(Revised)

For discussion
on 26 February 2021

FCR(2020-21)94

ITEM FOR FINANCE COMMITTEE

HEAD 140 – GOVERNMENT SECRETARIAT: FOOD AND HEALTH BUREAU (HEALTH BRANCH)
Subhead 700 General non-recurrent
New Item "Indemnity Fund for Adverse Events Following Immunization with Coronavirus Disease-2019 Vaccines"

Members are invited to approve the creation of a new commitment of $1 billion under Head 140 Government Secretariat: Food and Health Bureau (Health Branch) Subhead 700 General non-recurrent for the setting up of an Indemnity Fund for Adverse Events Following Immunization with Coronavirus Disease-2019 Vaccines.

PROBLEM

The Government is setting up an Indemnity Fund for Adverse Events Following Immunization with Coronavirus Disease-2019 (COVID-19) Vaccines (AEFI Fund) to cover the indemnities offered to vaccine manufacturers under bilateral purchase agreements, and to provide support to individuals who have proof of suffering unexpected serious adverse events (SAEs) associated with a COVID-19 vaccine.

PROPOSAL

2. The Secretary for Food and Health, proposes the creation of a new commitment of $1 billion under Head 140 Government Secretariat: Food and Health Bureau (Health Branch) (FHB(H)) for the setting up of an AEFI Fund.

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JUSTIFICATION

Procurement of vaccines

3. The Government has been adopting a "two-pronged" strategy to procuring vaccines meeting the criteria of safety, efficacy and quality. In addition to joining the COVAX Facility led by the World Health Organization (WHO), we have entered into advance purchase agreements (APAs) with individual vaccine developers for obtaining additional supplies, having regard to the advice of the Joint Scientific Committees[1] under the Department of Health (DH) and experts as well as scientific evidence and clinical data. We target to procure at least one vaccine from each of the four technology platforms[2]. In terms of volume, we plan to cater for at least two times the Hong Kong population as a hedging strategy.

4. As at 9 February 2021, we have reached agreement with three vaccine developers to procure vaccines developed from different technology platforms. Under a two-dose regime, the quantity of the three vaccines procured is in aggregate sufficient to cover 1.5 times of the entire Hong Kong population. Details are set out below. We are also continuing discussions on other APAs.

(i) A maximum of 7.5 million doses of CoronaVac developed by Sinovac Biotech (Hong Kong) Limited. CoronaVac is developed from the inactivated virus technology platform[3]. We are seeking early arrival of the vaccine in Hong Kong.

(ii) A maximum of 7.5 million doses of BNT162b2 jointly developed by German manufacturer BioNTech and Fosun Pharma. BNT162b2 is developed from the mRNA technology platform[4]. The first batch of one million doses is expected to be delivered in end-February 2021.

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1 The Scientific Committee on Emerging and Zoonotic Diseases and the Scientific Committee on Vaccine Preventable Diseases.

2 A vaccine platform refers to a tool or technology that uses a base carrier which can be modularised with target antigenic components of pathogens such that the body can produce antibodies to fight against the said pathogen. The four common vaccine technology platforms are: mRNA, inactivated virus, viral vector and protein subunit.

3 Involve taking the disease-carrying virus or bacterium, and inactivate or kill it using chemicals, heat or radiation.

4 Involve delivering a specific set of instructions to our cells, either as DNA or mRNA, for them to make the specific protein that we want our immune system to recognize and respond to.

(iii) A maximum of 7.5 million doses of AZD1222 jointly developed by AstraZeneca and the University of Oxford. AZD1222 is developed from the viral vector technology platform[5]. Supplies of the doses are expected to start arriving in Hong Kong by batches by the end of the second quarter of 2021 the earliest.

Authorization of vaccines

5. According to the Prevention and Control of Disease (Use of Vaccines) Regulation (Cap. 599K) (the Regulation) was made by the Chief Executive in Council on 23 December 2020, the Secretary for Food and Health may, under a state of public health emergency, authorize the use of COVID-19 vaccines which fulfil the criteria of safety, efficacy and quality for the purpose of vaccination programmes conducted by the Government on the advice of an advisory panel appointed by the Chief Executive (Advisory Panel). The Regulation also specifies the conditions and procedures which the vaccine manufacturer or its representative, importer or wholesale dealer must follow when submitting application for authorization for emergency use. In particular, the applicant must have obtained authorization (including for emergency use) from a regulatory authority in a place outside Hong Kong and provide information relevant to the safety, efficacy and quality of the vaccine.

