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

立法會秘書處 法律事務部
LEGAL SERVICE DIVISION
LEGISLATIVE COUNCIL SECRETARIAT

來函檔號 YOUR REF : FHB/H/53/4
本函檔號 OUR REF : LS/B/2/19-20
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By Fax (2840 0467)
29 November 2019

Ms Iris YICK
Assistant Secretary for Food and Health (Health)4A
Food and Health Bureau
19/F, East Wing
Central Government Offices
2 Tim Mei Avenue, Tamar
Hong Kong

Dear Ms YICK,

Pharmacy and Poisons (Amendment) Bill 2019

We are scrutinizing the Bill with a view to advising Members.

We set out in the Annex our observations on the legal and drafting aspects of the Bill. We would appreciate it if you would let us have the Administration's response in bilingual form by 13 December 2019.

Yours sincerely,

(Wendy KAN)
Assistant Legal Adviser

Encl.

c.c. Department of Justice
(Attn: Mr Michael LAM, Senior Assistant Law Draftsman
Miss Annet LAI, Government Counsel) (By Fax: 3918 4613)
Legal Adviser
Senior Assistant Legal Adviser 3
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Annex

Part I: Legal issues

Clause 1(2) of the Bill

1. Under the proposed regime of the Bill, manufacturers of advanced therapy products ("ATPs") such as operators of certain hospitals, and manufacturers who prepare, or repackage as finished products, pharmaceutical products (including ATPs) for clinical trial, are required to obtain manufacturer licences under the Pharmacy and Poisons Ordinance (Cap. 138). Pursuant to clause 1(2) of the Bill, the Bill (if passed) ("the Amendment Ordinance") would come into operation on a day to be appointed by the Secretary for Food and Health by notice published in the Gazette. Would the Administration inform Members the target commencement date(s) of the Amendment Ordinance? Would sufficient time be given to these manufacturers for preparing for the applications of the licences and compliance with the relevant regulatory requirements including those contained in the Pharmacy and Poisons Regulations (Cap. 138A), and the codes of practice and the Good Manufacturing Practice Guide ("GMP Guide") issued by the Pharmacy and Poisons Board ("the Board")? Would revisions be required to be made to the codes of practice and GMP Guide in view of the Amendment Ordinance, and if so, when would these revisions be issued and take effect?

2. According to paragraph 14 of the Legislative Council ("LegCo") Brief (File Ref.: FHB/H/53/4) issued by the Food and Health Bureau on 16 October 2019, given that the collection of cells or tissues may take place outside the manufacturer's premises, extra requirements in respect of ATPs (such as donor selection and testing) will be imposed via the licensing conditions of relevant ATP manufacturers. For manufacturers of pharmaceutical products whose licences are granted prior to the commencement of the Amendment Ordinance, would they be required, after the commencement of the Amendment Ordinance, to apply for a new licence for the manufacturing of ATPs even if the ATPs intending to be manufactured fall under the current definition of "pharmaceutical product" under Cap. 138 and are covered by the licence granted? If not, how could those extra requirements in respect of ATPs be imposed?

Clause 3 of the Bill

3. Under the proposed definition of "manufacture" in the proposed section 2(1) of Cap. 138, manufacture, in relation to an ATP (i.e. a gene therapy product, a somatic cell therapy product, or a tissue engineered product, that is for human use), would not include the individual dispensing on a prescription or otherwise of an ATP the dispensing of which does not involve substantial manipulation of cells or tissues. "Substantial manipulation", in relation to cells or tissues, as defined in the proposed section 2(1) of Cap. 138, would not include the manipulation processes set out in the proposed new Schedule to Cap. 138. According to footnote 2 of the LegCo Brief, manipulation of cells or tissues that alters the biological characteristics, physiological functions or structural properties of the cells or tissues is considered as substantial manipulation ("the Alteration Effect"). It is noted that whilst references to the Alteration Effect are embodied in the proposed new definitions of "somatic cell therapy product" and "tissue engineered product" in the proposed section 2(1) of Cap. 138 respectively, no such reference is made in the proposed definition of "manufacture". Please clarify whether manipulation of cells or tissues with the Alteration Effect would be considered as substantial manipulation for the proposed definition of "manufacture" of ATPs. If so, please consider adding the reference to the Alteration Effect in the proposed definition of "manufacture".

4. According to paragraph 5 of the LegCo Brief, the proposed new definition of ATPs to be added to Cap. 138 is made with reference to the definition adopted by the European Union ("EU"). With respect to the proposed new definition of "somatic cell therapy product" in the proposed section 2(1) of Cap. 138, it appears that the requirements stated in its paragraph (b)(ii) (i.e. restoring, correcting or modifying physiological functions) are not provided for in the definition of "somatic cell therapy medicinal product" in the relevant EU legislation (please see Part IV of Annex I to Directive 2001/83/EC). Please explain the reason(s) for including such requirements in the proposed new definition of "somatic cell therapy product" in Cap. 138.

