《預防及控制疾病 (使用疫苗) 規例》
(第 599 章，附屬法例 K)

Prevention and Control of Disease (Use of Vaccines) Regulation
(Cap. 599 sub. leg. K)

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(《法例發布條例》(第 614 章) 第 5 條)
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制定史

本為 2020 年第 258 號法律公告 —— 2020 年第 8 號編輯修訂紀錄，2021 年第 234 號法律公告，2022 年第 144 號法律公告

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(第 599 章，附屬法例 K)

目錄

Prevention and Control of Disease (Use of Vaccines) Regulation

(Cap. 599 sub. leg. K)

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《預防及控制疾病 (使用疫苗) 規例》

(由行政長官會同行政會議根據《預防及控制疾病條例》(第 599 章) 第 8 條訂立)

[2020 年 12 月 24 日]

1. 生效日期

本規例自 2020 年 12 月 24 日起實施。

2. 釋義

在本規例中 ——

申請認可者 (authorization applicant) 就應某人的申請而批出的認可而言，指該人；

局長 (Secretary) 指醫務衞生局局長；*(2022 年第 144 號法律公告)*

使用 (use) 就疫苗而言，包括分發、供應、要約供應、管有、處方、配發和施用；

非註冊疫苗 (non-registered vaccine) 指未經註冊的疫苗；

指明目的 (specified purpose) 指 ——

(a) 執行一項由政府推行的計劃的目的，該計劃旨在對公眾人士或部分公眾人士緊急施用認可疫苗，以預防、抵禦、阻延或以其他方式控制指明疾病的個案或傳播，或緩解指明疾病所引致的嚴重或可危及性命的病況；或

(b) 符合以下說明的任何其他合理目的 ——

(i) 關於使用認可疫苗以預防、抵禦、阻延或以其他方式控制指明疾病的個案或傳播，或緩解指明疾病所引致的嚴重或可危及性命的病況；及

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))

[24 December 2020]

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);

(ii) 由局長指明的；

指明疾病 (specified disease) 指 2019 冠狀病毒病，即本條例附表 1 第 8A 項所指明者；

疫苗 (vaccine) 指符合以下說明的藥劑製品 ——

(a) 含有抗原性物質，或用意為在對某人施用該製品之後，刺激該人體內產生抗原性物質；及

(b) 用意為刺激某人的免疫系統，以產生對指明疾病的免疫力；

接種者 (recipient) 就疫苗而言，指屬該疫苗施用對象的人；

《第 138A 章》 (Cap. 138A) 指《藥劑業及毒藥規例》(第 138 章，附屬法例 A)；

註冊 (registered) 指根據《第 138A 章》第 36 條註冊；

認可 (authorization) 指根據第 3(1) 條批出的認可；

認可疫苗 (authorized vaccine) 指根據第 3(1) 條認可的非註冊疫苗；

藥劑製品 (pharmaceutical product) 具有《藥劑業及毒藥條例》(第 138 章) 第 2(1) 條所給予的涵義；

顧問專家委員會 (advisory panel) 指根據第 9 條委出的委員會。

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 Health; *(L.N. 144 of 2022)*

