For immediate release

White particles found in Quadrivalent influenza vaccines are inert and non-toxic cellulose without concern on quality, safety and efficacy

110,000 doses of flu vaccines are recommended to be released for use

Hong Kong, 28 December 2018 - In response to the issue that white particles were found in several syringes of Quadrivalent influenza vaccines (QIV) in Taiwan earlier this year, Sanofi Pasteur completed thorough investigation and the results concluded the found white particles are inert and non-toxic cellulose. Safety, quality and efficacy of the batch are unaffected. As all samples collected by the Department of Health (DH) passed the sterility test conducted by Government accredited laboratory, Sanofi Pasteur recommends that around 110,000 doses of QIV from the same batch which were put on hold in November are to be released for use.

Sanofi Pasteur takes this incident very seriously. Patient safety and quality standards of our products are always our top priority.

During an inspection conducted by Sanofi Pasteur and the Taiwan Food and Drug Administration (TFDA), white particles were found in a batch of QIV. TFDA released some sample syringes to Sanofi Pasteur Taiwan office. The samples were immediately sent to the Sanofi Pasteur's Headquarters in France for detailed analysis and investigation.

According to our record, around 175,000 doses from the concerned batch of QIV (Batch number: R3J721V; Lot number: R3J72) had been imported into Hong Kong. The immediate step had been taken on 27 November to suspend the release of around 110,000 doses of QIV from the same batch as a precautionary measure.

Sanofi Pasteur completed thorough investigation of the samples. The result concluded the white particles are inert and non-toxic cellulose. Quality, safety or efficacy of the batch is unaffected.

In fact, the Hong Kong SAR Government laboratory's testing of vaccine samples of the affected batch and other batches of QIV from Sanofi Pasteur revealed that no foreign matters were found. DH also inspected close to 2,100 samples (about 1,300 samples from the affected batch and about 800 samples from other batches) of QIV earlier and the inspection result revealed that no particles were detected. Samples were also sent for sterility testing to be conducted by a Government accredited laboratory. DH announced today (28 December) that all samples of the affected batch of QIV as well as other batches of QIV passed the sterility test.

Sanofi Pasteur confirms that these influenza vaccine batches have been manufactured in compliance with Good Manufacturing Practices (GMP) requirements and are fully complied with the product release specifications that Health authorities have defined or approved, we consider the affected batch of QIV in the warehouse could be released for use.

In compliance with international quality standards and our relentless pursuit for the highest product quality, Sanofi Pasteur will consider all possible enhancement actions aiming to reduce the probability of having similar incidents in the future.

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