Health and Healthcare Improvement Directorate Pharmacy and Medicines Division

The Scottish Government

T: 0131-244 2528 0131-244 2375 E: irene.fazakerley@scotland.gsi.gov.uk 2 November 2011

IMMEDIATE MESSAGE TO:

- 1. Directors of Pharmacy
- 2. Chief Pharmacists NHS Boards
- 3. Hospital Pharmacy Managers
- 4. Medical Directors NHS Boards
- 5. Chief Executives NHS Boards

Dear Healthcare Professional,

DRUG ALERT NO 26 - CLASS 2 ACTION WITHIN 48 HOURS

Please see the attached drug alert for onward transmission as below. Please could all Directors of Pharmacy forward this alert to:-

- CommunityPharmacists
- Hospital Pharmacists
- Chief Pharmacists to forward on to Medicines Information Pharmacists
- 1. Please could Medical Directors forward this alert to:-
 - Accident & Emergency Departments
 - Dental Practitioners
 - General Practitoners
 - Directors of Public Health
 - Relevant Clinics
 - Chief Executives of NHS Board

Thank you for your co-operation.

Yours sincerely

IRENE FAZAKERLEY Pharmacy and Medicines Division



Safeguarding public health Defective Medicines Report Centre 151 Buckingham Palace Road London SW1W 9SZ Telephone +44 (0)20 3080 6574



DRUG ALERT

CLASS 2 MEDICINES RECALL

Action Within 48 Hours

PATIENT AND PHARMACY OR EQUIVALENT LEVEL RECALL

Date: 02 November 2011

EL (11)A/26

Our Ref: MDR 68-10/11

Dear Healthcare Professional,

GABA GMBH (Distributor Colgate-Palmolive (UK) Ltd)

Colgate Periogard 0.2% Oromucosal SolutionPL 3137/0001(Chlorhexidine Digluconate)			
Batch Number	Expiry Date	Pack Size	First Distributed
9196CHG11B	Jan 2012	300ml	Aug 2009
9197CHG11B	Jan 2012	300ml	Sep 2009
9198CHG11B	Jan 2012	300ml	Aug 2009
0103CHG12B	Oct 2012	300ml	Apr 2010
0103CHG11B	Oct 2012	300ml	May 2010
0104CHG11B	Oct 2012	300ml	Apr 2010
0155CHG11B	Dec 2012	300ml	Jul 2010
0158CHG11B	Dec 2012	300ml	Jul 2010
0158CHG12B	Dec 2012	300ml	Jul 2010
0250CHG11B	Jan 2013	300ml	Sep 2010
1068CHG11B	Aug 2013	300ml	Mar 2011
1069CHG11B	Aug 2013	300ml	Mar 2011
1236CHG11B	Jan 2014	300ml	Oct 2011
1237CHG11B	Jan 2014	300ml	Oct 2011

MHRA Distribution:

Regional Contacts for NHS Trusts and Provider Units Chief Pharmacists: England, Scotland, Wales, Northern Ireland Prison Health Policy Unit (DH) Chief Pharmacists: Jersey, Guernsey, Alderney, Sark, Isle of Man, Gibraltar Special Hospitals Healthcare Commission for distribution to Independent Health Care Establishments Primary Care Trusts (England)

Medicines and Healthcare products Regulatory Agency (MHRA) 151 Buckingham Palace Road London SW1W 9SZ UK T 020 3080 6000 www.mhra.gov.uk

An executive agency of the Department of Health



Date: 02 November 2011

EL (11)A/26

MDR 68-10/11

Colgate-Palmolive (UK) Ltd is recalling the above batches because microbial contamination with a Burkholderia species has been detected in some batches. All unexpired batches are being recalled as a precaution.

There have been no reports of illness associated with this issue. However, Burkholderia species can cause infection in individuals with a compromised immune system, or those with chronic lung conditions such as cystic fibrosis. There is little medical risk to healthy individuals.

Consumers are asked to contact Colgate-Palmolive (UK) Ltd on 00 800 321 321 32 for details on how to return product. Pharmacists are asked to quarantine all unexpired stock of the product and return it to their original wholesaler

For medical information enquiries, please call Colgate-Palmolive (UK) Ltd on 01483 464513

For queries relating to stock return please contact your wholesaler. If further information is required, please contact 00 800 321 321 32.

As this product is a GSL medicine, Colgate-Palmolive (UK) Ltd, in consultation with the Agency, has expanded the scope of this recall to include patient level notification. This notification will be supported by press notifications by the marketing authorisation holder and the MHRA.

Recipients of this Drug Alert should bring it to the attention of relevant contacts by copy of this letter. Primary Care Trusts are asked to forward this to relevant clinics, General Practitioners, Dental Practitioners and Community Pharmacists.

Yours faithfully

Alison Bunce Pharmaceutical Assessor, DMRC