

# Government announces investigation results regarding packaging defects of BioNTech vaccine and arrangements for resumption of vaccination service

The Government today (April 1) received from German drug manufacturer BioNTech the investigation results regarding packaging defects of the vial caps of the BioNTech vaccine (batch 210102) and the follow-up proposal. The Government took note of the investigation results and announced the arrangements for resumption of vaccination service of the BioNTech vaccine starting from April 5 under the Government vaccination programme.

According to the information provided by Fosun Industrial Co., Limited (Fosun) and German drug manufacturer BioNTech, BioNTech has completed the relevant investigation and analysis regarding defects found in a small number of vial caps in a batch of vaccines supplied to the Hong Kong and Macao regions. It is confirmed that the occurrence of the said problem is only associated with vaccine packaging under transport conditions. The production process and quality of the vaccine are found to be intact.

Results of further investigation including repeated tests and comparisons revealed that the occurrence of defects in the vial caps of the BioNTech vaccine was resulted from the crimping process during fill and finish in which the container integrity could not be effectively ensured for the said batch of vaccines (batch 210102). If the metal cap of the said batch of vials was not optimally crimped, there might be ingress of ambient gas into the vials under the ultra-cold storage and transport environment (i.e. -70 degrees Celsius). The subsequent thawing procedures conducted might lead to increased air pressure in the vials and thus over-pressure in some vials and leakages from the vials, etc. Having conducted further tests, the relevant problem was also observed in other batches (including batch 210104) which were filled and finished at the same plant (including the crimping process). In contrast, for batches not filled and finished at the same plant (including the crimping process), the problem was not observed after conducting the same tests repeatedly.

After conducting detailed analysis of the testing statistics and results of random sampling, the German drug manufacturer BioNTech considered that there was no evidence that pointed to any safety risks for batches 210102 and 210104 of the BioNTech vaccine. The drug manufacturer indicated that in view the vaccine was stored under ultra-cold conditions, the risk of microbial contamination was very low. Also, as of now, no relevant adverse event had been discovered under the continuous monitoring mechanism. The German drug manufacturer BioNTech also indicated that, even if the vials had the above problems, the integrity of the messenger RNA and lipid nanoparticles was not affected. Having regard to the above results, the drug manufacturer

confirmed that the safety and efficacy of the vaccine were not affected by the aforesaid issue, hence members of the public who had received the BioNTech vaccine did not need to worry. That said, for the sake of prudence, batches 210102 and 210104 will continue to be put on hold at the request of the drug manufacturer until completion of the final investigation report. The Government is also prepared to follow the recommendation of the drug manufacturer to suitably handle the relevant batches at a later time, including no longer administering the relevant batches of the BioNTech vaccine.

On the other hand, according to information provided by Fosun, a batch of around 300 000 doses of the BioNTech vaccine which were produced in Germany and filled and finished at another plant in Germany was expected to arrive Hong Kong from Germany on April 2. To ensure that problems similar to those mentioned above which might have led to packaging defects will not happen to the relevant batch of vials, German drug manufacturer BioNTech has conducted a series of stringent tests and assessment, including pressure tests conducted on more than 15 000 vials which had been stored in ultra-cold conditions. It was confirmed that the aforesaid problems were not found. German drug manufacturer BioNTech and Fosun will also enhance sampling and monitoring to ensure the integrity of the vials. The Government will also continue to provide relevant information to all healthcare professionals responsible for handling vaccines at Community Vaccination Centres (CVCs), with a view to effectively detecting the occurrence of similar problems. A Government spokesman pointed out that the relevant problem was discovered under the stringent checking procedures at the Government's CVCs. This demonstrates that the relevant procedures are working well and can effectively prevent similar problems from occurring to the vaccines.

Fosun and German drug manufacturer BioNTech have indicated to the Government that they will support the Government vaccination programme and provide a stable supply of vaccines for Hong Kong, with a view to ensuring that the vaccination programme can continue to be implemented at full speed.

The Government will resume BioNTech vaccination for the public on April 5. Persons who have bookings to receive the vaccine on or after April 5 can go to the CVC they selected at the originally booked time slot, and need not make another appointment afresh.

For persons who have made an appointment for taking the second dose BioNTech vaccination on or before April 4, the Government will reserve a vaccination slot for them on a day between April 5 and 10, so that they can get the second dose vaccination as early as possible. For those who have made an appointment for taking the first dose BioNTech vaccination between March 24 and April 4, a new vaccination slot will also be reserved for them before the reopening of online booking for BioNTech vaccine. The above two categories of persons will be notified of the appointment details via SMS messages starting from April 2.

"If the persons concerned do not want to take the vaccination slot reserved, they can change the time slot via the online booking system on the

designated website for the COVID-19 Vaccination Programme starting from 9am on April 3, after first cancelling the time slot assigned. As registration for BioNTech vaccination in the early phase of service resumption is expected to be keen, persons wishing to change the reservation may end up getting a rather late time slot due to insufficient supply of vaccination places. As such, we appeal to these people, especially those who need to take the second dose vaccination early, to accept as far as possible the vaccination slot reserved for them, to ensure that they can get the due protection offered by the vaccine,” said the spokesman.

The categories of priority groups under the vaccination programme have been increased to 14, covering persons aged 30 or above, students aged 16 or above studying outside Hong Kong and domestic helpers. A new CVC at the Ho Man Tin Sports Centre will commence operation on April 5, bringing the number of CVCs administering BioNTech vaccine to 21. Persons belonging to the priority groups can make BioNTech vaccination bookings through the online booking system starting from 9am on April 3.

As regards Sinovac vaccine, the public can make reservations for receiving the vaccination at eight CVCs and the 18 general out-patient clinics of the Hospital Authority. They can also make appointments for vaccination with private doctors or clinics participating in the programme.

Members of the public can visit the designated website, [www.covidvaccine.gov.hk](http://www.covidvaccine.gov.hk), to make reservations for vaccination and to learn more about COVID-19 vaccines.