

## DH's response to media enquiries on suspected adverse events following immunisation with COVID-19 vaccine

In response to media enquiries on suspected miscarriage reports following immunisation with a COVID-19 vaccine, a spokesperson for the Department of Health (DH) responded today (April 14) as follows:

On April 12, the DH received a report of a suspected adverse event following immunisation (AEFI) with a COVID-19 vaccine from the Hospital Authority (HA). The case involved a 32-year-old woman. According to the HA, the woman could not give a clear account of her pregnancy information. She tested pregnant on April 10 and experienced vaginal bleeding and lower abdominal pain and expelled her foetus the next day (April 11). She attended the Accident and Emergency Department of Queen Mary Hospital for medical advice and her foetus was certified dead on the same day. According to the HA's assessment of the gestational age of the foetus by weight, the foetus was estimated to be around 23 to 24 weeks old. According to information, the woman received a dose of the Comirnaty COVID-19 vaccine at the St Paul's Hospital Community Vaccination Centre on April 8. There was no record that the woman complained of feeling unwell during observation at the Vaccination Centre.

In addition, the DH received another report of a suspected adverse event from the HA on April 8 that involved another 32-year-old woman. She tested pregnant on March 25 and sought medical treatment at the Accident and Emergency Department of Queen Elizabeth Hospital on March 31 due to vaginal bleeding. After assessment, she was found to have had a miscarriage. According to information, the woman received a dose of the Comirnaty COVID-19 vaccine at the Choi Hung Road Badminton Centre Community Vaccination Centre on March 23. There was no record that the woman complained of feeling unwell during observation at the Vaccination Centre.

The DH has already contacted the HA for more information to assist in the assessment of the two cases. Currently, there is no evidence indicating that the two cases were related to vaccination.

According to the established mechanism, the DH will refer the cases to the Expert Committee on Clinical Events Assessment Following COVID-19 Immunisation (Expert Committee) for conducting causality assessment.

According to the World Health Organization, an AEFI is any medical occurrence that follows immunisation and that does not necessarily have a causal relationship with the usage of the vaccine.

The Vaccination Fact Sheet of Comirnaty states that COVID-19 vaccines are not routinely recommended during pregnancy, unless the woman is

considered to be at very high risk of SARS-CoV-2 exposure and subject to very high risk of COVID-19 complications. Women who are pregnant or breastfeeding, think they may be pregnant or are planning to have a baby should ask their doctor for advice before receiving the Comirnaty vaccine. Currently, the Vaccination Fact Sheet of CoronaVac states that the CoronaVac vaccine should not be given to pregnant women.

According to the risk communication plan endorsed by the Expert Committee, the figures and summaries of clinical events received will be released and updated regularly through the designated website. When a case of a suspected adverse event fulfilling the reporting criteria of an AEFI involving death within 14 days of vaccination is received, it will be announced via a press release as soon as possible.

According to the statistics collected by the DH, episode for inpatient discharges and deaths in hospitals for spontaneous abortion in 2017 to 2019 was about 3 500 to 3 900 each year in Hong Kong.