

Government responds to approval of vaccine by Sinovac for emergency use

With regard to a media report casting doubt on the approval procedures for authorising the vaccine by Sinovac and leading people to falsely believe that the Government has lowered the standards for authorising the vaccine by Sinovac, the Government pointed out on February 18 that the relevant report is not truthful and provided a response as follows:

On January 25, Sinovac Biotech (Hong Kong) Limited (Sinovac) submitted an application to the Secretary for Food and Health for the authorisation of its COVID-19 vaccine (CoronaVac COVID-19 Vaccine (Vero Cell), Inactivated) for emergency use in accordance with the Prevention and Control of Disease (Use of Vaccines) Regulation (Cap. 599K) (the Regulation). It also then provided supporting documents and information.

The Advisory Panel on COVID-19 Vaccines (Advisory Panel) convened two meetings on February 10 and February 16 respectively for the relevant application. It reached a consensus for submitting a recommendation to the Secretary for Food and Health to approve the vaccine by Sinovac, thereby establishing that the benefits for using the vaccine to protect against COVID-19 outweigh the risks.

The procedures for the Advisory Panel to examine the information and data and the Government to approve the authorisation are stringent and comprehensive. The procedures met all the relevant requirements under the Regulation and were no different from those adopted for approving another vaccine for emergency use in Hong Kong (Comirnaty) earlier.

With respect to the requirement that the information submitted needs to be published in medical journals, Sinovac has indicated that it has considerable difficulties in compiling the relevant information for publication in a short period of time. Sinovac has provided to the Department of Health the Phase 1 and 2 clinical data that it had submitted to the World Health Organization (WHO) and National Medical Products Administration (NMPA), the Phase 3 clinical information of trials conducted in Brazil, as well as the Phase 3 clinical information of trials conducted in Turkey and Indonesia. The relevant data has been examined and assessed by the 12 experts of the Advisory Panel. The experts on the Advisory Panel have all participated in peer reviews in their respective academic fields. With reference to the relevant requirements of WHO guidelines, the Advisory Panel conducted the assessment in a thorough, objective and holistic manner. The relevant procedures are on par with the peer reviews normally conducted for academic journals. The assessment procedures for the relevant information are not different despite the relevant information has not yet been published in medical journals.

According to the Regulation, the Secretary for Food and Health can authorise a vaccine under the following situations: (a) a regulatory

authority in a place outside Hong Kong that performs the function of approving pharmaceutical products has approved the vaccine for administration to persons, including for emergency use; or (b) the vaccine is listed in accordance with the emergency use listing procedure by the WHO or is in the list of prequalified vaccines published by the WHO. In other words, under the framework of the Regulation, approval by the WHO is not an essential requirement for authorising a vaccine for emergency use in Hong Kong. In fact, a number of overseas regulatory authorities have approved vaccines for emergency use before the individual vaccines (including the "Comirnaty" vaccine) were listed for emergency use/prequalified by the WHO. Currently, the Sinovac vaccine has been approved for use by the regulatory authorities of Brazil, Turkey, Indonesia, Chile and Mexico, and the NMPA. Casting doubt on the authorisation procedures for emergency use due to authorisation from the WHO yet to be obtained stems from misunderstanding of the mechanism for authorising vaccines for emergency use in the international arena.

The Government spokesman said, "The Government will ensure that COVID-19 vaccines satisfy the criteria of safety, efficacy and quality before arranging for members of the public to receive the vaccines. Our work will continue to adhere to the principles of openness and transparency, so that the public can grasp correct and comprehensive information on the vaccines."

Government announces 2019 COVID-19 Vaccination Programme (with video)

The Government announced today (February 18) the arrangements for the territory-wide COVID-19 Vaccination Programme.

A Government spokesman said that the Government had purchased three different vaccines with a total of 22 500 000 doses, which would be sufficient for vaccinating all people in Hong Kong. As the vaccines will arrive in Hong Kong in batches, there is a need for the Government to identify priority groups for vaccination with a view to taking forward the programme in a gradual and orderly manner.

