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Bills Committee on Pharmacy and Poisons (Amendment) Bill 2019

Background brief prepared by the Legislative Council Secretariat

Purpose

This paper provides background information on the Pharmacy and Poisons (Amendment) Bill 2019 ("the Bill") and gives a brief account of the discussion by the Panel on Health Services ("the Panel") on the Administration's proposals in relation to the regulation of advanced therapy products.

Background

2. Advanced therapy products are innovative pharmaceutical products based on genes, cells and tissues for human use. At present, the Pharmacy and Poisons Ordinance (Cap. 138) ("the Ordinance") and its subsidiary legislation set out the regulatory framework for pharmaceutical products and medicines. However, the current definition of "pharmaceutical products" or "medicine" under the Ordinance[1] does not make reference specifically to advanced therapy products.

3. Following an adverse incident took place in October 2012 whereby the deceased underwent infusion of processed blood products provided by a beauty service company, there was wide public concern over the health risk brought by premises where products for advanced therapies were stored and/or processed for human application. In November 2012, the Working Group on Regulation of Premises Processing Health Products for Advanced Therapies ("the Working Group") was set up under the Steering Committee on Review of the Regulation

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[1] Under section 2 of the Pharmacy and Poisons Ordinance, "pharmaceutical product" and "medicine" mean any substance or combination of substances (a) presented as having properties for treating or preventing disease in human beings or animals; or (b) that may be used in, or administered to, human beings or animals, either with a view to (i) restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action; or (ii) making a medical diagnosis.

of Private Healthcare Facilities[2] ("the Steering Committee") to study appropriate regulatory control in this regard. The Working Group issued its report in 2014 in which five recommendations were put forth for consideration of the Steering Committee.[3] In gist, it was recommended that a comprehensive legislative framework should be introduced to regulate advanced therapy products for medical treatment and clinical trials according to their risks.

4. Subsequently, the Task Force on Regulation of Advanced Therapeutic Products in Hong Kong ("the Task Force") was set up in December 2017 to advise the Government in the formulation of the regulatory framework for advanced therapy products. Having taken into account the recommendations of the Working Group and the Task Force, the Administration launched a two-month public consultation exercise on the Consultation Document on Regulation of Advanced Therapy Products[4] in April 2018 which set out the proposed regulatory framework for gene therapy products and high-risk cell and tissue therapy products for human use. According to the Consultation Report on Regulation of Advanced Therapy Products promulgated by the Administration in October 2018,[5] the respondents generally supported the proposal.

The Bill

5. The Bill was gazetted on 18 October 2019 and received its First Reading at the Legislative Council ("LegCo") meeting on 30 October 2019. The Bill seeks to amend the Ordinance and the Pharmacy and Poisons Regulations (Cap. 138A) ("the Regulations") to (a) provide for a definition of advanced therapy products in the Ordinance; (b) subject these products to the current regulatory framework of pharmaceutical products under the Ordinance and the Regulations which include registration prior to marketing, prior approval for clinical trials, and import and export control as well as certain proposed special requirements in respect of licensing, labelling, record keeping and sample keeping; and (c) provide for related matters. The key features of the Bill are

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[2] The Administration established the Steering Committee on Review of Regulation of Private Healthcare Facilities in October 2012 to conduct a holistic review of the regulation of private healthcare facilities. The Steering Committee is underpinned by four working groups, namely (a) Working Group on Differentiation between Medical Procedures and Beauty Services; (b) Working Group on Defining High-risk Medical Procedures/Practices Performed in Ambulatory Setting; (c) Working Group on Regulation of Premises Processing Health Products for Advanced Therapies; and (d) Working Group on Regulation of Private Hospitals.

[3] The report of the Working Group issued in 2014 can be assessed at the website of the Food and Health Bureau (https://www.fhb.gov.hk/download/press_and_publications/otherinfo/180500_phf/Report_on_WG3_of_Regulation_of_Premises_Advanced_Therapies_2014_e.pdf).

[4] The Consultation Document can be assessed at the website of the Department of Health (http://www.advancedtherapyinfo.gov.hk/cbb/en/doc/cd-en.pdf).

[5] The Consultation Report can be assessed at the website of the Department of Health (http://www.advancedtherapyinfo.gov.hk/cbb/en/doc/ATP_Consultation_Report_en.pdf).

set out in paragraphs 5 to 15 of the LegCo Brief (File Ref.: FHB/H/53/4) issued by the Food and Health Bureau on 16 October 2019.