6. Fosun Industrial Co., Ltd. submitted an application in early January 2021 for the authorization of its vaccine developed in collaboration with BioNTech. Having reviewed the recommendation of the Advisory Panel, the Secretary for Food and Health authorized the vaccine on 25 January 2021. Sinovac Biotech (Hong Kong) Limited also submitted an application in early February for the authorization of its vaccine. The Advisory Panel has reached a consensus to put up a recommendation to the Secretary for Food and Health to authorize the vaccine.

Vaccination programme

7. With the expected delivery of the first batch of vaccines in end-February, our plan is that starting from early March, members of the public can get vaccinated under a vaccination programme led by the Government, on a voluntary basis and free of charge. Our goal is to provide vaccines for the majority of the population within 2021. Having considered experts' views and the supply of vaccines, we will provide vaccination for the priority groups first, including groups

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[5] Involve using a safe virus that serves as a platform or vector to deliver the protein of the germ of interest into the body.

which have higher risks of coming into contact with the COVID-19 virus, groups which have greater mortality rates after contracting the disease, and/or groups which may easily transmit the virus to the vulnerable or weak if infected (e.g. healthcare workers, elders and staff of residential care homes). Furthermore, we are reviewing other target groups which may need to receive vaccination early due to their work nature or other needs.

8. The vaccine developed by BioNTech in collaboration with Fosun Pharma has more stringent requirements for transport and storage (the vaccines must be stored at -70 degrees Celsius, and can only survive in a 2 to 8 degrees Celsius environment for five days) and also require correct thawing procedures. In order to ensure the quality of the vaccines and that the vaccination procedures adhere to requirements, we will set up Community Vaccination Centres in 18 districts in Hong Kong. As regards the other two vaccines, we expect that they will be handled following the arrangements for seasonal influenza vaccination in general, whereby vaccination will be provided to members of the public through private hospitals and clinics. Members of the public will receive a vaccination card for record after vaccination. The relevant record can be uploaded to the Electronic Health Record Sharing System. The COVID-19 Electronic Testing Record System launched by the Government will also include an "Electronic Vaccination Record" feature for convenient download by the public.

Pharmacovigilance

9. The unprecedented rapid development of the COVID-19 vaccines on novel platforms followed by their rapid deployment on a mass scale poses unique challenges in monitoring vaccine safety. Pharmacovigilance activities and timely detection and assessment of adverse events following COVID-19 vaccination are the first step in ensuring the continuous verification of vaccine safety.

10. WHO strongly recommends that high quality surveillance systems capable of identifying both known Adverse Event Following Immunization (AEFI) seen in clinical trials and potential rare adverse events or Adverse Events of Special Interest (AESI) (i.e. a pre-specified medically-significant event that has the potential to be causally associated with a vaccine product that needs to be carefully monitored and confirmed by further special studies) should be implemented to identify any safety issues.

11. DH will strengthen its pharmacovigilance mechanism and adopt the strategies promulgated by WHO to conduct safety surveillance of COVID-19 vaccines. There will be normal and stimulated spontaneous reporting

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of AEFIs by healthcare professionals and the pharmaceutical industry and active surveillance of AEFIs, in particular, AESIs in collaboration with the academia from the University of Hong Kong. In addition, the authorization applicant is required to provide and update safety information as required under the Regulation for review of its benefits and risk profile.

12. With a view to providing independent assessment of potential causal link between AEFIs and the COVID-19 vaccines, making necessary recommendations on actions to be taken in response to potential safety signals and communicating with the relevant stakeholders, an Expert Committee on Clinical Events Assessment following COVID-19 Immunization (Expert Committee) has been established comprising members with expertise in pediatrics, pharmacology, haematology, immunology, pharmacy, forensic pathology, neurology, microbiology, etc., appointed by the Director of Health[6]. When there are cases which require experts of other specialties (e.g. geriatric medicine and respiratory medicine), they will be invited to discuss the cases on a need basis. To facilitate the collection of possible adverse events associated with COVID-19 vaccines, two lists, with one on AEFI for passive surveillance and the other on AESI for active surveillance, have been endorsed by the Expert Committee, having regard to clinical data and scientific researches and with reference to information published by the WHO as well as the European Medicines Agency funded ACCESS (vACCine covid-19 monitoring readinESS) project[7]. The two lists are set out at Enclosure. The list will be reviewed from time to time. Once there is report or information received, the Expert Committee will assess any potential causal link of a particular case demonstrating AEFI or AESI with the relevant COVID-19 vaccine received.

Encl.

