



中華人民共和國香港特別行政區政府總部食物及衛生局  
Food and Health Bureau, Government Secretariat  
The Government of the Hong Kong Special Administrative Region  
The People's Republic of China

Our Ref. : (55) in FHB/H/53/4 Pt.1  
Your Ref. :

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10 April 2018

Ms Maisie LAM  
Clerk to Panel  
Panel on Health Services  
Legislative Council Secretariat  
Legislative Council Complex  
1 Legislative Council Road  
Central

Dear Ms LAM,

**Public Consultation on  
Regulation of Advanced Therapy Products**

I am writing to inform you that the Department of Health has launched a public consultation on the Regulation of Advanced Therapy Products (ATPs) and the Consultation Document can be downloaded at [http://www.advancedtherapyinfo.gov.hk/cbb/en/popup\\_atp\\_consultation\\_en.html](http://www.advancedtherapyinfo.gov.hk/cbb/en/popup_atp_consultation_en.html).

ATPs refer to high-risk cell and tissue-based products. They may offer great medical potential and the science is rapidly evolving. A regulatory framework is needed to properly recognize and control their research and therapeutic use so as to safeguard public health. Taking reference of the regulations of cells and tissues for human use in overseas jurisdictions, the Government proposes to adopt a risk-based approach to regulate ATPs intended for use in human as pharmaceutical products under the Pharmacy and Poisons Ordinance (Cap. 138).

The Consultation Document has set out a proposal to amend the Pharmacy and Poisons Ordinance to include the definition of ATPs under the definition of pharmaceutical products. Requirements on product registration, licensing of manufacturers and distributors, import/export control, approval for clinical trials, labelling, record keeping and adverse event reporting for pharmaceutical products would apply for these products. The Consultation Document also sets out additional requirements to cater for the unique nature of these products, including specific labelling and record keeping requirements, licensing conditions for manufacturers, etc.

The public consultation commenced on 3 April until 2 June 2018. The Administration will further consider the way forward when the result of the consultation is available.

Should you have further queries, please feel free to contact the undersigned.

Yours sincerely,



( Bill LI )

for Secretary for Food and Health

c.c. Director of Health (Attn: Mr Lot CHAN)