

LEGISLATIVE COUNCIL BRIEF

VACCINATION PROGRAMME: HUMAN SWINE INFLUENZA, PNEUMOCOCCAL AND SEASONAL INFLUENZA

INTRODUCTION

At the meeting of the Executive Council on 9 June 2009, the Council ADVISED and the Chief Executive ORDERED that the following vaccination programme should be pursued –

Human Swine Influenza

- (a) Government to initiate immediately the process for procurement of human swine influenza (HSI) vaccines for a target group of the population recommended by the Scientific Committees of the Centre for Health Protection, i.e. healthcare workers, young children, elderly and persons with certain pre-existing medical conditions. We will gather facts from various vaccine manufacturers on the quality, availability and price of HSI vaccines; prepare tender for the eventual procurement of the vaccines; and seek funding approval from the Finance Committee of the Legislative Council;
- (b) through tendering, Government to place an order for the procurement of five million doses to cover the target group of about two million people, as vaccine manufacturers have recommended that two doses are required for each person. The order will include safeguard clauses to require eventual approval of the vaccines from overseas drug authorities such as those of the US and/or the European Union;
- (c) after the vaccines are delivered, the Government to administer a one-off vaccination programme covering the target group;

- (d) this vaccine programme is free for the target group but vaccination is voluntary. Government is prepared to release about one million doses to the private medical sector on a cost recovery basis to cater for demand of persons outside the target group who wish to receive vaccination voluntarily; and

Pneumococcal and Seasonal Flu Vaccinations for the Elderly

- (e) to enhance the protection of HSI vaccination for the elderly aged 65 and above through complementary pneumococcal and seasonal flu vaccinations, as detailed in paragraphs 16 to 19 below.

JUSTIFICATIONS

Scientific Evidence

2. Newly confirmed cases of HSI have continued to emerge in 74 countries/areas with over 24 000 cases as at 8 June 2009, including 136 fatal cases. In Hong Kong, there were 41 imported cases up to 8 June 2009. Having regard to the global situation of HSI and the recent development of disease transmission in countries/areas in the region, most experts agree that local transmission in Hong Kong is both imminent and inevitable.

3. Although the HSI virus appears to be relatively mild so far outside Mexico, it has resulted in a number of deaths mainly among persons with pre-existing medical conditions. It is uncertain at this point in time whether the HSI virus remains mild, or will become more virulent or severe. According to the World Health Organization (WHO), seasonal influenza vaccine is unlikely to provide protection against the virus.

4. Past records suggest that seasonal influenza (of different variety of virus strain and type from season to season) accounts for about 1,000 deaths in Hong Kong every year. However, even if the severity of HSI remains similar to seasonal influenza, it is as yet unclear if hospitalisation needs and deaths arising from it would substitute or add to that of seasonal influenza, particularly for the coming influenza peak.

5. The Scientific Committees of the Centre for Health Protection (CHP), which comprise local experts in the field, have held discussions on the subject. Based on current scientific information, the Scientific Committees recommend the following target group to receive HSI vaccines as and when the vaccines became available. The target group, which has an estimated population of around two million, includes -

- (a) healthcare workers in both the public and private sectors;
- (b) children aged six months or above and below six years old;
- (c) elderly persons aged 65 and above; and
- (d) persons at higher risk of death and complications from HSI due to pre-existing medical conditions¹.

6. The Scientific Committees have also recommended elderly persons aged 65 and above to receive vaccination against pneumococcal bacteria and seasonal influenza. Pneumococcal and seasonal influenza vaccines play an important role alongside HSI vaccine in mitigating the impact of HSI epidemic in Hong Kong. They complement HSI vaccine in reducing deaths and hospitalizations among elderly people when the latter are infected with HSI. For example, pneumonia due to pneumococcal infection is a major and well established complication of influenza (and hence HSI) among elders. A recent study by the University of Hong Kong also showed that pneumococcal and seasonal flu vaccinations in elderly people were effective in reducing pneumonia and hospital admissions.

Risks Involved for HSI Vaccines

7. In considering whether HSI vaccines should be provided, various clinical circles have discussed the following uncertainties and risks involved –

- (a) Vaccines to be produced at this stage could only be based on the HSI strain currently available. It is uncertain whether and how the virus will mutate as the epidemic evolves. However, there is good scientific evidence to show that such vaccines should be able to afford a degree of cross protection against HSI infection in general.
- (b) While some vaccine manufacturers have started to develop HSI vaccines and conducted clinical trials on the prototype, the vaccines have not been applied on a large scale so far. Rare but severe vaccine adverse reactions may not be apparent in clinical trials until mass vaccination is administered. Possible side effects include the Guillain-Barré Syndrome² which can cause paralysis sometimes resulting in permanent disability.

