DH monitors safety of breast implants

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A spokesman for the Department of Health (DH) said today (September 30) that the department is monitoring a medical device safety alert related to the risk of Breast Implant-associated Anaplastic Large Cell Lymphoma (BIA-ALCL) in patients implanted with breast implants.

The DH noted that the Australian Therapeutic Goods Administration is recently taking a precautionary measure to suspend certain models of breast implants for six months and recall them from its market due to risk of BIA-ALCL after a review of BIA-ALCL cases in Australia and laboratory test results. Earlier, other overseas regulatory authorities also reported that they have been monitoring the safety and performance of breast implants, as well as the occurrence of BIA-ALCL.

BIA-ALCL is a rare disease that develops near breast implants. It is a type of cancer that affects the immune system and may develop many months or years after a breast implant procedure. It is not a cancer of the breast tissue. BIA-ALCL usually presents as an accumulation of fluid between the implant and the surrounding tissue. BIA-ALCL may also present as lump in the breast or armpit. The vast majority of BIA-ALCL are cured by removal of the implant and the capsule surrounding the implant. While the cause is unknown, possible risk factors include implants with larger surface area, roughness of their wall as a result of the materials used in the production of the device, and long-term inflammation around the implant.

At this time, regulatory authorities in both the United States and Australia do not recommend removal of breast implants in patients who have no symptoms due to the low risk of developing BIA-ALCL.

"Women with breast implants should be aware of the common presenting symptoms, such as swelling, lump or pain. If they have any of the presenting symptoms, they should consult their implanting surgeons or surgeons experienced in this field. Meanwhile, women without symptoms may discuss with their doctors during routine follow-ups if they have any concerns," the spokesman said.

The DH has informed stakeholders including the Hospital Authority, private hospitals and medical professional associations about the latest regulatory actions in Australia. So far, the DH has not received any report of BIA-ALCL in Hong Kong arising from breast implants.

"The department will continue to closely monitor the situation, follow up with the manufacturers or local suppliers, and take appropriate actions if needed," the spokesman added.

Ends/Monday, September 30, 2019

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