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Panel on Health Services

**Information note prepared by the Legislative Council Secretariat
for the special meeting on 16 December 2020**

Procurement and administration of coronavirus disease 2019 vaccines

According to the World Health Organization ("WHO"), coronavirus disease 2019 ("COVID-19") will not vanish without an effective treatment method and vaccine. According to WHO, as at 10 December 2020, 52 candidate vaccines for protecting against COVID-19 were undergoing clinical trials for assessing safety and efficacy, with 13 of them entering phase 3 clinical trial.¹ The types of these candidate vaccines include (a) inactivated or weakened virus vaccines, which use a form of the virus that has been inactivated or weakened so it does not cause disease, but still generates an immune response; (b) protein-based vaccines, which use harmless fragments of proteins or protein shells that mimic the COVID-19 virus to safely generate an immune response; (c) viral vector vaccines, which use a virus that has been genetically engineered so that it cannot cause disease, but produces coronavirus proteins to safely generate an immune response; and (d) Ribonucleic acid ("RNA") and Deoxyribonucleic acid ("DNA") vaccines, a cutting-edge approach that uses genetically engineered RNA or DNA to generate a protein that itself safely prompts an immune response.

2. When safe and effective vaccines are found and received regulatory approval, COVAX, a global alliance of which WHO is one of the leaders, will facilitate the equitable access and distribution of these vaccines. The aim of COVAX is to have the vaccines delivered to the participating countries/economies by the end of 2021. According to WHO, COVAX will allocate vaccines across countries according to a framework under which

¹ The draft landscape of COVID-19 candidate vaccines can be accessed at WHO's website at <https://www.who.int/publications/m/item/draft-landscape-of-covid-19-candidate-vaccines> (English version only).

vaccines will be rolled out in two phases. In the first phase, they will be allocated according to population size to all participating countries at the same time, with a view to protecting people at greatest risk of infection and of severe disease. Prioritized groups include frontline health and care workers at high risk of infection, older adults, and those people at high risk of death because of underlying conditions like heart disease and diabetes. In the second phase, as more doses are produced, the vaccines should go to groups less at risk of being infected or of suffering badly. At least two billion vaccine doses are expected to be available by late 2021.

3. Locally, the Administration has adopted a two-pronged approach to procure vaccines meeting the criteria of safety, efficacy and quality for the Hong Kong population. The Administration joined the COVAX Facility on the one hand to procure vaccine doses for 35% of the Hong Kong population as a form of safety net to cater for the needs of the most vulnerable groups in society and, on the other hand, entered into advance purchase agreements ("APAs") with individual vaccine developers.² The Administration aimed to procure at least two candidate vaccines from different vaccine developers and different vaccine platforms under APAs and the doses procured would serve at least twice the local population. The Pharmacy and Poisons Board of Hong Kong and the Department of Health will accord priority to applications for registration of the relevant vaccines, with a view to expediting the approval process while ensuring the safety, efficacy and quality of the vaccines. Depending on the development of the epidemic situation, the Administration will consider implementing all necessary measures to enable the emergency use of vaccines which have been proven to be safe and effective and does not rule out the possibility of emergency legislation in times of need. According to the Administration, depending on the quantity of vaccines procured, the suitable groups for application and information on adverse events etc., the following groups should be accorded priority in receiving vaccination: (a) those having higher risks of coming into contact with the COVID-19 virus (e.g. healthcare workers); (b) those having greater mortality rates after contracting the disease (e.g. the elderly, chronic patients); and/or (c) those which may easily transmit the virus to the vulnerable or weak if infected (e.g. staff of residential care homes). These priority groups are expected to be around three million people. The Administration will enable members of the public to be vaccinated on a voluntary basis and propose to provide the vaccination free of charge.

² The Finance Committee of the Legislative Council approved on 28 September 2020 the creation of a new commitment of \$8,441.3 million for the procurement and administration of vaccines against COVID-19.

4. An oral question concerning the supply of COVID-19 vaccines was raised at the Council meeting of 2 December 2020. The question and the Administration's reply are in **Appendix I**. On 11 December 2020, the Chief Executive announced the latest development of COVID-19 vaccine procurement. The relevant press releases issued by the Administration on 12 December 2020 are in **Appendix II**.