5. Similarly, with respect to the proposed new definition of "tissue engineered product" in the proposed section 2(1) of Cap. 138, it is noted that the reference to the Alteration Effect in paragraph (a)(i)(A) of the definition (i.e. cells or tissues that have been subject to substantial manipulation so that their biological characteristics, physiological functions or structural properties relevant for the intended regeneration, repair or replacement have been altered) does not seem to be mirrored on the Alteration Effect embodied in the definition of "tissue engineered

product" in the relevant EU legislation (i.e. the cells or tissues have been subject to substantial manipulation, so that biological characteristics, physiological functions or structural properties relevant for the intended regeneration, repair or replacement are achieved (please see Regulation (EC) No 1394/2007)). Please clarify the reason(s) for not adopting the definition used in the relevant EU legislation.

Clause 9 of the Bill

6. Under the proposed regulation 31(1)(d) of Cap. 138A, the option of labelling the container of each pharmaceutical product with the number of the provisional certificate of drug/product registration of the pharmaceutical product issued by the Board, instead of with the number of the certificate of drug/product registration issued by the Board, would be removed. Please explain the reason(s) for such removal.

7. A licensed manufacturer is required, under the proposed new regulation 31(1)(g) of Cap. 138A, to label or cause to be labelled the container of each ATP with certain particulars, including the unique donation identifier and unique recipient identifier assigned in accordance with the codes of practice issued by the Board. What are the unique donation identifier and unique recipient identifier? Would the identity of the donor and recipient concerned be disclosed? Would an animal donor be assigned with a unique donation identifier?

Clause 13 of the Bill

8. The proposed regulation 39(1) of Cap. 138A requires that the books, records and documents referred to in that regulation must be preserved by certain persons, including the licensed wholesale dealer or licensed manufacturer concerned, in the premises in which the transaction recorded took place. It is however noted that the proposed new regulation 39(2) of Cap. 138A does not prescribe the place where the books, records and documents relating to ATPs referred to in that regulation ("specified documents") must be preserved by the licensed wholesale dealer or licensed manufacturer concerned ("specified person"). Please explain the reason(s) for not prescribing so.

9. Under the proposed regulation 39(2)(a) of Cap. 138A, the records and documents referred to in subparagraphs or proposed subparagraphs (d), (e), (f) and (g) of regulation 35(1) of Cap. 138A, which are covered in the proposed regulation 39(1) of Cap. 138A, are excluded from the list of specified documents, whilst other subparagraphs

or proposed new subparagraphs of that regulation 35(1) are included. Please explain the reason(s) for such exclusion.

10. Please clarify the respective meanings of "insolvent" and "bankrupt" as set out in the proposed new regulation 39(2)(b) of Cap. 138A. Would "insolvent" refer to the insolvency of a company and "bankrupt" refer to the bankruptcy of a natural person? With respect to "insolvent", would the word denote the situation where a company is unable to pay debts as they fall due, including without limitation where a company is in liquidation? As to "bankrupt", would the word denote only to the situation where a natural person has been adjudged bankrupt by a court?

11. If the answers in paragraph 10 above are in the affirmative, it is noted that pursuant to the proposed new regulation 39(2)(b) of Cap. 138A, where a specified person is a company, it is required to transfer the specified documents to the Board when it becomes unable to pay debts when they fall due, even though it is not yet in liquidation. However, where a specified person is a natural person, he or she is not required to transfer the specified documents to the Board even if he or she becomes unable to pay debts when they fall due, provided that he or she is yet to be adjudged bankrupt or has not entered into a voluntary arrangement as defined by section 2 of the Bankruptcy Ordinance (Cap. 6) with his or her creditors. Please clarify the reason(s) for making such different requirements.

12. Please also clarify the reason(s) for not providing for, in the proposed new regulation 39(2)(b) of Cap. 138A, the return of the specified documents to the specified person concerned by the Board in the event that the specified person, whether being a company or a natural person, subsequently becomes solvent again without proceeding to liquidation or bankruptcy.

Part II: Drafting issues

Clause 3(3) of the Bill

13. It is noted that the proposed definition of "pharmaceutical product" under the proposed section 2(1) of Cap. 138 basically follows the current definition provided for in section 2(1) of Cap. 138, with the addition of an express inclusion of an ATP. It is however noted that the words "is presented" (i.e. in paragraph (a)(i) of the proposed definition) in

the English text is rendered as "對....的表述或其狀況顯示" in the Chinese text, as opposed to "被表述為" (i.e. in paragraph (a) of the current definition) in the existing section 2(1) of Cap. 138. It is also noted that the same Chinese renditions for "presented as" in the English text are adopted for the proposed new definitions of "somatic cell therapy product" and "tissue engineered product" in the proposed section 2(1) of Cap. 138 respectively. Please explain the reason(s) for proposing to adopt such Chinese renditions.

Clause 11(4) of the Bill

14. Under the proposed new regulation 35(1)(h)(i) of Cap. 138A, "the name and address of the person from whom the cells or tissues used for the preparation of the product were obtained" in the English text is rendered as "提供配製該製品的細胞或組織的人的姓名或名稱，以及其地址" in the Chinese text. It is noted that "name of the person" in the English text is rendered as "人的姓名或名稱" in the Chinese text. Please confirm whether "the person" in the context of this regulation may include a person other than a natural person, such as a company.

Clause 13(5) of the Bill

15. Under the proposed new regulation 39(2)(b)(ii) of Cap. 138A, the Chinese rendition of "creditors" in the English text should be "債權人", instead of "債務人".