

**立法會**  
**Legislative Council**

LC Paper No. LS26/20-21

**Paper for the House Committee Meeting  
on 8 January 2021**

**Legal Service Division Report on  
Subsidiary Legislation Gazetted on 23 December 2020**

<b>Tabling in LegCo</b>	: Council meeting of 6 January 2021
<b>Amendment to be made by</b>	: Council meeting of 3 February 2021 (or that of 24 February 2021 if extended by resolution)
<b>Prevention and Control of Disease (Use of Vaccines) Regulation</b>	<b>(L.N. 258)</b>
<b>Compulsory Quarantine of Certain Persons Arriving at Hong Kong (Amendment) (No. 9) Regulation 2020</b>	<b>(L.N. 259)</b>
<b>Compulsory Quarantine of Persons Arriving at Hong Kong from Foreign Places (Amendment) (No. 6) Regulation 2020</b>	<b>(L.N. 260)</b>
<b>Prevention and Control of Disease (Regulation of Cross-boundary Conveyances and Travellers) (Amendment) (No. 3) Regulation 2020</b>	<b>(L.N. 261)</b>

L.N. 258 to L.N. 261 are made by the Chief Executive ("CE") in Council under section 8 of the Prevention and Control of Disease Ordinance (Cap. 599) having regard to the latest situation of public health emergency<sup>1</sup> relating to COVID-19 ("disease").

L.N. 258

2. L.N. 258 (i.e. Cap. 599K) is a new regulation which provides a legal framework under which the Secretary for Food and Health ("Secretary") may, on application, authorize a vaccine for the disease that is not registered under the Pharmacy and Poisons Regulations (Cap. 138A) ("vaccine") for the purpose of carrying out a vaccination programme conducted by the Government on an emergency basis for combating the disease or for certain other reasonable purpose as specified by the Secretary ("specified purpose").

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<sup>1</sup> Public health emergency is defined in section 8(5) of Cap. 599 to mean, among others, the occurrence of or the imminent threat of a disease, an epidemic or a pandemic that has a high probability of causing a large number of deaths or serious disabilities (whether or not long-term) in the population.

3. Key provisions of L.N. 258 are summarized as follows:
- (a) before the Secretary authorizes a vaccine, the Secretary must, having regard to the advice of the advisory panel, take into consideration the safety, efficacy and quality of the vaccine;
  - (b) members of the advisory panel may be appointed by CE if such members are considered to have relevant expertise for advising the Secretary on granting, revoking and imposing conditions to, an authorization of a vaccine;
  - (c) an authorization may only be made if (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 the vaccine for administration to persons other than on an experimental or trial basis, 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 the authorization is necessary and is in the public interest; and (iii) there is no or insufficient supply of, or the vaccine is an alternative to, registered vaccines or other authorized vaccines;
  - (d) if the Secretary decides to grant an authorization, the Secretary must publish a notice of authorization in the Gazette (such notice not being subsidiary legislation and hence not subject to amendment by the Legislative Council ("LegCo")) stating, among others, the name of the vaccine authorized, name and address of the relevant manufacturer of the vaccine, the date on which the authorization takes effect and the conditions (if any) attached to the authorization. An authorization of a vaccine is effective for a period of 12 months after the date on which the authorization takes effect unless extended or revoked by the Secretary;
  - (e) the Secretary must put in place a mechanism for monitoring any adverse event occurred to the person to whom the vaccine is administered ("recipient") associated with the administration of vaccines;
  - (f) a person who is responsible for administering the vaccine to a recipient must ensure that, before the vaccine is so administered, the recipient (or a person who is legally capable of giving the consent on the recipient's behalf) ("the person concerned") has been informed that the vaccine is authorized under L.N. 258 instead of registered and of any other information as may be specified by the Secretary and that the person concerned has given consent to the administration of the vaccine; and

- (g) certain provisions of Cap. 138A (including the requirements concerning the registration of a pharmaceutical product; and the disclosure of composition of medicines) do not apply in relation to the supply or the possession by a person of the vaccine under or for the purpose of performing, a Government contract, or the use of vaccine for a specified purpose, so as to allow such use without contravening those provisions.

4. L.N. 258 also provides for immunity from civil liability of members of the advisory panel in relation to the giving of advice and that of certain persons who prescribe, dispense or are responsible for administering, an authorized 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.

