LEGISLATIVE COUNCIL BRIEF

Prevention and Control of Disease Ordinance (Cap. 599)

PREVENTION AND CONTROL OF DISEASE (USE OF VACCINES) REGULATION

INTRODUCTION

At the meeting of the Executive Council on 23 December 2020, the Council **ADVISED** and the Chief Executive ("CE") **ORDERED** that **the Prevention and Control of Disease (Use of Vaccines) Regulation** ("the Regulation") (at Annex) should be made under section 8 of the Prevention and Control of Disease Ordinance (Cap. 599) ("the Ordinance") to empower the Secretary for Food and Health ("SFH") to, having regard to the advice of an advisory panel of persons with the relevant expertise to be appointed by CE, authorize a vaccine for COVID-19 virus, that is not yet registered under the Pharmacy and Poisons Regulations (Cap. 138 sub. leg. A) ("Cap. 138A"), on an emergency basis, for a specified purpose (which is defined in the Regulation as the purpose of carrying out a Government vaccination programme or a reasonable purpose specified by SFH).

JUSTIFICATIONS

Latest Local Situation

2. As of 19 December 2020, the Centre for Health Protection of the Department of Health ("DH") had recorded a total of 8 079 cases of COVID-19. Over the past two weeks (6 to 19 December 2020), a total of 1 276 cases were reported, with 1 192 local cases (of which 438 cases involved unknown sources of infection) and 84 imported cases.

3. The third wave of the epidemic in Hong Kong, which began in early July 2020, has subsided by late September, but new local cases especially those with unknown sources continue to be reported. There had been an increase in the number of cases in November, with a sharp rise since late

November. In the past 2 weeks (6 to 19 December 2020), the number of new cases had stayed at a high level, with a daily average of over 90 cases. Locally acquired cases contributed to over 93% of the cases reported, with the 7-day moving average of the number of local cases at 84.7 (on 19 December 2020).

4. Clusters of locally-acquired cases related to various venues/settings were being reported, particularly since the second half of November. Apart from the dancing/singing cluster, outbreaks were also reported at food premises, residential care homes for the elderly ("RCHE") / residential care homes for the disabled ("RCHD"), workplace/construction sites, etc., including a number of large clusters involving over 20 cases. Compared with the situation during the "third wave", the clusters/outbreaks in the current wave appear to be growing more rapidly in terms of the number as well as the size of the clusters. The dance/singing cluster had continued to grow in size, with up to 730 cases recorded (as at 19 December 2020) since the reporting of the first case in mid-November. Of particular concern are the outbreaks involving RCHE/RCHD, as the residents are often vulnerable populations, and are more prone to infection and complications. In addition, there are increased number of clusters involving residents from the same residential buildings necessitating frequent activation of multi-disciplinary response team, with ensuing evacuation of residents to quarantine sites. The potential impact of environmental factors at residential buildings contributing to transmission of infection could be significant, particularly when considering the dense living conditions and the large number of aged building structures in Hong Kong.

5. The number of local cases of unknown links/sources is increasing. Among the locally-acquired cases reported in the past 2 weeks (6 to 19 December 2020), over 36% were of unknown sources/ links. The 7-day moving average of the number of locally-acquired cases of unknown links/ sources has reached 33.4 (on 19 December 2020), compared to the level of 23.4 (on 6 December 2020). This signifies that diffuse silent transmission is actively ongoing in the community. Despite the extensive investigation and contact tracing efforts, contact tracing alone would not be sufficient to control the transmission. The epidemic situation is getting increasingly severe, with increasing risks of massive community outbreaks. There is an urgent need to further tighten social distancing measures, together with stringent environmental and personal hygiene measures, to prevent escalation of the epidemic situation into explosive community outbreaks.

