Australian Society *of* Plastic Surgeons

Update regarding breast implants and BIA-ALCL

The TGA is proposing to take regulatory action in relation to a number of breast implants that have been associated with Breast Implant Associated Anaplastic Large Cell Lymphoma (BIA-ALCL).

The TGA has formed a view regarding proposed regulatory action in relation to 31 of textured implants. The TGA is required by law to provide the sponsors of affected implants with an opportunity to make submissions in response to proposed regulatory action. The TGA will then take into consideration each sponsor's submission when deciding what, if any, regulatory action should be taken in relation to particular sponsor's device(s).

Sponsors were notified of the TGA's preliminary view on 8 July 2019 and have been given two weeks to respond. The TGA will then evaluate the submissions as a priority. You will be notified about specific regulatory actions for particular products and the affected brand(s) of implants when a decision has been made. This information will also be made available to the public.

The TGA has been monitoring and investigating the issue of BIA-ALCL since it first released a statement about the association of ALCL with breast implants in 2011. Since 2016 a TGA breast implant expert working group has provided advice to TGA with consideration of the latest information available. This expert panel comprises plastic surgeons, cosmetic surgeons, breast-cancer surgeons, cancer epidemiologists, pathologists, data analysts, public health practitioners and consumers.

The TGA has also been working closely with the Australian Breast Device Registry (ABDR). The ABDR was established by the Australian Government to track the long-term safety and performance of breast implants and is independently managed by Monash University. The ABDR is endorsed by Australian surgical societies, the breast implant expert working group and the TGA as the central repository of data for all breast device issues, including BIA-ALCL. Data is provided from public and private hospitals and day surgeries in all states and territories.

To date, there have been 99 confirmed cases in Australia of anaplastic large cell lymphoma in women with breast implants, and four have died as a result of their disease. Of note is that in all Australian cases of BIA-ALCL the implants involved were not smooth surface implants, but rather were textured or had a polyurethane coating. Current expert opinion is that risk of BIA-ALCL increases with increased texturing of implants used.

Australia is recognised as a leader in efforts to monitor and understand BIA-ALCL. The TGA has been liaising with other international regulators to advise and keep informed with international progress. Regulatory action in other countries has varied. The United States of America Food and Drug Administration (FDA) has not taken any action apart from publishing information on its website while Canada and France have banned highly textured

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implants from their markets. The French Agency of Medicine and Health Products Safety (ANSM) published on 4 April 2019, that macro-textured and polyurethane-coated implants would no longer be supplied in France. Health Canada, on 28 May 2019 suspended its only macro-textured implant, Allergan Biocell, from the market. Polyurethane coated implants are not available in Canada. The United Kingdom Medicines and Healthcare products Regulatory Agency (MHRA) continues to collect and analyse information from UK healthcare professionals and other sources about BIA-ALCL. The National Institute for Public Health and the Environment (RIVM) in the Netherlands published its decision on 17 May 2019 that the devices will not be subject to further regulatory action in the Netherlands, at this time.

In April 2019, the TGA requested additional information and implant samples from sponsors of implants on the Australian market. The TGA, as part of the ongoing work regarding breast implant associated cancer, has now completed a review of those breast implants, including a laboratory assessment of implant samples to confirm the surface textures were classified as smooth, micro- or macro-textured in accordance with the relevant international standard. An external expert on statistics has undertaken analysis of case data, in addition to clinical and statistical analysis undertaken by TGA.

As BIA-ALCL is a rare disease, but as the disease most commonly appears eight years after implantation, the number of diagnoses is likely to increase in coming years. Ongoing monitoring and review will be required. BIA-ALCL is usually cured if detected early, and so consumer and health professional education is essential. The TGA will continue to provide updates and information online, including dedicated pages for both consumers and health professionals.