Appendix

COVID-19 Vaccination Programme
Vaccination Fact Sheet, eHealth Registration and Personal Information Collection Statement

Appointment of COVID-19 vaccination can be made through the online booking system. If you have chronic illnesses, please consult your doctor for suitability of vaccination before booking. Before online booking, please read carefully the Vaccination Fact Sheet, eHealth Registration and Personal Information Collection Statement below.

(A) I. Vaccination Fact Sheet of CoronaVac COVID-19 Vaccine (Vero Cell), Inactivated

1. What is CoronaVac and what it is used for[1]

CoronaVac is indicated for active immunization against COVID-19 disease caused by SARS-CoV-2 virus.

The vaccine is authorized for use under the Prevention and Control of Disease (Use of Vaccines) Regulation (Cap. 599K). It has not been registered in Hong Kong under the Pharmacy and Poisons Ordinance (Cap. 138).

CoronaVac is indicated for susceptible people aged 18 and above. Data from clinical trials showed that neutralizing antibodies would be induced after vaccination. In the phase III clinical trial conducted outside China, only 5.10% participants enrolled was 60 years and above, hence, the efficacy evidence of people aged 60 and above is insufficient. The subsequent clinical trials will be carried out for further evaluation of efficacy in this population. When using CoronaVac among people aged 60 and above by relevant medical institutions, the health status and exposure risk shall be considered.

Please note, to expedite the availability of CoronaVac to Hong Kong, some of the textual information (include English name; dosing interval and expiry date) in the sales pack/label and the drug insert of the initial shipment of CoronaVac are different from the version provided by the vaccine supplier upon its authorization for emergency use under Cap 599K. Nevertheless, all the information provided in this factsheet are matched with the authorized one. As there might be a chance of the product information updated from time to time, you may also wish to visit the below link for latest information:-
https://www.fhb.gov.hk/download/our_work/health/201200/e_evaluation_report_CoronaVac.pdf

I (and the carer) have read and understood the above information of item 1

2. What you need to know before you receive CoronaVac[1]

CoronaVac should not be given to

- People with history of allergic reaction to any component (active* or inactive* ingredients, or any material used in manufacturing process) of the vaccine or similar vaccines;
- People with previous severe allergic reactions to vaccine (eg, acute anaphylaxis, angioedema, dyspnea, etc.);
- People with severe neurological conditions (eg, transverse myelitis, Guillain-Barré syndrome, demyelinating diseases, etc.);
- Patients with uncontrolled severe chronic diseases;
- Pregnant and lactating women.

*Including inactivated SARS-CoV-2 Virus (CZ02 strain), aluminum hydroxide, disodium hydrogen phosphate dodecahydrate, sodium dihydrogen phosphate monohydrate, and sodium chloride.

Precautions

- Due to the insufficient data of persistence of protection induced by this vaccine, necessary protective measures should be taken in line with prevention and control of the COVID-19 epidemic.
- For patients with acute diseases, acute exacerbation of chronic diseases, severe chronic diseases, allergies and fever, the vaccine should be used with caution; if necessary, delay vaccination after doctor's evaluation.
- For diabetic patients and people with convulsions, epilepsy, encephalopathy, mental illness or family history, the vaccine should be used with caution.
- For patients with thrombocytopenia or hemorrhagic diseases, intramuscular injection of this product may cause bleeding, so it should be used with caution.

[1] Following information provided by drug company/vaccine supplier

- The safety and efficacy data of this product on people with impaired immune function (such as malignant tumor, nephrotic syndrome, AIDS patients) have not been obtained, and the vaccination of this product should be based on individual considerations.
- People who inject human immunoglobulin should receive this vaccine at least one month apart to avoid affecting the immune effect.
- Do not use it again if there is any adverse reaction of nervous system after vaccination.
- Like other vaccines, the protective effect may not reach 100% for all recipients.
- Observe for 30 minutes after vaccination.

Women of childbearing age:
The data collected from clinical trials on women with unexpected pregnancy after vaccination are very limited, and it is insufficient to decide the risk of adverse pregnancy outcomes after vaccination.