According to the recommendations of the two scientific committees under the Centre for Health Protection of the Department of Health and the four expert advisers appointed by the Chief Executive, and taking into account the supply situation of the vaccines, the Government decided to arrange priority vaccination for the five groups below:

1. Healthcare staff and staff involved in anti-epidemic work;
2. Persons aged 60 or above (A maximum of two carers who accompany elderly people aged 70 or above can also receive vaccination);
3. Residents and staff of residential care homes for the elderly and

persons with disabilities;

4. People providing essential public services;

5. People providing cross-boundary transportation or working at control points and ports.

There will be four channels of vaccination, namely 29 Community Vaccination Centres (CVCs) in the 18 districts across the territory, over 1 200 private doctors of more than 1 500 clinics participating in the programme, 18 general out-patient clinics of the Hospital Authority (HA), as well as residential care homes for the elderly and for persons with disabilities.

Health care staff will provide vaccination services to the public at the CVCs. Among the CVCs, five of them will provide the Sinovac vaccine while 24 of them will provide the Fosun Pharma/BioNTech vaccine. The CVCs will commence operation in phases, depending on the arrival of the vaccines in Hong Kong, the quantity of vaccines and the situation of vaccination. Only one vaccine will be administered in a CVC.

The 29 CVCs will operate from 8am to 8pm daily. Members of the public can select the vaccine to be inoculated, and reserve the time and place of their first and second doses through the 24-hour online booking system on the designated website (www.covidvaccine.gov.hk). If necessary, people can seek assistance for making online bookings from post offices or the estate management offices of the public housing estates they reside. After vaccination, they will receive paper vaccination records. They can also download their electronic vaccination records via the "iAM Smart" mobile app.

The spokesman said members of the public must make prior appointments for receiving vaccinations in CVCs or in the 18 general out-patient clinics of the HA so that adequate vaccines can be reserved according to the bookings and wastage reduced.

For residents of residential care homes for the elderly and persons with disabilities as well as nursing homes, the Government will arrange outreach vaccination teams formed by doctors and nurses to provide vaccination services to them.

After launching the vaccination programme, the Government will, having regard to the actual situation, consider covering people aged between 16 and 59 with chronic diseases as well, and then other members of the public under 60.

The spokesman said that for the two vaccines procured under the advance purchase agreement, the first batch of one million doses of Sinovac will arrive in Hong Kong tomorrow, while the first batch of one million doses of the Fosun Pharma/BioNTech vaccine, manufactured in Germany, are expected to arrive by the end of this month.

The vaccination programme will open for online appointments starting from next Tuesday (February 23). The priority groups can receive the Sinovac

vaccine at the five CVCs and the 18 general out-patient clinics of the HA starting from February 26. More than a thousand of private doctors participating in the programme are also expected to administer Sinovac vaccine before mid March.

The spokesman said that vaccination is a top priority of the anti-epidemic measures. Members of the public are encouraged to fight the virus by getting vaccinated early so that to enable Hong Kong to fight successfully the epidemic as soon as possible.

For information about the vaccination, please visit the designated website at www.covidvaccine.gov.hk .

Government completed investigation of false positive virus testing results by a private laboratory

The Food and Health Bureau (FHB) and the Department of Health (DH) have completed the investigation of the false positive virus testing results by a private laboratory, and requested the private laboratory to continue to strictly follow the improvement measures to ensure that such incident will not occur again.

The concerned private laboratory is BGI. In late January and earlier this month, the Public Health Laboratory Services Branch (PHLSB) of the DH, when conducting confirmatory tests for preliminary positive specimens referred by the concerned private laboratory on January 29, February 1 and 2, found that the COVID-19 testing results of some of these specimens to be negative. The Hospital Authority (HA) arranged new specimens to be collected from these cases for further testing, which were also tested negative. The incident involved 16 false positive results, including 8 cases from the Targeted Group Testing Scheme for teaching and non-teaching staff and staff of boarding section of special schools on January 29; and 4 cases from the compulsory testing arrangement for residents and visitors of Heng Lok House of Tin Heng Estate in Tin Shui Wai on February 1. The other 4 cases pertained to specimens collected from a mobile testing station and a community testing centre.

The Government attaches great importance to the incident of false positive testing results by the private laboratory. The private laboratory was requested to conduct thorough investigation, submit investigation report with improvement measures.

