L.N. 258 of 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 anthorized 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.

Wendy LEUNG
Clerk to the Executive Council

COUNCIL CHAMBER

23 December 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).