

Medical Device/Equipment ALERT

Ref. MDEA(NI)2008/050

Issued: 3rd July 2008



HEALTH ESTATES

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For:

IMMEDIATE ACTION	
ACTION	✓
UPDATE	
INFORMATION	

	Section			
<p>Medical Device/Equipment: Lancing devices (used in pharmacy settings) – all brands.</p>	▶ ①			
<p>Problem: Risk of transmission of blood borne infections between patients if a lancing device is used for multiple patient testing, contrary to the manufacturer's instructions for use.</p>	▶ ②			
<p>Action by: Pharmacy staff involved in capillary blood sample collection using lancing devices.</p>	▶ ③			
<p>Action: To obtain a capillary blood sample use only:</p> <ul style="list-style-type: none"> • either a disposable, single-use lancing device <p>or</p> <ul style="list-style-type: none"> • a multiple-patient system intended by the manufacturer to be used by healthcare professionals on more than one patient <p>Do not use: lancing devices intended for self-testing by individual patients.</p>	▶ ④			
<p>Distributed by NIAIC to:</p> <table style="width: 100%; border: none;"> <tr> <td style="width: 50%; border: none;"> Chief Executive of each HSS Board Chief Executive of each HSS Trust Chief Executive of each Agency NIAIC Liaison Officers </td> <td style="width: 50%; border: none;"> General Medical Practitioners Community Pharmacists Hospices </td> </tr> </table>	Chief Executive of each HSS Board Chief Executive of each HSS Trust Chief Executive of each Agency NIAIC Liaison Officers	General Medical Practitioners Community Pharmacists Hospices	▶ ⑤	
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<p>Contacts Details of NIAIC contacts for technical and clinical aspects.</p>	▶ ⑥			
<p>Action deadlines for the Safety Alert Broadcast System for HPSS Trusts (SABS)</p>	▶ ⑦			
<table style="width: 100%; border: none;"> <tr> <td style="width: 33%; border: none;"> Acknowledge Receipt of Alert: 7th July 2008 </td> <td style="width: 33%; border: none;"> Action Under Way: 1st August 2008 </td> <td style="width: 33%; border: none;"> Action Complete: 1st September 2008 </td> </tr> </table>	Acknowledge Receipt of Alert: 7 th July 2008	Action Under Way: 1 st August 2008	Action Complete: 1 st September 2008	
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This Alert is on our web site: <http://sabs.dhsspsni.gov.uk>

1. DEVICE/EQUIPMENT:

Lancing devices (used in pharmacy settings) – all brands.

2. PROBLEM:

The MHRA is aware that lancing devices, intended for self-test use by an individual patient, are being used by community pharmacists to obtain capillary blood samples from more than one patient. In these self-test devices, the lancet is single-use and discarded after each use. The firing mechanism and end cap, however, are reusable. This means that the end cap may have residual blood on it which has a significant potential to transmit blood borne infections if it is inappropriately used on more than one patient.

The NIAIC has already issued three Medical Device/Equipment Alerts linking the transmission of hepatitis B to the use of the wrong type of lancing device (MDEA(NI)2004/51, MDEA(NI)2005/84 and MDEA(NI)2006/72). These can be downloaded from the NIAIC website (see www.dhsspsni.gov.uk/niaic).

3. ACTION BY:

Pharmacy staff involved in capillary blood sample collection using lancing devices.

4. ACTION:

Pharmacy staff involved in the management, provision and use of lancing devices for taking capillary blood samples should ensure that appropriate devices are selected and used in accordance with the manufacturer's instructions.

To obtain a capillary blood sample use only

- either a disposable, single-use lancing device (that combines the lancet and the firing mechanism into one unit, both of which are used once and then discarded)
- or
- a multiple-patient system intended by the manufacturer to be used by healthcare professionals on more than one patient (the main body of these systems contains the firing mechanism which is reusable but the systems have a disposable single-use end cap and lancet, both of which are used once and then discarded).
- The NHS Purchasing and Supply Agency Centre for Evidence-based Purchasing published a Buyer's Guide to Lancing Systems (CEP 07025) in November 2007, which can be downloaded from its website (see www.pasa.nhs.uk/cep).

5. ONWARD DISTRIBUTION TO:

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

- Chief pharmacists
- Clinical pathologists
- Clinical pathology directors
- Diabetes nurse specialists
- Diabetes, directors of
- Hospital pharmacies
- Hospital pharmacists
- Infection control nurses
- Infection prevention and control directors
- Pharmacists
- Community diabetes specialist nurses
- Community pharmacists
- General practitioners
- Infection control nurses
- Pharmaceutical advisors
- Practice managers
- Independent Health and Social Care Providers – Private Hospitals and Clinics, Residential and Nursing Homes through RQIA

6. CONTACTS:

Enquiries to NIAIC should quote reference number MDEA(NI)2008/050 and be addressed to:
Northern Ireland Adverse Incident Centre (NIAIC)
Health Estates
Estate Policy Directorate
Stoney Road
Dundonald
Belfast BT16 1US

Tel: 028 9052 3868
Fax: 028 9052 3900
Email: NIAIC@dhsspsni.gov.uk

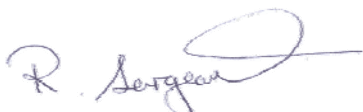
7. FEEDBACK:

Action deadlines for the Safety Alert Broadcast System for HPSS Trusts (SABS)

Acknowledge Receipt of Alert:
7th July 2008

Action Under Way:
1st August 2008

Action Complete:
1st September 2008



Robert Sergeant
NIAIC Operational Manager

HOW TO REPORT ADVERSE INCIDENTS

Adverse Incidents relating to medical devices, non-medical equipment, plant and buildings should be reported to NIAIC as soon as possible. Advice on how to report is given in MDEA(NI)2007/01. If you are in doubt about how to report incidents, please speak to your liaison officer or contact NIAIC using the telephone number provided. Adverse Incident reporting forms and an on-line reporting facility are available on the NIAIC website at www.dhsspsni.gov.uk/niaic

Heath Estates is an Executive Agency of the Department of Health, Social Services and Public Safety