

**Vaccination Programme:
Human Swine Influenza,
Pneumococcal and Seasonal Influenza**

**Response to issues raised by
the Legislative Council Panel on Health Services on 10 June 2009**

Purpose

This note sets out the Administration's response to the issues raised by the Panel on Health Services at its special meeting on 10 June 2009.

Procurement of Human Swine Influenza vaccines

2. To allow fair competition amongst potential suppliers, the human swine influenza (HSI) vaccines will be procured through open tender.

3. We will include in the tender documents the technical specifications of the vaccines to ensure that they are of good quality. As far as the manufacturer is concerned, we would require the Good Manufacturing Practices (GMP) status of the manufacturer, detailed information on the production and quality control facilities, documentary proof of the qualifications and experience of its professional and technical personnel, and the manufacturing methods being in compliance with the requirements set out by the World Health Organization (WHO) for the manufacturing of influenza vaccines. We would also lay down a number of quality requirements of the vaccines, such as limits of bacterial endotoxins, ovalbumen (i.e. egg albumen), total protein, and the adjuvant used (if any), and would require the supplier to provide the master formula of the vaccine and a batch release certificate to demonstrate that the batch meets all the quality and safety requirements of the WHO. Moreover, we would require eventual approval of the vaccines by the drug regulatory authorities of either the United States or the European Union as a condition in the procurement contract.

Risks involved in receiving HSI vaccine

4. The main risk involved in HSI vaccine is its possible side effects. Rare but severe vaccine adverse reactions may not be apparent in clinical trials until mass vaccination is administered. One of the possible side effects is the Guillain-Barré Syndrome (GBS) which is a rare neurological disorder causing paralysis and respiratory difficulties. According to medical literature, every year there are about one to two GBS cases per 100,000 population, most of which have no identifiable cause. Seasonal influenza vaccination may be associated with an excess incidence of one GBS case per one million vaccinations. During the swine flu outbreak at Fort Dix, USA in 1976, a higher incidence (up to 10 times) of GBS was observed among persons receiving swine flu vaccines at that time compared with those who did not. Experts of the Scientific Committees of the Centre for Health Protection note that modern HSI vaccine preparations contain a much lower dose of swine flu antigen than the 1976 swine flu vaccine, and quality control of vaccines has improved substantially in recent decades.

5. In considering whether a defined population group is recommended to receive vaccination, the Scientific Committees have assessed the protective benefits of vaccination for the defined population group against potential side effects including rare ones like GBS. The rationale for vaccinating health care workers with HSI vaccine is to maintain essential medical service for the public during the pandemic. The other specified target groups (elderly, young children and people with pre-existing medical conditions) are at increased risk of medical complications, hospitalisation and death arising from HSI. If these at-risk groups do not receive vaccination, they have a greater chance succumbing to HSI than experiencing the rare possible side effect of GBS associated with the vaccine.

Assessment of the usage of HSI vaccine

6. The eventual take-up rate of the vaccine would depend on various factors including the development of the pandemic in the next few months and public perception of the possible side effects of the vaccine. Demand for the vaccine would be greater if more people got infected and came down with serious illnesses. The cost involved in procuring and providing five million

doses of HSI vaccines should be seen as the “insurance premium” to be paid by the community for safeguarding public health against HSI.

Detailed Analysis made by the Scientific Committees

7. In drawing up the recommendations, the Scientific Committees examined the worldwide epidemiology of the disease and took into account priority groups proposed by different health authorities, including WHO, the United States, the United Kingdom and Australia.

8. Priority groups recommended for HSI vaccination should be determined taking into account factors including the severity of clinical illness and complications, attack rates, potential vaccine adverse events, maintenance of essential workforce to deliver healthcare services, etc. Assuming HSI vaccines are available and based on current knowledge about HSI infection, such priority groups include –

- (a) healthcare workers;
- (b) persons with certain pre-existing medical conditions;
- (c) elderly persons aged 65 years and above; and
- (d) children aged 6 months to below 6 years.

9. The balance between benefits of vaccination and potential risk of adverse vaccine effects is less clear for other groups of the population at this point in time. Further scientific evidence is needed to make a case for vaccination in other groups of the population.

Vaccination arrangements for the elderly

10. For elderly aged 65 and above who are now on the Government Influenza Vaccination Programme (GIVP), the vaccination of HSI, pneumococcal and seasonal flu vaccines will be delivered mainly in public hospitals and clinics. For elderly currently not on the GIVP, we would discuss with the private medical sector their participation in the vaccination programme besides the option of provision by the public sector. We would also try to solicit the assistance of other agencies for delivering the vaccination.

11. We will brief the Panel on Health Services on the implementation of the vaccination programme for HSI, pneumococcal and seasonal flu in October after the details have been worked out.

Number of elderly on GIVP

12. In 2008-09, out of the 410 000 elderly aged 65 and above who are eligible to receive seasonal flu vaccination under the GIVP, about 210 000 of them had received the vaccination. Amongst them, over 58,000 are residents of care homes for the elderly. The vaccination rate for this group of elderly was over 90%.

Healthcare workers who received seasonal influenza vaccination

13. In 2008-09, the coverage rate of seasonal influenza vaccination for healthcare workers was 57-70% in residential care homes, 60% in the Department of Health and 40% in the Hospital Authority.

Advice Sought

14. Members are invited to note the content of this paper.

Food and Health Bureau
June 2009