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Paper for the House Committee meeting on 12 June 2020

Report of the Bills Committee on Pharmacy and Poisons (Amendment) Bill 2019

Purpose

This paper reports the deliberations of the Bills Committee on Pharmacy and Poisons (Amendment) Bill 2019 ("the Bills Committee").

Background

2. According to the Administration, Advanced Therapy Products ("ATPs") are innovative medical products based on genes, cells and tissues. The Administration considers that while ATPs offer great medical potential for benefiting patients, due to their complicated nature, the risks and long-term side effects of ATPs need to be carefully managed. There is currently no dedicated regulatory framework for ATPs. As stated in paragraph 3 of the Legislative Council ("LegCo") Brief (File Ref.: FHB/H/53/4) issued by the Food and Health Bureau on 16 October 2019, in view of the high risks associated with the rapid scientific advancement, the Administration considers it necessary to introduce a clear and dedicated regulatory framework on the research and therapeutic use of ATPs in order to safeguard public health and facilitate their development. Furthermore, given that the manufacture of ATPs can be in small batch and personalized, the Administration considers that introducing a clear regulatory framework with international standards can facilitate the research and development of scientific institutions.

3. According to paragraph 20 of the LegCo Brief under reference, following the recommendations of the Working Group on Regulation of Premises Processing Health Products for Advanced Therapies ("Working Group")[1] and the Task Force on Regulation of Advanced Therapeutic Products

[1] The Working Group was set up under the Steering Committee on Review of Regulation of Private Healthcare Facilities in 2012. It comprised members from academia in the fields of biotechnology and clinical research, relevant medical specialties and laboratory professions, trade and industry sector and consumer group. In 2014, the Working Group recommended that ATPs should be regulated according to their risks.

in Hong Kong ("Task Force")[2], the Administration proposed that gene therapy products and high-risk cell and tissue therapy products should be designated as ATPs and regulated as pharmaceutical products under the Pharmacy and Poisons Ordinance (Cap. 138). In the 2018 Policy Address, the Chief Executive announced that the Government would introduce legislation to regulate ATPs with an aim to safeguarding public health.[3]

The Pharmacy and Poisons (Amendment) Bill 2019 ("the Bill")

4. The Bill seeks to amend Cap. 138 and the Pharmacy and Poisons Regulations (Cap. 138 sub. leg. A) (Cap. 138A) to:

(a) regulate the manufacture, supply and labelling of, and the keeping of records relating to ATPs, namely, gene therapy products, somatic cell therapy products and tissue engineered product; and

(b) make related amendments.

Details of the major proposals of the Bill are set out in paragraphs 5 to 15 of the LegCo Brief under reference.

5. The Bill, if passed, would come into operation on a day to be appointed by the Secretary for Food and Health by notice published in the Gazette.

The Bills Committee

6. At the House Committee meeting on 8 May 2020, members agreed to form a bills committee to scrutinize the Bill. The membership list of the Bills Committee is at **Appendix I**.

7. Under the chairmanship of Hon Alice MAK, the Bills Committee has held a meeting with the Administration. The Bills Committee has also invited the public to provide written submissions on the Bill. [4]

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[2] The Task Force comprised eight expert members including the Chairman. It was set up in December 2017 to advise the Government on the formulation of the regulatory framework for ATPs and related matters.

[3] Please refer to paragraph 201 of the 2018 Policy Address.

[4] In line with the established practice, a notice to invite written submissions was posted on the website of LegCo and the 18 District Councils were also invited to provide written submissions. By the closing date, no submissions were received.

Deliberations of the Bills Committee

Proposed new definition of Advanced Therapy Products

8. Members note that with reference to the definition adopted by the European Union ("EU"), the Administration proposes that the definition of ATPs to be added to Cap. 138 would cover any of the following products that is for human use –

(a) a *gene therapy product*, e.g. genetically engineered immune cells for the treatment of certain types of cancer;

(b) a high-risk *somatic cell therapy product*, e.g. cultured stem cells from fat tissue for the treatment of chronic inflammation of the gut; and

(c) a high-risk *tissue engineered product*, e.g. cultured corneal epithelial cells for the treatment of burns of the eyes.

The Administration has advised that cells or tissues that have been subject to substantial manipulation[5] and/or intended for non-homologous use[6] would be considered as high-risk.

9. Noting the Administration's explanation that the proposed new definition of ATPs to be added to Cap. 138 is made with reference to the definition adopted by EU, the Legal Adviser to the Bills Committee has pointed out that 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). Members have requested the Administration to explain the reason(s) for including such requirements in the proposed new definition of "somatic cell therapy product" in Cap. 138.

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[5] According to footnote 2 of the LegCo Brief, manipulations of cells or tissues that alter the biological characteristics, physiological functions or structural properties of the cells or tissues would be considered as substantial manipulation. Specifically, substantial manipulation would be a manipulation of cells or tissues that is not cutting, grinding, shaping, centrifugation, soaking in antibiotic or antimicrobial solutions, sterilization, irradiation, cell separation, concentration or purification, filtering, lyophilization, freezing, cryopreservation or vitrification.

