Seasonal Influenza Vaccine (SIV) Containing White Particles Q&A

1. **What would be the impact on health if I received affected SIV?**

   According to Sanofi-Aventis' investigation report on the batch of quadrivalent SIVs containing white particles, the test results revealed that the white particles were inert and non-toxic cellulose. Sanofi-Aventis concluded that the safety, quality and efficacy of this batch of quadrivalent SIVs are unaffected and no safety risk is posed to the individuals received the vaccine.

   If there is no discomfort after influenza vaccination, the public needs not be over concerned.

   If you experience discomfort after influenza vaccination, please consult your doctor.

2. **How is vaccine production monitored and regulated?**

   According to the Pharmacy and Poisons Ordinance (Cap. 138), pharmaceutical products (including vaccines) must meet the safety, efficacy and quality requirements and must be registered by the Pharmacy and Poisons Board before they can be supplied in Hong Kong. For manufacturers, the most important and effective way to ensure the quality and safety of their products is to strictly comply with the Good Manufacturing Practices (GMP) for medicines. At present, the pharmaceutical products registered in Hong Kong, whether locally manufactured or imported, their manufacturers must comply with GMP requirements of the Pharmaceutical Inspection Cooperation Scheme (PIC/S).

   According to the World Health Organization (WHO) guidelines on the regulatory preparedness for provision of marketing authorization of human pandemic influenza vaccines in non-vaccine-producing countries, the procured vaccines should be manufactured in accordance with GMP, and tested for quality and safety by the vaccine manufacturer, including sampling before dispatch. Such vaccines should be released by Nationally controlled laboratory of the vaccine manufacturer in accordance with the WHO "Guideline for independent lot release of vaccines by regulatory authorities".

3. **Does the Department of Health (DH) sample vaccines for analysis?**

   DH generally does not sample vaccines for analysis as it would delay the supply of vaccines to the market. This practice is similar to the international drug surveillance measures. DH will closely monitor the latest developments of international regulation of vaccines and follow up accordingly. Regarding the regulation of vaccine production, please refer to Q&A (2) above.

4. **If I have not received influenza vaccine this season, should I proceed now?**

   If you have not received influenza vaccine this season, please proceed to vaccination as soon as possible.

5. Do individuals who have been vaccinated by the affected batch have to receive vaccination again?

DH has not received reports of any particles found in the quadrivalent SIVs imported into Hong Kong. Although the quadrivalent SIVs are from the same batch, the investigation report concluded that the safety, quality and efficacy of this batch of quadrivalent SIVs are unaffected and no safety risk is posed to the individuals received the vaccine.

If there is no discomfort after influenza vaccination, the public needs not be over concerned.

If you experience discomfort after influenza vaccination, please consult your doctor.

6. Will the Government recall the affected SIV?

The investigation report concluded that the safety, quality and efficacy of this batch of quadrivalent SIVs are unaffected and no safety risk is posed to the individuals received the vaccine.

7. Can the suspended batch of SIVs be reinstated?

The investigation report concluded that the safety, quality and efficacy of this batch of quadrivalent SIVs are unaffected and no safety risk is posed to the individuals received the vaccine. 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). Healthcare staff are reminded to visually inspect the SIVs before administering them to ensure that there is no abnormality.

8. How can DH and Hospital Authority (HA) ensure the SIVs provided do not contain particles?

Medical personnel under DH and HA will visually inspect the vaccine before providing quadrivalent SIVs to ensure that the vaccine does not contain particles.

Department of Health