Council Business Division 2
Legislative Council Secretariat
15 December 2020

Appendix I

Press Releases *2 December 2020*

LCQ3: Coronavirus Disease 2019 vaccines

Following is a question by the Hon Jeffrey Lam and a reply by the Secretary for Food and Health, Professor Sophia Chan, in the Legislative Council today (December 2):

Question:

The Government has earmarked over \$8.4 billion in the current financial year for procuring Coronavirus Disease 2019 vaccines (COVID-19 vaccines) and administering them to members of the public. On the other hand, queries concerning the efficacy and safety of vaccination have been raised from time to time in recent years, and such "anti-vaccination" thinking may dampen the public's desire for being administered the COVID-19 vaccines. In this connection, will the Government inform this Council:

(1) of the details of the preparatory work for procuring COVID-19 vaccines and administering them to members of the public; whether it will expedite the registration process of COVID-19 vaccines, assist private healthcare institutions in procuring the vaccines, and provide free vaccination for specific groups of persons;

(2) whether persons who have been administered, either in or outside Hong Kong, those COVID-19 vaccines recognised by the World Health Organization will be granted exemption from quarantine requirements upon entry into the territory, so as to facilitate cross-boundary flow of people; and

(3) whether it has set any target vaccination coverage rates for the COVID-19 vaccines; if so, of the measures in place to ensure that the target rates will be achieved; the measures in place to curb the deliberate spread of rumours about the vaccines?

Reply:

President,

My consolidated reply to the various parts of the question raised by the Hon Jeffrey Lam is as follows:

According to the views of the World Health Organization (WHO) and health experts, COVID-19 will not vanish without an effective treatment method and vaccine. The WHO earlier indicated that although we can expect safe and effective COVID-19 vaccines to be available in 2021, the supply of the vaccines is expected to be limited. Relatively large scale administration of the vaccines can only be expected in the latter half of 2021. We also expect that the first batch of vaccines needs to be reserved for high risk groups such as healthcare workers and the elderly, etc. According to information provided by the WHO, as at 1 December, there were 48 candidate vaccines for protecting against COVID-19 undergoing clinical trials for assessing safety and efficacy. Out of them, 11 had entered phase 3 clinical trial. Although no vaccine has yet obtained approval from regulatory authorities for human application, the Hong Kong SAR Government has adopted a "two-pronged" approach to procure vaccines meeting the criteria of safety, efficacy and quality for the Hong Kong population. The candidate vaccines under consideration include those developed or

manufactured in Mainland China and overseas.

Under the "two-pronged" approach, we have on one hand joined the COVAX Facility led by the WHO to procure vaccine doses for 35 per cent of the Hong Kong population as a form of safety net to cater for the needs of the most vulnerable groups in society. On the other hand, we will enter into advance purchase agreements (APAs) with individual vaccine developers with a view to procuring additional supplies. Our goal is to procure at least two candidate vaccines from different vaccine developers and different vaccine platforms under APAs. The doses procured would serve at least twice the Hong Kong population. When entering into APAs, we will make reference to the relevant scientific evidence and clinical data and consult the views of the relevant Scientific Committees under the Department of Health (DH) and expert groups. The safety, efficacy and quality of the vaccines will be the priority factors for consideration in procurement. At the same time, we will also consider the development progress of the vaccines, the technology used and practical circumstances and limits, such as logistics, storage of the vaccines and cold chain management, etc.

While proactively procuring COVID-19 vaccines, the Pharmacy and Poisons Board of Hong Kong and DH will accord priority to applications for registration of the relevant vaccines, with a view to expediting the approval process while ensuring the safety, efficacy and quality of the vaccines. In view that the COVID-19 epidemic is a public health emergency, the Government's priority is to procure and administer vaccines which are safe and effective for our population. Depending on need, we will consider implementing all necessary measures to enable the emergency use of vaccines which have been proven to be safe and effective. At this juncture, we do not rule out the possibility of emergency legislation in times of need.

