

# Government welcomes passage of Pharmacy and Poisons (Amendment) Bill 2019

The Food and Health Bureau welcomed the passage of the Pharmacy and Poisons (Amendment) Bill 2019 (the Bill) by the Legislative Council today (July 17).

The Pharmacy and Poisons Ordinance (Cap. 138) (the Ordinance) has been amended to introduce a clear regulatory framework for Advanced Therapy Products (ATPs) which cover gene therapy products, somatic cell therapy products and tissue engineered products. The rapid scientific advancement in the research and development of ATPs offers great medical potential for benefiting patients. At the same time, ATPs need to be carefully managed due to their complicated nature, risks and possible long-term side effects.

The Secretary for Food and Health, Professor Sophia Chan, said, "Due to the high-risk and complex nature of ATPs, a clear and dedicated regulatory framework on the research and therapeutic use of ATPs will safeguard public health and facilitate their development."

Under the new regulatory framework, ATPs will form a specific subset of pharmaceutical products under the Ordinance. As such, requirements for pharmaceutical products under Cap. 138 and other relevant ordinances will apply to ATPs. Licensed manufacturers of ATPs are also required to comply with the Good Manufacturing Practices and relevant labelling and record keeping requirements.

The new regulatory regime will come into operation on a day to be appointed by the Secretary for Food and Health by a notice published at the Gazette (about one year later). As such, the industry will have ample time to get prepared before the new regulatory framework come into operation.