

Government announces initial investigation results regarding packaging defects of BioNTech vaccine

The Department of Health (DH) had earlier noticed that there was an accumulated number of cases of packaging defects (including loose vial caps, leakages from the vials, etc.) regarding the BioNTech vaccines (batch no. 210102). The DH immediately notified the vaccine supplier (Fosun Industrial Co., Limited (Fosun) and German drug manufacturer BioNTech) and requested for prompt follow-up. At the same time, in view that the supplier has launched an urgent and comprehensive investigation on the packaging defects, the Government agreed to the supplier's recommendation and suspended vaccination of batch 210102 and 210104 of the BioNTech vaccines in Hong Kong for the sake of prudence and as a precautionary measure. The Government today (March 27) received the initial investigation results from Fosun.

To ensure that the BioNTech vaccines supplied to Hong Kong are safe, efficacious and can meet the requirements of quality, Fosun and BioNTech have launched a comprehensive investigation covering all aspects of the supply chain to find out the potential causes that may lead to the packaging defects, including the filling and packaging processes at BioNTech's plant in Germany, the procedures for transporting the vaccines from Germany to Hong Kong after packaging, the logistical arrangements and storage after arrival of the vaccines at Hong Kong, and procedures for checking and handling of the vaccines at Community Vaccination Centres. According to the investigations completed by Fosun and BioNTech so far, there is no indication of any obvious systemic factors during the processes from filling and packaging to administration that could have led to the relevant packaging defects. At this juncture, the investigation results do not rule out that the relevant situation is caused by environmental conditions during the long-haul transport process. That said, having regard to consolidated figures from the investigation, it is believed that the relevant situation is not related to cold-chain and logistical management. As regards the other vaccine doses which were delivered to Hong Kong, random sample testing of vaccine vials which are intact did not uncover any issue of vaccine leakage.

According to the initial investigation results, Fosun and German drug manufacturer BioNTech considered that there is no evidence indicating any safety risks of the BioNTech vaccines delivered to Hong Kong (batch no. 210102 and 210104). Members of the public who have received the BioNTech vaccines do not need to worry. The subsequent investigation work will mainly target on ascertaining the integrity of the intrinsic properties of the relevant batches of vaccine, and that the batches are safe for use. The Government is actively following up with Fosun and German manufacturer BioNTech to strive to complete the investigation procedures within a week. The Government will also keep close liaison with the supplier on the supply of the remaining doses of vaccine, with a view to ensuring that

implementation of the vaccination programme in Hong Kong can be continued.

A Government spokesman said, "Ensuring that the COVID-19 vaccines meet the requirement of safety, efficacy and quality is the prime consideration of the Government when implementing the vaccination programme. We will continue to implement the vaccination programme based on scientific evidence and in adherence to the principles of openness and transparency, and at the same time allow the public to grasp the latest information on the relevant vaccines. Premised on the condition of safety, the Government will strive to resume the administration of the BioNTech vaccine for members of the public as soon as possible, so as to protect public health and the health of our citizens."