[6] According to footnote 3 of the LegCo Brief, non-homologous use would mean the use of cells or tissues in the recipient is not for the same essential functions as those in the donor.

10. The Administration has explained that in adapting the EU definitions to Cap. 138, it has taken into account the local circumstances, regulatory need and consistency with the overall regulatory framework under Cap. 138. From the perspective of public health, 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) of the definition, and hence should also be regulated as ATPs.[7] This is also in line with the proposed definition of "pharmaceutical product" in paragraph (a)(ii)(A).[8]

11. The Legal Adviser to the Bills Committee has also advised that with respect to the proposed new definition of "tissue engineered product" in the proposed section 2(1) of Cap. 138, 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). Members have requested the Administration to clarify the reason(s) for not adopting the definition used in the relevant EU legislation.

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[7] Clause 3 of the Bill provides -

*"**somatic cell therapy product*** (體細胞療法製品) means a product that—

(a) contains or consists of any of the following cells or tissues—

(i) cells or tissues that have been subject to substantial manipulation so that their biological characteristics, physiological functions or structural properties relevant for the intended clinical use have been altered;

(ii) cells or tissues that are not intended to be used for the same essential functions in their recipient as in their donor; and

(b) is presented as having properties for, or may be used in or administered to human beings with a view to—

(i) treating, preventing or diagnosing a disease; or

(ii) restoring, correcting or modifying physiological functions,

through the pharmacological, immunological or metabolic action of those cells or tissues;"

[8] Clause 3 of the Bill provides -

*"**pharmaceutical product*** (藥劑製品)—

(a) means a substance or combination of substances that—

(i) is presented as having properties for treating or preventing disease in human beings or animals; or

(ii) may be used in or administered to human beings or animals with a view to—

(A) restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action; or

(B) making a medical diagnosis; and

(b) includes an advanced therapy product;"

12. The Administration has clarified that different expressions of the "alteration effect" have been used in the EU definitions of "somatic cell therapy medicinal product" ("have been altered")[9] and "tissue engineered product" ("are achieved"). According to the Administration, the two expressions constitute no material difference from the regulatory point of view. In order to maintain the consistency of the expression of the "alteration effect" in the proposed new 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.

13. Members have enquired whether the above differences would render the proposed new definitions of "somatic cell therapy product" and "tissue engineered product" to be added to Cap. 138 more or less stringent than the corresponding definitions adopted by EU. The Administration has confirmed that while the proposed new definitions of "somatic cell therapy product" and "tissue engineered product" under the Bill would differ from those used in the relevant EU legislation, the differences would constitute no material difference from the regulatory point of view.

Record keeping for Advanced Therapy Products

14. Members note that it is proposed in the Bill that a licensed wholesale dealer or licensed manufacturer ("specified person") supplying ATP for use by a registered medical practitioner or registered dentist would be required to record the name and address of the medical practitioner or dentist, as well as records related to storage and transport, etc. It is also proposed that such records in respect of ATP must be kept for a period of 30 years after the expiry date of the product. If the specified person ceases to operate, the records must be transferred to the Pharmacy and Poisons Board ("the Board"). Details would be specified in the respective codes of practice. On the rationale for the long duration of the record-keeping requirement in respect of ATPs, the Administration has explained that ATPs are recent development and the scientific advancement in the field evolves rapidly. There is little information on their safety and efficacy, thus a longer duration of record keeping requirement to ensure sufficient monitoring and tracing would be imposed. The Administration has advised that the proposed requirement on the duration of record-keeping is drawn up with reference to international practices.

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[9] 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

15. Members note that the proposed new regulation 39(2)(b) of Cap. 138A in clause 13(5) of the Bill provides for the transfer of the specified documents to the Board if the specified person becomes insolvent or bankrupt or has entered into a voluntary arrangement as defined by section 2 of the Bankruptcy Ordinance (Cap. 6) with the specified person's creditors. The Administration has explained that according to the relevant 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. For this Bill, the policy 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.

16. With respect to the proposed new regulation 39(2)(b) of Cap. 138A, the Legal Adviser to the Bills Committee has enquired with the Administration as to whether "insolvent" would refer to the insolvency of a company and "bankrupt" would refer to the bankruptcy of a natural person. Further, enquiry has been made as to whether, with respect to "insolvent", the word would denote the situation where a company is unable to pay debts as they fall due, including without limitation where a company is in liquidation, and with respect to "bankrupt", the word would denote only to the situation where a natural person has been adjudged bankrupt by a court. If so, according to the proposed new regulation 39(2)(b) of Cap. 138A, where a specified person is a company, it would be 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 would not be 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 Cap. 6 with his or her creditors.

