Business Facilitation Advisory Committee
Wholesale and Retail Task Force

Regulatory Framework for Advanced Therapy Products (ATPs)

Purpose

This paper aims to brief members on the regulatory framework for Advanced Therapy Products (ATPs) in Hong Kong.

Background

2. ATPs are innovative medical products based on genes, cells and tissues. Their development is one of the fastest moving areas in the medical field at present. The rapid scientific advancement in the research and development of ATPs offers great medical potential for benefiting patients. At the same time, due to their complicated nature and limited knowledge and experience, the risks and long-term side effects of ATPs need to be carefully managed.

3. The Government introduced the Pharmacy and Poisons (Amendment) Bill 2019 ("the Bill") to the Legislative Council ("LegCo") in October 2019 with a view to implementing the recommendations of the Working Group on Regulation of Premises Processing Health Products for Advanced Therapies and the Task Force on Regulation of Advanced Therapeutic Products in Hong Kong, by amending various provisions of the Pharmacy and Poisons Ordinance, Cap. 138 ("PPO") and the Pharmacy and Poisons Regulations Cap. 138A ("PPR") to regulate ATPs.

4. The Bill was passed by the LegCo on 17 July 2020 and published in the Gazette as the Pharmacy and Poisons (Amendment) Ordinance 2020 ("Amendment Ordinance") on 24 July 2020. All the provisions of the Amendment Ordinance have come into operation on 1 August 2021.

The Legal Framework for ATPs

5. Under the PPO, ATPs are regulated as a specific subset of pharmaceutical products in Hong Kong. ATPs include gene therapy products, somatic cell therapy products and tissue engineered products for human use. PPO provides clear definitions for the above three specific type of products. Products which fall under either one definition would be classified as ATPs. As a result, regulatory requirements for pharmaceutical products under the PPO and the PPR, as well as other relevant ordinances, apply to ATPs.

6. ATPs must be registered with the Pharmacy and Poisons Board of Hong Kong ("the Board") in accordance with the PPR prior to marketing. A Certificate for Clinical Trial is required for the purpose of conducting a clinical trial on ATPs on human beings.

7. All facilities that substantially manipulate[1]cells or tissues for human use must obtain a manufacturer licence under the PPR. All licensed manufacturers of ATPs are required to comply with the Good Manufacturing Practices (GMP) of the Pharmaceutical Inspection Co-operation Scheme (PIC/S) and also the Code of Practice (COP) promulgated by the Board.

8. Distributors of ATPs must be either a licensed wholesale dealer or a licensed manufacturer authorized to handle or manufacture ATPs.

9. Due to the complicated nature of ATPs and the lack of clinical experience in their usage, their risks and long-term side effects need to be carefully monitored and managed. In order to allow prompt and complete tracing of ATPs for quality or safety reasons, licensed manufacturers and wholesale dealers are required to keep the ATP records for 30 years. Extra requirements on labelling specific to ATPs are stipulated in the PPR in order to enhance traceability of the products.

[1] As stipulated in the Schedule to the PPO, the following processes are NOT substantial manipulations: cutting; grinding; shaping; centrifugation; soaking in antibiotic or antimicrobial solutions; sterilization; irradiation; cell separation, concentration or purification; filtering; lyophilization; freezing; cryopreservation; vitrification.

10. Other than the regulatory requirements under the PPO and PPR, importation or exportation of ATPs by a licensed wholesale dealer, a licensed manufacturer or a holder of Certificate for Clinical Trial, as the case may be, must be covered by an import or export licence issued under the Import and Export Ordinance (Cap. 60).

Implementation of the Regulatory Framework for ATPs

11. The Drug Office of the Department of Health ("DH"), as the professional and executive arm of the Board, assisted the Board in the implementation of the enhanced regulatory framework for ATPs.

12. The Drug Office and the Board have prepared a series of guidance documents relevant to ATPs for the industry and healthcare professionals. New edition of COPs for Holders of Wholesale Dealer Licence, Licensed Manufacturers and Registered Authorized Persons, Listed Seller of Poisons and Authorized Seller of Poisons have also been issued by the Board.

13. In order to allow various stakeholders to better understand the regulatory updates on ATPs, prior to the commencement of the Amendment Ordinance, the Drug Office has organized a total of 11 briefing sessions between December 2020 and February 2021.

14. To inform various stakeholders as well as members of the public on the commencement of the Amendment Ordinance and the regulatory updates on ATPs, the Drug Office has issued relevant press releases and letters to trade.

15. To further enhance the communications with the stakeholders, the Drug Office has established a dedicated webpage with comprehensive information on regulation of ATPs under the Drug Office's website. The Amendment Ordinance, relevant regulatory information, promotional materials (i.e. pamphlets for consumers, booklets for healthcare professionals, and infographics) and guidance documents relating to ATPs, as well as new edition of COPs are uploaded to the dedicated webpage.

16. Relevant promotional materials and banners have also been posted to the website of DH and the Facebook page of the Centre for Health Protection. Hard copies of pamphlets for consumers have been distributed to members of

LegCo, District Offices, private hospitals, patient groups and associations of beauty trade.

17. Members are invited to note the content of this paper.

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