5. L.N. 258 will expire at midnight on 23 December 2021 except that the provisions in relation to the granting of the immunity from civil liability as stated in paragraph 4 above will continue to have effect after the expiry of L.N. 258.

#### L.N. 259

6. Under the Compulsory Quarantine of Certain Persons Arriving at Hong Kong Regulation (Cap. 599C), a person arriving at Hong Kong from a place in China other than Hong Kong ("relevant person") are placed under compulsory quarantine for 14 days from the date of arrival if the relevant person has stayed in a certain place in China or a certain foreign place for 14 days ("specified period") immediately before their arrival at Hong Kong.

7. L.N. 259 amends Cap. 599C, among others, to:

- (a) empower the Secretary, by notice published in the Gazette (such notice not being subsidiary legislation), to specify (i) different quarantine periods for different categories of relevant persons; and (ii) different specified periods for different places in which any of the relevant persons has stayed before the arrival;
- (b) provide that both the quarantine period and the specified period must not exceed 28 days; and
- (c) tighten one of the conditions for cancellation of a quarantine order under Cap. 599C so that a person against whom a quarantine order is made must produce a certificate issued by a public authority in the Mainland or Macao certifying that the person completed, on the date of the person's arrival at Hong Kong or the day before, a quarantine of a period that is not shorter than the quarantine period under the quarantine order.

8. By G.N. (E.) 265 of 2020 published in the Gazette on 23 December 2020, the Secretary has specified 21 days to be the specified period and quarantine period under Cap. 599C for the relevant person who has stayed in the United Kingdom ("UK") before arrival at Hong Kong. By G.N. (E.) 272 of 2020 published in the Gazette on 24 December 2020, the places covered have been extended to the effect that any relevant person who has stayed in any place outside China before arrival at Hong Kong (i.e. including a person having stayed in the UK) during the 21-day specified period must be placed under compulsory quarantine for 21 days from the date of arrival. Upon the commencement of G.N. (E.) 272 of 2020 on 25 December 2020, G.N. (E.) 265 of 2020 was suspended.

#### L.N. 260

9. Under the Compulsory Quarantine of Certain Persons Arriving at Hong Kong from Foreign Places Regulation (Cap. 599E), a person arriving at Hong Kong from a place outside China ("target person") must be placed under compulsory quarantine for 14 days from the date of arrival if the target person has stayed in a certain foreign place or a certain place in China for 14 days ("prescribed period") immediately before their arrival at Hong Kong.

10. L.N. 260 amends Cap. 599E, among others, to:

- (a) empower the Secretary, by notice published in the Gazette (such notice not being subsidiary legislation), to specify (i) different quarantine periods for different categories of target persons; and (ii) different prescribed periods for different places in which any of the target person has stayed before the arrival; and
- (b) provide that both the quarantine period and the prescribed period must not exceed 28 days.

11. By G.N. (E.) 266 of 2020 published in the Gazette on 23 December 2020, the Secretary has specified 21 days to be the prescribed period and the quarantine period under Cap. 599E for the target person who has stayed in UK before arrival at Hong Kong. By G.N. (E.) 273 of 2020 published in the Gazette on 24 December 2020, the places covered have been extended to the effect that any target person who has stayed in any place outside China (i.e. including a person having stayed in UK) during the 21-day prescribed period before arrival at Hong Kong must be placed under compulsory quarantine for 21 days from the date of arrival. Upon the commencement of G.N. (E.) 273 of 2020 on 25 December 2020, G.N. (E.) 266 of 2020 was suspended.

#### L.N. 261

12. The Prevention and Control of Disease (Regulation of Cross-boundary Conveyances and Travellers) Regulation (Cap. 599H) mainly provides a mechanism under which regulatory measures may be imposed on cross-boundary conveyances (i.e. aircraft or vessels) arriving (or about to arrive) at Hong Kong from a place

outside Hong Kong and the relevant travellers on those conveyances. The definition of relevant traveller in section 2(1) of Cap. 599H includes a person on a certain conveyance who, on the day on which the person boarded the conveyance or during the 14 days ("stated period") before that day, has stayed in a place specified by the Secretary under Cap. 599H.