Pregnant or lactating women:
The clinical data of pregnant and lactating women are not available at present.

People aged 60 and above:
The benefit of using CoronaVac generally exceeds the risk of not using any vaccines in persons aged 60 and above. Phase I and II data on individuals aged 60 and above showed that the vaccine is safe and immunogenic. There is limited phase III efficacy data for individuals aged 60 and above because of small sample size.

Other medications and CoronaVac
- Concomitant use with other vaccines: no clinical study has been carried out on the evaluation of immune response with other vaccines on the immunogenicity at the same time (before, after or at the same time).
- Concomitant use with other drugs: immunosuppressive drugs, such as immunosuppressive drugs, chemotherapy drugs, antimetabolic drugs, alkylating agents, cytotoxic drugs, corticosteroid drugs, etc., may reduce the immune response to this product.
- Patients undergoing treatment: for patients undergoing treatment, please consult the medical professional before using CoronaVac to avoid possible drug interactions.

I (and the carer) have read and understood the above information of item 2

3. How CoronaVac is given[1]

Two doses should be administered for primary immunization. The second dose is given 28 days after the first dose. 0.5 mL per dose.

CoronaVac should be administered by intramuscular injection in the deltoid region of the upper arm.

It has not been determined whether this product requires booster immunization.

I (and the carer) have read and understood the above information of item 3

4. Possible side effects[1]

Very common side effects: may affect ≧10% people
- injection site: pain
- headache
- fatigue

Common side effects: may affect 1%-10% people
- injection site swelling, pruritus, erythema, induration
- myalgia
- nausea
- diarrhea
- arthralgia
- cough
- chills
- pruritus
- loss of appetite
- rhinorrhea
- sore throat
- nasal congestion
- abdominal pain

Uncommon side effects: may affect 0.1%-1% people

- burn at injection site
- vomit
- hypersensitivity
- abnormal skin and mucosa
- fever
- tremor
- flushing
- edema
- dizziness
- drowsiness

Rare side effects: may affect 0.01%-0.1% people

- muscle spasms
- eyelid edema
- nosebleeds
- abdominal distension
- constipation
- hyposmia
- ocular congestion
- hot flashes
- hiccup
- conjunctival congestion

Serious adverse event

- No serious adverse event related to vaccination was identified up to 3 February 2021.

I (and the carer) have read and understood the above information of item 4

5. Reporting of adverse events after immunization

The Department of Health ("DH") has an adverse drug reaction ("ADR") reporting system which receives adverse events following immunization (AEFIs) reports to monitor the safety of COVID-19 vaccines. If you have any suspected adverse event occurred after immunization, please alert healthcare professionals (e.g. doctors, dentists, pharmacists, nurses and Chinese medicine practitioners), when seeking their advice, to report the AEFIs to the DH if they consider that the AEFIs may be associated with the vaccination.

For continuously monitoring of the safety and clinical events associated with COVID-19 Vaccination, your personal data collected for vaccination and your clinical data held by the Hospital Authority and the relevant private healthcare facilities and healthcare professionals, may be accessed and used by the Department of Health and relevant organizations collaborated with the Government (including the University of Hong Kong) insofar as such information is necessary for the monitoring.

In situations when pain or redness at the injection site increases after 24 hours from injection; or your side effects are worrying you or do not seem to be going away in a few days, please contact your doctor.

If you do seek medical attention, make sure you tell the healthcare professionals about your vaccination details and show them your vaccination record card if available. Healthcare professionals will then make proper assessment and, if necessary, report any AEFI that is deemed medically significant to the Department of Health for further action and assessment. Please allow the healthcare professional to report the AEFI, with your consent to passing the adverse event case information, personal and clinical data to the Department of Health for continuous monitoring the safety and clinical events associated with COVID-19 Vaccination.

