

Medical Device/Equipment ALERT

Ref. MDEA(NI)2007/92

Issued: 30th October 2007

For:

IMMEDIATE ACTION	
ACTION	✓
UPDATE	✓
INFORMATION	



HEALTH ESTATES

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	Section								
Medical Device/Equipment: Counterfeit Durex condoms.	▶ ①								
Problem: Counterfeit Durex condoms have been placed on the UK market.	▶ ②								
Action by: All those involved in condom distribution including: <ul style="list-style-type: none"> • pharmacies • contraception services (family planning) • youth services • genitourinary medicine/sexual health clinics. 	▶ ③								
Action: – See section (4) on page 2 for full list of actions in relation to this Alert.	▶ ④								
Distributed by NIAIC to: <table style="width: 100%; border: none;"> <tr> <td style="width: 50%;">Chief Executive of each HSS Board</td> <td style="width: 50%;">General Medical Practitioners</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> For onward distribution see Section 5	Chief Executive of each HSS Board	General Medical Practitioners	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 Practitioners								
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Contacts Details of manufacturer contacts and NIAIC contacts for technical aspects.	▶ ⑥								
Feedback Requirements to NIAIC None Required.	▶ ⑦								

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

1. DEVICE/EQUIPMENT:

Product name on counterfeit packs	Lot number printed on counterfeit packs	Previously available as genuine product?	Previous NIAIC advice
Durex extra safe 3 pack	20604354	Yes	MDEA(NI)2006-68
Durex ribbed 3 pack	20905271	Yes	No previous NIAIC advice
Durex ribbed 3 pack	20904142	Yes	No previous NIAIC advice
Durex ribbed 3 pack	299118	No	No previous NIAIC advice
Durex performa 3 pack	TGL4142	Yes	MDEA(NI)2006/79
Durex select 3 pack	P4379	Yes	No previous NIAIC advice
Durex fetherlite 3 pack	21405074	Yes	MDEA(NI)2006/79
Durex arouser 3 pack	20906043	No	No previous NIAIC advice
Durex gossamer 3 pack	21405074	No	MDEA(NI)2006/79

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.

SSL International plc believes that all previously available genuine Durex products bearing the above lot numbers will by now have been sold as they were distributed before November 2006.

Advice to GPs:

This Medical Device Alert is being sent to GPs for information only, in circumstances where patients may seek advice about the contents of this Notice. GPs need take no further action on receipt of this Alert.

3. ACTION BY:

All those involved in condom distribution including:

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

4. ACTION:

- **Suppliers and retailers should:**
 - identify affected products and do not supply.
 - contact Durex Consumer Careline (0800 338 739) to discuss disposal or replacement.
- **Healthcare professionals should:**
 - advise people who may have been supplied with counterfeit condoms to contact the Durex Consumer Careline (0800 338 739).
 - consider counselling targeted groups such as those with HIV infection.
 - report any adverse incidents involving counterfeit condoms to the NIAIC and the manufacturer.
- **Users should:**
 - inform their local Trading Standards office if they believe that they have purchased counterfeit condoms
 - 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
- Clinical Directors
- Nurse Directors
- Obstetricians & Gynaecologists
- Supplies Staff (RSS)
- Family Planning clinics
- GU Medicine Clinics
- Trust Pharmacy Managers
- Directors of Public Health
- Social Care Staff
- Independent Health and Social Care Providers – Private Clinics, through RQIA
- 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

Enquiries to NIAIC should quote reference number MDEA(NI)2007/092 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:

None Required.



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

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