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

3. 局長可為指明目的認可疫苗

(1) 為預防、抵禦、阻延或以其他方式控制指明疾病的個案或傳播，或為緩解指明疾病所引致的嚴重或可危及性命的病況，局長可應申請而為指明目的，認可非註冊疫苗。

(2) 上述申請須 ——

(a) 由以下人士提出 ——

(i) 如疫苗符合第 (4)(a)(i) 款提述的條件 —— 就該疫苗而言屬《第 138A 章》第 36(1)(a)、(b) 或 (c) 條所描述的人；或

(ii) 如疫苗符合第 (4)(a)(ii) 款提述的條件 ——

(A) 第 (i) 節所描述的人；或

(B) 在香港以外的該疫苗的製造商，或該製造商的分支機構、附屬公司、代表、代理人或分發商；及

(b) 按局長指明的方式提出，並附有局長指明的資料。

(3) 局長認可疫苗之前，須在顧及顧問專家委員會的意見下，考慮 ——

(a) 疫苗的安全性；

(b) 疫苗的效能；及

(c) 疫苗的質素。

(4) 局長只可在以下前提下認可疫苗 ——

(a) 該疫苗符合任何以下條件 ——

(i) 有在香港以外某地方的、職能為批准供在該地方使用的藥劑製品的規管機構，已批准該疫苗

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

施用在人體上 (但並非屬實驗或試驗性質)，包括作緊急使用，而不論該項批准是否受制於任何條件、局限或限制；

(ii) 該疫苗列入世衞的緊急使用清單，或列載於世衞所公布的資格預審疫苗清單；

(b) 局長認為，為了緊急提供該疫苗以應付指明疾病對公眾健康構成的威脅，有關認可屬必要，並且是符合公眾利益的；及

(c) 局長認為就指明目的而言，該疫苗屬以下疫苗以外的另一選擇，或沒有以下疫苗供應，或以下疫苗供應不足：經註冊的疫苗或其他認可疫苗。

(5) 局長就尋求認可的申請作出決定後，須 ——

(a) 將有關決定以書面通知提出申請的人；及

(b) 如局長拒絕申請 —— 在該通知中述明拒絕的理由。

(6) 局長如決定批出認可，則須就該項認可在憲報刊登公告，公告須述明 ——

(a) 認可的疫苗的名稱；

(b) 該項認可的生效日期；

(c) 申請認可者的姓名或名稱及地址；

(d) 該疫苗的製造商的名稱及地址；及

(e) 根據第 4 條對該項認可附加的條件 (如有的話)。

(7) 在本條中 ——

批准 (approve) 包括授權和准許 (不論實際如何稱述)。

(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.

4. 規限認可的條件

(1) 局長可在顧及顧問專家委員會的意見後 ——

(a) 對認可附加其認為適當的條件；

(b) 更改該條件；或

(c) 撤銷該條件。

(2) 局長如更改或撤銷對認可附加的條件，則須 ——

(a) 將有關更改或撤銷，以書面通知申請認可者；及

(b) 就有關更改或撤銷，在憲報刊登公告。

5. 認可的有效期

(1) 疫苗的認可 ——

(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) 在第 3(6)(b) 條提述的日期生效；及

(b) 在以下情況下，即不再有效 ——

(i) 該項認可根據第 6 條撤銷；或

(ii) 如該項認可沒有如此撤銷 —— 第 (2) 款提述的期間屆滿。

(2) 為施行第 (1)(b)(ii) 款，有關期間是有關認可的生效日期後的 12 個月期間，但局長可藉在憲報刊登的公告 *，將該期間延長，而每次延長的期間，不可多於 6 個月。

編輯附註：

* 請瀏覽政府物流服務署管理的憲報網頁，以查閱有關的疫苗認可。

6. 撤銷認可

(1) 局長可在顧及顧問專家委員會的意見後，撤銷認可。

(2) 在不局限第 (1) 款的原則下，如有以下情況，局長可撤銷認可 ——

(a) 局長認為有關認可疫苗的風險，大於其裨益；或

(b) 對該項認可附加的某條件不獲遵從。

(3) 局長如撤銷認可，則須 ——

(a) 將有關撤銷以書面通知申請認可者，並在該通知中述明撤銷的理由；及

(b) 就該項撤銷在憲報刊登公告。

(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.

Editorial Note:

* Please visit the Gazette website maintained by the Government Logistics Department for the vaccine authorization.