¹ Pre-existing medical conditions include chronic cardiovascular, pulmonary, metabolic, renal, neurological diseases, as well as immunosuppressive disorders, pregnancy, etc.

² Guillain-Barré Syndrome (GBS) is a rare neurological disorder causing paralysis and even respiratory difficulties. Seasonal influenza vaccination may be associated with an excess incidence of GBS of 1 per 1 million among vaccinees. 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 compared with those who did not, though a causal relationship remains controversial. Experts of Scientific Committees of the CHP note that modern HSI vaccine preparations should be safer as they use a much lower dose of swine flu antigen than the 1976 vaccine.

- (c) Manufacturers may use different adjuvants³ for the HSI vaccines. Non-adjuvanted vaccines or those with the traditional alum adjuvant are considered by some in the Scientific Committees as safer mainly due to their long history of use, whereas those with the newer adjuvants have a much shorter and weaker track record. However, it is understood that the newer adjuvants have two main advantages over the non-adjuvanted or alum-adjuvanted vaccines in that (i) they are dose-sparing, i.e. they require less antigen thus allowing the production of more doses in total and (ii) they may confer added cross-protection against different strains of the virus. The Scientific Committees consider that non-adjuvanted vaccines or those adjuvanted with alum have a better safety profile but recognise that preference on the procurement necessarily needs to also take into account factors such as availability and timing of delivery.
- (d) Vaccines being developed have yet to obtain approval from overseas drug authorities such as those of the US and the European Union, pending the necessary clinical trials. According to vaccine manufacturers, regulatory approval is expected towards the end of the year. For Hong Kong, such vaccines would be deployed only after regulatory approval by an overseas authority and consequential local registration by the Department of Health (DH).

Need for Early Procurement of HSI Vaccines

8. While regulatory approval of the HSI vaccines is still outstanding, we need to take a decision soonest possible for Government to start the process of procuring the vaccines. As a city without local capability and capacity of manufacturing vaccines, taking an early decision is the only way that Hong Kong could secure adequate supply of vaccines as international demand is becoming strong. According to various sources including press reports, a number of countries are already taking steps to secure, stockpile or research into HSI vaccines, including US, Australia, UK, France, Belgium, Sweden, Finland and Thailand, and advance purchase agreements are in place between different major OECD countries and vaccine manufacturers. Mass production of HSI vaccines takes considerable lead-time. While multiple manufacturers are competing to produce such vaccines (via different methods), some major manufacturers have already indicated that governments would need to confirm orders within the next few weeks in order for supply to be guaranteed. When there are competing demands especially

³ Adjuvants are chemical substances added to vaccines to enhance their potency in stimulating the body's immune response. For example, alum is the most traditional adjuvant added to vaccines. Vaccine companies have explored other more potent adjuvants in recent years.

major bulk orders from various governments, it is unlikely that smaller orders such as those from Hong Kong would be given priority.

9. We propose to initiate immediately the process for the procurement of the vaccines, including commencing the tendering procedures and negotiations with the manufacturers. As there is a lead time of four to six months between placing the order and delivery, we will have to order now so that the vaccines are ready for use in the coming flu season. Vaccine manufacturers have recommended that two doses are required for each person. We will order five million doses to cover the target group of about two million people, and the other one million doses will be released to the private medical sector on a cost recovery basis to cater for demand of persons outside the target group who wish to receive vaccination voluntarily at their own cost. Hong Kong is placing a very small order in the global context. We may be required to pay a deposit which is not refundable. In fact for such a small order, it is possible that the manufacturers will require full payment to be made before delivery.

10. HSI vaccines are only available to governments so far. There is no alternative to Government procuring the vaccines unless we decide not to take the recommendation of the Scientific Committees to vaccinate the target group. If we do not start the procurement for HSI vaccines now, as mentioned in paragraph 8 above, it is unlikely that we will be able to secure supply later this year.

11. The Scientific Committees consider that the balance between benefits of HSI 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. Moreover, oseltamivir (known by trade name as Tamiflu) and zanamivir (known by trade name as Relenza) remain effective chemoprophylaxis and treatment options against HSI so far, and can contain the viral load of the patients and the risk of infecting others to a reasonably low level. Both oseltamivir and zanamivir are maintained in the Government's antiviral stockpile.

Implementation Plan of HSI Vaccination

Tender

12. We will adhere to the usual open tender procedures and will safeguard Government's interests during the procurement process.