The Global Race for a COVID-19 Vaccine

6. With a view to putting a stop to the pandemic as quickly as possible, vaccine developers have taken forward clinical trials of COVID-19 candidate vaccines at an unprecedented speed, compressing the development and trial processes which typically take up to five to ten years to less than one year. According to the Landscape of COVID-19 Candidate Vaccines published by the World Health Organization ("WHO"), as at 31 December 2020, 60 candidate vaccines are under clinical trials for safety and efficacy evaluation, with 11 of them having entered the most advance phase 3 clinical trial. Generally speaking, there are four main technology platforms for developing COVID-19 vaccines, namely mRNA, viral vector, inactivated virus and protein subunit. To date, no vaccine has yet obtained full registration approval by healthcare authorities of any jurisdiction for human application.

Hong Kong's Vaccine Procurement Strategy

7. Securing sufficient supplies of safe and efficacious vaccines for the population is crucial to safeguarding the public's health and suppressing the COVID-19 epidemic in Hong Kong so that normal operations of society can gradually resume. All along, the Government has adopted a "two-pronged" strategy to procuring vaccines meeting the criteria of safety, efficacy and quality. In addition to joining the COVAX Facility ("COVAX") led by the WHO, we have also been negotiating with individual vaccine developers for entering into advance purchase agreements ("APAs") to directly procure supplies of the candidate vaccines, having regard to the advice of the Joint Scientific Committees under DH and expert group as well as scientific evidence and clinical data. We have secured funding of about $8.4 billion from the Finance Committee ("FC") of the Legislative Council ("LegCo") for procurement and administration of COVID-19 vaccines.

8. For APAs, the Government's goal is to procure at least two candidate vaccines from different vaccine developers and technology platforms. In order to ensure that every citizen has access to the vaccines, our goal is to secure sufficient doses to cater for at least two times the Hong Kong population as a hedging strategy, having considered that the attrition rate of COVID-19 vaccines is expected to be around 50%. As at 31 December 2020, we have reached agreement with three vaccine developers to procure three different 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.

(i) A maximum of 7.5 million doses of the CoronaVac developed by Sinovac Biotech (Hong Kong) Limited. The CoronaVac is developed from the inactivated virus technology platform. The first batch of 1 million doses is expected to be delivered to Hong Kong in January 2021 the earliest and can be administered to members of the public upon obtaining the relevant authorization under the new regulation.

(ii) A maximum of 7.5 million doses of BNT162b2 jointly developed by BioNTech and Fosun Pharma. BNT162b2 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.

(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. 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.

9. As regards COVAX, there is an allocation mechanism premised on equal access to the vaccines and the number of doses allocated to a participant hinges on a myriad of factors, including the total demand by COVAX participants, the participant's corresponding pro rata share, and the total number of doses made available by the relevant vaccine developer. Given the keen global demand for vaccines in the initial phase, COVAX has indicated that doses are likely to be provided only in the latter half of 2021. We have indicated to procure doses for up to 35% of our population, though supply in excess of the initial 20% would depend on global demand and supply at that time.

Existing Registration Regime for Pharmaceutical Products

10. Hong Kong has a long-standing regulatory framework and registration system for pharmaceutical products. Pursuant to Cap. 138A, medicines (pharmaceutical products) must be registered with the Pharmacy and Poisons Board ("PPB") prior to their sale in the market. "Pharmaceutical products" including vaccines are required to conform to the

relevant criteria on safety, efficacy and quality before they can obtain registration.

11. At present, Hong Kong adopts secondary evaluation in processing registration applications of new chemical or biological entities, and this means we mainly rely on approvals from overseas competent drug regulatory agencies or authorities which have conducted primary evaluation[1] and fully complied with the technical standards and requirements promulgated by the International Council for Harmonisation[2]. In view of the unprecedented speed in the development of vaccine for the prevention or protection against the transmission of COVID-19, the available data related to the safety, quality and efficacy are not sufficient for attaining full market approvals from overseas drug regulatory authorities as most of the phase 3 clinical trials on the vaccines are still ongoing. Given the nature of the threat we face, there is a compelling case, on public health grounds, to put in place a legislative framework that enables us to take the very unusual step of allowing, as soon as possible, the use of a tested COVID-19 vaccine based on the totality of available evidence showing that the vaccines are safe and effective, and to enable on-going monitoring of safety, quality and efficacy data to support the eventual transition of the emergency approval to full registration by the PPB.

