Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

Medical Device Alert

MDA/2016/020 Issued: 26 October 2016 at 11:00

Managing diabetes: patients should not change their insulin delivery device without checking with their healthcare specialist.

Summary

If patients are contacted directly by a manufacturer or other organisation to try using a different insulin therapy system they should first discuss this with their diabetes specialist to avoid risk of hyperglycaemia, hypoglycaemia or diabetic ketoacidosis.

Action

Healthcare professionals are requested to have systems in place to remind their diabetic patients:

- to use devices that have been recommended or prescribed for them by their diabetes specialist
- not to stop or change their prescribed insulin management regimen without seeking the advice of their diabetes specialist
- to contact their diabetes specialist if they are invited by a manufacturer to trial a new device e.g. via social media

Action by
Diabetes healthcare professionals

Deadlines for actions
Actions underway: 09 November 2016
Actions complete: 21 December 2016

Device details

Examples of insulin delivery systems affected by this alert:

- disposable patch pumps
- reusable ambulatory infusion pumps
- handsets
- insulin cartridges

Department of Health An Roinn Sláinte Männystrie O Poustie www.health-ni.gov.uk

NHS National Services Scotland

Llywodraeth Cymru Welsh Government

Distribution

If you are responsible for cascading these alerts in your organisation, these are our suggested distribution lists.

Trusts (NHS boards in Scotland)
CAS and SABS (NI) liaison officers for onward distribution to all relevant staff including:
- Diabetes clinics/outpatients
- Diabetes nurse specialists
- Diabetes, directors of

NHS England area teams
CAS liaison officers for onward distribution to all relevant staff including:
- General practitioners
- General practice managers
- General practice nurses

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.

Enquiries

England
Send enquiries about this notice to MHRA, quoting reference number **MDA/2016/020** or **2016/009/029/291/001**

Technical aspects
Jenifer Hannon or Roopa Prabhakar, MHRA

Tel: 020 3080 7153 or 020 3080 7293

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Clinical aspects
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Reporting adverse incidents in England
Through Yellow Card https://yellowcard.mhra.gov.uk/

Northern Ireland
Alerts in Northern Ireland are distributed via the NI SABS system.

Enquiries and adverse incident reports in Northern Ireland should be addressed to:

Northern Ireland Adverse Incident Centre
CMO Group
Department of Health, Social Services and Public Safety

Tel: 028 9052 3868

Email: niaic@health-ni.gov.uk

https://www.health-ni.gov.uk/niaic

Reporting adverse incidents in Northern Ireland
Please report directly to NIAIC using the forms on our website.

Scotland

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

Incident Reporting and Investigation Centre
Health Facilities Scotland
NHS National Services Scotland

Tel: 0131 275 7575
Fax: 0131 314 0722

Email: nss.iric@nhs.net

Reporting adverse incidents in Scotland

NHS Boards and Local Authorities in Scotland – report to Health Facilities Scotland.

Contractors such as private hospitals carrying out NHS work and private care homes that accept social work funded clients – report to Health Facilities Scotland.

Private facilities providing care to private clients report to the Care Inspectorate and MHRA.

Wales

Enquiries in Wales should be addressed to:
Healthcare Quality Division
Welsh Government

Tel: 02920 823 624 / 02920 825 510

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

Reporting adverse incidents in Wales

Report to MHRA through Yellow Card https://yellowcard.mhra.gov.uk/ and follow specific advice for reporting in Wales in MDA/2004/054 (Wales).