

Office of The Ombudsman announces results of direct investigation into Government's mechanism for monitoring vaccines provided by private healthcare facilities

The following is issued on behalf of the Office of The Ombudsman:

The Ombudsman, Ms Winnie Chiu, today (March 4) announced the completion of a direct investigation into the Government's mechanism for monitoring vaccines provided by private healthcare facilities (PHFs).

In July 2019, there were local incidents involving medical centres allegedly providing counterfeit nine-valent human papillomavirus (HPV) vaccines. The incidents were widely reported by the media and the Office of The Ombudsman had also received related complaints. The Ombudsman considers that the Government must play the role of a gatekeeper properly to ensure the quality and safety of vaccines. This direct investigation aims at examining the Government's mechanism for monitoring vaccines provided by PHFs and exploring room for improvement, if any, as well as enhancing public understanding of the Government's monitoring efforts.

Investigation by the Office found that for those vaccines that are in general less prone to parallel import or counterfeiting, the Government has already put in place a quite comprehensive monitoring mechanism for such vaccines provided by PHFs. Nevertheless, for vaccines with excessive demand, the authorities' monitoring mechanism had been inadequate in the past. The inadequacies include a pharmaceutical product's supply and demand in the market not being included in the risk assessment factors under the Department of Health (DH)'s market surveillance mechanism, the DH having no authority to conduct routine inspections at PHFs solely on the grounds of investigating counterfeit vaccines, and education and publicity targeted at the main groups receiving the vaccination being insufficient and behind time. Fortunately, the DH and the Customs and Excise Department (C&ED) took prompt action in the wake of the incidents involving nine-valent HPV vaccines, conducted investigations at the PHFs involved and made arrests. Meanwhile, the two departments also implemented a number of strengthened monitoring measures, including conducting special inspections on those licensed wholesale dealers who had imported unregistered nine-valent HPV vaccines for the purpose of re-export, the DH referring all import/export permits already issued involving unregistered nine-valent HPV vaccines to the C&ED for post-shipment verification, and carrying out proactive investigation against suspicious PHFs. The number of complaints about nine-valent HPV vaccines has plummeted since.

However, neither the Food and Health Bureau nor the DH took the

initiative to explain in detail to the public the Government's mechanism for monitoring vaccines provided by PHFs or the strengthened monitoring measures introduced in response to those incidents so as to allay public doubts and enlighten them on how to protect their own health and welfare (for instance, by knowing how to find out if the vaccines have been registered and verify the authenticity of the nine-valent HPV vaccines). Actually, an informed and alert general public can render the Government's monitoring and enforcement efforts much more effective.

In the investigation report, the Office has made four recommendations to the Government: (1) to keep a close watch on the effectiveness of the strengthened monitoring measures and make adjustments when necessary; (2) to include a pharmaceutical product's supply and demand in the market as a risk assessment factor under the DH's market surveillance mechanism; (3) to review the information dissemination mechanism regarding serious incidents involving pharmaceutical products; and (4) to enhance the transparency of information about newly introduced vaccines.

The full investigation report has been uploaded to the website of the Office of The Ombudsman at www.ombudsman.hk for public information.