REGULATORY FRAMEWORK FOR EMERGENCY USE OF COVID-19 VACCINE

12. The legislative framework allows for emergency use authorization – a mechanism that is based on the totality of scientific evidence available concluding that the vaccines are safe and effective, to enable the public to gain early access to promising investigational vaccines when those products have not yet received full registration approval.

13. The Secretary for Food and Health ("SFH"), upon application by a vaccine manufacturer or its representative, importer, or wholesale dealer, for

[1] To conduct primary evaluation of registration applications, the raw data and result together with the rationale of the study (e.g. comparison with existing treatment for a disease, unmet medical need, new drug indication or new formulation, etc.) and study protocol (e.g. how many subjects to generate results with statistical power, the choice of end points such as surrogate or clinical, single-blind or double-blind, randomization, etc.) for conducting human clinical trials shall be evaluated by specialized experts in the fields of toxicology, pharmacology, statistics, etc.

[2] The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use ("ICH") is unique in bringing together the regulatory authorities and pharmaceutical industry to discuss scientific and technical aspects of drug registration. ICH regulators is required to implement the final Guidelines to ensure that safe, effective, and high quality medicines are developed and registered.

authorization, having regard to the advice of an advisory panel served by persons with relevant expertise to be appointed by CE, may, on an exceptional basis, authorize a vaccine for a specified purpose, with a power to attach conditions to the authorization. It is envisaged that conditions to be attached to an authorization may include requiring the applicant to submit ongoing clinical trial data and report adverse event after vaccination, etc.

14. It should be stressed that while emergency access to vaccines is critical, we remain mindful of a vaccine's safety and efficacy standards, with adequate and promising data from phase 3 clinical studies supporting the positive benefit-risk profile for emergency use that vaccine candidates must meet. Thus, SFH may authorize a vaccine only if (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 other than on an experimental or trial basis, 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.

15. We have set up the advisory panel, comprising experts from relevant fields to advise SFH, on a case-by-case basis, on the authorization of COVID-19 vaccine(s) for emergency use based on, among others, the available data concerning safety and efficacy and scientific evidence, and on matters related to administration of the vaccine(s). In addition, on-going safety monitoring and submission of new clinical data would be required for review from time to time. The law also requires that SFH put in place a mechanism for monitoring any adverse event associated with the administration of the vaccines. Informed consent must be obtained before the vaccine is administered to the recipients.

16. To ensure that members of the advisory panel tender advice to the Government and the workforce of health professionals (e.g. doctors and nurses) take part in administering the authorized vaccines for a specified purpose without worries of possible claims of civil liability, the Regulation provides immunity to them, who have acted in good faith, as appropriate.

INDEMNITY FUND

17. Even under normal circumstances, vaccines that are approved for general use may, in rare cases, cause unexpected serious adverse events ("SAEs"). 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 if this risk is not addressed. It is hence common in bilateral deals for governments purchasing the vaccines to 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. To cover for the indemnity offered to vaccine manufacturers under bilateral purchase agreements, and to provide support for individuals who have proof of suffering unexpected SAEs associated with a vaccine pending, or in lieu of, their civil actions against a vaccine manufacturer, an indemnity fund will be set up. While relevant details are to be worked out, the claims of unexpected SAEs should be backed up through the monitoring of adverse drug reaction under the pharmacovigilance programme that DH is setting up specific to COVID-19 vaccines.

