立法會
Legislative Council

LC Paper No. CB(4)526/20-21

Ref : CB2/SS/2/20

Paper for the House Committee

Fourth report of the Subcommittee on Subsidiary Legislation Relating to the Prevention and Control of Disease

Purpose

This paper reports on the deliberations of the Subcommittee on Subsidiary Legislation Relating to the Prevention and Control of Disease ("the Subcommittee") on the Prevention and Control of Disease (Use of Vaccines) Regulation (L.N. 258 of 2020) ("the Regulation").

The Regulation

2. The Regulation is a new regulation which was published in the Gazette on 23 December 2020 to provide a legal framework under which the Secretary for Food and Health ("the Secretary") may, on application, authorize a vaccine for the disease that is not registered under the Pharmacy and Poisons Regulations (Cap. 138A) ("the 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"). It came into operation on 24 December 2020 and will expire at midnight on 23 December 2021 except that the provisions[1] in relation to the granting of the immunity from civil liability will continue to have effect after the expiry thereof.

3. The Regulation was tabled before the Legislative Council ("LegCo") at its meeting on 6 January 2021 and is subject to negative vetting by LegCo.

---

[1] Sections9(2) and (3) and 10 of the Regulation.

The Subcommittee

4. At the House Committee meeting on 8 January 2021, Members agreed that the Regulation should be studied by the Subcommittee.

5. The expiry of the scrutiny period of the Regulation has been extended from the Council meeting of 3 February 2021 to the Council meeting of 24 February 2021 by a resolution passed at the Council meeting on 27 January 2021.

6. Under the chairmanship of Dr CHIANG Lai-wan, the Subcommittee has held three meetings with the Administration to discuss the Regulation.

Deliberations of the Subcommittee

Vaccine procurement

7. According to paragraph 6 of the LegCo Brief on the Regulation, securing sufficient supplies of safe and efficacious vaccines for the population is crucial to safeguarding the public's health and suppressing the COVID-19 epidemic in Hong Kong so that normal operations of society can gradually resume. Members are gravely concerned about the progress of the procurement of vaccines and whether there could be a choice of vaccines to members of the public. In this connection, some members, including Ms Elizabeth QUAT, asks whether the vaccine developed by Sinopharm, which has been vaccinated on the Mainland, will be procured.

8. The Administration has advised that according to the World Health Organization ("WHO") and health experts, COVID-19 will not come under control without effective treatment and vaccination. The Administration has been adopting a "two-pronged" strategy to procure vaccines for protecting against COVID-19 for the entire Hong Kong population. The Administration has on one hand joined the COVAX Facility led by WHO, and at the same time directly entered into advance purchase agreements ("APAs") with individual vaccine developers for obtaining greater supplies of vaccines at an earlier time.

9. Regarding APAs the Administration has further advised that it has reached preliminary agreements with three vaccine developers, namely Sinovac Biotech (Hong Kong) Limited, FosunPharma and BioNtech, and AstraZeneca, to procure vaccines sufficient for 1.5 times the Hong Kong population. According to the latest information provided by the vaccine supplier, the first batch of 1 million doses of the FosunPharma/BioNTech vaccine to be supplied to Hong Kong are undergoing safety and quality testing. Subject to the completion and passing of

the relevant tests, the vaccine is expected to arrive in Hong Kong from Germany in late February 2021 and it has been authorized on 25 January 2021 for emergency use in Hong Kong in accordance with the Regulation. As regards the other two vaccines, the AstraZeneca vaccine is expected to be available in Hong Kong in the third quarter of 2021 and prerequisite clinical information for the Sinovac vaccine is still pending. At this stage, the Government's goal remains to procure vaccines developed by different developers using different technology platforms, and to secure sufficient doses to cater for at least two times the entire population. Due to the different arrival time and logistics arrangement, it is expected that different vaccines will be provided at different time and location. Members of the public falling under the prevailing priority or target groups may choose where and when to receive their vaccine.

10. On members' enquiry about the vaccine developed by Sinopharm, due to non-disclosure agreement signed with the vaccine manufacturers, the Administration cannot disclose details of its discussion with individual vaccine manufacturers until APAs with the manufacturers concerned are announced. Whether or not a vaccine will be authorized is to be decided by the Administration having regard to the advice of the advisory panel. The Administration has stressed that a vaccine could be authorized for emergency use only if (a) a regulatory authority in a place outside Hong Kong that performs the function of approving pharmaceutical products has approved the vaccine for administration to persons other than on an experimental or trial basis, including for emergency use; or (b) the vaccine is listed in accordance with the emergency use listing procedure by WHO or is on the list of prequalified vaccines published by WHO. In granting the authorization, the Secretary must have regard to the advice of the advisory panel, and take into account the safety, efficacy and quality of the vaccine.