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. 疫苗的使用

(1) 《第 138A 章》第 36(1) 及 38(1) 條及附表 5 第 12 段 (***有關條文***)，並不就以下事宜而適用 ——

(a) 由某人根據一份政府合約，向政府供應非註冊疫苗；或

(b) 某人為執行一份政府合約，而管有非註冊疫苗，不論執行者是該人或另一人亦然。

(2) 如認可疫苗是為指明目的而使用，則就此而言，有關條文並不適用。

(3) 如認可疫苗是為指明目的而施用於在香港的接種者的，則局長須訂立機制，以監察任何發生在該等接種者身上的、與施用該疫苗相關的不良情況。

(4) 在本條中 ——

政府合約 (Government contract) 指政府屬訂約一方的合約。

8. 施用認可疫苗須取得知情同意

(1) 每名負責為指明目的而對某接種者施用認可疫苗的人，均須確保在如此施用該疫苗之前 ——

(a) 以下的人已獲告知，該疫苗根據本規例獲認可而非註冊，以及局長所指明的任何其他資料 ——

(i) 該接種者；或

(ii) 如該接種者在法律上沒有能力對施用該疫苗一事給予同意 (***相關同意***)—— 在法律上有能力代表該接種者給予相關同意的人；及

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

(b) (a)(i) 或 (ii) 段 (視情況所需而定) 提述的人已給予相關同意。

(2) 就本條而言，某人如符合以下情況，即屬負責對某接種者施用認可疫苗 ——

(a) 該人對該接種者施用該疫苗；或

(b) 該人屬監督對該接種者施用該疫苗的註冊醫生。

(3) 法律或其他規定對負責施用認可疫苗的人施加的其他責任，不受第 (1) 款影響。

9. 顧問專家委員會

(1) 行政長官可委出一個委員會，組成委員會的人士，須獲行政長官認為具備相關專門知識，以就施行第 3(3)、4(1) 或 6(1) 條向局長提供意見。

(2) 凡顧問專家委員會成員就施行第 3(3)、4(1) 或 6(1) 條提供意見，而真誠就提供意見作出任何作為或有任何不作為，該成員無須為該等作為或不作為承擔民事法律責任。

(3) 政府為第 (2) 款提述的作為或不作為負有的法律責任，不受該款影響。

9A. 某些委員會及顧問團成員的豁免

(1) 凡第 (2) 款指明的委員會或顧問團的成員就 ——

(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.

9A. Immunity of members of certain committees and panel

(1) A member of any of the committees and panel specified in

(a) 為指明目的而使用認可疫苗；或

(b) 於認可疫苗為指明目的而施用於在香港的接種者後，發生在該接種者身上的臨牀事件，

向政府提供意見，而真誠就提供意見作出任何作為或有任何不作為，該成員無須為該作為或不作為承擔民事法律責任。

(2) 有關委員會及顧問團如下 ——

(a) 由衞生署設立的、名為 " 新冠疫苗臨床事件評估專家委員會 " 的委員會；

(b) 由衞生署設立的、名為 " 新發現及動物傳染病科學委員會 " 的委員會；

(c) 由衞生署設立的、名為 " 疫苗可預防疾病科學委員會 " 的委員會；及

(d) 由行政長官為向其提供關於指明疾病的意見而委任的、名為 " 行政長官專家顧問團 " 的顧問團。

(3) 政府為第 (1) 款提述的作為或不作為負有的法律責任，不受該款影響。

(2021 年第 234 號法律公告)

10. 司法管轄權及豁免

(1) 第 (2) 款適用於作出以下作為的人士 (***有關人士***) ——

(a) 為指明目的處方或配發認可疫苗，以對接種者施用；或

subsection (2) 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 to the Government in respect of—

(a) the use of an authorized vaccine for a specified purpose; or

(b) any clinical event that occurs to a recipient in Hong Kong to whom an authorized vaccine was administered for a specified purpose.

(2) The committees and panel are—

(a) a committee established by the Department of Health (***Department***) and known as the Expert Committee on Clinical Events Assessment Following COVID-19 Immunisation;

(b) a committee established by the Department and known as the Scientific Committee on Emerging and Zoonotic Diseases;

(c) a committee established by the Department and known as the Scientific Committee on Vaccine Preventable Diseases; and

(d) a panel appointed by the Chief Executive for giving advice to the Chief Executive in respect of the specified disease and known as the Chief Executive's Expert Advisory Panel.

(3) Subsection (1) does not affect any liability of the Government for the act or omission referred to in that subsection.

(L.N. 234 of 2021)

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) 負責為指明目的而對接種者施用認可疫苗 (第 8(2) 條所指者)。

(2) 凡有關人士真誠就施用有關疫苗作出任何作為或有任何不作為，因此對接種者造成損失或損害，則在該等損失或損害是由固有風險所引致的範圍內，該人士無須為該等損失或損害承擔民事法律責任，上述固有風險指關乎施用該疫苗的安全性的風險，而該風險可歸因於該疫苗在製成時具有的固有特性。

(3) 政府為第 (2) 款提述的損失或損害負有的法律責任，或該款所不適用的人為該款提述的損失或損害負有的法律責任，均不受該款影響。

(4) 凡有認可疫苗為指明目的而施用，如該疫苗的接種者就該疫苗提出申索，則香港法院對該申索具有專有司法管轄權。

11. 若干公告並非附屬法例

根據第 3(6)、4(2)(b)、5(2) 或 6(3)(b) 條刊登的公告，不是附屬法例。

12. 失效日期

(1) 本規例在 2022 年 12 月 23 日午夜失效。

(2) 儘管有第 (1) 款的規定，第 2、9(2) 及 (3)、9A 及 10 條在本規例失效後繼續有效，猶如該等條文未有失效一樣。

(2021 年第 234 號法律公告)

(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. *(E.R. 8 of 2020)*

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 2022.

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

(L.N. 234 of 2021)