Availability

13. It is generally anticipated that manufacturers will be able to produce the first batch of vaccines around September this year. Given the lead time for going through clinical trials and approval processes with relevant drug regulatory authorities of the advanced economies, most notably the US Food and Drug Administration and the EU European Medicines Agency, vaccines may become commercially available towards the end of this year.

Delivery

14. The actual vaccination will be delivered principally by the public sector or subject to further discussion, also with the private medical sector. We shall discuss with the private medical sector.

Free but Voluntary Vaccination

15. We propose to administer the vaccination for the target group free of charge, in order to induce those in the target group to take the new vaccine, both for their own sake and for minimizing the spread of HSI in the community, at a time when HSI is expected to be a clear threat. The service is one-off. The vaccination will be voluntary in nature. It is a common law principle that a person is generally at liberty to decline to undergo treatment (including vaccination), and it is unlawful to administer treatment to an adult without his consent. The Prevention and Control of Disease Ordinance (Cap 599) only provides for the power to place a person under medical surveillance, quarantine or isolation, but does not provide for any power to compel a person to receive vaccination. It would also be ultra vires to put a person under quarantine simply because he refuses to be vaccinated. Any other form of making the vaccination mandatory (e.g. making vaccination a requirement for people undertaking certain jobs) would be undesirable, as the Government may have to bear the responsibility or liability for any complications or other problems arising from the vaccination. All existing vaccination programmes in Hong Kong are voluntary.

Pneumococcal and Seasonal Flu Vaccines for the Elderly

16. In accordance with previous recommendations of the Scientific Committees, the Government is now running a scheme called Government Influenza Vaccination Programme (GIVP) under which target groups (i.e. at-risk and/or under-privileged) are provided with free seasonal flu vaccines at public hospitals or clinics. The private sector does not participate in this programme. The existing scheme is not administered by reference to age. For background information, at present some 200,000 elderly aged 65 and

above having chronic illness or receiving Comprehensive Social Security Assistance (CSSA) are receiving vaccinations under the programme.

17. The elderly population group is most prone to hospitalization and is already the heavy user of public hospital services. In view of the clear scientific evidence of the efficacy of the proposed pneumococcal and seasonal flu vaccinations for the elderly population in reducing hospitalization, complications and mortality mentioned in paragraph 6 above, it is imperative that we should aim for a high vaccination rate among this group. We propose to achieve this by making the vaccinations available to the elderly population without their having to pay extra fees as far as possible. Our proposal is to extend the provision of pneumococcal and seasonal flu vaccines to **all** elderly aged 65 and above. Unlike seasonal flu vaccine which has to be administered every year, one pneumococcal vaccination is effective for ten years. Many developed countries including the UK, US, and Australia are already offering free pneumococcal and seasonal flu vaccines to all elderly.

18. Specifically, we propose to provide the elderly population aged 65 and above with the two vaccines through the following –

For elderly on GIVP

- (a) Expanding the GIVP to provide pneumococcal vaccination free of charge, in addition to existing seasonal flu vaccination, for elderly people aged 65 and above. Along with existing arrangement, the vaccinations will take place in public hospitals and clinics.

For elderly not on GIVP

- (b) For those elderly aged 65 and above who are not on GIVP, they will receive pneumococcal and seasonal flu vaccinations in the private medical sector. Government will discuss with private medical doctors on the reimbursement arrangements for those participating in the scheme. This is separate from the existing vouchers provided to elderly aged 70 and above under the Elderly Health Care Voucher three-year pilot scheme (five vouchers of HK\$50 each for each year). We should note that the Elderly Health Care Voucher pilot scheme is only offered to all elderly people aged 70 and above, whereas our present proposal provides vaccinations to all elderly at 65 and above. Setting the eligibility to elderly at 65 and above, as against 70, for vaccination purpose is based on the recommendation of the Scientific Committees that this population group has a higher rate of hospitalisation and complications arising from influenza and pneumococcal bacteria. It should not have any implications on other elderly schemes.

19. The pneumococcal and seasonal flu vaccinations for the elderly will be administered first starting in the last quarter of 2009.

IMPLICATIONS OF THE PROPOSAL

Annex

20. The proposed vaccination programme has financial and civil service implications as set out at the Annex. The proposal which is voluntary in nature is in conformity with the Basic Law, including provisions concerning human rights. It has no productivity and environmental implications. In overall terms, the proposals are not expected to have any significant economic implications. The proposals of extending pneumococcal and seasonal flu vaccinations to elderly aged 65 and above and the introduction of new HSI vaccine to the target group have no significant sustainability implications although they should help safeguard the public health and safety of the Hong Kong residents.

