

Medical Device Alert

Ref: MDA/2014/047 Issued: 17 December 2014 at 15:00

Device
Autopen insulin pen injection devices. Manufacturer: Owen Mumford.

Problem	Action
<p>Risk of hyperglycaemia, which could lead to immediate and long-term deterioration of health.</p> <p>Affected devices may have a mechanical fault which could cause the dose selector to revert to zero resulting in the devices not delivering the correct dose of insulin.</p>	<ul style="list-style-type: none"> • Advise users to stop using affected devices and to seek a replacement pen. Ensure that a suitable alternative device is available to enable them to maintain their insulin regime. • Discontinue supply of all affected devices. • Quarantine and return any remaining stock of affected devices to the manufacturer.
Action by	
<ul style="list-style-type: none"> • Pharmacists • Healthcare professionals • Those involved in purchasing, supplying and using these devices. 	
CAS deadlines	Contact
<p>Action underway: 24 December 2014</p> <p>Action complete: 19 January 2015</p>	<p>Manufacturer Marketed Product Support Team Owen Mumford Ltd Tel: 01993 812 021 Email: technical.support@owenmumford.co.uk</p>

Device

Autopen 24 1 unit pen Product code: AN4210. PIP code 293-5096.



Autopen 24 2 unit pen. Product code: AN4200. PIP code 293-5070.



Autopen Classic 1 unit pen. Product code: AN3810. PIP code 273-3178.



Autopen Classic 2 unit pen. Product code: AN3800. PIP code 260-3561.



To identify affected devices still within their packaging, look for the following packaging lot codes on the outer carton.

Packaging lot code	Product code	Product name
7VJ	AN3810	3ml 1 Unit Autopen Classic
7WB	AN4200	Autopen 24 3ml 2 Unit
7WC	AN4210	Autopen 24 3ml 1 Unit
7WD	AN3800	3ml 2 Unit Autopen Classic
8CN	AN4200	Autopen 24 3ml 2 Unit
8CP	AN4200	Autopen 24 3ml 2 Unit
8CR	AN4210	Autopen 24 3ml 1 Unit
8EL	AN3800	3ml 2 Unit Autopen Classic
8EM	AN3810	3ml 1 Unit Autopen Classic
8JK	AN4210	Autopen 24 3ml 1 Unit
8JM	AN3800	3ml 2 Unit Autopen Classic
8JN	AN3810	3ml 1 Unit Autopen Classic
8JP	AN4210	Autopen 24 3ml 1 Unit
8VV	AN4200	Autopen 24 3ml 2 Unit
8VW	AN4200	Autopen 24 3ml 1 Unit

To identify affected devices without packaging look for the following production lot codes, which can be found on the lower part of the pen body.

Production lot code (stamped on pen)	Product code	Product name
7RT	AN3810	3ml 1 Unit Autopen Classic
7PN	AN4200	Autopen 24 3ml 2 Unit
7PP	AN4210	Autopen 24 3ml 1 Unit
7RV	AN3800	3ml 2 Unit Autopen Classic
8KK	AN3800	3ml 2 Unit Autopen Classic
8XD	AN4200	Autopen 24 3ml 2 Unit

The 3-letter lot code is stamped here



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)
- OFSTED (directors of children's services) 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
- Ambulance services directors
- Ambulance staff
- Chief pharmacists
- Clinical governance leads
- Community children's nurses
- Community diabetes specialist nurses
- Community hospitals
- Community nurses
- Diabetes clinics/outpatients
- Diabetes nurse specialists
- Diabetes, directors of
- Dietetics departments
- Dieticians
- District nurses
- Endocrinology units
- Endocrinology, directors of
- Equipment stores
- Health and safety managers
- Health visitors
- Hospital at home units
- Hospital pharmacies
- Hospital pharmacists
- Outpatient clinics
- Paediatric medicine, directors of
- Paediatric nurse specialists
- Paediatric wards
- Paediatricians
- Paediatrics departments
- Pharmaceutical advisors
- Pharmacists
- Purchasing managers
- Risk managers
- School nurses

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 pharmacists
- General practitioners
- Practice managers
- Practice nurses

Social services

Liaison officers for onward distribution to all relevant staff including:

- Care at home staff
- Care management team managers
- Community care staff
- Day centres (older people, learning disabilities, mental health, physical disabilities, respite care, autistic services)
- In-house residential care homes

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
- 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.

Contacts

Manufacturer

Marketed Product Support Team

Owen Mumford Ltd

Brook Hill,

Woodstock

Oxfordshire

OX20 1TU

Tel: 01993 812 021

Fax: 01993 813 466

Email: technical.support@owenmumford.co.uk

England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2014/047** or **2014/011/027/601/009**.

Technical aspects

Sonal Vara and Bina Mackenzie
Medicines & Healthcare Products Regulatory Agency
Floor 4
151 Buckingham Palace Road
London SW1W 9SZ
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Fax: 020 8754 3965
Email: sonal.vara@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

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.irc@nhs.net

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

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

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