Queensland Health

Information for General practitioners

Textured breast implants and tissue expanders

23 January 2020

Queensland Health response to TGA regulatory action on textured breast implants and tissue expanders

In August 2019, Allergan recalled their un-implanted BIOCELL textured breast implants and tissue expanders from the Australian market after a review found the devices have a small risk of causing Breast Implant Associated Anaplastic Large Cell Lymphoma (BIA-ALCL).

On 28 November 2019, the TGA imposed further regulatory action in relation to ALL breast implants and tissue expanders currently available in Australia, resulting in the suspension of some textured breast implant products, and stricter safety and quality controls on All other breast implants and tissue expanders remaining available for use in Australia.

Internationally, a number of women with textured breast implants have been diagnosed with the rarely occurring BIA-ALCL. The main symptoms of BIA-ALCL include swelling in the breast, and less commonly, lump formation in the breast or armpit. Implants which have a smooth surface have not been associated with BIA-ALCL.

Although the risk of BIA-ALCL is very low, Queensland Health is notifying all women who have been identified as having received textured breast implants or tissue expanders associated with increased risk of BIA-ALCL through the Queensland public health system. Patients will be contacted from 23 January 2020. Where General Practitioner (GP) details are known, they will be sent a letter and GP information sheet to assist consultation and referral should this be necessary.

All women with textured breast implants are advised to be aware of BIA-ALCL symptoms and to perform regular breast self-examinations. Women are advised to consult their doctor if symptoms develop, if any changes are noticed on self-examination, or if they have any concerns. If signs or symptoms are present, arrange an ultrasound (+/- aspirate), where possible. Post-operative breast swelling is expected after breast implant surgery. Surgeons will advise patients how long post-operative swelling should be expected based on individual patient assessment.

Testing for BIA-ALCL is only recommended if symptoms are present. Because BIA-ALCL is rare, experts do not recommend removal of breast implants where there are no problems with the implant. If already removed, the advice remains the same with regards to regular self-examination, yearly review by a general practitioner and referral to a specialist where appropriate.

For information about the recall and risks of breast implants, visit http://conditions.health.qld.gov.au/HealthCondition/condition/21/52/830/breast-implant-associated-anaplastic-large-ce or

Information on the TGA regulatory actions for breast implant devices at:

https://www.tga.gov.au/alert/update-safety-and-performance-concerns-suspended-breast-implants