

Quadrivalent seasonal influenza vaccines previously suspended pass quality testing

The Department of Health (DH) today (December 28) announced that samples of a batch of quadrivalent seasonal influenza vaccines (SIVs) (box label: R3J721V; syringe label: R3J72), which was previously suspended for use by licensed drug wholesaler Sanofi-Aventis Hong Kong Limited (Sanofi), have passed the sterility testing conducted by the Government's accredited laboratory.

Following the announcement of the suspension of a batch of Sanofi's quadrivalent SIVs on November 27, the DH immediately inspected close to 2 100 samples (about 1 300 samples from the affected batch and about 800 samples from other batches) of quadrivalent SIVs from the vaccine supplier's warehouse and the DH's clinics. The inspection result revealed that no particles were detected. Meanwhile, the Government Laboratory's testing of vaccine samples of the affected batch and other batches of SIVs from the same supplier earlier revealed that no foreign matter was found.

Moreover, the DH also received Sanofi's investigation report on white particles found in the batch of quadrivalent SIVs in Taiwan. The test results revealed that the white particles were inert and non-toxic cellulose. Sanofi concluded that the quality, safety and efficacy of this batch of quadrivalent SIVs are not affected.

Taken together the investigation findings, there is no evidence to suggest quality problems to impede the use of the batch of quadrivalent SIVs supplied to Hong Kong. The DH will inform the healthcare sector that the batch of SIVs can be resumed for use provided that they have been stored under appropriate temperature (i.e. 2 to 8 degrees Celsius).

A spokesman for the DH said, "The DH will continue to monitor the safety and quality of SIVs supplied to Hong Kong. Healthcare staff are reminded to visually inspect the SIVs before administering them to ensure that there is no abnormality."

The spokesman stressed that SIVs are a safe and effective way of preventing seasonal influenza and its complications. As it is already late December and Hong Kong will soon enter the winter influenza season, members of the public, particularly those in high-risk groups, are urged to receive vaccination as soon as possible for protection against seasonal influenza as it takes about two weeks to develop antibodies.