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Panel on Health Services

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Legislative proposal for regulation of advanced therapy products

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

2. 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 was set up under the Steering Committee on Review of the Regulation of Private Healthcare Facilities[2] to study appropriate regulatory control in this regard.

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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.

[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.

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.

3. Subsequently, the Administration set up a Task Force on Regulation of Advanced Therapeutic Products in Hong Kong ("the Task Force") in 2017 to advise the regulatory framework. The Administration conducted a two-month public consultation exercise on the Consultation Document on Regulation of Advanced Therapy Products[4] from 3 April to 2 June 2018. It was proposed that a definition of advanced therapy products which were of high-risk be provided for under the definition of "pharmaceutical product" in the Ordinance such that these products would be subject to the existing requirements on product registration, licensing of manufacturers and distributors, import and export control, approval for clinical trials, labelling, record keeping and adverse event reporting applicable to all pharmaceutical products. Having regard to the unique nature of these products, the following additional requirements were proposed:

(a) manufacturers would be required to comply with guideline or standard on control of cells and tissues for production of advanced therapy products and relevant Good Manufacturing Practice guide. Manufacturing would include preparation of advanced therapy products for the purpose of clinical trials or treatment of a particular patient;

(b) the unique donation identifiers or product codes and patient identifiers should be labeled on the advanced therapy products in formats specified by the regulatory authority; and

(c) manufacturers and distributors would be required to keep additional information such as storage, transport, and the medical practitioner who was responsible for the use of the product to ensure sufficient monitoring and traceability. These records would be required to be kept for 30 years.

It was proposed that regulation of low-risk cell and tissue therapies would be taken forward at the next stage of work of the Task Force.[5]

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[3] The report 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] Examples of low-risk cell and tissue therapies include blood transfusion, cord blood banking for therapeutic uses, cornea transplant and bone marrow transplant.

4. The Administration promulgated the Consultation Report on Regulation of Advanced Therapy Products on 30 October 2018.[6] With broad support from the community on the proposed regulatory framework, the Administration plans to introduce the legislative proposal for the regulation of advanced therapy products into the Legislative Council in the 2018-2019 legislative session.

5. The Administration will brief the Panel on Health Services on the legislative proposal on 15 April 2019.

Council Business Division 2
Legislative Council Secretariat
10 April 2019

[6] 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).