DH follows up Field Safety Corrective Action notice by Olympus Hong Kong and China Limited

The Department of Health (DH) today (November 5) announced that it has received a Field Safety Corrective Action (FSCA) notice from the Olympus Hong Kong and China Limited (Olympus) regarding one of their products, namely the Olympus High Flow Insufflation Unit (Model number: UHI-4). Olympus has become aware of patients experiencing complications due to excessive insufflation during use and the DH is closely monitoring the situation. To date, the DH has not received any reports of adverse events related to this issue.

The device is mainly used by doctors to inflate the abdomen or colon with carbon dioxide gas during laparoscopic or endoscopic surgeries. Over insufflation may lead to complications including air embolism, arrhythmias, pneumothorax, and potentially death. The concerned device in this incident would not be used or operated by general public, and it is not listed under the Medical Device Administrative Control System set up by the DH.

A spokesman for the DH stated that its Medical Device Division (MDD) has always been closely monitoring safety alerts of medical device issued by relevant local and overseas regulatory authorities as well as the World Health Organization, under the established mechanism, and will take action according to actual circumstances as appropriate, including maintaining contacts with local suppliers and notify relevant stakeholders, such as the Hospital Authority, private hospitals, and medical professional associations, as well as publishing safety alert summary and special alerts on its website etc.

The DH noticed that a medical device recall was issued by the United States (US) Food and Drug Administration (FDA) on October 31, requesting Olympus America to notify users in the US to cease using the affected device until a root cause investigation is completed. The DH has taken a proactive approach with a view to ensuring safety and addressing the issue effectively. The MDD of the DH has swiftly reached out to Olympus to obtain information regarding the incident, and requested them to notify affected customers and ensure appropriate follow-up actions are carried out. Also, the MDD has posted a Special Alert on its website to provide the latest development of the incident and updated information. In addition, the DH also promptly informed relevant stakeholders about the latest situation and urged them to contact the supplier as soon as possible if they are utilising the concerned device.

According to information provided by Olympus, approximately 200 units of the concerned device have been distributed to public hospitals, private hospitals and a day procedure centre locally. Olympus has informed users through an FSCA notice, highlighting cases of patients experiencing complications due to over insufflation during use and includes an amendment

to the instructions for use, aimed at reducing the risk of such complications. The DH understands that the process of notifying the affected institutes has been completed yesterday (November 4).

"The DH will continue to closely monitor the situation and maintain ongoing communication with the relevant local supplier and stakeholders." the spokesman added.