OTHER OPTIONS

18. Currently, pursuant to the Pharmacy and Poisons Ordinance (Cap. 138), medicines (pharmaceutical products) must be registered with the PPB prior to their sale in the market. "Pharmaceutical product" includes vaccines. Due to the reasons explained in paragraph 11 above, there is no option besides introducing a new legislative framework to allow the use of non-registered COVID-19 vaccines in Hong Kong outside the existing drug registration regime in emergency situations.

THE REGULATIONS

19. The main provisions of the Regulation are set out below –

(a) **Section 3** provides that for preventing, protecting against, delaying or otherwise controlling the incidence or transmission of, or mitigating a serious or life threatening condition arising from COVID-19, SFH may, on application, authorize a vaccine that is not registered under Cap. 138A for a specified purpose. In granting authorization, SFH must have regard to the advice of the advisory panel consisting of persons with relevant expertise, and take into account the following considerations -

i. the safety of the vaccine;
ii. the efficacy of the vaccine; and
iii. the quality of the vaccine.

It further provides that SFH may authorize a vaccine only if–

i. a regulatory authority in a place outside Hong Kong that performs the function of approving pharmaceutical products for use in that place has approved the vaccine for administration to persons other than on an experimental or trial basis, including for emergency use, or 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;
ii. SFH considers that, for making the vaccine available urgently to deal with the threat to public health, the authorization is necessary and is in the public interest; and
iii. SFH considers that, for a specified purpose, there is no or insufficient supply of, or the vaccine is an alternative to, registered vaccines or other authorized vaccines.

(b) Sections 4, 5 and 6 respectively provide for the power to attach conditions to an authorization, the effective period of an authorization and the revocation of an authorization. In particular, SFH has to consult the advisory panel before attaching, varying or revoking a condition of an authorization or revoking an authorization. The authorization will cease to have effect after 12 months (or other periods as extended by SFH) or its earlier revocation.

(c) **Section 7** provides that relevant requirements under Cap. 138A do not apply in relation to –

i. certain use of a non-registered vaccine in connection with a Government contract;
ii. the use of an authorized vaccine for a specified purpose.

It further requires that SFH must put in place a mechanism for monitoring any adverse event occurred to the recipients associated with the administration of the vaccines.

(d) **Section 8** requires that before an authorized vaccine is administered to a person (i.e. recipient), each person who is

responsible for administering the vaccine must ensure that the recipient[3] has been informed that the vaccine has been authorized under this Regulation instead of registered under Cap. 138A and relevant consent has been given by the recipient.

(e) **Section 9** provides that CE may appoint a panel of persons who are considered by CE to have relevant expertise for advising SFH. It also provides for the immunity from civil liability of such panel members for an act done or omitted to be done in good faith in relation to the giving of advice for the purposes of the Regulation.

(f) **Section 10** provides for the immunity from civil liability of persons who prescribes or dispenses, or is responsible for administering, an authorized vaccine for a specified purpose in relation to loss or damage resulting from any risk as to the safety of the administration of the vaccine attributable to the intrinsic property of the vaccine as manufactured.

(g) **Section 12** provides for the expiry of the Regulation.

LEGISLATIVE TIMETABLE

20. The legislative timetable is as follows –

Publication in the Gazette	23 December 2020
Commencement	24 December 2020
Tabling at Legislative Council	6 January 2021

IMPLICATIONS OF THE PROPOSAL

21. The proposal under the Regulation is in conformity with the Basic Law, including the provisions concerning human rights. LegCo FC has approved funding of about $8.4 billion for the procurement and administration of vaccine. Funding, as well as any additional manpower resources, for the proposed indemnity fund will be sought separately in accordance with the established practice.

[3] In case of a person who is not legally capable of giving consent, the person who is legally capable of giving consent on that person's behalf.

PUBLIC CONSULTATION

22. Given the exigency of the situation, public consultation was not feasible.

PUBLICITY

23. We issued a press release and announced the Regulation at a press conference on 23 December 2020. A spokesperson was also made available to respond to public or media enquiries.