Proposed AEFI Fund

13. Even under normal circumstances, vaccines that are approved for general use may, in rare cases, cause SAEs which may be unexpected. Those involved in their manufacture, distribution and administration can normally get insurance to cover this risk. Given the unprecedented nature and scale of the COVID-19 pandemic, however, normal insurance will not be available from the outset. The lack of such coverage may limit or delay access to vaccines as manufacturers are reluctant to deliver to a certain market if this risk is not addressed. It is hence common in bilateral deals for governments purchasing the vaccines to

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[6] Membership of the Expert Committee can be found in the following press release - https://www.info.gov.hk/gia/general/202101/25/P2021012500829.htm

[7] ACCESS Protocol. Background rates of Adverse Events of Special Interest for monitoring COVID-19 vaccines Version 1.1 September 21 2020. (https://vac4eu.org/wp-content/uploads/2020/09/ACCESS_BGRprotocolSept212020.pdf).

indemnify manufacturers against product liability claims, except where willful misconduct or gross negligence may be involved. At the same time, people receiving vaccines who suffer unexpected SAEs associated with a vaccine or its administration deserve compensation, principally through civil actions against the vaccine manufacturer. However, making claims through the legal system is both costly and complex, with elements of uncertainty. Other jurisdictions have introduced schemes in various forms to enable the public to get easy access to financial remedies should an SAE occur.

14. We propose to set up an AEFI Fund with an initial fund size of $1 billion to cover the indemnities offered to COVID-19 vaccine manufacturers under bilateral purchase agreements, and to provide support to individuals who have proof of suffering SAEs associated with a vaccine administered under the Government's current COVID-19 Vaccination Programme, pending, or in lieu of, their civil actions against a vaccine manufacturer. In the latter case, the AEFI Fund would provide emergency relief without going through the legal proceedings and other formalities.

15. After a report arising from an SAE falling under the AEFI or AESI list is received, the affected individual will be eligible for a lump-sum payment at a level corresponding to the event under the Fund if the below two conditions are met –

(a) there is certification by a registered medical practitioner of the SAE; and

(b) the evaluation outcome of the Expert Committee cannot rule out that the event is not associated with the administration of a vaccine under the Government's COVID-19 Vaccination Programme.

For (a), as an additional safeguard, the affected individual may be required to undergo medical examination by public sector doctors if necessary.

16. We propose initially that claims to the AEFI Fund should be made within two years of vaccination of the last dose of the vaccine. The time limit will be reviewed nearer the time, having regard to the pattern and timing of occurrence of listed events. The proposed maximum payment levels are set out in the table below –

/**Payout** …..

Payout for death associated with listed SAEs

Age of deceased individual (as at the date of last dose of vaccination)	Amount of payout (per individual)
under 40	$2,500,000
40 or above	$2,000,000

Payout for injuries associated with listed SAEs

Age of injured individual (as at the date of last dose of vaccination)	Maximum Amount of payout (per individual)
under 40	$3,000,000
40 or above	$2,500,000

The administration fee of setting up and operating the AEFI Fund will be charged to the Fund. The levels of maximum payouts for fatal and injuries cases for younger individuals and those older have been drawn up with reference to the amounts of compensation under the Employees' Compensation Ordinance (Cap. 282).

17. It should be stressed that receiving payment from the Fund will not affect the right of an individual to seek legal recourse for damages or loss against the vaccine manufacturer. A claimant can still undertake civil action against any person responsible for bodily injury. However, a claimant cannot receive double indemnity. If a claimant receives compensation as adjudged in court, the amount he/she has previously received from the AEFI Fund will be offset from the court's award.

ANTICIPATED BENEFITS

18. The COVID-19 pandemic has caused an unprecedented health challenge across the globe. The absence of an effective treatment or a vaccine combined with an exponential growth in infections have led many countries/places, including Hong Kong, to implement measures with far-reaching implications, including temporary border closures or stringent control measures, restrictions on non-essential travel, confinement and quarantine arrangements, with the objective of preventing the transmission of the disease from other places and, worse still, leading to a major community outbreak. For Hong Kong, the Government has been implementing measures under the two-pronged strategy to reduce population mobility in and out of Hong Kong including imposing quarantine and other related requirements on arrivals as well as to enhance social distancing in the community.

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19. Even with the implementation of the above measures, according to the views of the WHO and health experts, COVID-19 will not vanish without an effective treatment method and vaccine. Having efficacious and safe COVID-19 vaccines that can provide some form of protection from being infected, or bring the health detriments to a minimum having contracted the virus, is one of the most important measures we look to relying on to safeguard the life and health of our population, as well as protect our healthcare system, which has been running at the brink of full capacity since the pandemic. It is also our hope for our society to gradually resume normal operations. The AEFI Fund serves to provide immediate financial assistance for individuals inadvertently injured by COVID-19 vaccine meant for public good and increasing confidence in the COVID-19 Vaccination Programme. The AEFI Fund will also provide assurance to the public and encourage them to join the vaccination programme.