Delivery of vaccines

11. Mr YIU Si-wing is concerned that arising from the Administration's new 14-day hotel quarantine plus 7-day medical surveillance requirement for the Hong Kong-based pilots and cabin crew of airlines, their cargo capacity will be reduced. The Administration is therefore requested to make a comprehensive assessment of whether Hong Kong has sufficient air cargo capacity to ensure timely delivery of vaccines.

12. According to the Administration, it strives to ensure the timely delivery of COVID-19 vaccines to Hong Kong. As mentioned in paragraph 9 above, the FosunPharma/BioNTech vaccine is expected to be delivered in late February 2021. The Administration has been closely liaising with the Airport Authority and FosunPharma. It will closely monitor the impact of any latest quarantine

requirements on the delivery schedule and make immediate arrangements if necessary.

Timetable and locations for vaccination

13. Members urge the Administration to provide vaccination as soon as possible and ask about the timetable for vaccination. Some members, including Mr Wilson OR, are also concerned about the locations for vaccinations and stress the importance of sufficient number of vaccination centres to avoid long waiting queue, which is conducive to the spread of COVID-19 and undesirable particularly for the elderly and chronic patients. They also ask whether members of the public are to receive the vaccine twice at the same location under the two-dose regime and whether the public could choose the type of vaccine to be received. Some members, including Mr SHIU Ka-fai, also ask whether the vaccination will be administered on a compulsory basis.

14. The Administration estimates that starting in late February 2021, members of the public can get vaccinated under a vaccination programme led by the Administration. The vaccination is free of charge and on a voluntary basis instead of compulsory. The Administration's goal is to provide vaccines for the majority of the population within 2021. In view that the FosunPharma/BioNTech vaccine has more stringent requirements for transport and storage[2] and also require correct thawing procedures, the Administration will set up Community Vaccination Centres in 18 districts in Hong Kong in order to ensure the quality of the vaccines and that the vaccination procedures adhere to requirements. For vaccines developed by Sinovac and AstraZeneca, it is planned that the vaccination will be provided through private hospitals and clinics, following the arrangements for seasonal influenza vaccination. The Administration points out that the vaccine administrated at the Community Vaccination Centres will be different from that at the private clinics. Hence, members of the public are to receive the two doses of vaccines at the same location. They will be required to make at the same time online appointments for both doses. The recipients will have an electronic record after vaccination and they will be reminded through electronic means of the date and time for receiving the second dose of vaccines. As regards the choice of vaccine by a recipient, it is expected that the FosunPharma/BioNTech vaccine will be provided in Community Vaccination Centres. If members of the public prefer another type of vaccine, they could pick a different location for vaccination where the vaccine of their choice will be available**.**

---

[2] The vaccines must be stored at -70 degree Celsius, and can only survive in a 2 to 8 degrees Celsius environment for five days.

Manpower arrangement

15. Some members, including Mr CHAN Chun-ying, are concerned whether there is sufficient manpower for the vaccination programme. They worry that private doctors may be reluctant to participate in the programme if vaccine recipients need to stay in the clinics concerned for about 30 minutes to enable the staff of the clinics to observe whether the recipients suffer from any adverse side effects. Such observation arrangement may adversely affect the business of the private doctors. In this connection, the Chairman asks the Administration whether private doctors will be remunerated for administering the vaccination.

16. The Administration has clarified that the 30-minute observation period is for the FosunPharma/BioNTechvaccinewhich is to be administered in Community Vaccination Centres, while private doctors will be mainly responsible for administering in their clinics vaccines developed by Sinovac and AstraZeneca following the arrangements for seasonal influenza vaccination, for which the duration of the observation is not yet confirmed. The industry has been supportive of the vaccination programme and the Administration does not envisage major problems caused by the vaccination to the normal operation of the clinics concerned. The doctors concerned will receive a reimbursement from the vaccination programme. The Administration will encourage private doctors to participate in the work of Community Vaccination Centres.

Priority groups for vaccination

17. Some members, including Mr LUK Chung-hung and Mr Wilson OR, ask whether there will be priority groups for vaccination and, if so, whether they include cleansing workers, people at high risk of exposure to COVID-19 virus and people of the transport sector who need to travel frequently.

18. The Administration has advised that it will accord priority for vaccination to groups which have higher risks of coming into contact with the COVID-19 virus (e.g. healthcare workers), groups which have greater mortality rates after contracting the disease (e.g. the elderly, chronic patients), and/or groups which may easily transmit the virus to the vulnerable or weak if infected (e.g. staff of residential care homes). Furthermore, it is reviewing other target groups which may need to receive vaccination early due to their work nature or other needs. Besides the priority groups, the Administration will basically arrange vaccination for citizens according to their age groups, starting with relatively older persons and gradually extending to younger groups. It will announce the details of the vaccination arrangement in due course.