BACKGROUND

24. 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 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.

25. Section 8 of the Ordinance empowers the CE in Council to make regulation on an occasion of a public health emergency for the purposes of preventing, combating or alleviating the effects of the public health emergency and protecting public health. Among others, the occurrence of a novel infectious disease or the imminent threat of an epidemic that has a high probability of causing a large number of deaths or serious disabilities (whether or not long term) in the population constituted a public health emergency.

ENQUIRIES

26. For enquiries on this brief, please contact the Food and Health Bureau at 3509 8765.

Food and Health Bureau
December 2020

Prevention and Control of Disease (Use of Vaccines) Regulation

Contents

Prevention and Control of Disease (Use of Vaccines) Regulation

(Made by the Chief Executive in Council under section 8 of the Prevention and Control of Disease Ordinance (Cap. 599))

1. Commencement

This Regulation comes into operation on 24 December 2020.

2. Interpretation

In this Regulation—

advisory panel (顧問專家委員會) means the panel appointed under section 9;

authorization (認可) means an authorization granted under section 3(1);

authorization applicant (申請認可者), in relation to an authorization, means the person on whose application the authorization is granted;

authorized vaccine (認可疫苗) means a non-registered vaccine that is authorized under section 3(1);

Cap. 138A (《第 138A 章》) means the Pharmacy and Poisons Regulations (Cap. 138 sub. leg. A);

non-registered vaccine (非註冊疫苗) means a vaccine that is not registered;

pharmaceutical product (藥劑製品) has the meaning given by section 2(1) of the Pharmacy and Poisons Ordinance (Cap. 138);

recipient (接種者), in relation to a vaccine, means the person to whom the vaccine is administered;

registered (註冊) means registered under regulation 36 of Cap. 138A;

Secretary (局長) means the Secretary for Food and Health;

specified disease (指明疾病) means the coronavirus disease 2019 (COVID-19), which is specified in item 8A of Schedule 1 to the Ordinance;

specified purpose (指明目的) means—

(a) the purpose of carrying out a programme that is conducted by the Government to administer authorized vaccines to members of the public, or a section of the public, on an emergency basis, for preventing, protecting against, delaying or otherwise controlling the incidence or transmission of, or mitigating a serious or life-threatening condition arising from, the specified disease; or

(b) any other reasonable purpose that—

(i) relates to the use of an authorized vaccine for preventing, protecting against, delaying or otherwise controlling the incidence or transmission of, or mitigating a serious or life-threatening condition arising from, the specified disease; and

(ii) is specified by the Secretary;

use (使用), in relation to a vaccine, includes distribute, supply, offer for supply, possess, prescribe, dispense and administer;

vaccine (疫苗) means a pharmaceutical product that—

(a) contains an antigenic substance or is intended to stimulate, after the product has been administered to a person, the production of an antigenic substance in that person's body; and

(b) is intended to stimulate a person's immune system to produce immunity to the specified disease.

3. Secretary may authorize vaccine for specified purpose

(1) For preventing, protecting against, delaying or otherwise controlling the incidence or transmission of, or mitigating a serious or life-threatening condition arising from, the specified disease, the Secretary may, on application, authorize a non-registered vaccine for a specified purpose.

(2) The application must be—

(a) made by—

(i) for a vaccine that satisfies the condition referred to in subsection (4)(a)(i)—a person who, in relation to the vaccine, is one described in regulation 36(1)(a), (b) or (c) of Cap. 138A; or

(ii) for a vaccine that satisfies the condition referred to in subsection (4)(a)(ii)—

(A) a person described in subparagraph (i); or

(B) a manufacturer of the vaccine outside Hong Kong, or a branch, subsidiary, representative, agent or distributor of the manufacturer; and

(b) made in the manner, and accompanied by the information, specified by the Secretary.