For further information on vaccine information and side effects, please visit the website at https://www.covidvaccine.gov.hk/

I (and the carer) have read and understood the appended (A) I. information, including contraindications (and possible adverse events) in receiving COVID-19 vaccination. I (and the carer) have also fully understood his/her obligation and liability under this consent form.

I (and the carer) have read and understood the vaccine product is authorized under the Prevention and Control of Disease (Use of Vaccines) Regulation (Cap. 599K) for specific purpose for prevention of COVID-19 infection but has not been registered under the Pharmacy and Poisons Ordinance (Cap. 138), and agree to receive the documented COVID-19 vaccine.

I (and the carer) have consented the Department of Health and the relevant organizations collaborated with the Government (including the University of Hong Kong)'s access to and use of his/her personal data contained herein and his/her clinical data held by the Hospital Authority and the relevant private healthcare facilities and healthcare professionals, for the purpose of continuously monitoring the safety and clinical events associated with COVID-19 Vaccination by the Department of Health insofar as such access and use are necessary for the purpose.

(A) II. Vaccination Fact Sheet of Comirnaty COVID-19 mRNA Vaccine (BNT162b2) Concentrate for Dispersion for Injection

1. What is Comirnaty and what it is used for[1]

Comirnaty is a vaccine used for preventing COVID-19 caused by SARS-CoV-2 virus. Comirnaty is given to adults and adolescents from 16 years of age and older. The vaccine causes the immune system (the body's natural defences) to produce antibodies and blood cells that work against the virus, so giving protection against COVID-19.

As Comirnaty does not contain the virus to produce immunity, it cannot give you COVID-19.

The vaccine is authorized for use under the Prevention and Control of Disease (Use of Vaccines) Regulation (Cap. 599K) for the specific purpose of preventing COVID-19 infection. It has not been registered in Hong Kong under the Pharmacy and Poisons Ordinance (Cap. 138).

I (and the carer) have read and understood the above information of item 1

2. What you need to know before you receive Comirnaty[1]

Comirnaty should not be given

- if you are allergic to previous dose of Comirnaty, or to the active substance or any of the other ingredients of this medicine including the following: [(4-hydroxybutyl)azanediyl]bis(hexane-6,1-diyl)bis(2-hexyldecanoate) (ALC-0315); 2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide (ALC-0159); 1,2-Distearoyl-sn-glycero-3-phosphocholine (DSPC); cholesterol; potassium chloride; potassium dihydrogen phosphate; sodium chloride; disodium phosphate dihydrate; sucrose and water for injection.

Warnings and Precautions

Talk to your doctor, pharmacist or nurse before you are given the vaccine if:

- you have ever had a severe allergic reaction or breathing problems after any other vaccine injection or after you were given Comirnaty in the past.
- you have ever fainted following any needle injection.
- you have a severe illness or infection with high fever. Vaccination should be delayed for individuals suffering from acute febrile diseases.
- you have a bleeding problem, you bruise easily or you use a medicine to prevent blood-clots.
- you have a weakened immune system, because of a disease such as HIV infection or a medicine such as corticosteroid that affects your immune system.

As with any vaccine, the 2-dose vaccination course of Comirnaty may not fully protect all those who receive it and it is not known how long you will be protected.

Children and adolescents

Comirnaty is not recommended for children aged under 16 years.

Other medicines and Comirnaty

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines or have recently received any other vaccine.

Pregnancy and breast-feeding

COVID-19 vaccines are not routinely recommended during pregnancy, unless the woman is considered at very high risk of SARS-CoV-2 exposure and subject to very high risk of COVID-19 complications. While it is also not routinely recommended for breastfeeding women, those with high clinical need for protection against COVID-19 may be offered vaccination. If you are pregnant or

breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before you receive this vaccine.

Driving and using machines
Some of the effects of vaccination mentioned in section 4 (Possible side effects) may temporarily affect your ability to drive or use machines. Wait until these effects have worn off before you drive or use machines.

Comirnaty contains potassium and sodium
This vaccine contains less than 1 mmol potassium (39 mg) per dose, that is to say essentially 'potassium-free'.
This vaccine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.