Savings and Cost Avoidance

20. In face of the pandemic, economic contraction for Hong Kong in 2020 as a whole will likely be close to the official forecast of -6.1% as put out in mid-November, which would be the most severe recession on record. Unemployment rate hit a 16-year high at 6.4%. While it is still uncertain the long-term effects that vaccines will have in suppressing the virus, we envisage that, if a sufficient percentage of the population gets vaccinated, a certain extent of herd immunity can be created in the community, which in the long term can slow down the spread of the virus. Given the sweeping and unprecedented scale of economic loss and havoc the pandemic has caused globally, there is no way to for us to estimate with any accuracy at this stage on the potential savings and cost avoidance that successful vaccines for suppressing the pandemic can bring to our society. Furthermore, many of the savings and cost avoidance would be intangible in nature, for example, ridding the inconvenience of restricted travel and social distancing.

FINANCIAL IMPLICATIONS

21. We propose the creation of a new non-recurrent commitment of $1 billion under FHB(H) for the setting up of AEFI Fund. As the vaccination programme is still at an initial stage globally, we have adopted a broad-brush approach in arriving at our estimates. In fact, the payout from the AEFI Fund may also be affected by court or arbitration awards which cannot be predicted at this stage. The actual cash flow and disbursement will depend on the number of applications received and approved.

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PUBLIC CONSULTATION

22. We briefed the LegCo Panel on Health Services on the framework of the AEFI Fund as part of our briefing on the 2020 Policy Address initiatives under the Food and Health Bureau at the Panel meeting on 8 January 2021.

BACKGROUND

23. The COVID-19 pandemic has caused an unprecedented health challenge across the globe. As at 7 February 2021, a total of 222 countries/territories/areas reported over 105.7 million cases and over 2.3 million deaths. In a public statement by the WHO on 3 June, it stipulated that the COVID-19 virus would stay for some time until a safe vaccine or effective treatment became available.

Food and Health Bureau
February 2021

(Revised)

Enclosure to FCR(2020-21)94

List of Serious or Unexpected Adverse Events Following Immunization of Coronavirus Disease-2019 (COVID-19) Vaccines

Note: Not all events under the two lists may be considered as serious adverse events eligible for payout under the Indemnity Fund for Adverse Events Following Immunization with COVID-19 Vaccines. Further classification on the severity of the events need to be drawn up.

1. Acute peripheral facial paralysis (Bell's Palsy)
2. Anaphylactoid reaction
3. Anaphylaxis
4. Any other severe and unusual events that are thought by health workers or the public to be related to immunization
5. Death *when associated with COVID-19 vaccine adverse event*
6. Disability *when associated with COVID-19 vaccine*
7. Encephalomyelitis
8. Encephalopathy
9. Guillain Barre Syndrome
10. Hospitalization *when associated with COVID-19 vaccine adverse event*
11. Sepsis
12. Septicaemia
13. Thrombocytopenia
14. Toxic shock syndrome
15. Transverse myelitis

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List of Adverse Events of Special Interest of COVID-19 Vaccines

1. (Idiopathic) Thrombocytopenia
2. Acute aseptic arthritis
3. Acute cardiovascular injury
4. Acute disseminated encephalomyelitis (ADEM)
5. Acute kidney injury
6. Acute liver injury
7. Acute pancreatitis
8. Acute respiratory distress syndrome
9. Anaphylaxis
10. Anosmia, ageusia
11. Arrhythmia
12. Bell's Palsy (Acute peripheral facial paralysis)
13. Chilblain – like lesions
14. Coagulation disorders
15. Coronary artery disease
16. COVID-19 disease (by levels of severity) –
    Level 1: Hospitalization for COVID-19 (confirmed or suspected),
    Level 2: ICU admission in those with COVID-19 related admission;
    Level 3: Acute respiratory distress requiring ventilation (ARDS) during a hospitalization for COVID-19;
    Level 4: Death during a hospitalization for COVID-19 (any cause)
17. Death (any causes)
18. Erythema multiforme
19. Fetal growth restriction
20. Generalized convulsion
21. Gestational Diabetes
22. Guillain-Barré Syndrome
23. Haemorrhagic disease

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24. Heart failure
25. Major congenital anomalies
26. Maternal death
27. Meningoencephalitis
28. Microangiopathy
29. Microcephaly
30. Multisystem inflammatory syndrome in children
31. Myocarditis
32. Narcolepsy
33. Neonatal death
34. Preeclampsia
35. Preterm birth
36. Rhabdomyolysis
37. Single Organ Cutaneous Vasculitis
38. Spontaneous abortions
39. Stillbirth
40. Stress cardiomyopathy
41. Subacute thyroiditis
42. Sudden death
43. Termination of Pregnancy for Fetal Anomaly
44. Thromboembolism
45. Transverse myelitis
46. Type 1 Diabetes
