

Medical Device Alert

Immediate action

Ref: MDA/2011/013 Issued: 11 February 2011 at 14:00

Device

Alco-Prep[®] alcohol skin preparation pads, swabs and swabsticks manufactured by H&W cv since 2007

Also supplied in drug administration kits and needle exchange packs by :

- Frontier Medical Group
- MSD/(Schering Plough)
- Novartis Pharmaceuticals UK



Problem

Recall due to potential bacterial contamination of swabs which may lead to skin infection. Immunocompromised individuals are at greater risk of serious infection.

This recall is confined to the alcohol swabs and does not affect the medicines or other components of the drug administration kits or needle exchange packs.

Action by

All those who supply and use these affected swabs, drug administration kits and needle exchange packs, in particular:

- pharmacists and needle and syringe programmes
- supplies departments.

CAS deadlines

Action underway: 18 February 2011

Action complete: 04 March 2011

Action

If you supply these swabs, quarantine them and do not supply the affected products.

Recipients of drug administration kits or needle exchange packs, which include affected swabs:

- do not use the affected swabs
- use an alternative product for skin preparation or, if appropriate, alternative means of skin preparation.

Dispose of affected swabs safely and securely.

Contact

Manufacturer/supplier

Frontier Medical Group : Tel: 01495 235811

MSD/(Schering Plough) : Tel: 01992 467272

Novartis Pharmaceuticals : Tel: 01276 698370

Device

All alcohol skin preparation pads, swabs and swabsticks manufactured by H&W cv manufactured since September 2007 and up to and including April 2010, with lot numbers beginning with '7' up to and including those beginning with '0D'. These are indicated on each alcohol pad pouch.

An example lot number is: '9E300', which indicates that it was produced in 2009 (9), May (E) plus a production number (300).

Problem

Triad Group Inc, a sub-contractor of H&W cv, has identified a potential *Bacillus cereus* contamination of these swabs and has therefore initiated a recall of all swab products manufactured since September 2007. H&W cv has issued a [Field Safety Notice](#) (dated 19.01.2011) following up on Triad Group's global recall. This has also been followed up by [Field Safety Notices](#) from the following suppliers, which includes further information on the range of products affected by this action:

- Frontier Medical Group - who supply them separately and as part of their needle exchange packs;
- MSD/(Schering Plough) - who supply them with ViraferonPeg pre-filled pens and IntronA products;
- Novartis Pharmaceutical UK - who supply them with Extavia application kits.

Distribution

This MDA has been sent to:

- NHS trusts in England (Chief Executives)
- Care Quality Commission (CQC) (Headquarters) for information
- Health Protection Agency (HPA) (Directors)
- Health Protection Scotland
- Local Authorities in Scotland
- HSC trusts in Northern Ireland (Chief Executives)
- NHS boards in Scotland (Chief Executives)
- NHS boards and trusts in Wales (Chief Executives)
- Primary care trusts in England (Chief Executives)
- Social services in England (Directors)

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 clinical departments
- All outpatient clinics
- All staff
- All wards
- Chief pharmacists
- Clinical governance leads
- Clinical pathologists
- Dentists
- Dermatologists
- Diabetes clinics/outpatients
- Diabetes nurse specialists
- Diabetes, directors of
- Drug treatment service managers
- Haematologists
- Haemodialysis nurses
- Hospital pharmacies
- Hospital pharmacists
- Infection prevention and control directors
- IV nurse specialists
- Medical directors

- Microbiologists
- Needle and syringe programme co-ordinators
- Nursing executive directors
- Nutrition nurses
- Paramedics
- Patient transport managers
- Peritoneal dialysis units
- Pharmacists
- Phlebotomists
- Point of care testing co-ordinators
- Purchasing managers
- Risk managers
- Staff supporting patients receiving haemodialysis at home
- Supplies managers

Health Protection Agency

Directors for onward distribution to:

- Consultants in communicable disease control
- Health protection nurses

Primary care trusts

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

- Chiropodists
- Commissioners of drug treatment services
- Community children's nurses
- Community diabetes specialist nurses
- Community hospitals
- Community midwives
- Community nurses
- Community pharmacists
- District nurses
- General practitioners
- Health visitors
- Immunisation co-ordinators
- Infection control nurses
- Minor injury units
- Needle and syringe programme co-ordinators
- NHS walk-in centres
- Nutritional nurse specialists
- Occupational health departments
- Palliative care teams
- Pharmaceutical advisors
- Podiatrists
- Practice managers
- Practice nurses
- School nurses
- Walk-in centres

Social services

Liaison officers for onward distribution to all relevant staff including:

- Care at home staff
- Community care staff
- In-house domiciliary care providers (personal care services in the home)
- Occupational health departments

Independent distribution

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

This alert should be read by:

- Care homes providing nursing care (adults)
- Clinics
- Hospices
- Hospitals in the independent sector
- Independent treatment centres
- Nursing agencies
- Private medical practitioners

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/Supplier - all

H&W cv

Torenstraat 20
3384 Glabbeek
Belgium
Tel: +16 77 14 12
Fax: +16 77 12 40
Email: wim.steegmans@h-w.be

Frontier Medical Group

Newbridge Road Industrial Estate
Blackwood
South Wales
NP12 2YN
Tel: 01495 235811
Fax: 01495 235808
Email: info@frontiermedical.eu

MSD/(Schering Plough)

Hertford Road
Hoddesdon
Hertfordshire
EN11 9BU
Tel: 01992 467272
Fax: 01992 468175

Novartis Pharmaceuticals UK Ltd

Frimley Business Park
Camberley
Surrey
GU16 7SR
Tel: Novartis Medical Information: 01276 698370

England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2011/013** or **2011/001/024/081/008**

Technical aspects

Sally Mounter
Medicines & Healthcare products Regulatory Agency
Floor 4
151 Buckingham Palace Road
London SW1W 9SZ
Tel: 020 3080 7168
Fax: 020 8754 3965
Email: sally.mounter@mhra.gsi.gov.uk

Clinical aspects

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Medicines & Healthcare products Regulatory Agency
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151 Buckingham Palace Road
London SW1W 9SZ
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Fax: 020 8754 3965
Email: nicola.lennard@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

Enquiries and adverse incident reports in Scotland should be addressed to:
Incident Reporting and Investigation Centre
Health Facilities Scotland
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:

Dr Sara Hayes

Senior Medical Officer

Medical Device Alerts

Welsh Assembly Government

Cathays Park

Cardiff CF10 3NQ

Tel: 029 2082 3922

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

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