For discussion **FCR(2009-10)29**
on 19 June 2009

ITEM FOR FINANCE COMMITTEE

HEAD 37 – DEPARTMENT OF HEALTH
Subhead 700 General non-recurrent
New Item "Human Swine Influenza Vaccination"
New Item "Pneumococcal and Seasonal Influenza Vaccination"

Members are invited to approve the following new commitments for 2009-10 -

(a) a new commitment of $700 million for procurement of human swine influenza vaccine and the related injection; and

(b) a new commitment of $268 million for procurement of pneumococcal and seasonal influenza vaccines and the related injection.

PROBLEM

Human swine influenza (HSI) (Influenza A H1N1) is now a clear pandemic threat. We need to safeguard public health by devising a programme to provide vaccines to protect the target group of population which is more vulnerable and has a higher rate of hospitalisation and complications arising from HSI, seasonal influenza as well as the associated pneumococcal infections, which are all vaccine preventable diseases. Procurement process has to start early to secure a guaranteed supply of HSI vaccines as production capacity is limited against a strong global demand.

PROPOSAL

2. The Secretary for Food and Health proposes to create two new commitments for the Department of Health (DH) to meet the estimated expenditure of –

/(a) .....

(a) procuring five million doses of HSI vaccine to cover the estimated two million people in the target group as recommended by the Scientific Committees of the Centre for Health Protection (CHP), i.e. healthcare workers, young children, elderly and persons with certain pre-existing medical conditions; and another 500 000 people who are not in the target group but wish to receive vaccination at their own cost (according to vaccine manufacturers, each person needs two doses). We will also cover the injection cost for those in the target group. The estimated expenditure for the procurement of vaccines and the related injection cost in 2009-10 is $700 million; and

(b) procuring pneumococcal and seasonal flu vaccines and providing injection for elderly aged 65 and above, as recommended by the Scientific Committees of the CHP. The estimated expenditure for the procurement of vaccines and the related injection cost in 2009-10 is $268 million.

JUSTIFICATION
HSI Vaccination

Scientific evidence

3. Newly confirmed cases of HSI have continued to emerge in more than 74 countries/areas with over 25 000 cases as at 10 June 2009, including 140 fatal cases. In Hong Kong, there were 49 cases up to 10 June 2009. The first cluster of indigenous cases was confirmed on 11 June 2009. The threat of HSI on public health is imminent and the situation in winter would be even more severe.

4. 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.

5. Past records suggest that seasonal influenza (of different variety of virus strains and types 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.

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6. The Scientific Committees of the 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 become 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 conditions.[1]

7. In making the above recommendation, the Scientific Committees are aware that the new HSI vaccine being developed has 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. One of the possible side effects is the Guillain-Barré Syndrome (GBS) which is a rare neurological disorder causing paralysis and even 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. The relationship between seasonal influenza vaccination and the very rare condition of GBS is nothing new and has been discussed for many years. 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 compared with those who did not, though a causal relationship remains controversial. Experts of Scientific Committees note that modern HSI vaccine preparations should be safer as they use a much lower dose of swine flu antigen than the 1976 vaccine. 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. Since the specified target groups (paragraphs 6(b), (c) and (d) above) are at increased risk of medical complications, hospitalisation and death arising from HSI, the Scientific Committees are of the opinion that the benefits of HSI vaccination outweigh its risks in these target groups.

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

8. 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.

Risks involved for HSI vaccines

9. 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) Possible side effects of HSI vaccines are uncertain at this stage as mentioned in paragraph 7 above.

(c) Manufacturers may use different adjuvants[2] 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.

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[2] 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.

(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, we will require eventual approval of the vaccines from overseas drug authorities such as those of the US and/or the European Union and the vaccines would be deployed only after such approval is obtained and consequential local registration by the DH.

Need for early procurement of HSI vaccines

10. While regulatory approval of the HSI vaccines is still outstanding, we need to start the process of procuring the vaccines early. 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. As a city without local capability and capacity of manufacturing vaccines, starting the procurement process early 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 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 to guarantee supply. When there are competing demands especially major bulk orders from various governments, it is unlikely that smaller orders such as those from Hong Kong would be given priority.

11. We propose to proceed with the procurement process expeditiously with the objective of securing vaccines 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 another 500 000 people who are not in the target group. Hong Kong is placing a very small order in the global context. We may be required to pay a deposit which is not refundable.

12. 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 10 above, it is unlikely that we will be able to secure supply later this year.

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13. 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 in case there is an outbreak. The eventual take-up rate of the vaccine would depend on the development of the pandemic in the next few months. It is possible that the take-up rate would be low if the epidemic eases, but chances are more people would be infected by HSI with the arrival of the flu season in winter which would result in a greater demand of the vaccine.

Implementation plan

Tender

14. We will adhere to the usual open tender procedures. We will include provisions in the tender documents to ensure the quality of the vaccine. Other relevant factors such as the payment schedule, delivery timetable and price would also be considered before deciding on the award of the tender. We will safeguard Government's interests during the procurement process.

