Government releases Consultation Report on Regulation of Advanced Therapy Products

The Government today (October 30) released the Consultation Report on Regulation of Advanced Therapy Products (ATPs), which summarises the views received during the public consultation and maps out the way forward for the regulation of ATPs.

"As revealed by the public views collected, there was broad support for the proposed regulatory framework for ATPs set out in the consultation document to regulate ATPs as pharmaceutical products under the regulatory regime of the Pharmacy and Poisons Ordinance, Cap 138, including pre- and post-marketing control, licensing of traders and import/export control," a spokesman for the Department of Health (DH) said.

"The Government will proceed to take forward the proposals along the direction set out in the Consultation Report and is now working on the detailed legislative proposal with a view to introducing the relevant Amendment Bill to the Legislative Council in 2019," the spokesman added.

The public consultation on the regulation of ATPs was conducted between April 3 and June 2 this year. During the consultation period, the DH held three briefing sessions to engage various organisations and stakeholders in the community and a total of 127 participants attended the briefing sessions to express their views. They included representatives of academia, medical professionals and bodies, public and private hospitals, and the industry. In addition, 28 written submissions were received.

For further information about the consultation and access to the Consultation Report, please visit the website at www.advancedtherapyinfo.gov.hk/cbb/en/level.html.