13. L.N. 261 amends Cap. 599H, among others, to:
- (a) replace "the 14 days" in the definition of "relevant traveller" by "a specified period"; and
  - (b) empower the Secretary, by notice published in the Gazette (such notice not being subsidiary legislation), to specify different stated periods (which must not exceed 28 days) for different places specified by the Secretary under Cap. 599H.

14. By G.N. (E.) 267 of 2020 published in the Gazette on 23 December 2020, the Secretary has specified that for the relevant traveller who has stayed in in UK, 21 days is the stated period for the purposes of Cap. 599H. By G.N. (E.) 274 of 2020 published in the Gazette on 24 December 2020, the places covered have been extended to include any specified place outside China (including UK) for the purposes of Cap. 599H. Upon the commencement of G.N. (E.) 274 of 2020 on 25 December 2020, G.N. (E.) 267 of 2020 was suspended.

15. By G.N. (E.) 275 of 2020 published in the Gazette on 24 December 2020, the Secretary has specified 21 specified places<sup>2</sup> to which Cap. 599H is applicable and a set of conditions (e.g. to produce documentary proof on a negative nucleic acid test result for COVID-19 and confirmation of room reservation in a designated quarantine hotel in Hong Kong for not less than 21 nights) applicable to the relevant travellers. Upon the commencement of G.N. (E.) 275 of 2020 on 25 December 2020, the previous Government notice for the regulation of cross-boundary conveyances and travellers with effect from 24 December 2020 (i.e. G.N. (E.) 268 of 2020 published in the Gazette on 23 December 2020) was suspended.

### Consultation

16. According to paragraph 22 of the LegCo Brief on L.N. 258 and paragraph 16 of the LegCo Brief on L.N. 259 to L.N. 261 (no file reference provided for the two LegCo Briefs) issued by the Food and Health Bureau in December 2020, the Administration is of the view that given the exigency of the situation, public consultation is not feasible.

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<sup>2</sup> Other specified places include: Bangladesh, Belgium, Ethiopia, France, India, Indonesia, Kazakhstan, Nepal, Pakistan, the Philippines, Russia, South Africa, Turkey, United Kingdom, United States of America, Canada, Ecuador, Germany, Romania, Ukraine and all other countries except China.

17. As advised by the Clerk to the Panel on Health Services, the Panel has not been consulted on L.N. 258 to L.N. 261. At the special meeting of the Panel on 16 December 2020, the Panel discussed matters relating to the procurement and administration of the vaccines. Members generally agreed that there was a need for the Administration to authorize the urgent use of certain vaccines for the purpose of carrying out a Government vaccination programme for members of the public under the current state of public health emergency. However, concerns were raised on certain issues including the conditions to be attached to an authorization to ensure that the vaccines would adhere to the requirements of safety, efficacy and quality, and the liability of the vaccine manufacturers for any adverse events occurred to the recipients associated with the administration of the vaccines or the failure of any batches of the vaccines to meet the safety requirements.

### Commencement

18. L.N. 258 to L.N. 261 came into operation on 24 December 2020.

### **Concluding observations**

19. The Legal Service Division is seeking clarifications on certain legal and drafting matters of L.N. 258 and will report further, if necessary. No difficulties have been identified in relation to the legal and drafting aspects of L.N. 259 to L.N. 261.

### **Other matters**

#### Government notices made by the Secretary under the Prevention and Control of Disease (Requirements and Directions) (Business and Premises) Regulation (Cap. 599F)

##### *Latest requirements and directions in relation to catering business*

20. By G.N. (E.) 2 of 2021 published in the Gazette on 4 January 2021, the Secretary has specified and directed that for a period of 14 days from 7 January 2021 to 20 January 2021, in respect of all catering businesses, except those exempted under Cap. 599F, the selling or supplying of food and drink for consumption on the premises of the catering business must be ceased, and any such premises (or part thereof) where food or drink is sold or supplied for consumption on the premises must be closed, from 6:00 pm to 4:59 am of the subsequent day (i.e. dine-in services can now only operate until 5:59 pm every night). Protective measures (e.g. wearing masks except when consuming food or drink at a table, body temperature screening, provision of hand sanitisers and display of the

LeaveHomeSafe venue QR code obtained at the entrance of the premises) are extended. Other restrictions, such as suspension of live performance and dancing, and no more than two persons being seated together at one table, continue to be effective.