Availability

15. 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

16. The service is one-off. The actual vaccination will be delivered principally by the public sector free of charge to those in the target group, in order to induce them to take the new vaccine, both for their own sake and for minimising the spread of HSI in the community, at a time when HSI is expected to be a clear threat. The one million doses of vaccines for those who are not in the target group will be released to the private medical sector on a cost recovery basis. Persons outside the target group who wish to receive vaccination voluntarily have to do so at their own cost. We shall further discuss with the private medical sector on their participation in the vaccination programme. We will appeal to them to join Government to fight against the pandemic for the cause of public health.

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Voluntary vaccination

17. 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

18. 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 solely 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 every year.

19. The Scientific Committees have recommended all 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 death and hospitalisation 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.

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20. The elderly population group is most prone to hospitalisation 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 hospitalisation, complications and mortality, 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.

Implementation plan

21. We propose to provide the elderly population aged 65 and above with the two vaccines through the following –

(a) For elderly on GIVP
Expanding the GIVP to provide pneumococcal vaccination free of charge, in addition to existing seasonal flu vaccination, for elderly people aged 65 and above having chronic illness or receiving CSSA. The vaccinations will take place in public hospitals and clinics.

(b) For elderly not on GIVP
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 $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 aged 65 and above. Setting the eligibility to elderly aged 65 and above, as against aged 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.

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

/**FINANCIAL** .....

FINANCIAL IMPLICATIONS

HSI Vaccination

23. For HSI vaccines, the one-off non-recurrent expenditure covering the vaccine and injection costs for the target group in 2009-10 will be borne by Government. Our initial understanding from possible suppliers is that each dose would cost about $80 - $100. The injection cost is estimated to be $50 per dose, 90% of which is manpower cost while the remaining is expenditure on necessary equipment, logistics support for the delivery of vaccines and administrative overheads etc. The cost for the vaccine and injection is budgeted to be $700 million as follows –

Number of recipients	Dose per recipient	Cost per dose (ballpark) ($)	Injection cost per dose ($)	Total cost for vaccines and injection ($m)
2 000 000 (Target Group)	2	100	50	600
500 000 (Non Target Group)	2	100*	Not provided	100
Total Cost				**700**

* To be recovered at cost from the recipients.

Pneumococcal Vaccination for the Elderly

24. For the pneumococcal vaccine, the expenditure for covering all elderly aged 65 and above in 2009-10 is as follows –

Number of recipients	Dose per recipient	Cost per dose (ballpark) ($)	Injection cost per dose ($)	Total cost for vaccines and injection ($m)
886 000	1	140	50	168.34

Say,
$168 million

/Seasonal .....

Seasonal Flu Vaccination for the Elderly

For elderly on GIVP

25. Under the GIVP, all elderly people aged 65 and above in the at-risk and/or under-privileged group are already entitled to seasonal flu vaccination. Recurrent funding is already committed for this purpose. The related expenditure under the 2009-10 GIVP is as follows –

Number of recipients	Dose per recipient	Cost per dose (ballpark) ($)	Injection cost per dose ($)	Total cost for vaccines and injection ($m)
220 000	1	100	50	33

For elderly not on GIVP

26. The estimated expenditure in 2009-10 covering all elderly aged 65 and above who are not on the existing GIVP is as follows –

Number of recipients	Dose per recipient	Cost per dose (ballpark) ($)	Injection cost per dose ($)	Total cost for vaccines and injection ($m)
666 000	1	100	50	99.9

Say,
$100 million

Overall Cost Implications

27. The total estimated cost for the various vaccines and injections in 2009-10 is $1,001 million. Of this amount, $33 million is already provided for under Head 37 – Department of Health (paragraph 25 above). We therefore propose the creation of two new commitments of $700 million for implementing HSI vaccination and $268 million for implementing pneumococcal and seasonal influenza vaccinations in 2009-10.

PUBLIC CONSULTATION

28. On 10 June 2009, we consulted the Legislative Council (LegCo) Panel on Health Services. Members of the Panel supported the proposed vaccination programme and noted our plan to seek funding approval from the Finance Committee of the LegCo. Some Members were concerned about the possible side effects of the HSI vaccines and the implementation of the vaccinations. We have explained to Members that after balancing the risks involved, it is more beneficial for the target group to receive HSI vaccines. The Administration will work out the detailed implementation plan for the vaccinations and brief Members of the Panel on Health Services in due course. We have also briefed the District Council Chairmen and Vice Chairmen who support the proposed vaccination programme.

BACKGROUND

29. The first imported case of HSI in Hong Kong was confirmed on 1 May 2009. Since then Government has stepped up disease control effort on all fronts. We have instituted a series of rigorous entry screening measures at our border control points, including health declaration and temperature screening. Our efforts have helped to delay the import and transmission of this new infectious disease in Hong Kong.

Food and Health Bureau
June 2009