July 2018

Joint Statement between ABS, BAAPS, BAPRAS & MHRA on BIA-ALCL

The Association of Breast Surgeons (ABS), the British Association of Aesthetic Plastic Surgeons (BAAPS), the British Association of Plastic, Reconstructive and Aesthetic Surgeons (BAPRAS), with other experts have been working in close collaboration with the Medicines and Healthcare products Regulatory Agency (MHRA) to evaluate the risk factors associated with Breast Implant Associated - Anaplastic Large Cell Lymphoma (BIA-ALCL).

MHRA has been aware of Anaplastic Large Cell Lymphoma reported in relation to breast implants (ALCL) elsewhere in the world since 2010, with the first UK case reported in 2012. Since then this rare disease has become the subject of increased scientific attention and, as of 2016, the provisional term Breast Implant Associated-ALCL (BIA-ALCL) was agreed by the World Health Organisation to describe a specific type of ALCL.

In response to the emerging information about BIA- ALCL, and with the need for it to be considered as a potential diagnosis in breast conditions, MHRA published two Medical Device Alerts in 2011 (MDA2011/017), and in 2014 (MDA2014/027), and recently updated their dedicated webpage on GOV.uk.

This is to raise awareness of the condition, advise surgeons of how it presents, and to encourage central reporting of cases. All cases of BIA-ALCL or suspected BIA-ALCL, should be reported to MHRA via the Yellow Card Scheme.

In addition to these alerts, MHRA is collaborating closely with their European and international regulatory counterparts. MHRA continues to collect evidence and investigate the disease.

As part of their investigations MHRA has established an independent clinical expert advisory group, the Plastic, Reconstructive and Aesthetic Surgery Expert Advisory Group (PRASEAG). Members include representatives from BAPRAS, ABS, BAAPS, the Royal College of Pathologists, Royal College of Radiologists and also toxicology, immunology, cancer biology, pathology and microbiology experts. There is also a representative of breast cancer patient support organisations in the Group. As the role of the group develops and, because the disease and potential associations are so complex, other specialists may be invited to join in the future.

The initial remit of the PRASEAG is to review all evidence regarding BIA-ALCL. In particular, PRASEAG is looking at theories regarding the aetiology of the disease, methods of diagnosis (and their validity) and the

potential levels of risk to patients who have had breast implants of any type for either cosmetic or reconstructive indications. Current evidence indicates there is an association between breast implants and BIA-ALCL, but this seems to involve many factors. One of the suggested theories is the role of surface texture of implants and the way some patients react to having an implant in place. However, active research is on-going and is yet to provide a definitive answer. To date, there appears to be no evidence of 'clustering' of cases in the United Kingdom and the disease remains rare. The most up to date figures for the UK indicate an estimated risk of around 1 in 28,000. BIA-ALCL can appear several years after the implant was introduced and most commonly presents with rapid, painless swelling of one breast. If diagnosed early, BIA-ALCL can be successfully treated, usually with surgery alone. While considering what is currently known, PRASEAG will also review any new and emerging evidence from this country and internationally.

PRASEAG continues to provide clinical oversight to MHRA to assist in any regulatory steps it may wish to consider in its role of protecting patient safety. In that context, PRASEAG agree with other international experts that BIA-ALCL remains rare and, based on evidence to date, there appears be no need for regulatory action to stop the use of implants. However, it is essential all patients who are considering a breast implant for reconstructive or cosmetic purposes are made fully aware of the potential risks by their surgeon. We also advise anyone who already has an implant in place and wishes to have more information about BIA-ALCL to make an appointment to see the surgeon who performed their operation for advice.

It is hoped this statement will reassure patients that this matter is being taken very seriously by all concerned, and we wish to make it clear this issue is being actively pursued from clinical and scientific viewpoints, by both the regulator and the wider clinical and scientific community.

The advice continues to be if patients have any concerns following their breast implant surgery, especially late onset swelling around one implant, they should consult their General Practitioner or their implanting surgeon.

ABS ASSOCIATION OF BREAST SURGERY

BAAPS

BAPRAS British Association of Plastic Reconstructive and Aesthetic Surgeons

MHRA