I (and the carer) have read and understood the above information of item 2

3. How Comirnaty is given[1]

- Comirnaty is given after dilution as an injection of 0.3 mL into a muscle of your upper arm.
- You will receive 2 injections, given at least 21 days apart.
- After the first dose of Comirnaty, you should receive a second dose of the same vaccine after 21 days to complete the vaccination course.
- If you have any further questions on the use of Comirnaty, ask your doctor, pharmacist or nurse.

I (and the carer) have read and understood the above information of item 3

4. Possible side effects[1]

Like all vaccines, Comirnaty can cause side effects, although not everybody gets them.

Very common side effects: may affect more than 1 in 10 people
- injection site: pain, swelling
- tiredness
- headache
- muscle pain
- joint pain
- chills, fever

Common side effects: may affect up to 1 in 10 people
- injection site redness
- nausea

Uncommon side effects: may affect up to 1 in 100 people
- enlarged lymph nodes
- feeling unwell
- pain in limb
- insomnia
- injection site itching

Rare side effects: may affect up to 1 in 1,000 people
- temporary one sided facial drooping

Not known (cannot be estimated from the available data)
- severe allergic reaction

I (and the carer) have read and understood the above information of item 4

5. Reporting of adverse events after immunization

The Department of Health ("DH") has an adverse drug reaction ("ADR") reporting system which receives adverse events following immunization (AEFIs) reports to monitor the safety of COVID-19 vaccines. If you have any suspected adverse event occurred after immunization, please alert healthcare professionals (e.g. doctors, dentists, pharmacists, nurses and Chinese medicine practitioners), when seeking their advice, to report the AEFIs to the DH if they consider that the AEFIs may be associated with the vaccination.

For continuously monitoring of the safety and clinical events associated with COVID-19 Vaccination, your personal data collected for vaccination and your clinical data held by the Hospital Authority and the relevant private healthcare facilities and healthcare professionals, may be accessed and used by the Department of Health and relevant organizations collaborated with the Government (including the University of Hong Kong) insofar as such information is necessary for the monitoring.

In situations when pain or redness at the injection site increases after 24 hours from injection; or your side effects are worrying you or do not seem to be going away in a few days, please contact your doctor.

If you do seek medical attention, make sure you tell the healthcare professionals about your vaccination details and show them your vaccination record card if available. Healthcare professionals will then make proper assessment and, if necessary, report any AEFI that is deemed medically significant to the Department of Health for further action and assessment. Please allow the healthcare professional to report the AEFI, with your consent to passing the adverse event case information, personal and clinical data to the Department of Health for continuous monitoring the safety and clinical events associated with COVID-19 Vaccination.

For further information on vaccine information and side effects, please visit the website at https://www.covidvaccine.gov.hk/

I (and the carer) have read and understood the appended (A) II. information, including contraindications (and possible adverse events) in receiving COVID-19 vaccination. I (and the carer) have also fully understood his/her obligation and liability under this consent form.

I (and the carer) have read and understood the vaccine product is authorized under the Prevention and Control of Disease (Use of Vaccines) Regulation (Cap. 599K) for specific purpose for prevention of COVID-19 infection but has not been registered under the Pharmacy and Poisons Ordinance (Cap. 138), and agree to receive the documented COVID-19 vaccine.

I (and the carer) have consented the Department of Health and the relevant organizations collaborated with the Government (including the University of Hong Kong)'s access to and use of his/her personal data contained herein and his/her clinical data held by the Hospital Authority and the relevant private healthcare facilities and healthcare professionals, for the purpose of continuously monitoring the safety and clinical events associated with COVID-19 Vaccination by the Department of Health insofar as such access and use are necessary for the purpose.

(B) Give Joining Consent to the Electronic Health Record Sharing System (eHealth)

After successful registration in eHealth, you and your clinical staff can review the record of the COVID-19 vaccination in eHealth. For more details about eHealth, please refer to eHealth website (https://www.ehealth.gov.hk) and related leaflets.

