監測及流行病學處

衞生防護中心
Centre for Health Protection
保障市民健康
Protecting Hong Kong's health

Surveillance
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Dear Doctor,

Recall of four batches of H1N1 vaccines produced by Sanofi Pasteur in the United States

You may be aware that Sanofi Pasteur announced a recall of four batches (approximately 800,000 doses) of H1N1 vaccines distributed in the United States (US). I am writing to provide you further information on the incident.

During a routine stability testing by Sanofi Pasteur, the amount of antigen of a batch of "Influenza A (H1N1) 2009 Monovalent Vaccine" in pediatric syringes that had been distributed in the US was found to have dropped below a pre-specified limit. As a result of this finding, Sanofi Pasteur tested additional lots and found that three other lots that had been distributed also had an antigen content that, while properly filled at the time of manufacturing, was later measured to be below pre-specified limits.

There are no safety concerns with these lots of H1N1 vaccine. All lots successfully passed pre-release testing for purity, potency and safety. According to the US Centers for Disease Control and Prevention, the potency of these four vaccine lots is only slightly below the "specified" range. The vaccine in these lots is still expected to be effective in stimulating a protective response despite this slight reduction in the concentration of antigen. There is no need to re-administer a dose to those who received vaccine from these lots.

Sanofi Pasteur is investigating the cause of the problem. **The same vaccine packaged in other dosing forms, such as pre-filled syringes for older children adults, and multi-dose vials, continues to meet specifications.**

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The Centre for Health Protection is a professional arm of the Department of Health for disease prevention and control

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Sanofi Pasteur is also supplying human swine influenza (HSI) vaccine to Hong Kong under the brand name (Panenza®). France, Spain and Luxemburg are also using Panenza® for their HSI vaccination programmes. The vaccination programmes in these countries are unaffected so far.

The recalled batch, manufactured in the US, consists of pre-filled syringes for pediatric use. **This batch is different from our Hong Kong batch which consists of multi-dose vials manufactured by a vaccine facility in France.**

The Pharmaceutical Service of the Department of Health has scrutinized the batch certificates and Quality Control reports of the batch received in Hong Kong and confirm that this batch meets all the potency requirements. DH will continue to liaise with Sanofi Pasteur to obtain further information and updates. **The HSI vaccination programme in HK will proceed as planned.**

Yours sincerely,

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