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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

Our Ref.： *FHB/H/53/4*
Your Ref.： *LS/B/2/19-20*

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Dear Ms KAN,

Pharmacy and Poisons (Amendment) Bill 2019

I refer to your letter dated 29 November 2019 regarding the Pharmacy and Poisons (Amendment) Bill 2019 ("the Bill"). Our response is set out in the ensuing paragraphs.

(a) Legal Issues

Clause 1(2) of the Bill

Paragraph 1 of the incoming letter

2. Pursuant to clause 1(2) of the Bill, the Pharmacy and Poisons (Amendment) Ordinance 2019 ("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. The Administration intends to set the commencement date at least **12 months** after the passage of the Bill to allow sufficient time for the industry to get prepared. The Administration will keep in view the latest development and readiness of relevant traders to

ensure that sufficient time would be allowed before implementation of the new regulatory requirements.

3. The current Good Manufacturing Practice Guide ("GMP Guide") is the Guide to Good Manufacturing Practice for Medicinal Products (PE 009-11) published by the Pharmaceutical Inspection Co-operation Scheme ("PIC/S GMP Guide"). As the PIC/S GMP Guide is also applicable to the manufacturing of ATPs, no revision is required to be made as a result of the legislative amendment.

4. Pursuant to the amendments to regulations 31(1) and 35(1) of the Pharmacy and Poisons Regulations (Cap. 138A) ("PPR"), the codes of practice for licensed manufacturers and holders of wholesale dealer licence will be revised to include the requirements for the assignment of the product code, unique donation identifier and unique recipient identifier, etc. The revised codes of practice will be issued and take effect before the commencement of the Amendment Ordinance.

Paragraph 2 of the incoming letter

5. In accordance with regulation 29(3) of the PPR, the Pharmacy and Poisons (Manufacturers Licensing) Committee issues licenses for the manufacture of pharmaceutical products. The licenses list out various licensing conditions imposed by the relevant committee. Some of these licensing conditions specify the scope and types of pharmaceutical products that the holder is authorised to manufacture. If a licensed manufacturer intends to expand the scope of the license to cover the manufacture of advanced therapy products ("ATPs"), the manufacturer is required to apply for the change of the licensing conditions. New licensing condition(s) in relation to the requirements in respect of ATPs will be imposed upon approval if applicable.

Clause 3 of the Bill

Paragraph 3 of the incoming letter

6. The proposed definition of "substantial manipulation" refers to **manipulation processes** which are not set out in the proposed new Schedule to the Pharmacy and Poisons Ordinance (Cap. 138)("PPO"). Footnote 2 of the LegCo Brief provides a description of the **effects** brought about by manipulation processes which are regarded as substantial manipulation.

7. The proposed definitions of "somatic cell therapy product" and "tissue engineered product" serve to define what kinds of ***products pertaining to specified characteristics*** are considered as ATPs. Hence, there is a need to specify the effect as a result of the substantial manipulation, which is one of the specified characteristics of the product.

8. On the other hand, the definition of "manufacture" serves to define what kinds of ***operations or processes*** are considered as manufacturing of pharmaceutical product under the PPO and its subsidiary legislations. The key is whether certain operations or processes are involved, regardless of their actual effect. Hence, it is not appropriate to specify the "Alteration Effect" (as mentioned in your letter) in the proposed definition of "manufacture".

Paragraphs 4 and 5 of the incoming letter

9. The Bill aims to enhance the regulation of cell and tissue based products for human use in Hong Kong. In adapting the EU definitions to the PPO, we have taken into account the local circumstances, regulatory need and consistency with the overall regulatory framework under the PPO.

10. The Administration is of the view that from public health perspective, cells and tissue-based products which fall under paragraph (b)(ii) of the definition of "somatic cell therapy product" would impose risks similar to those products which fall under paragraph (b)(i) , and hence should also be regulated as ATPs. This is in line with the proposed definition of "pharmaceutical product" in paragraph (a)(ii)(A).

11. Different expressions of the "Alteration Effect" have been used in the EU definitions of "somatic cell therapy medicinal product" ("have been altered") [1] and "tissue engineered product" ("are achieved"). The two expressions constitute no material difference from regulatory point of view. In order to maintain the consistency of the expression of the "Alteration Effect" in the definitions of "tissue engineered product" and "somatic cell therapy product" in the Bill, the Administration is of the view that the same term "have been altered", which is easier to understand in the contexts, should be adopted for both definitions.

