Guidance for Applications for Authorization of Vaccines under the Prevention and Control of Disease (Use of Vaccines) Regulation (Cap. 599K)

Preface

This document aims to provide guidance on making applications for authorization of vaccines under the Prevention and Control of Disease (Use of Vaccines) Regulation ("the Regulation"), Cap. 599K, Laws of Hong Kong, and should be read in conjunction with the current laws governing pharmaceutical products in Hong Kong, which include but not limited to the following Ordinances and their relevant subsidiary legislations:

- Pharmacy and Poisons Ordinance (Cap. 138, Laws of Hong Kong)
- Antibiotics Ordinance (Cap. 137, Laws of Hong Kong)
- Undesirable Medical Advertisements Ordinance (Cap. 231, Laws of Hong Kong)
- Import and Export Ordinance (Cap. 60, Laws of Hong Kong)

2. If there is any inconsistency between this document and the prevailing legislations, the latter shall prevail. Applicants are strongly encouraged to familiarize themselves with the contents of this guidance notes before submitting their applications.

Authorization of Vaccines

3. The Secretary for Health ("the Secretary") may, on application, authorize a non-registered vaccine under the Pharmacy and Poisons Ordinance for 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 (i.e. COVID-19) or other reasonable purpose specified by the Secretary.

4. The requirement of registration of pharmaceutical products under section 36(1) and related requirement under section 38(1) and paragraph 12 of Schedule 5 of the Pharmacy and Poisons Regulation, Cap. 138A, Laws of Hong Kong, do not apply in relation to the supply by a person of a non-registered vaccine to the Government under a Government contract; or 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; or to the use of an authorized vaccine for the purpose specified in section 7(3) of the Regulation.

Criteria for Authorization

5. The Secretary may authorize a vaccine after having regard to the advice of the Advisory Panel on COVID-19 Vaccines ("the Advisory Panel"), in which members are appointed by the Chief Executive to have relevant expertise for advising the Secretary regarding the safety, efficacy and quality of the vaccine, and only if the vaccine satisfies the following conditions:

(i) A regulatory authority in 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; or the vaccine is listed in accordance with the emergency use listing procedure by World Health Organization ("WHO") or is in the list of prequalified vaccines published by WHO;

(ii) 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

(iii) The Secretary considers that, for the purpose specified in paragraph 3 above, there is no or insufficient supply of, or the vaccine is an alternative to, registered vaccines or other authorized vaccines.

Who Should Apply

6. If the vaccine is manufactured in Hong Kong, the applicant responsible for obtaining authorization of the vaccine is the manufacturer, or the wholesale dealer contracting with the manufacturer as described in section 3(2) of the Regulation.

7. If the vaccine is manufactured outside Hong Kong, the applicant responsible for obtaining authorization is the wholesale dealer who imported the vaccine, or the Hong Kong branch, subsidiary, representative, agent or distributor of the overseas manufacturer as described in section 3(2) of the Regulation.

8. If the vaccine is listed in either the emergency use listing procedure or prequalified vaccines published by the WHO, the applicant responsible for

obtaining authorization is either the person described in paragraph 6 or 7 above, or a manufacturer of the vaccine outside Hong Kong, a branch, subsidiary, representative, agent or distributor of the manufacturer.

How to Apply

9. The applicant should hand in a dossier with the following information (other than item (i), the applicant is advised to provide the documents in PDF format or other practical means of soft copies):

(i) A cover letter of application indicating the following information –

a. Name of the vaccine to be authorized
b. Name and address of the authorization applicant
c. Name and address of the manufacturer of the vaccine
d. An authorized person for the application with his/her contacts, including telephone and facsimile numbers, and email address
e. The availability of vaccine and supply planning in order to address the urgent need to deal with the threat to public health posed by the specified disease
f. Index of the content of the submission dossier

(ii) A copy of the business registration certificate of the applicant (if applicable)

(iii) Evidence of approval / authorization of the vaccine and the conditions, limitations or restrictions (if any) imposed by any drug regulatory authorities outside Hong Kong or prequalified or emergency use listed by the WHO

(iv) World-wide registration status of the vaccine

(v) Clinical and scientific documentation substantiating the safety and efficacy of the vaccine, that includes, but not limited to expert evaluation reports, published scientific papers in reputable peer-reviewed publications, assessment reports of overseas drug regulatory authorities, etc.