(3) Before the Secretary authorizes a vaccine, the Secretary must, having regard to the advice of the advisory panel, take into consideration—

(a) the safety of the vaccine;

(b) the efficacy of the vaccine; and

(c) the quality of the vaccine.

(4) The Secretary may authorize a vaccine only if—

(a) the vaccine satisfies any of the following conditions—

(i) a regulatory authority in a place outside Hong Kong that performs the function of approving pharmaceutical products for use in that place has approved, whether or not with any condition, limitation or restriction, the vaccine for administration to persons other than on an experimental or trial basis, including for emergency use;

(ii) the vaccine is listed in accordance with the emergency use listing procedure by WHO or is in the list of prequalified vaccines published by WHO;

(b) the Secretary considers that, for making the vaccine available urgently to deal with the threat to public health posed by the specified disease, the authorization is necessary and is in the public interest; and

(c) the Secretary considers that, for a specified purpose, there is no or insufficient supply of, or the vaccine is an alternative to, registered vaccines or other authorized vaccines.

(5) On determining an application for an authorization, the Secretary must—

(a) notify the person who makes the application of the decision in writing; and

(b) if the Secretary refuses the application—state the grounds for the refusal in the notification.

(6) If the Secretary decides to grant an authorization, the Secretary must publish a notice of the authorization in the Gazette stating—

(a) the name of the vaccine authorized;

(b) the date on which the authorization takes effect;

(c) the name and address of the authorization applicant;

(d) the name and address of the manufacturer of the vaccine; and

(e) the conditions (if any) attached to the authorization under section 4.

(7) In this section—

approve (批准) includes authorize and permit (however described).

4. Conditions of authorization

(1) The Secretary may, after having regard to the advice of the advisory panel—

(a) attach to an authorization any condition that the Secretary considers appropriate;

(b) vary the condition; or

(c) revoke the condition.

(2) If the Secretary varies or revokes a condition attached to an authorization, the Secretary must—

(a) notify the authorization applicant in writing of the variation or revocation; and

(b) publish a notice of the variation or revocation in the Gazette.

5. Effective period of authorization

(1) An authorization of a vaccine—

(a) takes effect on the date referred to in section 3(6)(b); and

(b) ceases to have effect when—

(i) the authorization is revoked under section 6; or

(ii) if the authorization is not so revoked—the period referred to in subsection (2) expires.

(2) For the purposes of subsection (1)(b)(ii), the period is a period of 12 months after the date on which the authorization takes effect, but the Secretary may, by notice published in the Gazette, extend the period, each time for a period of not more than 6 months.

6. Revocation of authorization

(1) The Secretary may, after having regard to the advice of the advisory panel, revoke an authorization.

(2) Without limiting subsection (1), the Secretary may revoke an authorization if—

(a) the Secretary considers that the risks of the authorized vaccine outweigh its benefits; or

(b) a condition attached to the authorization is not complied with.

(3) If the Secretary revokes an authorization, the Secretary must—

(a) notify the authorization applicant in writing of the revocation stating the grounds for the revocation; and

(b) publish a notice of the revocation in the Gazette.

7. Use of vaccine

(1) Regulations 36(1) and 38(1) of, and paragraph 12 of Schedule 5 to, Cap. 138A (***relevant provisions***) do not apply in relation to—

(a) the supply by a person of a non-registered vaccine to the Government under a Government contract; or

(b) the possession by a person of a non-registered vaccine for the purpose of the performance (by that person or another person) of a Government contract.

(2) The relevant provisions do not apply in relation to the use of an authorized vaccine for a specified purpose.

(3) If authorized vaccines are administered to recipients in Hong Kong for a specified purpose, the Secretary must put in place a mechanism for monitoring any adverse event occurred to the recipients associated with the administration of the vaccines.

(4) In this section—

Government contract (政府合約) means a contract to which the Government is a party.