(C) Personal Information Collection Statement

Covid-19 Vaccination Programme Booking

Personal Information Collection Statement

1. The Office of the Government Chief Information Officer ("OGCIO") will use the personal data collected in this booking system for the following purposes:
   - processing the booking request for receiving COVID-19 vaccines under vaccination programmes led by the Government, and handling enquiries relating to the booking;
   - carrying out matching procedures with Immigration Department to process the registration, vet the information and confirm the eligibility of registrants (for example, to confirm the provided Hong Kong Identity Card ("HKID") number is valid, the associated date of birth is correct as well as to check if the concerned holder of the HKID is deceased);
   - checking with the relevant government departments and organisations on the status of receiving COVID-19 vaccine of registrant;
   - verifying the quota for receiving vaccine at specific centres on a particular date and time;
   - informing relevant government bureaux or departments (B/Ds) and organisations for arranging vaccination and follow up after the vaccination;
   - transferring to the Department of Health and relevant organizations collaborated with the Government (including the University of Hong Kong) for continuous monitoring of the safety and clinical events associated with COVID-19 Vaccination under the COVID-19 Vaccination Programme;
   - collating statistics and carrying out analysis, where the statistical information obtained will not be released or made available to a third party in a form that identifies the data subjects or any of them.
2. It is not mandatory for registrant(s) to provide the personal data as required in this registration. However, if registrant(s) do not provide such personal data, OGCIO will be unable to process the booking request.

3. OGCIO shall hold the personal data securely in accordance with prevailing government information security requirements. Appropriate technical and organisational measures such as data encryption, access control and firewalls will be in place to protect the personal data against unauthorised or accidental access, processing, erasure, loss or use.

Transfer and/or Disclosure of the Data

4. The information provided by citizens in making the booking request(s) will not be used by the OGCIO for other purposes. OGCIO will also ensure that the retention period of the personal data is not kept longer than the time required for the purposes for which the data is collected.
5. For the purposes stated in paragraph 1 above, or where disclosure is authorised or required by law, personal data collected in this registration may be transferred and/or disclosed to relevant government B/Ds and organisations (including Food and Health Bureau, Department of Health, the University of Hong Kong and Hospital Authority) which are responsible for the vaccination programmes.

Data Access Request

6. i. You have the right to request for access to and correction of your own personal data provided in this registration under the Personal Data (Privacy) Ordinance (Cap 486) ("the Ordinance"), subject to any relevant exemption(s);
   ii. Please note that we shall or may refuse to comply with a data access request in the circumstances specified in section 20 of the Ordinance; and
   iii. Your requests or enquiries should be made by any one of the following means: (a) by email to enquiry_vaccinebooking@ogcio.gov.hk; (b) by fax to 2802 4549; or (c) by post to 15/F, Wanchai Tower, 12 Harbour Road, Wan Chai, Hong Kong.

The Electronic Health Record Sharing System (eHealth) Registration

Purposes of Collection

7. The Electronic Health Record Office ("eHRO") may collect your personal information including name, date of birth, identity document number, and telephone number for your registration and use of eHealth and related matters under the Electronic Health Record Sharing System Ordinance (Cap 625) (eHRSSO). Such matters include but are not limited to the following: the giving of and management of joining consent and/or sharing consent, updating of information in eHealth, receipt of eHealth notifications, withdrawal from eHealth. Your health information will be shared among healthcare providers, who have obtained sharing consent from you, via eHealth.

Classes of Transferes

8. Except with your prior consent, eHRO will not transfer or disclose the collected personal data and information to any third party except as stated below:
   i. the Department of Health, Hospital Authority or any person or entity whom we may appoint in writing to assist the Commissioner for the Electronic Health Record in performing a function and exercising a power, pursuant to eHRSSO;
   ii. any personnel, agent, adviser, auditor, contractor or service provider engaged by eHRO to provide services or advice (e.g. technical, security or data processing service, etc.) in connection with our operations; and
   iii. any person to whom eHRO is required to make disclosure to under any law or court order applicable in Hong Kong.