17. Taking into account the observations of the Legal Adviser to the Bills Committee, the Administration will propose to amend the proposed new regulation 39(2)(b) of Cap.138A by changing "becomes insolvent" for a specified person that is a company to "is commenced to be wound up or is dissolved without being wound up". The Administration has advised that the proposed amendment is technical in nature, and the revised wording reflects its policy intention. The Administration has also advised that in preparing the proposed amendment, reference has been made to paragraph (2)(g) of Schedule 2 to the Mandatory Provident Fund Schemes (General) Regulation (Cap.485 sub. leg. A). [10]

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[10] Paragraph (2)(g) of Schedule 2 to Cap. 485 A is extracted as follows -

"(g) provide for the contract to be terminated if the company constituting the investment manager is commenced to be wound up or is dissolved without being wound up; and".

18. The Legal Adviser to the Bills Committee has also enquired with the Administration on 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 status of the specified person, whether being a company or a natural person, regarding winding up/dissolution/bankruptcy subsequently changes. The Administration has advised that for the avoidance of doubt, once the specified person has transferred the specified documents to the Board, the documents would not be returned to the specified person, even though the event that led to the transfer ceases to exist. The Administration has explained that the purpose of record keeping can be achieved by the Board's keeping of the specified documents. Meanwhile, as the status of a specified person regarding winding up/dissolution/bankruptcy, etc. may change again, returning the specified documents to the specified person upon the change of status may create unnecessary administrative workload for both the Board and the specified person.

Publicity and manpower for implementation of the regulatory framework for ATPs

19. Hon Alice MAK considers that given the risks of ATPs and the popularity of "medical beauty services" which may involve the use of ATPs, the Administration should step up regulatory control of relevant advertisements so as to enhance protection for consumers. The Administration has advised that advertisements of ATPs which claim to have properties for treating diseases and advertisements of treatments involving the use of such ATPs are already subject to the regulation of the Undesirable Medical Advertisements Ordinance (Cap. 231). Hon Alice MAK has pointed out that certain treatments (e.g. those claiming to have health maintenance effects) may not be regarded as "medicine" and thus the advertisements of relevant treatments may fall outside the scope of Cap. 231. She considers that apart from introducing legislation to regulate ATPs, the Administration should step up public education and publicity on how to differentiate low-risk and non-invasive cosmetic treatments from high-risk treatments involving the use of ATPs, and on the importance of ensuring that high-risk treatments involving the use of ATPs are performed only by qualified medical professionals, so as to further enhance protection for consumers/patients. She has further asked whether the Department of Health ("DH") would, after passage of the Bill, deploy additional manpower to carry out relevant law enforcement (including conducting screening of advertisements and inspections) and public education work.

20. The Administration has advised that additional resources have been allocated to DH to carry out relevant preparatory work for the current legislative exercise. Among others, DH has set up a dedicated website on advanced therapy to provide the public with information on, among others, cord blood banking and cell therapy as well as tips for finding trustworthy service providers. Following the passage of the Bill, DH would launch a series of public education initiatives to enhance public understanding of ATPs and the risks involved in the use of ATPs. In doing so, DH would impress upon members of the public the importance of using ATPs and seeking relevant treatments only under the direction of qualified medical professionals.

21. As regards law enforcement, the Administration has advised that DH is responsible for enforcing Cap. 231. After passage of the Bill, DH would enhance screening of advertisements of ATPs and take necessary enforcement actions if warranted. DH would also conduct unannounced inspections and launch joint operations with the Police as necessary against premises suspected of involving in the provision of ATPs or relevant treatments.

Proposed amendment to the Bill

22. Members have not raised objection to the Administration's proposed amendment to the Bill as elaborated in paragraph 17. The amendment to be moved by the Administration is at **Appendix II**. The Bills Committee will not propose any amendment to the Bill.

Resumption of Second Reading debate

23. Subject to the moving of the proposed amendment to the Bill by the Administration, the Bills Committee supports the resumption of the Second Reading debate on the Bill at the Council meeting of 8 July 2020 the earliest.

Advice sought

24. Members are invited to note the deliberations of the Bills Committee.

Council Business Division 2
Legislative Council Secretariat
11 June 2020

Appendix I

Bills Committee on Pharmacy and Poisons (Amendment) Bill 2019

Membership list

Chairman	Hon Alice MAK Mei-kuen, BBS, JP
Members	Hon Abraham SHEK Lai-him, GBS, JP Hon CHAN Han-pan, BBS, JP Hon SHIU Ka-fai, JP Total : 4 Members
Clerk	Ms Joanne MAK
Legal Adviser	Ms Wendy KAN
Date	15 May 2020

Appendix II

Pharmacy and Poisons (Amendment) Bill 2019

Committee Stage

Amendment to be moved by the Secretary for Food and Health

Clause	Amendment Proposed
13(5)	By deleting the proposed regulation 39(2)(b) and substituting—

"(b) if, before the period referred to in subparagraph (a) expires—

(i) for a specified person that is a natural person—the specified person becomes bankrupt or enters into a voluntary arrangement as defined by section 2 of the Bankruptcy Ordinance (Cap. 6) with the person's creditors; or

(ii) for a specified person that is a company as defined by section 2(1) of the Companies Ordinance (Cap. 622)—the specified person is commenced to be wound up or is dissolved without being wound up,

the specified person must transfer the specified documents to the Board as soon as practicable after the event mentioned in sub-subparagraph (i) or (ii) occurs; and".