L.N. 176 of 2022

Prevention and Control of Disease (Use of Vaccines) (Amendment) Regulation 2022

Contents

Prevention and Control of Disease (Use of Vaccines) (Amendment) Regulation 2022

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

1. Prevention and Control of Disease (Use of Vaccines) Regulation amended

The Prevention and Control of Disease (Use of Vaccines) Regulation (Cap. 599 sub. leg. K) is amended as set out in sections 2 to 14.

2. Part 1 heading added

Before section 1—

Add

"**Part 1**

Preliminary".

3. Section 2 amended (interpretation)

(1) Section 2—

Renumber the section as section 2(1).

(2) Section 2(1), definition of ***registered***, before "means"—

Add

", in relation to a vaccine,".

(3) Section 2(1), definition of ***specified purpose***, paragraph (a)—

Repeal

everything after "out a"

Substitute

"Government vaccination programme; or".

(4) Section 2(1), definition of ***specified purpose***, paragraph (b)(i)—

Repeal

"an authorized"

Substitute

"a specified".

(5) Section 2(1)—

Add in alphabetical order

"***authorized officer*** (獲授權人員) means a public officer appointed under section 8B(1);

dispense (配發) has the meaning given by section 2(1) of the Pharmacy and Poisons Ordinance (Cap. 138);

function (職能) includes a power and a duty;

Government vaccination programme (政府疫苗接種計劃) means a programme that is conducted by the Government to administer specified vaccines to members of the public, or a section of the public, for—

(a) preventing, protecting against, delaying or otherwise controlling the incidence or transmission of the specified disease; or

(b) mitigating a serious or life-threatening condition arising from the specified disease;

specified vaccine (指明疫苗) means—

(a) an authorized vaccine; or

(b) a registered vaccine;".

(6) After section 2(1)—

Add

"(2) For the purposes of this Regulation, a person is responsible for administering a 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.".

4. Part 2 heading added

Before section 3—

Add

"**Part 2**

Authorization of Vaccine".

5. Section 3 amended (Secretary may authorize vaccine for specified purpose)

(1) Section 3(1)—

Repeal

everything before "Secretary"

Substitute

"(1) The".

(2) Section 3(4)(a)(ii), after "WHO;"—

Add

"and".

(3) Section 3(4)(b)—

Repeal

"urgently".

(4) Section 3(4)(b)—

Repeal

"; and"

Substitute a full stop.

(5) Section 3(4)—

Repeal paragraph (c).

6. Part 3 heading added

Before section 7—

Add

"**Part 3**

Use of Vaccine".

7. Section 7 amended (use of vaccine)

(1) After section 7(2)—

Add

"(2A) For a registered vaccine to be used for a specified purpose, if a change of any of the registrable particulars of the vaccine is approved under regulation 36A of Cap. 138A—

(a) despite the change and regulations 36(1B) and 36A(6)(a) of Cap. 138A, the vaccine is taken to remain registered; and

(b) regulation 36A(6)(b) and (c) of Cap. 138A does not apply in relation to the change.".

(2) Section 7(3)—

Repeal

"authorized"

Substitute

"specified".

(3) Section 7(4), definition of ***Government contract***—

Repeal the full stop

Substitute a semicolon.

(4) Section 7(4)—

Add in alphabetical order

"***registrable particulars*** (須註冊詳情) has the meaning given by regulation 35A of Cap. 138A.".

8. Section 8 amended (authorized vaccine to be administered with informed consent)

Section 8—

Repeal subsection (2).

9. Part 4 added

After section 8—

Add

"Part 4

Requirements for Administration of Specified Vaccine other than under Government Vaccination Programme

8A. Collection and provision of information regarding administration of vaccine

(1) A registered medical practitioner who is responsible for administering a specified vaccine to a recipient other than under a Government vaccination programme must—

(a) collect the following information—

(i) the name of the recipient;

(ii) the date of birth of the recipient;

(iii) the sex of the recipient;

(iv) the following information—

(A) if the recipient is the holder of an identity card—the number of the identity card; or

(B) otherwise—the type and number of a valid identification document of the recipient;

(v) the name and batch number of the vaccine;

(vi) the date of the administration; and

(vii) the dose sequence of the vaccine; and

(b) in accordance with subsection (2)—

(i) report, or cause to be reported, to the Director the administration of the vaccine; and

(ii) provide the Director with, or cause the Director to be provided with, the information mentioned in paragraph (a).

(2) For subsection (1)(b), the reporting and provision of information must be done—

(a) by using the eHealth System (Subsidies) or another electronic system specified by the Director in place of the eHealth System (Subsidies); and

(b) as soon as reasonably practicable (and, if a time is specified by the Director, within that time) after the administration of the vaccine.

(3) A matter to be specified by the Director under subsection (2) must be specified by means of a notice published on the website of the Department of Health.

(4) In this section—

identity card (身分證) has the meaning given by section 1A(1) of the Registration of Persons Ordinance (Cap. 177).

8B. Authorized officers

(1) The Director may, in writing, appoint any public officer as an authorized officer for the purposes of this Part.