Data Access and Correction Request

9. i. You have the rights of access and correction of the personal data provided under Personal Data (Privacy) Ordinance and the application forms for access to or correction of personal data can be obtained from the eHealth website (www.ehealth.gov.hk).
   ii. You may also contact the eHRO for more information. A non-excessive fee will be charged for complying with your data access request.
   iii. Enquiries concerning personal data provided, including data access requests and data correction requests should be addressed to Electronic Health Record Registration Office: (a) by email to ehr@ehealth.gov.hk; (b) by fax to 3467 6099; (c) by post to Unit 1193, 11/F, Kowloonbay International Trade & Exhibition Centre, 1 Trademart Drive, Kowloon Bay, Hong Kong.

Consent

I (and the carer) -

For Covid-19 Vaccination Programme Booking

- have read the above Personal Information Collection Statement and understand its content, and agree that OGCIO can process and use the personal data provided in this registration for the purpose of booking for receiving COVID-19 vaccine under vaccination programmes led by the Government;

and disclose the personal data provided in this registration to bureaux and departments (B/Ds) and organisations in relation to the programmes;

- agree for the personal data provided in this registration to be transferred to relevant B/Ds and organisations for the purpose of vaccination and follow up after the vaccination, including preparation of the vaccination record to facilitate the healthcare professional in the public and private sectors for the purpose of determining and providing necessary health care service to the recipient;
- understand that I consent to the access and use by the Department of Health and the relevant organizations collaborated with the Government (including the University of Hong Kong) of my clinical data held by the Hospital Authority and the relevant private healthcare facilities and healthcare professionals for the purpose of continuously monitoring the safety and clinical events associated with COVID-19 Vaccination by the Department of Health insofar as such access and use are necessary for the purpose;
- agree for the personal data provided in this registration to be used by OGCIO in processing the registration, vetting the information, confirming the eligibility for the registration, carrying out the matching procedures with Immigration Department and checking vaccination status with the relevant government departments or organisations;
- understand that OGCIO reserves the right to review any registration and may, as and when necessary, reject any registration if the provided information is invalid, inaccurate, or missing; and
- understand that the Government may contact me to verify the information and arrange the vaccination

Any person who registers on others' behalf must obtain the prior consent of the concerned individual before using his or her personal data in booking registration.

For eHealth Registration

- have read the above Personal Information Collection Statement and understand its content, and agree that eHRO can process and use the personal data provided in this registration to my registration and use of eHealth and related matters under the Electronic Health Record Sharing System Ordinance (Cap 625) (eHRSSO). Such matters include but are not limited to the following: the giving of and management of joining consent and/or sharing consent, updating of information in eHealth, receipt of eHealth notifications, withdrawal from eHealth.
- understand that my health information will be shared among healthcare providers, who have obtained my sharing consent, via eHealth.
- understand that eHRO may contact me to verify the information and handle related matters of my registration and use of eHealth.

I (and the carer) have read and agree to the terms and conditions above.

(D) Declarations

Information and personal data provided by me (and the carer) in the online application, i.e. personal identification document number, name, date of birth, contact number and vaccination target group, will be used for (i) processing the booking request for receiving COVID-19 vaccines under vaccination programmes led by the Government, and handling enquiries relating to the booking; (ii) verifying the relevant information to confirm the eligibility and the status of receiving COVID-19 vaccine of registrant; (iii) informing relevant government bureaux or departments (B/Ds) and organisations for arranging vaccination and follow up after the vaccination; (iv) transferring to the Department of Health and relevant organizations collaborated with the Government (including the University of Hong Kong) for continuous monitoring of the safety and clinical events associated with COVID-19 Vaccination under the COVID-19 Vaccination Programme; and (v) collating statistics and carrying out analysis, where the statistical information obtained will not be released or made available to a third party in a form that identifies the data subjects or any of them.

I (and the carer) hereby declare that all the information I (and the carer) have provided above is true and correct.

Hong Kong Special Administrative Region Government
3 March 2021