Advisory panel

19. Section 9(1) of the Regulation empowers the Chief Executive ("CE") to appoint a panel of persons ("the Advisory Panel") who are considered by CE to have relevant expertise for advising the Secretary for the purposes of section 3(3), 4(1) or 6(1). Some members, including Mr CHENG Chung-tai and Mr YIU SI-wing, ask whether there are any criteria or procedures for the Advisory Panel to follow in making its recommendations to the Secretary. They also ask whether the relevant papers and information provided to the Advisory Panel will be disclosed to the public and whether members of the Advisory Panel have declared their interests regarding vaccine development.

20. The Administration has advised that the main factors of consideration by the Advisory Panel are the safety, efficacy and quality of the vaccine. The Advisory Panel will review the relevant data and reports submitted by the vaccine manufacturer before making its recommendation. The relevantinformation of the vaccine will be made available in the public domain. All members of the Advisory Panel have made their declarations of interests.

Publicity, promotion and education

21. Several members have criticized that there is a lack of transparency of information regarding vaccines. In this connection, Ms Elizabeth QUAThas suggested that the Administration should provide an information kit or Frequently Asked Questions about the vaccines, and Mr SHIU Ka-fai has suggested the provision of information about the vaccines through advertisements as soon as possible. Some members, including Mr POON Siu-ping, Mr CHAN Chun-ying and Mr SHIU Ka-fai, request the Administration to consider providing incentives(e.g. cash reward or a certificate for quarantine-free access to the Mainland) to encourage members of the public to receive vaccination.

22. The Administration has explained that the information available at this stage is mostly generic and seeks to debunk rumours about the vaccines. The Administration will do well the work on information dissemination, promotion and education following the principles of openness, transparency, accuracy and timeliness. It will disseminate the benefits and correct information on vaccination, the views of experts and details of the vaccination programme, etc. to members of the public through various channels such as print, electronic and social media, with a view to enabling the public to adequately grasp the relevant information before vaccination, including the principles, formulation, usefulness and side effects, etc. This is to allay the public's concerns, and on this premise, encourage them to get vaccinated. It will also step up monitoring of false information on vaccines within the community and make clarifications and

debunk rumours as necessary. It has uploaded relevant information onto the Government's "COVID-19 Thematic Website", and will later set up a thematic website for the vaccination programme, so that members of the public can have access to correct and the most updated information and messages on vaccines from an official channel. The Administration will not consider the provision of a monetary incentive to encourage vaccination.

Mechanism for monitoring adverse event occurred to vaccine recipients

23. Under Section 7(3) of the Regulation, the Secretary must put in place a mechanism for monitoring any adverse event occurred to the person to whom the vaccine is administered ("the recipient") associated with the administration of vaccines. Mr CHENG Chung-tai enquires about the details of the mechanism, particularly whether there is a time limit on such monitoring.

24. The Administration has advised that to tie in with the vaccination programme as well as to monitor any adverse event that occurs to the recipient associated with the administration of the relevant vaccine, the Administration has set up the Expert Committee on Clinical Events Assessment Following COVID-19 Immunisation. That Committee will perform continuous monitoring of the possible adverse event following administration of COVID-19 vaccines, and provide professional views and suggestions on safety monitoring of the authorized vaccines. Under the monitoring mechanism imposed by section 7(3) of the Regulation, there are two types of monitoring (i.e. active and passive). Under active monitoring, the Administration will work with local university to retrieve specific adverse events primarily through medical records of the Hospital Authority to look for adverse reactions to vaccinations and check if such adverse reactions also occur to recipients after the administration of COVID-19 vaccines for identification of possible safety concern. Under passive monitoring, a recipient suspecting to have an adverse event following immunization ofCOVID-19 vaccine may consult a healthcare professional who may report the adverse event online to the Department of Health for assessment. There is no time limit for such reporting.

Informed consent

25. Section 8 of the Regulation requires a person who is responsible for administering an authorized vaccine to a recipient for a specified purpose to ensure that informed consent has been obtained before administering the vaccine. Dr Pierre CHAN is concerned about how a medical doctor administering the vaccine could obtain informed consent of a recipient if the information about the vaccine is incomplete.

26. The Administration has explained that for the purpose of obtaining informed consent of a recipient, it will provide a standard information kit for use by healthcare staff administering the vaccine in Community Vaccination Centres and those in private hospitals and clinics. The information kit, which contains information about the side effects and characteristics of individual vaccine and other information which a recipient may need to know, will be available before the launch of the vaccination programme. Such information will also be accessible online for perusal by members of the public when they make appointments for vaccination. New development and updated information of the relevant vaccines will be made public under the monitoring mechanism put in place under section 7(3) of the Regulation.

