

# Medical Device/Equipment ALERT

Ref. MDEA(NI)2006/68

Issued: 31 October 2006

For:

IMMEDIATE ACTION	
ACTION	✓
UPDATE	
INFORMATION	



**HEALTH ESTATES**

creating healing environments

	Section
<b>Medical Device/Equipment:</b> Counterfeit condoms Durex extra safe 3 pack – LOT 20604354	▶ ①
<b>Problem:</b> Counterfeit Durex condoms have been placed on the UK market.	▶ ②
<b>Action by:</b> All those involved in condom distribution including: <ul style="list-style-type: none"> <li>• contraception services (family planning)</li> <li>• pharmacies</li> <li>• youth services</li> <li>• genitourinary medicine/sexual health clinics.</li> </ul>	▶ ③
<b>Action:</b> <ul style="list-style-type: none"> <li>• Identify affected products and if found do not supply.</li> <li>• Contact Durex Consumer Careline to discuss disposal or replacement.</li> <li>• Advise people who may have been supplied with counterfeit condoms to contact the Durex Consumer Careline.</li> <li>• Report any adverse incidents involving counterfeit condoms to NIAIC and the manufacturer.</li> </ul>	▶ ④
<b>Distributed by NIAIC to:</b> Chief Executive of each HSS Board                      General Medical Practices Chief Executive of each HSS Trust Chief Executive of each Agency NIAIC Liaison Officers <b>For onward distribution see Section 5</b>	▶ ⑤
<b>Contacts</b> Details of manufacturer/supplier contacts and NIAIC contacts.	▶ ⑥
<b>Feedback Requirements to NIAIC</b> None required	▶ ⑦

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

## 1. DEVICE/EQUIPMENT:

Counterfeit condoms

Durex extra safe 3 pack – LOT 20604354.

***Genuine Durex products bearing any other lot numbers are not affected by this alert.***

## 2. PROBLEM:

Counterfeit Durex condoms have been placed on the UK market. The company have to date only found sources of the counterfeit product in the Greater London area with no reports from other areas at present.

Counterfeit condoms may not be manufactured to appropriate standards and may not provide adequate protection against sexually transmitted infections or pregnancy.

SSL International plc, the manufacturer of Durex condoms, has confirmed that genuine products bearing this lot number were distributed in the UK between March and May 2005. The manufacturer believes that all genuine products will now have been sold.

**SSL International plc has distributed an advisory letter to their customers (see appendix) and has placed advertisements in the national press.**

## 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 affected products and if found 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.
- Report any adverse incidents involving counterfeit condoms to the MHRA 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:

Enquires to the manufacturer should be address 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)2006/68 and be addressed to:

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

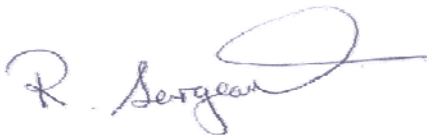
Tel: 028 9052 3868

Fax: 028 9052 3900

Email: [NIAIC@dhsspsni.gov.uk](mailto:NIAIC@dhsspsni.gov.uk)

## 7. FEEDBACK:

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

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

Dear Customer,

### Counterfeit Durex extra safe



It has been brought to our attention that a quantity of counterfeit condoms in fake Durex packaging has been supplied to some retail outlets in the UK.

As a result we are working proactively with the Medicines and Healthcare products Regulatory Agency (MHRA) to notify retailers of these fake products and provide clear instructions on what you should do if you come across them.

The fakes are:

- Durex extra safe three-packs displaying the code 20604354 on the base of the box, on the right hand side (see above).

You must check your stock of extra safe packs of three. If you have any of batch number 20604354 then you should contact our Customer Care department on the below telephone number who will arrange replacement of authentic product free of charge. We will not provide refunds for any counterfeit products.

If a consumer wants to return Durex extra safe condoms to you, we recommend the following course of action:

- Check the bottom of the box (only a small amount of packs of three are currently affected). If the pack does not carry the code 20604354, reassure the customer this product is genuine and can be used as normal.
- If the above code features on the pack, tell the consumer to contact the Durex careline on the below telephone number. They will arrange for the return of the product and will replace it free of charge.

These are illegal copies of a genuine batch of Durex extra safe condoms which we distributed more than a year ago. The last of the genuine batch was sold by us in May 2005, so any packs carrying the number 20604354 still in circulation are almost certainly counterfeit.

As the world's leading condom brand Durex has a reputation for being a trusted, reliable and safe method of barrier protection. We are completely committed to quality and maintaining the health and safety of our customers,

## Appendix to MDEA(NI)2006/68

and are working closely with MHRA to ensure people are made aware of this counterfeit product.

Durex has taken a proactive stance by placing information notices in UK newspapers to raise awareness of the issue to consumers and retailers. We have also issued a press release.

Should you have any queries please do not hesitate to contact the following carelines:

### Trade Enquiries

Contact SSL UK Customer Care Department on 0870 1222689

### **Consumer Enquiries**

Contact the Durex Careline on 0800 338 739

Yours sincerely,

Martyn Ward  
UK Managing Director  
Durex