(vi) The manufacturer's information and a copy of Good Manufacturing Practices ("GMP") certificate of the manufacturer

(vii) Detailed and complete qualitative and quantitative composition of the finished product issued by the manufacturer

(viii) Specifications of the vaccine issued by the manufacturer

(ix) Detailed method of analysis of the product for all tests stated in the finished product specifications

(x) Certificate of analysis of a representative batch of the finished product issued by the manufacturer

(xi) Stability test data of the vaccine in order to support the labelling of the storage conditions

(xii) Prototype sales pack (e.g. outer carton, container label, and other component(s) comprising the sales pack) for each pack size of the vaccine

(xiii) Package insert and documentary evidence showing that the content of the package insert has been approved by drug regulatory authorities outside Hong Kong

(xiv) Photograph image of the prototype sales pack, including the inner container / packaging and the unit dose form image of the product, clearly showing the complete content of the prototype sales pack and its component(s)

(xv) Risk management plan to be implemented in Hong Kong, and evidence that the content of the risk management plan is adopted by drug regulatory authorities outside Hong Kong, if any

(xvi) Any other documents to substantiate the safety, efficacy, and quality of the vaccine under application if deemed necessary (e.g. logistics plan for vaccine requiring stringent cold chain management, etc.)

(xvii) Justifications for missing any of the above requested information

10. Applicants should submit the applications together with the documents specified in paragraph 9 above to the Secretary:

Secretary for Health
C/O Department of Health
Room 1856, 18/F, Wu Chung House
213 Queen's Road East, Wanchai, Hong Kong

Determination of Application for Authorization

11. After considering the advice of the Advisory Panel and the totality of available information, the Secretary will determine the application for authorization in accordance with section 3 of the Regulation and notify the applicant in writing of the decision; and if the Secretary refuses the application, state the grounds for the refusal in the notification.

12. If the Secretary decides to grant an authorization, the Secretary will publish a notice of the authorization in the Gazette stating the following:

(i) Name of the vaccine authorized;

(ii) Date on which the authorization takes effect;

(iii) Name and address of the authorization applicant;

(iv) Name and address of the manufacturer of the vaccine; and

(v) Conditions (if any) attached to the authorization.

Conditions of Authorization

13. The Secretary may, after having regard to the advice of the Advisory Panel, attach to an authorization any conditions that the Secretary considers appropriate, and vary or revoke the condition(s) when deemed necessary. The Secretary will notify the authorization applicant in writing and publish a notice in the Gazette for any variation or revocation of conditions.

Effective Period of Authorization

14. An authorization of a vaccine will take effect on the date as specified in the notice of the authorization in the Gazette and cease to have effect when –

(i) the authorization is revoked; or

(ii) if the authorization is not so revoked, 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 six months.

Revocation of Authorization

15. The Secretary may, after having regard to the advice of the Advisory Panel, revoke an authorization. The Secretary may revoke an authorization if –

(i) the risks of the authorized vaccine outweigh its benefits; or

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

16. The Secretary will notify the authorization applicant in writing of the revocation stating the grounds for the revocation and publish a notice of the revocation in the Gazette.

Change of Details of Authorized Vaccine

17. The authorization applicant is required to submit relevant information and justifications / supporting evidence to the Secretary for any changes related to the authorized vaccine, including but not limited to the content of package insert, label, or any quality attributes. The changes should only be implemented after endorsement by the Secretary is obtained.

Enquiry

18. For enquiries, please contact Mr Michael YIM at 3974 4133, or tkyim@dh.gov.hk

Advisory Panel on COVID-19 Vaccines
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