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Legal Service Division Report on
Pharmacy and Poisons (Amendment) Bill 2019

I. SUMMARY

1.	**The Bill**	The Bill seeks to amend the Pharmacy and Poisons Ordinance (Cap. 138) and the Pharmacy and Poisons Regulations (Cap. 138A) to: (a) regulate advanced therapy products ("ATPs"), namely, gene therapy products, somatic cell therapy products and tissue engineered products, as pharmaceutical products under the legislative framework of Cap. 138 and Cap. 138A; and (b) provide for related matters.
2.	**Public Consultation**	The Administration conducted a public consultation on the proposed regulatory framework from April to June 2018. The respondents generally supported the proposal.
3.	**Consultation with LegCo Panel**	The Panel on Health Services ("Panel") was consulted on 15 April 2019. Members generally supported the legislative proposal but expressed certain concerns.
4.	**Conclusion**	The Legal Service Division is scrutinizing the legal and drafting aspects of the Bill. As the Bill proposes to introduce a new dedicated regulatory regime for ATPs and in view of the concerns expressed by the Panel, Members may wish to form a Bills Committee to study the Bill in detail.

II. REPORT

The date of First Reading of the Bill is 30 October 2019. Members may refer to the Legislative Council ("LegCo") Brief (File Ref.: FHB/H/53/4) issued by the Food and Health Bureau on 16 October 2019 for further details.

Object of the Bill

2. The Bill seeks to amend the Pharmacy and Poisons Ordinance (Cap. 138) and the Pharmacy and Poisons Regulations (Cap. 138A) to:

(a) regulate advanced therapy products ("ATPs") as pharmaceutical products under the legislative framework of Cap. 138 and Cap. 138A; and

(b) make related amendments.

Background

3. According to paragraph 2 of the LegCo Brief, ATPs are innovative medical products based on genes, cells and tissues. There is currently no dedicated regulatory framework for ATPs. As stated in paragraph 3 of the LegCo Brief, 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. Further, 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.

4. As mentioned in paragraph 20 of the LegCo Brief, following 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, 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 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.[1]

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

Provisions of the Bill

5. The key provisions of the Bill are summarized in the ensuing paragraphs.

Definition of ATP (clauses 3(3) and 4 of the Bill)

6. Under the proposed section 2(1) of Cap. 138, ATP is defined to mean a gene therapy product, a somatic cell therapy product, or a tissue engineered product, that is for human use. These products are also respectively defined in the proposed section 2(1) of Cap. 138.

Regulating ATPs as pharmaceutical products under Cap. 138 and Cap. 138A

7. Clause 3(2) and (3) of the Bill proposes to amend the current definition of "pharmaceutical product" under section 2 of Cap. 138 to include ATP so that the regulatory framework under Cap. 138 and Cap. 138A would apply to ATPs. These include registration prior to marketing, prior approval for clinical trials, and import and export control. Apart from the existing provisions of Cap. 138 and Cap. 138A, ATPs would also be subject to certain special requirements proposed in the Bill. These requirements are set out below.

Proposed licensing requirements for the manufacture of ATPs (clauses 3 and 4 of the Bill)

8. Regulation 29 of Cap. 138A currently provides that a person must not manufacture any pharmaceutical product on any premises unless the person is the holder of a licence to manufacture pharmaceutical products on those premises. A licence would therefore be required for the manufacturing of ATP under the proposed regime of the Bill. Under the proposed definition of "manufacture" in the proposed section 2(1) of Cap. 138, manufacture, in relation to ATPs, would not include the individual dispensing on a prescription or otherwise of an ATP the dispensing of which does not involve substantial manipulation of cells or tissues. "Substantial manipulation", in relation to cells or tissues, as defined in the proposed section 2(1) of Cap. 138, would not include the manipulation processes set out in the proposed new Schedule to Cap. 138. Under the proposed new section 38 of Cap. 138, the Director of Health may amend the Schedule by notice published in the Gazette and such notice would be subsidiary legislation subject to negative vetting by LegCo.

Proposed record keeping requirements applicable to ATPs (clauses 7, 11(1), (4) to (6) and 13 of the Bill)

9. The Bill seeks to amend regulations 28, 35 and 39 of Cap. 138A to require:

(a) a licensed wholesale dealer or licensed manufacturer to record, for each transaction by which ATP is supplied for use by a registered medical practitioner or registered dentist, the name and address of the practitioner or dentist;

(b) a licensed manufacturer to maintain adequate records in respect of each ATP prepared by the manufacturer that is sold or supplied for use by a registered medical practitioner or registered dentist which show the name and address of the practitioner or dentist;

(c) a licensed manufacturer to maintain adequate records in respect of each ATP prepared by the manufacturer containing or consisting of cells or tissues which show the name and address of the person from whom the cells or tissues used for the preparation of the product were obtained and the unique donation identifier; and

(d) a licensed wholesale dealer or licensed manufacturer to preserve the records relating to ATPs for a period of 30 years after the expiry date of the product, and provide for the transfer of the said records to the Pharmacy and Poisons Board if the ATP wholesale dealer or manufacturer ceases to operate.

Proposed labelling requirements applicable to ATPs (clause 9(4) of the Bill)

10. The Bill proposes to add to the list of particulars required to be labelled on the container of each pharmaceutical product currently under regulation 31 of Cap. 138A the product code and unique donation identifier of ATP, and where the ATP concerned is for autologous use only, the unique recipient identifier and the English words "For autologous use only" or the Chinese characters "只供自體使用".

Proposed obligation to keep photographs of ATPs (clause 10(1) to (4) of the Bill)

11. Under regulation 33(4) of Cap. 138A, a licensed manufacturer must, subject to certain exceptions, retain a control sample of each batch of finished products under suitable storage conditions for a prescribed period.

12. The Bill seeks to amend regulation 33 of Cap. 138A to provide that a licensed manufacturer of an ATP containing or consisting of cells or tissues would only be required to keep photographs that clearly present the prescribed particulars of each batch of finished products for a period of not less than one year after the expiry date of the products.

Offences

13. Pursuant to regulation 40 of Cap. 138A and section 34 of Cap. 138, failure to comply with any of the above proposed requirements would be an offence punishable by a fine at level 6 (currently $100,000) and imprisonment for two years.

Commencement

14. 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.

Public Consultation

15. As stated in paragraph 21 of the LegCo Brief, the Administration conducted a public consultation on the proposed regulatory framework from April to June 2018. According to the Administration, the respondents generally supported the proposal and the views received were summarized in the consultation report published in October 2018 and suitably incorporated in the legislative proposal.

Consultation with LegCo Panel

16. As advised by the Clerk to the Panel on Health Services ("Panel"), the Administration briefed the Panel on 15 April 2019 on the legislative proposals for introducing a regulatory framework for ATPs. Members generally supported the legislative proposals. They however raised concerns on certain issues, including the types of products and facilities that would fall within the regulatory framework, and the scope of the record keeping requirements for ATPs.

Conclusion

17. The Legal Service Division is scrutinizing the legal and drafting aspects of the Bill. As the Bill proposes to introduce a new dedicated regulatory regime for ATPs and in view of the concerns expressed by the Panel, Members may wish to form a Bills Committee to study the Bill in detail.

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