Deliberations of the Panel

6. The Panel was briefed on the progress of work of the Steering Committee which covered the recommendations of the Working Group on 21 July 2014, and was consulted on the Administration's proposals for the regulation of advanced therapy products on 15 April 2019. The major views and concerns of members are summarized in the following paragraphs.

7. When being briefed on, among others, the recommendations of the Working Group in July 2014, members were advised that subject to further studies and deliberation with parties concerned, a new and standalone legislative framework suitable to the unique circumstances of Hong Kong would be drawn up to regulate cells, tissues and health products for advanced therapies. In the meantime, the Administration would implement interim measures in particular educational campaign to increase the awareness of the trade and public on the potential risk associated with health products for advanced therapies. Members noted that at present, private laboratories operating outside hospital setting were subject to the relevant provisions under the Supplementary Medical Professions Ordinance (Cap. 359) and its subsidiary legislation.

8. The Administration subsequently consulted the Panel on 15 April 2019 on the proposals for the regulation of advanced therapy products. It was proposed that advanced therapy products would form a specific subset of pharmaceutical products under the Ordinance. There was a concern as to whether a blood specimen taken for blood tests but not for human use would constitute an advanced therapy product under the proposed legislative framework. The Administration explained that given that the existing definition of "pharmaceutical products" under the Ordinance was modelled on that of the European Union ("EU"), it had made reference to the definition of advanced therapy products adopted by EU. Under the proposed definition, an advanced therapy product meant a gene therapy product, a high-risk somatic cell therapy product and a high-risk tissue engineered product which were for human use. Cells or tissues that had been subject to substantial manipulation[6] and/or intended for non-homologous use[7] were considered high-risk.

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[6] Manipulations of cells or tissues that altered the biological characteristics, physiological functions or structural properties of the cells or tissues were considered as substantial manipulation. Specifically, substantial manipulation was a manipulation of cells or tissues that was not cutting, grinding, shaping, centrifugation, soaking in antibiotic or antimicrobial solutions, sterilization, irradiation, cell separation, concentration or purification, filtering, lyophilization, freezing, cryopreservation or vitrification.

[7] Non-homologous use meant the use of cells or tissues in the recipient was not for the same essential functions as those in the donor.

9. There were queries on whether the legislative proposals would regulate the use of advanced therapy products by registered healthcare professionals and premises processing advanced therapy products (including medical laboratory where no practice of registered medical practitioners or registered dentists took place) for diagnosis of a patient in the course of medical treatment by registered healthcare professionals.

10. The Administration advised that the legislative proposals sought to, among others, provide for a licensing regime for manufacturers of advanced therapy products. Licensed manufacturers would be required to comply with the Good Manufacturing Practices of the Pharmaceutical Inspection Co-operation Scheme, with details to be provided in the codes of practice to be issued by the Department of Health, and meet the various proposed special requirements in relation to the labelling of unique donation identifiers, products codes and recipient identifiers; the keeping of records and sale pack for the products; and the keeping of records related to the end-users, storage and transport, etc. On whether these records would contain information on the personal particulars of donors, the Administration advised in the negative.

11. There was a concern that the proposed record keeping requirement would only require manufacturers and wholesale dealers supplying advanced therapy products to the end-users to keep the record of the registered medical practitioner or registered dentist who was responsible for the use of the product for at least 30 years after the expiry date of the product. However, there was no requirement in relation to the keeping of records concerning the administration of these products to patients. The Administration advised that the administration of these products was a professional practice governed by the codes of conduct of the relevant professions.

12. On members' concern about the proposed penalties for offences relating to non-compliance with the proposed requirements, the Administration advised that the proposed penalties would be set at the same level as other offences under the Ordinance and the Regulations, i.e. a maximum fine at level 6 (currently $100,000) and imprisonment for two years.

Relevant papers

13. A list of the relevant papers on the LegCo website is in the **Appendix**.

Council Business Division 2
Legislative Council Secretariat
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Appendix

Relevant papers on the Pharmacy and Poisons (Amendment) Bill 2019

Committee	Date of meeting	Paper
Panel on Health Services	21.7.2014 (Item II)	Agenda Minutes
	15.4.2019 (Item IV)	Agenda Minutes

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