The concerned private laboratory has conducted a thorough investigation into the root cause leading to false positive results in accordance with the

Government's request, and submitted to the DH on February 11 a report examining the potential areas of lapses, including human error, reagents carryover or contamination and environmental contamination as well as the corrective and improvement measures taken. The concerned private laboratory adopted with effect from February 4 additional confirmatory tests on preliminary positive specimens as one of the corrective and improvement measures. It was noted that no further false positive results have been detected from BGI since February 4, after the corrective measure was implemented.

A spokesman of the Food and Health Bureau said, "The Government will continue to follow up the corrective and improvement measures in the report and closely monitor the accuracy of testing service provided by the concerned private laboratory to ensure that similar incident shall not occur again."

In accordance with the existing mechanism of the DH, specimens tested with a positive COVID-19 result in all private laboratories are considered preliminary positive. The specimens must be referred to the PHLSB in accordance with established procedures for confirmatory tests. After a positive result is confirmed by the PHLSB, the Centre for Health Protection will classify the case as a confirmed one. The DH may collect samples for the relevant cases again for further testing if necessary. From mid-November 2020 to February 14, 2021, a total of 3.76 million COVID-19 tests were conducted in Hong Kong, identifying 5 142 positive cases (0.14 per cent).

Persons affected by the incident were sent to HA's facilities and were subsequently tested negative and discharged. Close contacts of the persons affected have also left the quarantine centre. "We extend apologies to the persons affected by this incident," said the spokesman.

Government gazettes compulsory testing notice

The Government exercised the power under the Prevention and Control of Disease (Compulsory Testing for Certain Persons) Regulation (Cap. 599J) and published in the Gazette a compulsory testing notice, which requires any person who had been present at five specified premises during the specified period (persons subject to compulsory testing) to undergo a COVID-19 nucleic acid test.

Currently, in all districts in Hong Kong, if one or more new confirmed cases are found in the residential buildings (including buildings for both commercial and residential uses), or there are sewage samples tested positive which implied possible infection risks, the buildings will be included in the compulsory testing notice.

For testing targeting at workplaces, if two or more confirmed cases are found in a workplace, it will be included in the compulsory testing notice.

Five buildings fulfilling the above criteria were included in the compulsory testing notice today (February 18).

Details of the compulsory testing notice are as follows:

Any person who had been present at any specified premises listed in Annex 1 for more than two hours at any time during the period from February 5 to February 18, 2021 (including but not limited to visitors, residents and workers), have to undergo testing by February 20, 2021. If persons subject to compulsory testing have previously undergone testing between February 16 and February 18, 2021, they would be taken to have complied with the requirements set out in the compulsory testing notice.

Furthermore, a spokesman for the Food and Health Bureau reminds the public that in accordance with the compulsory testing notice issued earlier, all household members of close contacts are required to undergo compulsory testing. Any person who had lived with a person who is placed under quarantine pursuant to section 22 of the Prevention and Control of Disease Regulation (Cap. 599A) (person under quarantine) in the same residential unit on the date of commencement of quarantine or during the 14 days before that day, and who becomes aware of the quarantine of the person under quarantine when the relevant quarantine has not yet been completed, have to undergo testing within two days of he/she becoming aware of the person under quarantine has been placed under quarantine and report to the Government the result of the test by phone (at 6275 6901), fax (at 2530 5872) or email (ct@csb.gov.hk) within three days of undergoing the test.

The Government will set up mobile specimen collection stations at Sau Mau Ping Estate in Kwun Tong, Greenhill Villa in Sha Tin and Sai Kung Jockey Club Town Hall tomorrow (February 19). The service period of the mobile specimen collection stations at 100 Grandville Road in Tsim Sha Tsui and Tsuen Nam Road, Tai Wai (near Exit A of Tai Wai MTR Station) will be extended to February 21 (Sunday). The opening dates and operating hours of the mobile specimen collection stations in various districts providing free COVID-19 nucleic acid testing services for the general public are stated in Annex 2. Apart from mobile specimen collection stations, persons subject to compulsory testing can also choose to attend any of the community testing centres in all districts to receive testing free of charge.

