Department of Health and Hospital Authority's response to media enquiries on advance therapy products

The following is issued on behalf of the Hospital Authority:

In response to media enquiries about the issuance of licence for manufacturer of advanced therapy products by the Pharmacy and Poisons Board of Hong Kong, the Department of Health (DH) and the Hospital Authority (HA) today (October 13) issued the following statement:

In Hong Kong, advanced therapy products are regulated under the Pharmacy and Poisons Ordinance, Cap. 138 as pharmaceutical product.

The DH indicates that the Board has issued a licence for manufacturer on August 30 in accordance with the Pharmacy and Poisons Regulations, Cap. 138A, authorising a local company to manufacture autologous chimeric antigen receptor T (CAR-T) cells for clinical trial. The licence specifies that the company is authorised to manufacture CAR-T cells only for the purpose of clinical trial instead of any clinical treatment purpose. If the company wishes to manufacture the above-mentioned pharmaceutical product for clinical treatment purpose, the company must first apply to the Board for alteration of the licensing condition.

The DH supplements that any CAR-T cells for treatment purposes should apply to the Board for registration in accordance with the Regulations; the Board would only approve the application if the product meets the criteria of safety, efficacy and quality. In addition, any person who wishes to conduct clinical trial on human or medicinal test on animal must apply for a clinical trial certificate or medicinal test certificate in accordance with the Regulations. Using CAR-T cells product for clinical trial or treatment purpose without approval is illegal and may be considered as a criminal offence.

On the treatment side, the HA has commenced its CAR-T cell therapy pilot programme at Queen Mary Hospital in 2021. The service has already been extended to Hong Kong Children's Hospital and Prince of Wales Hospital. The HA is now prescribing Tisagenlecleucel for CAR-T cell therapy, which has already been registered for clinical use for two indications, namely patients up to 25 years of age with B-cell acute lymphoblastic leukaemia that is refractory, in relapse post-transplant or in second or later relapse, or adult patients with relapsed or refractory diffuse large B-cell lymphoma after two or more lines of systemic therapy. Currently, Tisagenlecleucel is the only CAR-T cell therapy drug registered in Hong Kong for clinical use. This CAR-T cell therapy drug is not manufactured by the above-mentioned pharmaceutical product manufacturer licensed on August 30.

The DH and the HA will continue to closely monitor the relevant development of the technology.