<u>Dispatch arrangements of quadrivalent</u> <u>seasonal influenza vaccines</u>

The Department of Health (DH) today (November 27) was informed by a licensed drug wholesaler, Sanofi-Aventis Hong Kong Limited (Sanofi), that it has decided to take a precautionary measure to suspend the market supply of a batch of quadrivalent seasonal influenza vaccines (SIVs) (box label: R3J721V; syringe label: R3J72) and arrange to dispatch a new batch of quadrivalent SIVs to local private healthcare facilities as soon as possible.

According to the information provided by Sanofi, around 175 000 doses of the affected batch of SIVs have been imported to Hong Kong and part of the batch has been distributed to the DH, the Hospital Authority and healthcare facilities. Based on the DH's preliminary statistics, there are around 100 000 doses of unused vaccines in Hong Kong. Sanofi has committed to contact relevant organisations and arrange to dispatch a new batch of vaccines as soon as possible.

"The DH has immediately suspended the use of the affected vaccines. The DH's services, including the Elderly Health Centres, will suspend seasonal influenza vaccination service until the supplier dispatched a new batch of SIVs. On the other hand, the School Outreach Vaccination Pilot Programme under the DH is not affected by the incident as SIVs used under the pilot programme are supplied by another company," a spokesman for the DH said.

The DH also reminded residential care home operators and visiting doctors to pay attention on whether they have procured the affected quadrivalent SIVs. If they have, they should suspend the use of such vaccines and contact Sanofi for relevant arrangements.

"The DH will be in touch with the Hospital Authority and relevant healthcare facilities. We will also closely monitor the relevant arrangements and keep in close contact with Sanofi. So far, the DH has not received any adverse reports in connection with the affected batch of SIVs. Members of the public are advised to consult healthcare professionals if they feel unwell after receiving seasonal influenza vaccination," the spokesman said.

According to the record of Sanofi, more than 20 million doses of quadrivalent SIVs have been supplied around the world in the current influenza season. So far, it has not received any report about the safety of vaccines being affected.

According to Sanofi, samples of the concerned batch of quadrivalent SIVs were found to contain white particles by Taiwan authority. The company said that it has not received any report regarding the presence of white particles in the same batch of SIVs currently supplied to Hong Kong, and that there is so far no evidence showing that the quality, safety or efficacy of the SIVs supplied to Hong Kong have been affected, or that safety risk is imposed to those receiving the vaccines.

The DH has requested Sanofi to submit a full investigation report regarding the presence of white particles in the affected batch of SIVs. The DH has also asked Sanofi and another supplier providing quadrivalent SIVs to Hong Kong to import additional quantities of vaccines to meet the local demand.