Persons subject to compulsory testing may choose to undergo testing via the following routes:

1. To visit any of the mobile specimen collection stations (see the list and target groups (if applicable) at www.coronavirus.gov.hk/eng/early-testing.html) for testing;
2. To attend any of the community testing centres (see the list at www.communitytest.gov.hk/en/);
3. To obtain a deep throat saliva specimen collection pack from any of the 121 post offices, vending machines set up at 20 MTR stations or 47 designated

general outpatient clinics (GOPCs) of the Hospital Authority and return the specimen to one of the designated specimen collection points (see the distribution points and times, and the specimen collection points and times, at www.coronavirus.gov.hk/eng/early-testing.html);

4. To undergo testing at any of the GOPCs of the Hospital Authority as instructed by a medical professional of the Hospital Authority;

5. To self-arrange testing provided by private laboratories which are recognised by the Department of Health (DH) and can issue SMS notifications in respect of test results (see the list

at www.coronavirus.gov.hk/pdf/List_of_recognised_laboratories_RTPCR.pdf); or

6. To use a specimen bottle distributed to the relevant specified premises by the Centre for Health Protection (if applicable), and return the specimen bottle with the sample collected as per relevant guidelines.

The spokesman cautioned that testing received at accident and emergency departments of the Hospital Authority or during hospital stays, or testing provided by private laboratories which cannot issue SMS notifications in respect of test results, does not comply with the requirements of the aforementioned compulsory testing notice.

"If persons subject to compulsory testing have symptoms, they should seek medical attention immediately and undergo testing as instructed by a medical professional. They should not attend the mobile specimen collection stations or the community testing centres."

Persons subject to compulsory testing must keep the SMS notification containing result of the test for checking by a law enforcement officer when the officer requires the persons to provide information about their undergoing the specified test.

Furthermore, persons subject to testing under the compulsory testing notices should, as far as reasonably practicable, take appropriate personal disease prevention measures including wearing a mask and maintaining hand hygiene, and, unless for the purpose of undergoing the specified test, stay at their place of residence and avoid going out until the test result is ascertained as far as possible.

Any enquiries on compulsory testing arrangements may be addressed to the hotline at 6275 6901, which operates daily from 9am to 6pm. If persons subject to compulsory testing plan to conduct testing at any of the community testing centres, they can check the centre's appointment status in advance. The hotlines of the community testing centres are available at www.communitytest.gov.hk/en/info/.

The Government will continue to trace possibly infected persons who had been to the relevant premises, and seriously verify whether they had complied with the testing notices. Any person who fails to comply with the testing notices commits an offence and may be fined a fixed penalty of \$5,000. The person would also be issued with a compulsory testing order requiring him or her to undergo testing within a specified time frame. Failure to comply with the order is an offence and the offender would be liable to a fine at level 4 (\$25,000) and imprisonment for six months.

Relevant officers of different government departments are empowered to perform certain functions under the relevant Regulations under the Prevention and Control of Disease Ordinance (Cap. 599), including requesting individuals to provide information and assistance when necessary. Any person who fails to comply with the relevant request commits an offence and would be liable to a fine at level 3 (\$10,000). Collection and use of any personal data for conducting COVID-19 tests must meet the requirements under the Personal Data (Privacy) Ordinance (Cap. 486). Government departments or testing service providers which handle the relevant information may provide the data to DH or other relevant departments for anti-epidemic purpose as necessary. The workflow does not involve the provision of any personal data to organisations or persons outside Hong Kong.

The spokesman said, "The Government urges all individuals who are in doubt about their own health conditions, or individuals with infection risks (such as individuals who visited places with epidemic outbreaks or contacted confirmed cases), to undergo testing promptly for early identification of infected persons."

[Reminder for Hong Kong residents returning to Hong Kong under Return2hk Scheme](#)

As many Hong Kong residents are returning to Hong Kong from the Guangdong Province after the Lunar New Year festive period, to ensure smooth immigration clearance at the boundary control points, the Government reminded the Hong Kong residents who wish to return to Hong Kong under "Return2hk – Travel Scheme for Hong Kong Residents returning from Guangdong Province or Macao without being subject to quarantine under the Compulsory Quarantine of Certain Persons Arriving at Hong Kong Regulation (Cap. 599C)" (Return2hk Scheme) that they should fulfil all the specified conditions in order to be exempted from the 14-day compulsory quarantine requirement upon their return.

