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25 January 2010

Dear Doctor,

Human Swine Influenza (HSI) Vaccines and Pregnancy-related Adverse Events

I am writing to provide you updated information regarding human swine influenza (HSI) vaccines and pregnancy-related adverse events.

The Centre for Health Protection (CHP) of the Department of Health (DH), through the surveillance system established since the launch of the HSI vaccination programme, has received reports of pregnancy-related adverse events including stillbirths and spontaneous abortions following HSI vaccination.

For the two stillbirth cases, while investigations for common causes of stillbirth including infection, genetic and metabolic disorders are ongoing, it should be noted that about 150-220 stillbirths were recorded every year in Hong Kong. There is no medical evidence presently to suggest that the stillbirths were related to HSI vaccination. According to international and local experience, the rate of stillbirth is about 0.3 to 0.5 percent of total deliveries.

Spontaneous abortions are also extremely common occurrences. It is estimated that one in five pregnancies (especially those in first trimester) may result in spontaneous abortion. With an annual live births of around 70,000, it is estimated that some ten thousand spontaneous abortion occur in Hong Kong every year. DH receives report of at least 3,000 spontaneous abortions every year.



According to the World Health Organization (WHO), studies to date do not show harmful effects from the HSI vaccines with respect to pregnancy or a developing embryo or fetus. On the other hand, HSI infected pregnant women have 10 times higher

chance to require hospitalization in intensive care units than infected persons in the general population and the benefits of vaccination far outweigh the risks. It is estimated that more than 258,000 pregnant women across Europe have been vaccinated with H1N1 vaccines. The number of pregnancy-related adverse events reported to date does not exceed what would be expected based on normal background rates in the absence of vaccination.

In January 2010, the Scientific Committees reaffirm their recommendations for HSI vaccination for the five target groups including pregnant women. The complete recommendation and its rationale can be obtained from the website of the CHP:

[http://www.chp.gov.hk/files/pdf/recommendations_on_human_swine_influenza_\(hsi\)_vaccination.pdf](http://www.chp.gov.hk/files/pdf/recommendations_on_human_swine_influenza_(hsi)_vaccination.pdf)

So far, at least 80 million people had received HSI vaccine worldwide. According to WHO and countries that have already launched HSI vaccination programmes, the frequency of adverse reactions reported is well within the expected range for seasonal influenza vaccines. In fact, the HSI vaccine will be incorporated into the seasonal influenza vaccine according to the WHO's recommended vaccine formulation for the 2010/11 influenza season for the Southern Hemisphere.

Let us work together to protecting Hong Kong's health.

Yours sincerely,



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