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).

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 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
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London SW1W 9SZ

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Fax: 020 8754 3965

Email: bayode.adisa@mhra.gsi.gov.uk
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Clinical aspects
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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

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.iric@nhs.net

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

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