

# Regulatory framework for Advanced Therapy Products to commence on August 1

The Department of Health (DH) today (June 25) said that all provisions of the Pharmacy and Poisons (Amendment) Ordinance 2020 (the Amendment Ordinance) to introduce a regulatory framework for Advanced Therapy Products (ATPs) will come into operation on August 1 this year.

The Amendment Ordinance introduces a clear regulatory framework for ATPs, which cover gene therapy products, somatic cell therapy products and tissue engineered products, in order to safeguard public health and facilitate the development of ATPs. After the Amendment Ordinance comes into operation, ATPs will form a specific subset of pharmaceutical products under the Pharmacy and Poisons Ordinance (Cap. 138). As such, requirements governing pharmaceutical products under Cap. 138 and other relevant ordinances will apply to ATPs. These include registration prior to marketing, obtaining prior approval for conducting clinical trials, licensing of manufacturers and distributors, and import/export control. Furthermore, there will be additional requirements on labelling and record keeping specific to ATPs to enhance traceability of the products.

To enable stakeholders to have a better understanding of the enhanced regulatory framework for ATPs, the Pharmacy and Poisons Board of Hong Kong has prepared guidance documents relevant to ATPs. In addition, the Board published in the Gazette today the following new editions of Codes of Practice (COPs), which will take effect on August 1 this year:

- \* Code of Practice for Holder of Wholesale Dealer Licence (2021);
- \* Code of Practice for Licensed Manufacturers and Registered Authorized Persons 2021;
- \* Code of Practice for Listed Seller of Poisons (2021); and
- \* Code of Practice for Authorized Seller of Poisons (2021).

The Amendment Ordinance, regulatory information and guidance documents relating to ATPs, and the new editions of COPs are available on the dedicated website of the Drug Office of the DH ([www.drugoffice.gov.hk/eps/do/en/pharmaceutical\\_trade/atp\\_regulation.html](http://www.drugoffice.gov.hk/eps/do/en/pharmaceutical_trade/atp_regulation.html)) and the website of the Board ([www.ppbhk.org.hk/eng/regulation\\_of\\_atp.html](http://www.ppbhk.org.hk/eng/regulation_of_atp.html)).