(2) An authorized officer must, if so required, produce written proof of his or her appointment before performing a function under section 8C.

(3) No personal liability is incurred by an authorized officer or a person acting under the officer's direction in respect of any act done or omitted to be done by the officer or person in good faith in the performance or purported performance of a function under section 8C.

(4) Subsection (3) does not in any way affect any liability of the Government in respect of any act done or omitted to be done by an authorized officer or a person acting under the officer's direction.

8C. Powers to conduct inquiry and require information etc.

If an authorized officer has reason to suspect that section 8A(1) is not being or has not been complied with, the officer may do any or all of the following—

(a) conduct any inquiry in order to obtain any information mentioned in section 8A(1)(a);

(b) require any person in possession of such information to provide the officer with such information;

(c) require any person to provide the officer with the assistance that the officer reasonably considers necessary to enable the officer to do anything mentioned in paragraph (a) or (b).

8D. Obstruction of authorized officer etc. prohibited

(1) A person must not delay, obstruct, hinder or molest an authorized officer who is performing a function under section 8C.

(2) A person must comply with a requirement made by an authorized officer under section 8C(b) or (c).

(3) A person who contravenes subsection (1) or (2) commits an offence and is liable on conviction to a fine at level 3.

(4) It is a defence for a person charged under subsection (3) to establish that the person had reasonable excuse for the contravention.

(5) A person is taken to have established a matter that needs to be established for a defence under subsection (4) if—

(a) there is sufficient evidence to raise an issue with respect to that matter; and

(b) the contrary is not proved by the prosecution beyond reasonable doubt.

(6) A person who, in purported compliance with a requirement made under section 8C(b), knowingly or recklessly provides any information that is false or misleading in a material particular commits an offence and is liable on conviction to a fine at level 3.".

10. Part 5 heading added

Before section 9—

Add

"**Part 5**

Miscellaneous".

11. Section 9A amended (immunity of members of certain committees and panel)

Section 9A(1)(a) and (b)—

Repeal

"an authorized"

Substitute

"a specified".

12. Section 10 amended (jurisdiction and immunity)

(1) Section 10(1)(a)—

Repeal

"an authorized"

Substitute

"a specified".

(2) Section 10(1)(a)—

Repeal

"a specified purpose"

Substitute

"the purpose of carrying out a Government vaccination programme".

(3) Section 10(1)(b)—

Repeal

everything after "administering"

Substitute

"a specified vaccine to a recipient for the purpose of carrying out a Government vaccination programme.".

(4) After section 10(3)—

Add

"(3A) For an act done or omitted to be done before the commencement of the Prevention and Control of Disease (Use of Vaccines) (Amendment) Regulation 2022—

(a) subsections (1) and (2) as amended by the Regulation do not apply; and

(b) subsections (1) and (2) as in force immediately before the commencement continue to apply.".

13. Section 11 amended (certain notices are not subsidiary legislation)

Section 11—

Repeal

"or 6(3)(b)"

Substitute

", 6(3)(b) or 8A(3)".

14. Section 12 amended (expiry)

(1) Section 12(1)—

Repeal

"2022"

Substitute

"2023".

(2) Section 12—

Repeal subsection (2)

Substitute

"(2) Despite subsection (1), the following provisions continue to have effect after the expiry of this Regulation as if those provisions had not expired—

(a) section 2 (in so far as it relates to a provision set out in paragraph (b) or (c));

(b) sections 8B(3) and (4), 9(2) and (3), 9A and 10(1), (2), (3) and (3A) (in so far as they relate to an act done or omitted to be done before the expiry of this Regulation); and

(c) section 10(4) (in so far as it relates to the administration of an authorized vaccine before the expiry of this Regulation).".

Carmen KONG
Clerk to the Executive Council

COUNCIL CHAMBER

6 September 2022

Explanatory Note

To cater for the possibility of a coronavirus disease 2019 (COVID-19) vaccine (***vaccine***) being registered under the Pharmacy and Poisons Regulations (Cap. 138 sub. leg. A) (***Cap. 138A***), this Regulation amends the Prevention and Control of Disease (Use of Vaccines) Regulation (Cap. 599 sub. leg. K) (***principal Regulation***) to—

(a) provide that a vaccine registered under Cap. 138A (***registered vaccine***) that is to be used for a specified purpose (including for carrying out a Government vaccination programme) is taken to remain registered and is not subject to recall under Cap. 138A despite a change of the vaccine's registrable particulars (such as its label or package insert); and

(b) extend the following matters to cover registered vaccines—

(i) the monitoring mechanism under section 7(3) of the principal Regulation; and

(ii) the immunity under sections 9A and 10 of the principal Regulation.

2. In addition, this Regulation amends the principal Regulation to—

(a) adjust certain conditions for authorizing a vaccine under the principal Regulation (***authorized vaccine***);

(b) require the collection and provision of certain information regarding the administration of a registered vaccine or authorized vaccine other than under a Government vaccination programme, and provide for the powers to take related actions; and

(c) extend the expiry date of the principal Regulation from 23 December 2022 to 23 December 2023.