Medical Device Alert

Ref: MDA/2014/004 Issued: 24 January 2014 at 15:00

Device

Counterfeit or non-CE marked dental medical devices.

Problem

Counterfeit or non-CE marked dental medical devices bought online could fail during use with a risk of injury to patient and user.

Action by

- Dental departments
- Dental nurses
- Dentists
- Dental therapists
- Dental hygienists
- Dental technicians
- General dental practitioners
- Orthodontic therapists

CAS deadlines

Action underway: 31 January 2014

Action complete: 07 February 2014

Note: These deadlines are for systems to be in place

Action

Only buy dental medical devices from a legitimate manufacturer or supplier.

Only use dental medical devices that have a medical device CE mark.

Report suspected counterfeit dental medical devices and adverse incidents involving dental medical devices to the MHRA:

Report **suspected counterfeit medical devices online**

Report **medical device adverse incidents online**

Advice from the British Dental Association (BDA): the **British Dental Industry Association (BDIA) website** has a list of companies that manufacture or supply legitimate dental medical devices - see 'Product Locator'.

Problem

The medical device CE mark is used to show compliance with the essential requirements for safety defined in the European medical device regulations. Devices that do not have a legitimate medical device CE mark may not have been tested for safety and could fail during use, with a risk of injury to patients and users.

Counterfeit dental medical devices can be difficult to distinguish from the genuine devices. Examples of counterfeit or non-CE marked dental medical devices bought online include portable X-ray units, high speed handpieces and curing lights.

The MHRA issued press releases about these problems in **August 2012**, **October 2013** and **December 2013**. Further information on counterfeit medical devices can also be found on the **MHRA website.**

Distribution

This MDA has been sent to:

- Care Quality Commission (CQC) (headquarters) for information
- Clinical commissioning groups (CCGs)
- 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)

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:

- Community dental practices
- Dental departments
- Dental nurses
- Dentists
- Maxillofacial departments
- Oral surgeons
- Purchasing managers
- Supplies managers
- Theatre managers
- Theatre nurses
- Theatres

NHS England area teams

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

- General dental practitioners

Independent distribution

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

This alert should be read by:

- Hospitals in the independent sector
- Independent treatment centres

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/2014/004** or **2013/011/013/401/027**

Technical aspects

Ian Smith (general dental medical devices) or David Grainger (imaging dental devices)
Medicines & Healthcare Products Regulatory Agency
Floor 4
151 Buckingham Palace Road
London SW1W 9SZ

Tel: 020 3080 7306 or 7199
Fax: 020 8754 3965

Email: ian.smith@mhra.gsi.gov.uk
david.grainger@mhra.gsi.gov.uk

Clinical aspects

Camilla Fleetcroft
Medicines & Healthcare Products Regulatory Agency
Floor 4
151 Buckingham Palace Road
London SW1W 9SZ

Tel: 020 3080 6097
Fax: 020 8754 3965

Email: camilla.fleetcroft@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

Tel: 029 2082 5801

Email: Haz-Aic@wales.gsi.gov.uk