

# Medical Device Alert

## Action

Ref: MDA/2011/017 Issued: 16 February 2011 at 14:30

### Device

Breast implants.

All types, makes and models.

### Problem

There is uncertain evidence that women with breast implants may have a very small but increased risk of anaplastic large cell lymphoma (ALCL) of the breast.

The MHRA has not received any adverse incident reports identifying ALCL in association with breast implants in the UK. Discussions with the relevant UK professional bodies have not identified any cases.

### Action by

- Directors of surgical units involved in breast reconstruction and augmentation
- Medical directors.
- Plastic surgeons and all surgeons involved in breast reconstruction and augmentation.
- Nurse executive directors.
- Specialist nurses involved in breast cancer care.
- General practitioners (for information only).

### CAS deadlines

Action underway: 02 March 2011

Action complete: 30 March 2011

### Action

- No change to current best practice is needed.
- If you are contacted by concerned women about this issue, reassure them that ALCL is a very rare form of cancer.
- During initial consultation and subsequent follow-up examinations encourage women to self examine for changes in their breast and seek medical advice if concerned.
- Report any confirmed cases of ALCL in women with breast implants to the MHRA.

## Problem

The FDA recently published a Safety Communication entitled 'FDA Medical Device Safety Communication: Reports of Anaplastic Large Cell Lymphoma (ALCL) in Women with Breast Implants'.

<http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/BreastImplants/ucm239996.htm#summary>.

In a thorough review of scientific literature published from January 1997 to May 2010, the FDA identified 34 unique cases of ALCL in women with breast implants throughout the world. The FDA's adverse event reporting systems also contains 17 reports of ALCL in women with breast implants. This is a very small fraction of the 5-10 million women who have received breast implants worldwide.

Anaplastic large cell lymphoma (ALCL) is a rare type of non-Hodgkin's lymphoma (NHL), a cancer involving the cells of the immune system. It is a very rare tumour in the breast, accounting for less than 1% of all breast malignancies.

To date there have been no corresponding reports of this disease association to the MHRA. The MHRA encourages all surgeons to report all adverse incidents, including cases of ALCL, to the adverse incident centre ([aic@mhra.gsi.gov.uk](mailto:aic@mhra.gsi.gov.uk)).

The MHRA will review any evidence that comes to light and take appropriate action as needed.

There is no indication for any routine action in the form of explantation or regular radiological examination including MRI. Women should be advised to self examine and consult their medical practitioner if they notice any changes in the breast or have any concerns.

## Distribution

This MDA has been sent to:

- NHS trusts in England (Chief Executives)
- HSC trusts in Northern Ireland (Chief Executives)
- NHS boards in Scotland (Chief Executives)
- NHS boards and trusts in Wales (Chief Executives)
- Primary care trusts in England (Chief Executives)

### Onward distribution

Please bring this notice to the attention of relevant employees in your establishment. Below is a suggested list of recipients.

#### Trusts

CAS and SABS (NI) liaison officers for onward distribution to all relevant staff including:

- Directors of surgical units involved in breast reconstruction or augmentation
- Medical directors
- Nurse executive directors
- Plastic surgeons and all surgeons involved in breast reconstruction or augmentation
- Specialist nurses involved in breast cancer care

#### Primary care trusts

CAS liaison officers for onward distribution to all relevant staff including:

- General practitioners
- Practice managers
- Practice nurses

### Independent distribution

#### Establishments registered with the Care Quality Commission (CQC) (England only)

This alert should be read by:

- Breast augmentation centres
- Hospitals in the independent sector
- Independent treatment centres
- Private medical practitioners

Please note: CQC and OFSTED do not distribute these alerts. Independent healthcare providers and social care providers can sign up to receive MDAs directly from the Department of Health's Central Alerting System (CAS) by sending an email to: [safetyalerts@dh.gsi.gov.uk](mailto:safetyalerts@dh.gsi.gov.uk) and requesting this facility.

## England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2011/017** or **2011/002/002/291/003**

### Technical aspects

Bayode Adisa or Ian Smith  
Medicines & Healthcare products Regulatory Agency  
Floor 4  
151 Buckingham Palace Road  
London SW1W 9SZ  
Tel: 020 3080 7223 / 7306  
Fax: 020 8754 3965  
Email: [bayode.adisa@mhra.gsi.gov.uk](mailto:bayode.adisa@mhra.gsi.gov.uk)  
[ian.smith@mhra.gsi.gov.uk](mailto:ian.smith@mhra.gsi.gov.uk)

### Clinical aspects

Dr Susanne Ludgate  
Medicines & Healthcare products Regulatory Agency  
Floor 4  
151 Buckingham Palace Road  
London SW1W 9SZ  
Tel: 020 3080 6800  
Fax: 020 8754 3965  
Email: [susanne.ludgate@mhra.gsi.gov.uk](mailto:susanne.ludgate@mhra.gsi.gov.uk)

## How to report adverse incidents

Please report via our website <http://www.mhra.gov.uk>  
Further information about **CAS** can be found at <https://www.cas.dh.gov.uk/Home.aspx>

## Northern Ireland

Alerts in Northern Ireland will continue to be distributed via the NI SABS system.  
Enquiries and adverse incident reports in Northern Ireland should be addressed to:

Northern Ireland Adverse Incident Centre  
Health Estates Investment Group  
Room 17  
Annex 6  
Castle Buildings  
Stormont Estate  
Dundonald BT4 3SQ  
Tel: 02890 523 704  
Fax: 02890 523 900  
Email: [NIAIC@dhsspsni.gov.uk](mailto:NIAIC@dhsspsni.gov.uk)  
<http://www.dhsspsni.gov.uk/index/hea/niaic.htm>

## How to report adverse incidents in Northern Ireland

Please report directly to NIAIC, further information can be found on our website <http://www.dhsspsni.gov.uk/niaic>

Further information about **SABS** can be found at <http://sabs.dhsspsni.gov.uk/>

## Scotland

Enquiries and adverse incident reports in Scotland should be addressed to:

Incident Reporting and Investigation Centre

Health Facilities Scotland

NHS National Services Scotland

Gyle Square

1 South Gyle Crescent

Edinburgh EH12 9EB

Tel: 0131 275 7575

Fax: 0131 314 0722

Email: [nss.irc@nhs.net](mailto:nss.irc@nhs.net)

<http://www.hfs.scot.nhs.uk/online-services/incident-reporting-and-investigation-centre-irc/>

## Wales

Enquiries in Wales should be addressed to:

Dr Sara Hayes

Senior Medical Officer

Medical Device Alerts

Welsh Assembly Government

Cathays Park

Cardiff CF10 3NQ

Tel: 029 2082 3922

Email: [Haz-Aic@wales.gsi.gov.uk](mailto:Haz-Aic@wales.gsi.gov.uk)

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