Medical Device Alert

Ref: MDA/2014/037 Issued: 26 September 2014 at 14:00

Device

All medical devices.

Problem

Delays in acting on Field Safety Notices (FSNs) can compromise patient safety.

MHRA is aware that FSNs sent by manufacturers are not always cascaded in an effective and timely manner to the relevant people that need to be aware of the reported problem and for the required actions to be carried out.

MHRA often has to issue Medical Device Alerts (MDAs) reminding users about manufacturers' FSNs where there is insufficient feedback that it has reached the appropriate people and been acted upon.

Action by

Chief executives/clinical governance leads supported by:
Risk managers, Medical Devices Safety Officers (MDSOs), Medical Devices Liaison Officers (MDLOs), CAS Officers, EBME managers, equipment library managers

Action

- Ensure there is a system in place for appropriate cascading of FSNs and to ensure action has been taken.
- **For England only**, ensure that relevant trusts/organisations as identified in the Patient Safety Alert NHS/PSA/D/2014/006 have a Medical Devices Safety Officer (MDSO) who is registered with the Central Alerting System (CAS).
- **For Northern Ireland only**, ensure trusts/organisations have a Medical Devices Liaison Officer (MDLO) registered with the Northern Ireland Adverse Incident Centre.

CAS deadlines

Action underway: 27 October 2014

Action complete: 26 November 2014

Note: These deadlines are for systems to be in place for cascading FSNs and for a MDSO to be in post (in England).

Contact

Adverse Incident Centre
Medicines & Healthcare products Regulatory Agency
Tel: 020 3080 7080
Email: aic@mhra.gsi.gov.uk

Problem

A Field Safety Notice (FSN) is a communication sent by medical device manufacturers, or their representatives, in connection with a Field Safety Corrective Action (FSCA). FSNs outline actions to be taken to reduce the risk of death or serious injury associated with the use of a medical device.

A manufacturer undertakes a FSCA for technical or clinical reasons connected with the characteristics or performance of a device, where death or serious injury might result. Manufacturers use a FSN to tell their customers about a FSCA that they are undertaking.

The MHRA assesses each FSCA and decides whether further advice is required e.g. a Medical Device Alert (MDA). If a MDA is issued it will then be distributed via the Central Alerting System (CAS recipients of MDAs are required to submit separate feedback on action taken). MDAs are not issued for every FSN.

We currently place manufacturers' FSNs on our website for information only and they will not normally require further action by you unless you have been contacted directly by the manufacturer or we have issued supplementary advice such as a Medical Device Alert.

It is very important that your organisation takes the actions detailed in the FSN and replies to the manufacturer, acknowledging receipt of the FSN. Your organisation's reply is the evidence that the manufacturer, and subsequently the MHRA, needs to monitor the progress of the FSCA. Without this reply the manufacturer cannot properly verify if the FSCA is complete and so the MHRA may need to issue advice. Your organisation could be liable if it does not act on safety information provided by the manufacturer and something goes wrong as a result.

For England only - Patient Safety Alert NHS/PSA/D/2014/006 issued 20 March 2014 highlights recommended changes to strengthen local clinical governance arrangements including the need to identify Medical Devices Safety Officers (MDSO) who will replace Medical Devices Liaison Officers (MDLO).

In the future, manufacturers will have access to the MDSO/MDLO contact list and will be requested to include MDSO contact when issuing FSNs. Therefore, it is important for MDSOs in England to be registered with the CAS team as requested in NHS/PSA/D/2014/006.

For Northern Ireland - MDLOs should be registered with the Northern Ireland Adverse Incident Centre and keep their contact details current with their appropriate body in accordance with their administration guidance.

Distribution

This MDA has been sent to:

- Care Quality Commission (CQC) (headquarters) for information
- Clinical commissioning groups (CCGs)
- Directors of public health
- HSC trusts in Northern Ireland (chief executives)
- Local authorities in Scotland (equipment co-ordinators)
- NHS boards and trusts in Wales (chief executives)
- NHS boards in Scotland (equipment co-ordinators)
- NHS England area teams
- NHS trusts in England (chief executives)
- OFSTED (directors of children's services) for information
- Public Health England (for information)
- Social services in England (directors)
- Special health authorities for information

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:

- All departments
- All staff
- All wards
- Clinical governance leads
- Community hospitals
- Community services
- Day surgery units
- EBME departments
- Equipment libraries and stores
- Equipment stores
- Health and safety managers
- Hospital pharmacies
- Maintenance staff
- Medical directors
- Minor injury units
- MRI units, directors of
- NHS walk-in centres
- Nursing executive directors
- Outpatient clinics
- Patient transport managers
- Purchasing managers
- Radiology departments
- Risk managers
- School nurses
- Sterile services departments
- Supplies managers
- Theatres
- Walk-in centres
- Wheelchair service managers

Public Health England

Directors for onward distribution to:

- Collaborating centres
- Consultants in communicable disease control
- Divisional directors
- Heads of department
- Heads of health, safety and quality
- Health protection nurses
- HPA laboratories
- Laboratory managers
- Regional business managers
- Regional directors
- Regional epidemiologists
- Regional leads
- Regional microbiologists
- Risk manager
- Safety officers

NHS England area teams

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

- Community optometrists
- Community pharmacists
- Dispensing opticians
- General dental practitioners
- General practitioners
- Nutritional nurse specialists
- Occupational health departments
- Optometrists
- Practice managers
- Practice nurses

Social services

Liaison officers for onward distribution to all relevant staff including:

- Back care/manual handling advisors
- Care at home staff
- Care management team managers
- Children’s disability services
- Community care staff

- Day centres (older people, learning disabilities, mental health, physical disabilities, respite care, autistic services)
- Disability equipment stores
- Education departments for equipment held in schools
- Environmental health officers
- Equipment stores
- Equipment supplies managers
- In-house domiciliary care providers (personal care services in the home)
- In-house residential care homes
- Loan store managers
- Loaned equipment store managers
- Occupational health departments
- Occupational therapists
- Schools with hoists
- Transport managers
- Wheelchair and seating service managers

Independent distribution

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

This alert should be read by:

- Adult placement
- Care homes providing nursing care (adults)
- Care homes providing personal care (adults)
- Clinics
- Domiciliary care providers
- Further education colleges registered as care homes
- Hospices
- Hospitals in the independent sector
- Independent treatment centres
- Nursing agencies
- Private medical practitioners

Establishments registered with OFSTED

This alert should be read by:

- Children's services
- Educational establishments with beds for children
- Residential special schools

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/2014/037** or **2013/012/012/081/011**

Technical aspects

Adverse Incident Centre
Medicines & Healthcare Products Regulatory Agency
Floor 4, 151 Buckingham Palace Road, London SW1W 9SZ

Tel: 020 3080 7080 Fax: 020 3118 9814

Email: aic@mhra.gsi.gov.uk

Clinical aspects

Mark Grumbridge
Medicines & Healthcare Products Regulatory Agency
Floor 4, 151 Buckingham Palace Road, London SW1W 9SZ

Tel: 020 3080 7128 Fax: 020 8754 3965

Email: mark.grumbridge@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

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

All requests regarding return, replacement or modification of the devices mentioned in this alert should be directed to the relevant supplier or manufacturer.

Other enquiries and adverse incident reports in Scotland should be addressed to:

Incident Reporting and Investigation Centre
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:

Improving Patient Safety Team
Medical Directorate, Welsh Government, Cathays Park, Cardiff CF10 3NQ

Email: improvingpatientsafety@wales.gsi.gov.uk