

# Medical Device Alert

## Immediate action

Ref: MDA(NI)2009-021 Issued: 27 March 2009 at 17:00

### Device

Insulin pen needles:  
Labelled as Novo Nordisk Ltd  
Novofine<sup>®</sup> Needles 31G,  
0.25 mm x 6 mm lot number  
08J02S.

The lot number can be found on  
the protective tab for the needle  
and on the carton label.



### Problem

- Counterfeit Novofine needles have been placed on the UK market.
- Affected products bear the lot number 08J02S.
- Use of counterfeit needles could lead to a number of adverse health outcomes, including infection.

### Action

- Do not supply products with lot number 08J02S.
- Advise people who may have been supplied with counterfeit needles not to use affected product and to contact Novo Nordisk for advice.
- Contact Novo Nordisk to discuss disposal and replacement.
- Report any adverse incidents involving counterfeit needles to the MHRA and the manufacturer.

### Action by

- Pharmacists
- Healthcare professionals
- Those involved in purchasing, supplying and using these devices.

### SABS deadlines

Action underway: 01 April 2009  
Action complete: 08 April 2009

### Contact

#### Manufacturer

David Wilkinson  
Head of Safety & Complaints, UK-Ireland  
Novo Nordisk Ltd

Tel: 01293 762 010  
E-mail: [dawi@novonordisk.com](mailto:dawi@novonordisk.com)

## Problem

Counterfeit Novofine needles have been placed on the UK market. There is no assurance that counterfeit needles have been manufactured to the appropriate standards. Possible consequences of the use of counterfeit needles could include adverse reactions to the materials used; pain and discomfort; difficulty in attaching the needle to the pen injection device and infection.

## Action

### Pharmacists supplying these devices:

- Do not supply needles with the lot number 08J02S.
- Quarantine affected needles from your current stock and contact Novo Nordisk for replacements.
- If a patient returns any Novofine needles with lot number 08J02S, supply the patient with a replacement and contact Novo Nordisk for replacement stock.

### Healthcare professionals managing patients who use these devices:

- Do not supply needles with the lot number 08J02S.
- Advise patients to return needles from lot number 08J02S to either their pharmacist or to Novo Nordisk.

## Distribution

The NIAIC has sent this MDA via SABS to:

- HSC Trust, HSS Board, and Agency's Chief Executive's
- HSC Trust, HSS Board, and Agency's SABS Liaison Officer
- Selected members of the DPSSPSNI
- Hospitals in the independent sector
- Hospices

## Onward distribution

Please bring this notice to the attention of all who need to know or be aware of it. This may include distribution by:

### Trusts to:

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

- |                                   |  |
|-----------------------------------|--|
| • A&E departments                 | • Community children's nurses          |
| • All wards                       | • Community diabetes specialist nurses |
| • Clinical governance leads       | • Community hospitals                  |
| • Diabetes clinics/outpatients    | • Community midwives                   |
| • Diabetes nurse specialists      | • Community nurses                     |
| • Diabetes, directors of          | • Community pharmacists                |
| • Diabetics departments           | • District nurses                      |
| • Endocrinology units             | • General practitioners                |
| • Endocrinology, directors of     | • Health visitors                      |
| • Health and safety managers      | • Occupational health departments      |
| • Intensive care units            | • Pharmaceutical advisors              |
| • Medical directors               | • Practice managers                    |
| • Nursing executive directors     | • Practice nurses                      |
| • Occupational health departments | • School nurses                        |
| • Outpatient clinics              |  |
| • Paediatric wards                |  |
| • Pharmacists                     |  |
| • Risk managers                   |  |
| • Supplies managers               |  |

**The Regulation and Quality Improvement Authority (RQIA) to:**

Headquarters for onward distribution to:

- All Nursing and Residential Home providers
- Domiciliary care providers
- Independent treatment centres
- Nursing agencies

**Boards to:**

SABS liaison officers for onward distribution to:

- Risk manager

**Central Services Agency (CSA) to:**

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

- Staff with responsibility for purchasing

## Contacts

### Manufacturer

David Wilkinson  
Head of Safety & Complaints, UK-Ireland  
Novo Nordisk Ltd  
Broadfield Park  
Brighton Road  
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West Sussex  
RH11 9RT

Tel: 01293 762 010

E-mail: [dawi@novonordisk.com](mailto:dawi@novonordisk.com)

### NIAIC

Enquiries in Northern Ireland, please send enquiries about this notice to the NIAIC quoting reference number **MDA(NI)2009-021** and addressed to:

Northern Ireland Adverse Incident Centre (NIAIC)  
Health Estates  
Estate Policy Directorate  
Stoney Road  
Dundonald  
Belfast  
BT16 1US

Tel: 02890 523868

Fax: 02890 523900

E-mail: [NIAIC@dhsspsni.gov.uk](mailto:NIAIC@dhsspsni.gov.uk)

<http://www.dhsspsni.gov.uk/index/hea/niaic.htm>

### How to report adverse incidents

Incidents relating to medical devices in Northern Ireland must be reported to the Northern Ireland Adverse Incident Centre (NIAIC) as soon as possible.

Further information about reporting incidents can be found in DB(NI)2008-001; and downloadable report forms are available from the NIAIC's website (<http://www.dhsspsni.gov.uk/niaic>).

Alternatively, further information and printed incident report forms are available from: NIAIC at the address above.

(An answerphone service operates outside normal office hours)

**Medical Device Alerts are available in full text on the NIAC website**

Further information about SABS can be found at <http://sabs.dhsspsni.gov.uk>

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