Administration of vaccines is key to the resumption of normal life for Hong Kong. Having regard to the suggestion of the Scientific Committees, our goal is to provide vaccines for the entire Hong Kong population. Depending on the quantity of vaccines procured, the suitable groups for application and information on adverse events, etc., groups which have higher risks of coming into contact with the COVID-19 virus (e.g. healthcare workers), groups which have greater mortality rates after contracting the disease (e.g. the elderly, chronic patients), and/or groups which may easily transmit the virus to the vulnerable or weak if infected (e.g. staff of residential care homes) should be accorded priority in receiving vaccination. The priority groups for vaccination is expected to be around 3 million people. In view that we need to provide vaccination for a large population within a short period of time, we are considering various solutions. We will enable members of the public to be vaccinated on a voluntary basis and propose to provide the vaccination free of charge. The Government has earmarked \$10 million for promotion and will strengthen publicity and education through various channels. We will also suitably clarify rumours and misinformation so as to increase the public's understanding of the effectiveness and safety of COVID-19 vaccines.

Our understanding is that, as of now, vaccine developers are mainly in direct negotiation with various Governments, with a view to reserving vaccines for them through advance purchase arrangements so as to support large scale vaccination programmes. While we do not rule out inviting private healthcare

organisations to participate in the programme to help with vaccination, we do not see the need of helping private healthcare organisations procure vaccines on their own to serve their clients at this stage.

The COVID-19 epidemic is wreaking havoc around the world and vaccine developers are launching clinical trials in various regions at unprecedented speed. With user statistics and immunisation responses of participants of the clinical trials gradually becoming available, we can obtain more information on the safety, efficacy and quality of the various COVID-19 vaccines, including their efficacy across different age groups, effective period, dosage, time between each doses, and adverse reactions, etc. The Government will closely monitor the development of COVID-19 vaccines and the epidemic situation in Hong Kong and around the world. At the same time, we will make reference to relevant guidelines promulgated by the WHO. Upon consolidating the relevant information and with regards to the anti-epidemic strategy of the Hong Kong SAR Government, we will holistically consider and formulate the vaccination programme. Details of the programme will be announced in due course.

Thank you, President.

Ends/Wednesday, December 2, 2020
Issued at HKT 14:55

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Press Releases

Government announces latest development of COVID-19 vaccine procurement

The Government announced on December 11 the latest development of COVID-19 vaccine procurement.

The Government has been adopting a "two-pronged" strategy to procure vaccines for protecting members of the public against COVID-19, including joining the COVAX Facility led by the World Health Organization and directly making advance purchases of vaccines from individual vaccine developers. For advance purchase agreements, the Government's goal is to procure at least two candidate vaccines from different vaccine developers and different vaccine technology platforms, and to procure sufficient doses to serve at least two times the Hong Kong population.

The Government has reached a preliminary agreement with Sinovac Biotech (Hong Kong) Limited to provide 7.5 million doses of vaccine to Hong Kong. This vaccine is developed from the inactivated virus technology platform. The first batch of one million vaccine doses is expected to be delivered to Hong Kong in January 2021 the earliest. After the vaccine obtains approval from the Government, arrangement will be made for the public to receive vaccination as soon as possible.

The Government has also reached an agreement with Fosun Pharma to procure a maximum of 7.5 million doses of the vaccine developed by Fosun Pharma in collaboration with the German drug manufacturer BioNTech (Pfizer is the collaboration partner of BioNTech in regions outside of Greater China). This vaccine is developed from the mRNA technology platform. The first batch of one million doses is expected to be delivered in the first quarter of 2021 the earliest.

For the two aforementioned vaccines, individuals are required to receive two doses. The amount of doses procured is sufficient to cover the entire Hong Kong population.

Moreover, the Government will soon enter into an agreement with AstraZeneca to procure 7.5 million doses of the vaccine it developed in collaboration with the University of Oxford. This vaccine is developed from the non-replicating viral vector technology platform. According to information available, supply of the vaccine will be slightly later and the doses are expected to start arriving in Hong Kong by batches by the end of the second quarter of 2021 the earliest.