8. Authorized vaccine to be administered with informed consent

(1) Each person who is responsible for administering an authorized vaccine to a recipient for a specified purpose must ensure that, before the vaccine is so administered—

(a) the following person has been informed that the vaccine is authorized under this Regulation instead of registered and of any other information as may be specified by the Secretary—

(i) the recipient; or

(ii) if the recipient is not legally capable of giving consent to the administration of the vaccine (***relevant consent***)—a person who is legally capable of giving the relevant consent on the recipient's behalf; and

(b) the person referred to in paragraph (a)(i) or (ii), as the case requires, has given the relevant consent.

(2) For the purposes of this section, a person is responsible for administering an authorized vaccine to a recipient if—

(a) the person administers the vaccine to the recipient; or

(b) the person is a registered medical practitioner who supervises the administration of the vaccine to the recipient.

(3) Subsection (1) does not affect any other duty imposed by law or otherwise on a person who is responsible for administering an authorized vaccine.

9. Advisory panel

(1) The Chief Executive may appoint a panel of persons who are considered by the Chief Executive to have relevant expertise for advising the Secretary for the purposes of section 3(3), 4(1) or 6(1).

(2) A member of the advisory panel is not civilly liable for an act done or omitted to be done by the member in good faith in relation to the giving of advice for the purposes of section 3(3), 4(1) or 6(1).

(3) Subsection (2) does not affect any liability of the Government for the act or omission referred to in that subsection.

10. Jurisdiction and immunity

(1) Subsection (2) applies to a person who—

(a) prescribes or dispenses an authorized vaccine for administration to a recipient for a specified purpose; or

(b) is responsible for administering an authorized vaccine to a recipient (within the meaning of section 8(2)) for a specified purpose.

(2) The person is not civilly liable for any loss or damage caused to the recipient by an act done or omitted to be done by the person in good faith in relation to the administration of the vaccine to the extent that the loss or damage results from any risk as to the safety of the administration of the vaccine attributable to the intrinsic property of the vaccine as manufactured.

(3) Subsection (2) does not affect any liability of the Government or any person to whom that subsection does not apply for the loss or damage referred to in that subsection.

(4) The courts of Hong Kong have exclusive jurisdiction over a claim of a recipient of an authorized vaccine administered for a specified purpose in relation to the vaccine.

11. Certain notices are not subsidiary legislation

A notice published under section 3(6), 4(2)(b), 5(2) or 6(3)(b) is not subsidiary legislation.

12. Expiry

(1) This Regulation expires at midnight on 23 December 2021.

(2) Despite subsection (1), sections 9(2) and (3) and 10 continue to have effect after the expiry of this Regulation as if those sections had not expired.

Clerk to the Executive Council

COUNCIL CHAMBER

2020

Explanatory Note

The main objects of this Regulation are—

(a) to empower the Secretary for Food and Health (***Secretary***) to authorize a coronavirus disease 2019 (COVID-19) vaccine (***vaccine***) for preventing, protecting against, delaying or otherwise controlling the incidence or transmission of, or mitigating a serious or life-threatening condition arising from, the disease for the purpose of carrying out a vaccination programme conducted by the Government on an emergency basis or certain other reasonable purpose specified by the Secretary (***specified purpose***) (section 3);

(b) to exclude the application of certain provisions of the Pharmacy and Poisons Regulations (Cap. 138 sub. leg. A) in relation to—

(i) the use of a vaccine in certain circumstances in connection with a Government contract; or

(ii) the use of a vaccine authorized by the Secretary (***authorized vaccine***) for a specified purpose,

so as to allow such use without contravening those provisions (section 7);

(c) to require a person who is responsible for administering an authorized vaccine to ensure that an informed consent has been obtained before administering the vaccine (section 8); and

(d) to provide for the immunity from civil liability of certain persons using an authorized vaccine in relation to loss or damage resulting from any risk as to the safety of the administration of the vaccine attributable to the intrinsic property of the vaccine as manufactured (section 10).