PUBLIC CONSULTATION

21. Initial sounding out of plans for such a programme has received general support from the medical community and positive feedback from the public in general. The Scientific Committees of CHP have held expert discussions on the subject at their meetings.

PUBLICITY

22. We will brief the Legislative Council Panel on Health Services and then seek funding approval from the Finance Committee of the Legislative Council. A press briefing will be held.

ENQUIRIES

23. Any enquiries on this Brief may be addressed to Ms Shirley LAM, Principal Assistant Secretary for Food and Health (Special Duty)² at 2973 8293.

Food and Health Bureau
June 2009

**VACCINATION PROGRAMME:
HUMAN SWINE INFLUENZA,
PNEUMOCOCCAL AND SEASONAL INFLUENZA**

FINANCIAL AND CIVIL SERVICE IMPLICATIONS

The financial and civil service implications of the proposed vaccination programme are set out below.

HSI

2. For HSI vaccines, the one-off non-recurrent expenditure for 2009-10 covering the vaccine and injection costs for the target group will be borne by the Government. The costs for the vaccines and injection for the target group population is budgeted to be HK\$600 million [(HK\$100 vaccine cost + HK\$50 injection cost covering staff and other administrative costs) x 4 million doses]. For the other one million doses catered for persons not in the target group but wish to receive vaccination at their own cost, Government will procure the vaccines first but will recover the vaccine cost and the administration cost afterwards. The cost that Government will need to incur upfront is HK\$100 million (HK\$100 vaccine cost x 1 million doses). As the actual demand is not known yet, we are unable to estimate at this stage the exact cost that could be recovered.

Seasonal Flu Vaccination for the Elderly

For Elderly not on GIVP

3. For the seasonal flu vaccines, the expenditure for 2009-10 covering all elderly aged 65 and above who are not on the existing GIVP is estimated to be HK\$99.9 million [(HK\$100 + HK\$50 injection cost) x 666,000 persons].

For Elderly on GIVP

4. Under the GIVP, all elderly people aged 65 and above in the at-risk and under-privileged group are already entitled to seasonal flu vaccination. The expenditure for 2009-10 will be HK\$33 million [(HK\$100 + HK\$50 injection cost) x 220,000 persons). Recurrent funding is already committed for this purpose.

Pneumococcal Vaccination for the Elderly

5. For the pneumococcal vaccines, the expenditure in 2009-10 for covering all elderly aged 65 and above is estimated to be HK\$168.34 million [(HK\$140 per dose + HK\$50 for injection) x 886,000 elderly].

Overall Cost Implications

6. The total estimated cost for the various vaccines and injections in 2009-10 is \$1.001 billion. Details are as shown at the Appendix. Of this amount, \$33 million is already committed (paragraph 4 above). We are therefore proposing the creation of a new commitment of \$968 million. We will seek funding approval from the Finance Committee of the Legislative Council.

7. All the cost estimates set out above are ballpark figures estimated on the basis of the latest information and assumptions available and are therefore subject to refinement taking into account the actual implementation details. Besides, additional staff resources and other administration costs (over and above the injection cost quoted above) may be required by DH and HA in administering the HSI vaccination programme, registering doctors and the elderly for seasonal and pneumococcal vaccinations and upgrading the IT systems, the logistics for the delivery and administration of vaccinations, the accounting arrangements as well as other support services. Such manpower and financial requirements will be worked out when more details can be made available in due course and the necessary provisions will be sought through the established resources allocation mechanism.

Rough Cost Estimates for Proposed Influenza and Pneumococcal Vaccination for 2009-10

Item no.	Description	Scope	Number of recipients (maximum total)	Dose per recipient	Cost per dose (ballpark) (\$)	Administering cost per dose (\$) (<i>Note 1</i>)	Annual cost (for vaccines and injection only) (\$m) (<i>Note 2</i>)
1	Human Swine Influenza Vaccines	Target group: (1) Children 6 mths - <6 yrs; (2) Elderly 65+; (3) persons with certain pre-existing medical conditions; and (4) Healthcare workers.	2,000,000	2	100	50	600.00
		Others not in the target group who wish to receive vaccination at their own cost	500,000	2	100	-	100.00
2	Seasonal Influenza Vaccines	Elderly 65 and above	886,000	1	100	50	132.90
3	Pneumococcal Vaccines	Elderly 65 and above	886,000	1	140	50	168.34
Total							1,001.24

Note:

1. The cost for administering the vaccination through the public sector is estimated to be about \$50 per dose.
2. For HSI, vaccine cost is one-off. For seasonal flu, cost has to be incurred annually. For pneumococcal for elderly, vaccine is effective for ten years but every year there will be new recipients (cohort of elderly turning 65).