINE

The Ministry of Health (MOH) has secured supplies from GlaxoSmithKline (GSK) for one million doses of its Influenza A (H1N1) vaccine. This is part of our phased and diversified approach in securing a sufficient quantity of the vaccine for our population. The GSK vaccines are expected for delivery by the end of this year.

2 Large scale vaccination, on a voluntary basis, will commence once we are satisfied with the safety and efficacy reviews of this vaccine, currently being undertaken internationally. A few countries have launched or announced their plans to conduct mass vaccinations for their people. We are closely watching their experience.

3 MOH will reserve part of the supply for essential personnel, including those in the healthcare sector. Most of the vaccines will be provided at cost to the GPs for use by their clientele. The cost of the GSK vaccine is comparable to the cost of normal seasonal flu vaccine. If the immediate demand exceeds the initial supply, we will advise the GPs to give greater priority to those who are at higher risk of developing complications from H1N1.

4 Influenza A (H1N1) remains pandemic globally. While it has remained relatively mild, and most patients have recovered fully from the disease, the virus may cause complications and even deaths amongst those with underlying medical problems, such as chronic lung diseases (e.g. asthma), diabetes, gross obesity, low immunity or those who are pregnant.

5 Vaccines are important medical interventions to reduce morbidity and mortality during a pandemic. The GSK contract should meet our immediate needs. MOH has an existing contract with Commonwealth Serum Laboratories (CSL) Australia Pte Ltd for further supplies of H1N1 vaccines.

Supplementary information

Notes about the H1N1 vaccine

- i) Currently, clinical trials to establish the safety and efficacy of H1N1 vaccines are still ongoing and limited safety data is just becoming available in September 2009.
- ii) Due to the urgent need to produce H1N1 vaccines quickly to meet the demands of the pandemic, drug regulatory authorities around the world have developed mechanisms for expediting the review of pandemic vaccines. In Singapore, the Health Sciences Authority (HSA) employs a similar approach of a 'rolling review' submission of pandemic vaccines. This allows vaccine manufacturers to submit data sets for regulatory review as and when they become available, without having to wait until all the data is ready before submission to the authority, as is the case for products reviewed under normal circumstances.
- iii) Based on available scientific data, HSA will advise MOH on the safety and efficacy of the vaccine.
- iv) Like all health products, no vaccine can be guaranteed to be 100 per cent safe. However, initial data available for the H1N1 vaccines and experience with other similar influenza vaccines suggest that these vaccines have a relatively good safety profile. Some serious adverse events related to this class of vaccines have been reported in the past but these have been rare. The common side effects associated with these vaccines include pain at the site of injection, fever, headache, muscle aches and pains. In rare circumstances, some patients may experience severe allergic reactions such as swelling and difficulty in breathing and swallowing, and adverse effects affecting the neuromuscular system such as Guillain Barre Syndrome (gradual paralysis and generalised loss of reflexes).
- v) As H1N1 vaccines may be used in a very large number of patients during a pandemic, certain adverse events which are too rare to show up in clinical trials may become apparent when a significant number of patients are given the vaccines. However, given the safety record of seasonal flu vaccines, such events are likely to be rare.
- vi) To address these safety concerns, the World Health Organisation has advised all countries who are considering administering the pandemic vaccines to conduct intensive monitoring for safety. In line with this, HSA will be intensifying its safety surveillance activities to closely monitor the safety of the pandemic vaccines as they are used, so that rapid action can be taken to safeguard the health and safety of the public if this becomes necessary.



Ministry of Health, Singapore
College of Medicine Building
16 College Road
Singapore 169854
TEL (65) 6325 9220
FAX (65) 6224 1677
WEB www.moh.gov.sg