中華人民共和國香港特別行政區
Hong Kong Special Administrative Region of the People's Republic of China

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By Fax (2537 7319)

7 January 2021

Ms Joan HUNG
Principal Assistant Secretary for
Food and Health (Health)6
Food and Health Bureau
19/F, East Wing Central Government Offices
2 Tim Mei Avenue, Tamar
Hong Kong

Dear Ms HUNG,

Prevention and Control of Disease
(Use of Vaccines) Regulation (L.N. 258 of 2020)

We are scrutinizing the captioned Regulation with a view to advising Members on its legal and drafting aspects. To facilitate Members' consideration of the Regulation, we should be grateful if you could clarify the following issues.

Legal aspect

Section 2 – definition of "specified purpose"

It is noted that unlike subparagraph (a) under the definition of "specified purpose" which clearly states that the specified purpose means the purpose of carrying out a programme that is conducted by the Government to administer the authorized vaccine for COVID-19 ("vaccine") to members of the public, a widely drafted term "any other reasonable purpose" is used in subparagraph (b). Please clarify:

(a) what "any other reasonable purpose that relates to the use of an authorized vaccine for preventing ..... the specified disease" under subparagraph (b)(i) will include; and

(b) what consideration will be taken into account when the Secretary for Food and Health ("Secretary") specifies such a reasonable purpose under subparagraph (b)(ii).

Section 4 – condition imposed on an authorization

Under section 4 of the Regulation, the Secretary may attach to an authorization granted to the vaccine any condition that the Secretary considers appropriate. According to paragraph 13 of the Legislative Council Brief (no file reference) issued by the Food and Health Bureau in December 2020 on the Regulation ("LegCo Brief"), 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 events after vaccination. It is noted that, under section 6, the Secretary may revoke an authorization if a condition attached to the authorization is not complied with. In the light of the above, please clarify the following matters:

(a) in addition to the conditions as set out in paragraph 13 of the LegCo Brief, what other conditions may be imposed by the Secretary; and

(b) except revocation of the authorization under section 6, whether there would be other legal consequence (such as fine or imprisonment) for an authorization applicant who is in breach of any conditions attached to the authorization, especially if such breach is related to submitting false or misleading clinical trial data or has caused an adverse effect on the health of a person to whom the vaccine is administered ("recipient"). If not, please provide justification for such arrangement.

Section 5

Under section 5 of the Regulation, the authorization of vaccine will be valid for a period of 12 months from the date on which the authorization takes effect and such period which may be extended each time for a period of 6 months (6-month period). Please clarify what consideration will be taken into account when the Secretary considers

granting such extension.

It is noted that one of the main objects of the Regulation is to empower the Secretary to authorize the vaccine that is not registered under the Pharmacy and Poisons Regulations (Cap. 138A) for the purpose of carrying out a vaccination programme conducted by the Government *on an emergency basis* [emphasis added]. However, the 6-month period under section 5 can be further extended for 6 more months in each time without limitation in numbers of such extension. It is further noted that under section 12, the Regulation will expire on 23 December 2021 (except for provisions relating to the immunity). In view of the above, please clarify:

(a) whether the arrangement of allowing the 6-month period under section 5 to be further extended without limitation in numbers would be contrary to the legislative intent that the authorization should be made *on an emergency basis* and for a limited period of time;

(b) in view of section 5, whether there would be a situation that the effective period of an authorization is still in force after the expiry of the Regulation; and

(c) if the answer to question (b) above is in the affirmative, how the Secretary could deal with the matters arising from the authorizations (e.g. the conditions attached to an authorization are not complied with) after the expiry of the Regulation.

Section 7

It is noted that under section 7(3), the Secretary must put in place a mechanism for monitoring any adverse event occurred to the recipients associated with the administration of the vaccines ("monitoring mechanism"). Please clarify whether there will be any other piece of legislation to give effect to the implementation of the monitoring mechanism. If not, please clarify whether and how the public would be able to know the details of the monitoring mechanism.

Section 10

Section 10 of the Regulation provides for the immunity from civil liability of persons who prescribe or dispense the vaccine for administration to a recipient for a specified purpose or are responsible for

administering the vaccine to a recipient 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. Please clarify:

(a) the meaning of "prescribes" and "dispenses". For the purposes of section 10, under what circumstances would a person be regarded as having prescribed or dispensed the vaccine for administration to a recipient for a specified purpose;

(b) whether the ambit of the immunity provided under section 10 covers the vaccine manufacturers; and

(c) regarding the expression "attributable to the intrinsic property of the vaccine as manufactured", what parameters have to be satisfied in order for a risk as to the safety of the administration of the vaccine be regarded as attributable to the intrinsic property of the vaccine as manufactured.

Indemnity fund

As stated in paragraph 17 of the LegCo Brief, the Government plans to set up an indemnity fund which is devised to indemnify vaccine manufacturers from claims of vaccine recipients as a result of unexpected serious adverse events. In view of the information provided by the Administration, please let the members know whether there will be any other piece of legislation to enable the implementation and operation of the indemnity fund. If not, please clarify whether and how the public would be able to know the details of the indemnity fund.

Drafting aspect

Section 9

As provided in section 9 of the Regulation, the Chief Executive ("CE") may appoint a panel of persons ("advisory panel") for advising the Secretary for the purposes of the relevant provisions concerning granting and revoking authorization of, and imposing conditions on the vaccine ("relevant powers"). The word "may", as used in section 9, means that CE is not legally bound to establish the advisory panel. However, it is noted that the relevant powers under sections 3, 4

and 6 of the Regulation can only be exercised by the Secretary having considered the advice of the advisory panel.

In the light of the above, should the word "may" in section 9 be changed to "must" so as to align with the legislative intent under sections 3, 4 and 6?

We look forward to receiving your reply in both English and Chinese as soon as practicable.

Yours sincerely,

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