Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

Medical Device Alert

MDA/2019/043 Issued: 11 December 2019 at 12:00 Valid until December 2020

Recall of Medicina IV Luer Slip syringe (IVS03) batch number 19040303

Summary

Manufactured by Medicina – syringes incorrectly packaged with a needle could mean they are not sterile and could cause a needlestick injury.

Action

Note: This is a targeted MDA sent to trusts supplied with these devices.

Affected trusts will receive this alert via the Central Alerting System (CAS).

- Identify and quarantine affected devices in stock – see the manufacturer's Field Safety Notice (FSN), dated 22 August 2019.
- Complete the 'FSCA Acknowledgement Form' in the FSN even if you don't have affected devices left in stock, and return it to quality.administrator@medicina.co.uk to arrange return of affected devices.
- Report suspected or actual adverse events involving these devices through your local incident reporting system and/or your national incident reporting authority as appropriate: England, Scotland, Northern Ireland, Wales. You should also report directly to manufacturers if your local or national systems do not.

Action by
All healthcare professionals who use these devices

Deadlines for actions
Actions underway: 27 December 2019
Actions complete: 08 December 2020

Medical Device Safety Officers (in England): ask the manufacturer to add you to their distribution list for field safety notices (FSNs). This is to help with reconciliation.

Remember: if your organisation receives an FSN from a manufacturer, always act on it. **Do not wait** for a communication from MHRA.

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

NHS National Services Scotland

Llywodraeth Cymru Welsh Government

Device details

Medicina product code	NHS supply chain code	Product description	Batch number	Date of manufacture	Expiry date
IVS03	FWC346	3ml Luer Slip syringe without needle	19040303	Apr-19	April 2024

The following photographs are included to help identify devices affected by this problem.

Conforming product

Defective product

Manufacturer contacts

Medicina
Tel: 0120 435 7588
Email: quality.administrator@medicina.co.uk

Distribution

This is a targeted MDA sent to trusts supplied with these devices.
Affected trusts will receive this alert via the Central Alerting System (CAS).

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

Trusts (NHS boards in Scotland)

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

- All departments
- All staff
- All wards

Enquiries

England

Send enquiries about this notice to MHRA, quoting reference number **MDA/2019/043** or **2019/008/022/601/002**.

Technical aspects

Emma Rooke and Eliz Mustafa, MHRA

Tel: 020 3080 6000

Email: DSS-TM@mhra.gov.uk

Clinical aspects

Devices Clinical Team, MHRA

Tel: 020 3080 7274

Email: dct@mhra.gov.uk

To report an adverse incident involving a medical device in England use the Yellow Card reporting page

Northern Ireland

Northern Ireland Adverse Incident Centre (NIAIC), CMO Group, Department of Health (Northern Ireland)

Tel: 028 9052 3868

Email: niaic@health-ni.gov.uk

To report an adverse incident involving a medical device in Northern Ireland use the forms on the website.

Alerts in Northern Ireland are distributed via the NICAS system.

Scotland

Incident Reporting and Investigation Centre (IRIC), Health Facilities Scotland, NHS National Services Scotland

Tel: 0131 275 7575

Email: nss.iric@nhs.net

To report an adverse incident involving a medical device in Scotland, email IRIC to request a webform account.

For more information, or if you can't access the webform, visit the website: how to report an adverse incident

Wales

Population Healthcare Division, Welsh Government

Tel: 03000 255278 or 03000 255510

Email: Haz-Aic@gov.wales

To report an adverse incident involving a medical device in Wales, use the Yellow Card reporting page and follow specific advice for reporting in Wales in MDA/2004/054 (Wales).

MHRA is a centre of the Medicines and Healthcare products Regulatory Agency, an executive agency of the Department of Health and Social Care.

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