A spokesman for the Food and Health Bureau said, "The global competition for vaccines is very vigorous, and it is expected that supply in the initial stage will be relatively tight. We will continue to negotiate procurement arrangements with other vaccine developers and strive to provide sufficient supplies of vaccines for the Hong Kong population as early as possible. At the same time, to expedite the registration procedures of vaccines in Hong Kong to allow the early use of the vaccines, we have commenced working on an emergency legislation to enable the emergency use of vaccines proven to be safe and effective in Hong Kong."

As regards the arrangements for vaccination, the Government's goal is to provide vaccines for the majority of the Hong Kong population within 2021 through vaccination programmes led by the Government. Members of the public can receive the vaccines on a voluntary basis free of charge. We will make reference to the views of the relevant Scientific Committees and the expert advisory group and arrange for priority groups to receive vaccination first, including groups which have higher risks of coming into contact with the COVID-19 virus (e.g. healthcare workers), groups which have greater mortality rates after contracting the disease (e.g. the elderly, chronic patients), and/or groups which may easily

transmit the virus to the vulnerable or weak if infected (e.g. staff of residential care homes). As the vaccines will arrive Hong Kong in batches, the Government will arrange for members of the public to receive vaccination as early as possible based on priority and the characteristics of the vaccines. The Government will announce the details of the vaccination programme in due course.

Ends/Saturday, December 12, 2020

Issued at HKT 1:04

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Press Releases

Government responds to media enquiries on COVID-19 vaccine procurement

Following the government's announcement yesterday (December 11) on the latest development of COVID-19 vaccine procurement, a spokesman for the Food and Health Bureau today (December 12) provided the following information in response to media enquiries.

The Government has reached an agreement with Fosun Pharma to procure a maximum of 7.5 million doses of the mRNA vaccine (BNT162b2) developed by Fosun Pharma in collaboration with the German drug manufacturer BioNTech. The vaccines supplied to Hong Kong will be manufactured in Europe. The first batch of one million doses is expected to be delivered in the first quarter of 2021 the earliest.

Regarding the arrangements for the procurement agreement, Fosun Pharma is the strategic partner of BioNTech in China. The two companies will work jointly on the development and commercialisation of the mRNA COVID-19 vaccine, developed based on BioNTech's proprietary mRNA technology platform, in Mainland China, Hong Kong, Macau and Taiwan. Under the terms of the agreement, for the purposes of development and commercialisation of the vaccine, Fosun Pharma Industrial will be responsible for clinical trials, regulatory applications as well as sales and marketing of the product in China. BioNTech will provide technical resources and pre-clinical research information necessary for making clinical trial applications and to facilitate the trials in the region. It will also provide the necessary products for the purposes of clinical trials as well as marketing and sales.

Currently, the BNT162b2 mRNA vaccine developed by BioNTech has been approved for emergency use by the health authorities of the United Kingdom and Canada. (Note: Pfizer is BioNTech's collaboration partner for the mRNA vaccine in regions other than China).

As regards the vaccine provided by Sinovac Biotech (Hong Kong) Limited (Sinovac) to Hong Kong, according to information provided by Sinovac, the relevant vaccine will be produced in Daxing District, Beijing. The first batch of one million doses is expected to be delivered to Hong Kong in January 2021 the earliest.

The SAR Government will also be obtaining 7.5 million doses of the vaccine developed by AstraZeneca in collaboration with the University of Oxford. The relevant vaccines are expected to start arriving in Hong Kong by batches by the end of the second quarter of 2021 the earliest. In view of the confidentiality agreement signed between the SAR Government and AstraZeneca, the manufacturing place of the relevant vaccine cannot be disclosed at this stage.

"The Government will continue to negotiate advance purchase agreements with other vaccine developers and strive to provide sufficient supplies of vaccines which are proven to be safe and effective for the Hong Kong population as early as

possible. After the relevant vaccines obtain approval from the Government, arrangement will be made for the public to receive vaccination as soon as possible." the spokesman added.

Ends/Saturday, December 12, 2020
Issued at HKT 23:48

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