The specified conditions under the Compulsory Quarantine of Certain Persons Arriving at Hong Kong Regulation (Cap. 599C) by the Secretary for Food and Health include:

- (1) not having been to places other than Hong Kong, Guangdong Province or Macao in the past 14 days;
- (2) being able to present the proof of a valid negative nucleic acid test result conducted in any medical institution located in Guangdong Province or Macao that is mutually recognised by the governments of Hong Kong and Guangdong/Hong Kong and Macao upon arrival; and

(3) holding a quota allocation of the Return2hk Scheme and returning to Hong Kong on the date and at the boundary control point as specified in the booking.

A Government spokesman said, "Hong Kong residents who wish to return to Hong Kong under the Return2hk Scheme should apply under a quota using the online booking system (www.quotabooking.gov.hk/cbt_booking/index_hk.jsp). The online booking system is now open for booking 24/7 to assist members of the public to make reservations at their convenience."

"Hong Kong residents who have successfully applied for a quota allocation should allow sufficient time for taking a COVID-19 nucleic acid test at one of the medical institutions mutually recognised by the governments of Hong Kong and Guangdong/Hong Kong and Macao, such that they present proof of a valid negative nucleic acid test result upon arrival in Hong Kong. The sample should be taken within three days prior to, or on the day of the person's entry into Hong Kong. Currently there are 51 recognised medical institutions in Guangdong Province, and four recognised medical institutions in Macao. The lists of recognised medical institutions are available on the dedicated website for the Return2hk Scheme."

As many Hong Kong residents are returning from the Guangdong Province to Hong Kong shortly, to expedite the clearance process, reduce waiting time and avoid network connection problems at the boundary control points, the Government spokesman strongly advised Hong Kong residents who intend to return to Hong Kong under the Return2hk Scheme to, apart from returning on the date and at the boundary control point as specified in their booking, complete the code conversion process through the "Yuekang code" ($\zeta^2\mu\mathfrak{a}^{\mathfrak{a}}\cdot\zeta\mathfrak{c}\frac{1}{4}$) or the "Macao Health Code" ($\mathfrak{x}\frac{3}{4}\mathfrak{a}^{\mathfrak{a}}\cdot\zeta\mathfrak{c}\frac{1}{4}$) within 24 hours before setting off to obtain a "Green" QR code (see attachments). A dedicated channel has been set up at the boundary control points for the use of travellers with a "Green" QR code. They should also bring along their Hong Kong identity card or other identification documents, the confirmation of a successful booking (i.e. an electronic copy or a printout of the booking confirmation page) as well as the proof of a valid negative nucleic acid test result (paper or electronic copy are both acceptable) for checking if necessary when they return to Hong Kong.

"If the code conversion process generates a QR code of a different colour (e.g. a 'Pink' QR code), it means the traveller has yet to fulfil all the specified conditions, and he or she may still be subject to the 14-day compulsory quarantine requirement upon entry into Hong Kong", said a Government spokesman.

The Government has produced user guides on "code conversion" for the easy reference of returning Hong Kong residents. They are available at the links below:

Transmission of the valid negative COVID-19 nucleic acid test result to the electronic health declaration system of the Department of Health through the "Yuekang code" ($\zeta^2\mu\mathfrak{a}^{\mathfrak{a}}\cdot\zeta\mathfrak{c}\frac{1}{4}$):

Video (in Chinese only): youtu.be/okGoaF70b2U

PDF version (English

version): www.coronavirus.gov.hk/pdf/Return2hk_Code_Conversion_Use_Guide_en.pdf

Transmission of the valid negative COVID-19 nucleic acid test result to the electronic health declaration system of the Department of Health through the "Macao Health Code" (澳門健康码)

Video (in Chinese only): youtu.be/CbHg6Bsb22Q

PDF version (English

version): www.coronavirus.gov.hk/pdf/Return2hk_Code_Conversion_Use_Guide_en.pdf

Details of the Return2hk Scheme and the lists of medical institutions mutually recognised by the governments of Hong Kong and Guangdong/Hong Kong and Macao, are available on the dedicated website (return2hk.gov.hk or www.return2hk.gov.hk). Members of the public may also call the hotline of the Return2hk Scheme at 3142 2330 if they have any enquiries.