Immunity from civil liability

27. Section 10 of the Regulation provides for the immunity from civil liability of 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 caused to the recipient by an act done or omitted to be done 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. Some members, including Mr Wilson OR and Dr CHENG Chung-tai, have expressed concern over the scope of such immunity.

28. The Administration has explained that the immunity does not cover vaccine developers, the Government and other related parties. The immunity is only provided for doctors-in-charge of the vaccination, as well as nurses, pharmacists or drug dispensers who assist in preparing or making available the vaccines for vaccination, to their acts done or omitted to be done in good faith in relation to the administration of the vaccine if the loss or damageresulting from any risk as to the safety of the administration of the vaccine is attributable to the intrinsic property of the vaccine as manufactured. These persons, however, are still civilly liable for any loss or damage which is not so attributable.

Handling of unused doses

29. Members note that the quantity of vaccines procured under the Administration's APAs exceeds that required by the entire population. In this connection, the Administration is requested to advise how unused doses of the vaccines procured by the Administration would be disposed of, including whether they would be returned to the manufacturers concerned, or be sold or donated to any other places. Some members, including the Chairman and Mr YIU Si-wing, also ask whether there is any exit clause under APAs with the three vaccine

developers and whether the quantity of vaccines procured thereunder could be adjusted.

30. According to the Administration, it is not appropriate to disclose the details of APAs which contain commercially sensitive information. As far as APAs are concerned, it is imperative that the Administration has the best possible plan to secure sufficient supplies of vaccines for the entire Hong Kong population. Having considered that not all candidate vaccines can be successfully developed and launched into the market, the Administration has set an initial goal to procure at least two candidate vaccines developed by different developers using different technology platforms, and to secure sufficient doses to cater for at least two times the entire population. As global competition for the vaccine is fierce, supply will be tight in the initial stage. The purpose of negotiating and entering into APAs is to reserve candidate vaccines which are more likely to be successful for the Hong Kong population at an earlier time, notwithstanding that the vaccines are still in development stage and have yet to obtain approval from relevant regulatory authorities.

31. The Administration has further advised that as explained in paragraph 9 above, vaccines sufficient for 1.5 times the Hong Kong population have been procured under APAs. If the Administration's strategy of negotiating and entering into APAs bears fruit and all vaccines reserved under APAs are successfully developed, the quantity procured will far exceed that required by the entire population. This is an inevitable price to pay for ensuring the adequate supply of vaccines for Hong Kong people at an earlier time. And the essence of APAs is that the Administration is obliged to procure an agreed quantity which is not to be reduced by a short fall in demand. If the Administration had adopted a conservative procurement strategy at the beginning, it would be most likely that the quantity of vaccines supplied would be insufficient to cater for the Hong Kong population. Hence, surplus supply is a possible outcome of the procurement strategy. As the vaccines have not yet arrived in Hong Kong for commencement of vaccination, public's response to the vaccines is unknown and it remains unclear whether there is clinical evidence on the need for regular vaccination. As such, it is premature at this stage to discuss the handling of surplus vaccines. The Administration will continue with its work on publicity, promotion and education outlined in paragraph 22 above, thereby increasing public confidence in vaccination.

Indemnity fund

32. According to paragraph 17 of the LegCo Brief on the Regulation, an indemnity fund will be set up to cover for the indemnity offered to vaccine manufacturers under bilateral purchase agreements, and to provide support for individuals who have proof of suffering unexpected serious adverse effects

associated with a vaccine pending, or in lieu of, their civil actions against a vaccine manufacturer. Some members, including Mr Wilson OR and Mr CHAN Chun-ying, have sought the Administration's clarification on whether a person who has serious complications after receiving the COVID-19 vaccination may make a claim against the vaccine manufacturer, and whether the indemnity fund will assist that person or provide financial support to that person directly. The Chairman has also suggested that matters relating to setting up of the indemnity fund should be brought, as early as possible and before members of the public receive vaccination, to the committee concerned for consideration.

33. The Administration has explained that the indemnity fund will cover the indemnities ultimately determined by court or arbitration and can provide in advance part of the indemnities in order to make available financial assistance to the member of the public as early as possible. The fund will be set up administratively and will provide financial support to individuals who have suffered serious side effects. The Administration is formulating the relevant mechanism and details and will seek funding approval from the Finance Committee of LegCo as soon as possible.

Recommendation

34. The Subcommittee raises no objection to the Regulation and will not propose any amendment to it.

Advice sought

35. Members are invited to note the deliberations of the Subcommittee.

Council Business Division 4
Legislative Council Secretariat
17 February 2021