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[1] In the EU definition of "somatic cell therapy medicinal product", the expression "biological characteristics, physiological functions or structural properties relevant for the intended clinical use have been altered" was adopted. Please see EU Directive 2001/83/EC, Part IV of Annex 1: https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/dir_2001_83_consol_2012/dir_2001_83_cons_2012_en.pdf

Clause 9 of the Bill

Paragraph 6 of the incoming letter

12. According to regulation 36(5) of the PPR, the Pharmacy and Poisons (Registration of Pharmaceutical Products and Substances: Certification of Clinical Trial/Medicinal Test) Committee may issue registration certificate of pharmaceutical product, and section 29(1)(qa) of the PPO provides that the Board may make regulations providing for the provisional registration of pharmaceutical products. However, as there is no operational need to issue provisional certificates, no provisions on provisional registration were made under the PPR. In this regard, the existing reference to "provisional certificate" in regulation 31(1)(d) of the PPR is no longer necessary. The proposed amendments to regulation 31(1)(d) serve to take the opportunity of this legislative exercise to remove the reference to provisional certificate to avoid confusion and reflect the current situation.

Paragraph 7 of the incoming letter

13. The unique donation identifier is a code consisting of characters and digits that can provide certain information about the donation (of cells or tissues) without revealing the identity of the donor. The unique donation identifier serves to ensure the traceability of the cells or tissues used for the preparation of ATPs and to avoid mix-up during the process. The unique donation identifier only applies to donation from human donor. For starting material(s) containing cells or tissues from animal, there is no need to assign an animal donor with a unique donation identifier. However, other information describing the nature of the animal cells or tissues would be required as a fulfillment of the proposed provision. Such requirements will be specified clearly in the relevant codes of practice.

14. The unique recipient identifier is a piece of information related to the patient (i.e. recipient), aiming to provide sufficient information to healthcare professionals to verify the identity of recipient. The unique recipient identifier would not readily reveal the identity of the patient and could only be comprehended or deciphered by the responsible healthcare professionals and/or institutions. Relevant details will be specified clearly in the relevant codes of practice.

Clause 13 of the Bill

Paragraph 8 of the incoming letter

15. The proposed regulation 39(2)(a) does not prescribe the place where the specified documents must be preserved by specified person in relation to ATPs. For such long period of record keeping (30 years), the Administration considers it reasonable to allow flexibility for the specified documents to be archived at a place away from the premises in which the transaction recorded took place or be stored electronically off-site.

Paragraph 9 of the incoming letter

16. The proposed regulation 39(2)(a) aims to maintain the traceability of the ATPs for a long period of time due to the nature and risk of the products. The information provided under regulation 35(1)(d), (e), (f) and (g) is not relevant to the whereabouts of the products. As the proposed regulation requires the manufacturer to preserve relevant information for a long period of time, balance has been struck on the burden to the manufacturer and the necessary information to maintain the traceability of ATPs.

Paragraphs 10 to 12 of the incoming letter

17. According to the EU Regulations, the person who markets the advanced therapy medicinal product should transfer relevant data to the regulatory authority in the case of bankruptcy or liquidation. The intention of the Administration is that when the specified person is expected to terminate operation, the specified person should transfer the specified documents to the Board. The Administration shall review and consider if a Committee Stage Amendment ("CSA") to the proposed regulation 39(2)(b)(i) is necessary to reflect the above intention.

(b) Drafting Issues

Paragraph 13 of the incoming letter

18. When considering whether a substance or combination of substances, or a product, "is presented as" having certain properties, various factors will be considered, including—

(a) any written or graphic descriptions on the product;

(b) any written, graphic or verbal descriptions relating to the product; and

(c) the dose form of the product (e.g. pills, injection, suppository, or transdermal patch).

19. To avoid the impression that "is presented" only covers descriptions relating to the product (i.e. factors (a) and (b) above), we have taken the opportunity to make a drafting improvement on the Chinese text to ensure that factor (c) is also covered. We consider that "對…的表述或其狀況顯示" can better reflect the policy intention stated above.

Paragraph 14 of the incoming letter

20. "The person" in the proposed new regulation 35(1)(h)(i) of PPR includes a person other than a natural person, such as a company.

Paragraph 15 of the incoming letter

21. We agree that the Chinese rendition of "creditors" in the proposed new regulation 39(2)(b)(ii) of PPR should be "債權人". We shall consider introducing a CSA in this regard.

Yours sincerely,

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for Secretary for Food and Health

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