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中華人民共和國香港特別行政區政府總部食物及衞生局
Food and Health Bureau, Government Secretariat
The Government of the Hong Kong Special Administrative Region
The People's Republic of China

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Your Ref.: LS/S/16/20-21

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By email (ahychiu@legco.gov.hk)
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Dear Mr Chui,

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

I refer to your letter dated 7 January 2021 with respect to the Prevention and Control of Disease (Use of Vaccines) Regulation (the Regulation) and provide our response in the ensuing paragraphs.

Legal aspect

Section 2 - definition of "specified purpose"

2. Section 3(1) of the Regulation provides that for preventing, protecting against, delaying or otherwise controlling the incidence or transmission of, or

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mitigating a serious or life-threatening condition arising from, the specified disease (i.e. COVID-19), the Secretary for Food and Health (SFH) may, on application, authorize a non-registered vaccine for a specified purpose. The term "specified purpose" is defined under section 2 to cover (a) the purpose of carrying out a vaccination programme that is conducted by the Government (i.e. the first limb); 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 SFH (i.e. the second limb).

3. In view that we need to provide vaccination for a large population within a short period of time, the Government will be responsible for overseeing the overall vaccination programme. While we are considering various solutions having regard to the logistical and storage requirements of the different types of vaccine that we will be obtaining, our thinking is that vaccination will mainly take place at the following settings: specially designated vaccination centres, institutions like residential care homes and hospitals, and clinics. The second limb serves to provide flexibility to cater for other types of engagement with service providers under which the government will not be conducting the vaccination programme directly, such as the giving of authorized vaccine to non-governmental organizations for administration of the vaccines to certain target group(s) under the oversight of the Government. In specifying such a "reasonable purpose", SFH will need to ensure that this satisfies the legal requirement, i.e. the purpose has to be related to the "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".

Section 4 - condition imposed on an authorization

4. Section 4 of the Regulation empowers SFH, after having regard to the advice of the advisory panel, to attach any condition to an authorization granted in relation to a vaccine. As we have explained in the relevant Legislative Council brief, such conditions are intended for the continuous monitoring of the safety, efficacy and quality of the authorized vaccine and may include requiring the applicant to submit ongoing clinical trial data and report adverse events after vaccination. This may also cover other requirements such as (i) implementing the Risk Management Plan for the authorized vaccine in Hong Kong as the applicant has proposed; and (ii) ensuring the authorized vaccine is distributed in accordance with the logistic plan as the applicant has proposed. A breach of a condition attached to an authorization may lead to revocation of the authorization under section 6 of the Regulation. Depending on the facts, circumstances and

available evidence of individual cases, certain acts such as forgery and the making of false declaration will be subject to legal consequences under existing law such as the Crime Ordinance (Cap. 200). The arrangement is similar to the current practice for a breach of conditions attached to registration of pharmaceutical products under the Pharmacy and Poisons Regulations (Cap. 138A).

Section 5 - the granting of extension of an authorization

5. Section 5 of the Regulation provides that the authorization of a vaccine will be valid for a period of 12 months and such period may be extended each time for a period not more than 6 months. The considerations that SFH will take into account for the need of any extension should be in line with the considerations under section 3(4)(b) and (c) of the Regulation for the authorization of the vaccine, i.e. whether extending the authorization is necessary and is in the public interest for making the vaccine available urgently to deal with the threat to public health posed by COVID-19, and whether for a specified purpose, there is no or insufficient supply of, or the vaccine is an alternative to, registered vaccines or other authorized vaccines. Though theoretically there could be a situation where the effective period of an authorization is still in force after the expiry of the Regulation, the authorization of a vaccine would only be extended when there is still a need for the emergency use of the vaccine and when the expiry date of the Regulation is to be amended to a later date. It is therefore unlikely that the Secretary may not be able to deal with matters arising from the authorization as suggested in your paragraph (c).

Section 7 - mechanism for the monitoring of any adverse event

6. Details of the mechanism for the monitoring of any adverse event after vaccination will be provided in an administrative manner, which would be in accordance with the current pharmacovigilance system for pharmaceutical products registered under Cap. 138A. The Government will also take reference from the guidelines on safety surveillance on COVID-19 vaccines promulgated by the World Health Organization to strengthen the monitoring of adverse events after vaccination. Information related to adverse events in particular serious or rare adverse events will be communicated and disseminated to the public via various channels such as websites, public announcement, etc.

Section 10 - immunity

7. "Prescribes" and "dispenses" refer respectively to advise or order the use of vaccine by a registered medical practitioner, and to supply the vaccine on and in accordance with a prescription given by a registered medical practitioner

and also the compounding or mixing of substances and the supplying of the same. For the purpose of section 10 of the Regulation, these refer respectively to the doctors-in-charge of the vaccination as well as any healthcare workers, e.g. nurses, pharmacists or drug dispensers who, on a doctor's prescription, assist to prepare or make available the vaccines for vaccination.

8. The immunity under section 10 of the Regulation does not cover vaccine manufacturers. As to the expression "attributable to the intrinsic property of the vaccine as manufactured", this refers to any property that is intrinsic or inherent in the vaccine itself, such as the formula or composition of the vaccine.

Indemnity fund

9. The Indemnity Fund will be set up administratively. We have briefed the Panel on Health Services of the Legislative Council (the Panel) on the framework of the fund during our briefing to the Panel on the Chief Executive's 2020 Policy Address on 8 January 2021. We are working out details of the fund for submission to the Legislative Council for funding approval. Subject to approval of the Legislative Council, details of the fund will be published on website and through other publicity materials.

Drafting aspect

Section 9

10. Section 9 of the Regulation seeks to empower the Chief Executive (CE) to appoint persons to the advisory panel. SFH may only exercise the power under section 3, 4 or 6 of the Regulation having regard to the advice of the advisory panel, and thus in effect, CE will have to appoint members of the advisory panel in order to enable the operation of the Regulation. Indeed, CE has already appointed the advisory panel on 28 December 2020 for a term covering the whole period when the Regulation is effective. We therefore consider that it is not necessary to change "may" to "must" in section 9.

Yours sincerely,

(Ms Joan HUNG)
for Secretary for Food and Health

c.c.

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