

# Medical Device/Equipment ALERT

Ref. MDEA(NI)2006/79

Issued: 20 December 2006

For:

<b>IMMEDIATE ACTION</b>	✓
ACTION	
UPDATE	
INFORMATION	



**HEALTH ESTATES**

creating healing environments

	Section								
<p><b>Medical Device/Equipment:</b> Counterfeit condoms: Durex fetherlite 3 pack – LOT 21405074 Durex performa 3 pack – LOT TGL4142 Durex gossamer 3 pack – LOT 21405074</p>	▶ ①								
<p><b>Problem:</b> Counterfeit Durex condoms have been placed on the UK market.</p>	▶ ②								
<p><b>Action by:</b> All those involved in condom distribution including:</p> <ul style="list-style-type: none"> <li>• contraception services (family planning)</li> <li>• genitourinary medicine/sexual health clinics.</li> </ul>	▶ ③								
<p><b>Action:</b></p> <ul style="list-style-type: none"> <li>• Identify products bearing any of the above lot numbers and do not supply.</li> </ul>	▶ ④								
<p><b>Distributed by NIAIC to:</b></p> <table style="width: 100%; border: none;"> <tr> <td style="width: 50%;">Chief Executive of each HSS Board</td> <td style="width: 50%;">General Medical Practices</td> </tr> <tr> <td>Chief Executive of each HSS Trust</td> <td>Community Pharmacists</td> </tr> <tr> <td>Chief Executive of each Agency</td> <td></td> </tr> <tr> <td>NIAIC Liaison Officers</td> <td></td> </tr> </table> <p><b>For onward distribution see Section 5</b></p>	Chief Executive of each HSS Board	General Medical Practices	Chief Executive of each HSS Trust	Community Pharmacists	Chief Executive of each Agency		NIAIC Liaison Officers		▶ ⑤
Chief Executive of each HSS Board	General Medical Practices								
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<p><b>Contacts</b> Details of manufacturer contacts and NIAIC contacts for technical aspects.</p>	▶ ⑥								
<p><b>Feedback Requirements to NIAIC</b> See section 7 for further details on feedback requirements for HPSS Trusts</p>	▶ ⑦								

This Alert is on our web site: <http://www.dhsspsni.gov.uk/niaic>

## 1. DEVICE/EQUIPMENT:

Counterfeit condoms:

Durex fetherlite 3 pack – LOT 21405074

Durex performa 3 pack – LOT TGL4142

Durex gossamer 3 pack – LOT 21405074

## 2. PROBLEM:

Counterfeit Durex condoms have been placed on the UK market. There is no assurance that counterfeit condoms have been manufactured to appropriate standards. Possible consequences could include inadequate protection against sexually transmitted infections (STI) or pregnancy, or adverse reactions to manufacturing residues.

### **Durex fetherlite 3 pack - LOT 21405074**

SSL International plc has confirmed that genuine Durex fetherlite 3 pack bearing lot number 21405074 were distributed in the UK between July 2005 and September 2005 and also in April 2006. The manufacturer believes that all genuine Durex fetherlite products will by now have been sold.

### **Durex performa 3 pack - LOT TGL4142**

SSL International plc has confirmed that genuine Durex performa 3 pack bearing lot number TGL4142 were distributed in the UK between January 2005 and April 2005 and also in March 2006. The manufacturer believes that all genuine Durex performa products will by now have been sold.

### **Durex gossamer 3 pack - LOT 21405074**

No genuine Durex gossamer 3 packs bearing lot number 21405074 have been distributed.

## 3. ACTION BY:

All those involved in condom distribution including:

- contraception services (family planning)
- pharmacies
- youth services
- genitourinary medicine/sexual health clinics.

## 4. ACTION:

- Identify products bearing any of the above lot numbers and do not supply.
- Contact Durex Consumer Careline to discuss disposal or replacement.
- Advise people who may have been supplied with counterfeit condoms to contact the Durex Consumer Careline.
- Consider counselling people who may have been supplied with counterfeit condoms about risks of pregnancy and STI transmission.
- Report any adverse incidents involving counterfeit condoms to the NIAIC and the manufacturer.

## 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:

- Liaison Officers
- Risk Managers
- Health & Safety Officers/Advisors
- Clinical Governance Leads
- Medical Directors
- Trust Pharmacy Managers
- Directors of Public Health
- Social Care Staff
- Independent Health and Social Care Providers – Private Clinics, through RQIA

- Clinical Directors
- Nurse Directors
- Obstetricians & Gynaecologists
- Supplies Staff (RSS)
- Family Planning clinics
- GU Medicine Clinics
- Allied Health Professionals
- Prison Healthcare Managers
- Sexual Health Promotion Units

## 6. CONTACTS:

Enquiries to the manufacturer should be addressed to:

Durex Consumer Careline  
 SSL International plc  
 Manchester M41 7HA  
 Tel: 0800 338 739  
 E-mail: [info@durex.co.uk](mailto:info@durex.co.uk)

Enquires to NIAIC should quote reference number MDEA(NI)2006/79 and be addressed to:

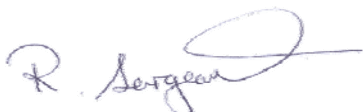
Northern Ireland Adverse Incident Centre (NIAIC)  
 Health Estates  
 Estate Policy Directorate  
 Stoney Road  
 Dundonald  
 Belfast BT16 1US

Tel: 028 9052 3868  
 Fax: 028 9052 3900  
 Email: [NIAIC@dhsspsni.gov.uk](mailto:NIAIC@dhsspsni.gov.uk)

## 7. FEEDBACK:

In accordance with PEL(06)17 the following acknowledgment of assurance should be given by HPSS Trusts **ONLY**:-

- |  |                         |
|--|-------------------------|
| <b>1. Deadline (Email received) :</b>  | <b>22 December 2006</b> |
| <b>2. Deadline (action underway) :</b> | <b>5 January 2007</b>   |
| <b>3. Deadline (action complete):</b>  | <b>26 January 2007</b>  |



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)2006/01. 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](http://www.dhsspsni.gov.uk/niaic)

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