DH follows up on adverse event reported by Hospital Authority

The Department of Health (DH) is following up on an adverse event reported by the Hospital Authority (HA) yesterday (September 11) relating to an incident involving an angiography system used on a 66-year-old man during a medical procedure at Queen Elizabeth hospital (QEH) on September 9.

A spokesman for the DH said that its Medical Device Division (MDD) immediately contacted the HA and the local responsible person (LRP) of the device to obtain details of the incident and conducted a follow up.

The medical device concerned, namely the Artis Zee Biplane, used for X-ray imaging in medical procedures, is a Class III general medical device listed under the Medical Device Administrative Control System (MDACS). The manufacturer is Siemens Healthcare GmbH.

The medical device concerned has been installed in QEH since April 2011 and is under regular maintenance by the manufacturer. The last maintenance check was conducted on July 24, 2024, and no abnormalities were found. After the incident, the LRP conducted an on-site investigation on September 10, obtained the event log from the system, and sent it to overseas manufacturer for further investigations into the underlying cause of the incident.

Preliminary information from the LRP revealed that the medical device concerned has been distributed to two public hospitals and one private hospital. Apart from maintaining liaison with the HA, the DH will inform stakeholders (including all private hospitals and relevant medical professional associations) to remind them of the incident and request them to contact the LRP as soon as possible if they are using the angiography system concerned. A special safety alert will be also posted on the MDD's website.

Since 2004, the DH has launched the voluntary MDACS, which includes listing systems for medical devices and traders as well as a post-market monitoring mechanism. Following a risk-based approach, LRPs can apply for listing of Classes II, III and IV general medical devices and Classes B, C and D in vitro diagnostic medical devices under the MDACS.

In terms of the post-marketing monitoring system, the MDACS includes monitoring of safety alerts of medical devices issued by other regulatory jurisdictions, and handling of safety alerts notified by manufacturers. Furthermore, taking reference to the recommendations of the Global Harmonization Task Force, the MDACS has established a Medical Device Adverse Event Reporting System to collect and conduct analyses on information related to adverse events for early detection of safety signals to protect the health of patients and users of the medical device.

"The DH will continue to closely monitor the situation and maintain

ongoing communication with the LRP," the spokesman added.