*Latest directions in relation to scheduled premises*

21. By G.N. (E.) 3 of 2021 published in the Gazette on 4 January 2021, the Secretary has directed that, for a period of 14 days from 7 January 2021 to 20 January 2021:

- (a) 13 types of scheduled premises<sup>3</sup> as set out in Part 1 of Schedule 2 to Cap. 599F must be closed; and
- (b) two types of scheduled premises (i.e. club-house and hotel/guesthouse) as set out in Part 1 of Schedule 2 to Cap. 599F may open subject to the requirements and restrictions detailed at Annex to G.N. (E.) 3 of 2021.<sup>4</sup>

Government notices made by the Secretary under the Prevention and Control of Disease (Prohibition on Group Gathering) Regulation (Cap. 599G)

22. In respect of the prohibition on group gatherings, the Secretary has, pursuant to section 4(1) of Cap. 599G, specified by G.N. (E.) 4 of 2021 published in the Gazette on 4 January 2021 the 14-day period from 7 January 2021 to 20 January 2021, during which no group gatherings of more than two persons may take place at a public place and at any premises in relation to which a direction issued under section 6 or 8 of Cap. 599F is in force. G.N. (E.) 4 of 2021 replaces the previous Government notice on the period for the application of the group gathering prohibition (i.e. G.N. (E.) 256 of 2020 published in the Gazette on 21 December 2020).

Government notices made by the Secretary under the Prevention and Control of Disease (Wearing of Mask) Regulation (Cap. 599I)

23. In respect of the requirement to wear masks, the Secretary has, pursuant to section 3(1) of Cap. 599I, specified by G.N. (E.) 5 of 2021 published in the Gazette on 4 January 2021 the 14-day period from 7 January 2021 to 20 January 2021, during which a person must wear a mask at all times while boarding or on

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<sup>3</sup> Those scheduled premises are: (1) amusement game centre; (2) bathhouse; (3) fitness centre; (4) place of amusement; (5) place of public entertainment; (6) premises (commonly known as party room) that are maintained or intended to be maintained for hire for holding social gatherings; (7) beauty parlour; (8) establishment (commonly known as club or nightclub) that is open late into the night, usually for drinking, and dancing or other entertainment; (9) karaoke establishment; (10) mahjong-tin kau premises; (11) massage establishment; (12) sports premises; and (13) swimming pool.

<sup>4</sup> For example, the requirement that a person must wear a mask at all times within any club-house except when taking a shower, and the restriction that any part(s) of the hotel/guesthouse being used or operated as bathhouse must be closed.

board a public transport carrier, or entering or present in an MTR paid area or a specified public place, save for any outdoor public places in any country parks and special areas as defined in section 2 of the Country Parks Ordinance (Cap. 208). G.N. (E.) 5 of 2021 replaces the previous Government notice on the period for the application of the requirement to wear masks (i.e. G.N. (E.) 257 of 2020 published in the Gazette on 21 December 2020).

Government notices made by the Secretary under the Prevention and Control of Disease (Compulsory Testing for Certain Persons) Regulation (Cap. 599J)

24. By G.N. (E.) 262 of 2020 published in the Gazette on 23 December 2020, the Secretary has specified the period of 14 days from 26 December 2020 to 8 January 2021 during which all medical practitioners who are registered in Part I and Part III of the General Register kept under section 6(1) of the Medical Registration Ordinance (Cap. 161) may exercise the power to require, by a compulsory testing direction, a person whom the medical practitioner attends to in the course of professional practice and clinically suspects to have contracted the disease to undergo a polymerase chain reaction-based nucleic acid test for COVID-19 ("specified test"), and appointed all members of the Auxiliary Medical Services and all police officers to perform a function under Cap. 599J concerning a requirement specified under a compulsory testing direction.

25. By G.N. (E.)s 263, 264, 269, 270, 271, 276, 277, 278, 279, 280, 281, 282, 283, 284, 285 and 286 of 2020 published in the Gazette from 23 to 31 December 2020 and by G.N. (E.)s 1, 6, 7, 8 and 9 of 2021 published in the Gazette on 2, 4 and 5 January 2021, the Secretary has specified various categories of persons to be persons who must undergo a specified test on or before certain periods as specified in the relevant Government notices. The Secretary has also specified certain periods as the periods during which a compulsory testing order may be issued under Cap. 599J for non-compliance with the relevant Government notices.

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