



Department of
**Health, Social Services
and Public Safety**

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AN ROINN

**Sláinte, Seirbhísí Sóisialta
agus Sábháilteachta Poiblí**

MÄNNYSTRIE O

**Poustie, Resydènter Heisin
an Fowk Siccar**

From The Chief Pharmaceutical Officer
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For Action: Assistant Director Pharmacy and Medicines Management
HSC Board & BSO
Heads of Pharmacy and Medicines Management of HSC Trusts
Regional Quality Improvement Authority

Our Ref: PHC/13/11

Date: 31 March 2011

DRUG ALERT MEDICINES RECALL

Dear Healthcare Professional

GlaxoSmithKline Consumer Healthcare

Otomize Ear Spray PL 0036/0042 (the marketing authorisation holder is Stafford Miller)
Dexamethasone 0.1%, Neomycin Sulphate 3250 units/ml, Glacial Acetic Acid 2%

Pack Size	Batch Number	Expiry Date	First Distributed
5ml bottle	P1B07/1	Aug-12	Mar 7 2011

GlaxoSmithKline Consumer Healthcare has advised us that a small number of individual cartons of the above batch are lacking an embossed batch number and expiry date. Bottles inside the cartons are all fully coded. Please note different actions are requested for wholesalers and Pharmacy/Clinic recipients as described below.

The batch cited above was distributed following an out-of-stock situation. We understand that there is likely to be a small amount remaining in the supply chain. GlaxoSmithKline have informed us that they have two batches of replacement stock available and in circulation and no further shortages are envisaged.

Pharmacists and Clinics are requested to inspect their stock and **return any uncoded cartons** to their original supplier (wholesaler) for credit.

Wholesalers actions are described on the following page.

Wholesalers are expected to have traded units (12 x 5ml unit cartons) and some individual packs (where traded units have been opened). Traded packs are all correctly coded on the outside but those coded P1B07/1 could contain uncoded individual cartons inside. Wholesalers are requested to **return:**

- 1. all traded packs bearing the above batch number (P1B07/1) and**
- 2. all individual cartons they hold irrespective of coding and batch number and**
- 3. any uncoded individual cartons returned from Pharmacies.**

For information, the batch numbers of acceptable replacement stock in circulation are P1B14/1 and P1B21/1. There is no requirement to return traded units of these batches.

Wholesalers will need to ensure all their staff are aware when this action has been completed and when new (and unaffected) batches are received.

We expect that the number of individual cartons at wholesalers will be very low. These could include the problem batch listed above plus acceptable cartons of the replacement batches. The requested action – to return all individual cartons at wholesalers irrespective of coding and batch number has been decided as the quickest and lowest-risk option which will minimise their workload. Traded packs of unaffected batches (including P1B14/1 and P1B21/1) should not be returned.

For enquiries relating to stock returns please call GlaxoSmithKline on 01452 376307.

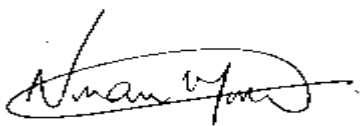
For medical information enquiries please call GlaxoSmithKline on 020 8047 2500.

Recipients of this Drug Alert are requested to bring it to the attention of relevant professionals

HSC Board/RQIA should bring this information to the attention of private hospitals/clinics registered with them and any other relevant care facilities.

The Business Services Organisation is asked to bring this information to the attention of Community Pharmacists and General Medical Practitioners directly.

Yours sincerely



DR NORMAN MORROW
Chief Pharmaceutical Officer

For information:
CMO
CNO
CDO
CSSO
SMO
Director, Health Estates
Public Health Branch
DHSSPS, Library
Extended nurse prescribers

Regional Medicines and Poisons Information Service
Regional Director of Supplies
RPQAS
Pharmaceutical Society of NI
Senior Prison Pharmacist
Prison Service, Dundonald House
Nursing Officer, Health Estates
Medical Officer, Castle Buildings
Regional Procurement Pharmacist
NICPLD