



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:** Pharmaceutical Leads HSC Board & BSO  
Directors of Pharmaceutical Services of HSC Trusts  
Regional Quality Improvement Authority

Our reference: PHC/14/09  
Date: 12 May 2009

## **DRUG ALERT**

### **MEDICINES RECALL**

**Allen and Hanburys  
Seretide 250 Evohaler**

**25 micrograms of salmeterol xinafoate and 250 micrograms of fluticasone propionate per actuation  
PL 10949/0339**

<b>Batch Number</b>	<b>Expiry Date</b>	<b>Pack Size</b>	<b>First Distributed</b>
1183R	06/2009	8 ml pressurised inhalers	9/10/2008

GlaxoSmithKline UK (GSK) and MHRA are recalling all remaining stock of the above batch due to the **possible** presence of counterfeit inhalers in the legitimate supply chain. Glaxo Wellcome UK Ltd is the marketing authorisation holder but this product is branded as an Allen and Hanburys item.

Analytical testing of counterfeits, with this batch number, has indicated that some parts of the counterfeit product are genuine. Performance tests have demonstrated that there **could** be a reduced patient dose if patients have obtained and used a counterfeit inhaler.

MHRA and GSK advice is that this batch should be recalled from pharmacy and wholesaler level as a precautionary measure.

GSK delivers its UK prescription medicines directly to points of dispensing. If dispensing customers have purchased Seretide Evohalers directly from GSK UK via their appointed Logistics Service Providers (Alliance Healthcare and AAH Pharmaceuticals) they can be confident that they have purchased an authentic product.

We understand that the vast majority of genuine inhalers from this batch were probably distributed and supplied several months ago. In order to optimise patient protection, recipients of this alert are requested to quarantine **any** remaining stocks of this batch, **irrespective of where purchased** and telephone GSK Customer Contact Centre on 0800 221441 for advice on return and credit.

For any Medical Information enquiries related to this case please call GSK on the above number.

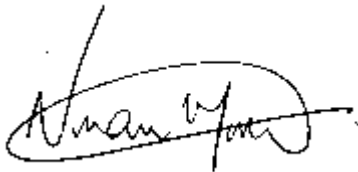
Healthcare Professionals or members of the public can report any safety concerns related to these products to the MHRA Yellow Card scheme. Details for online reporting are provided at <http://yellowcard.mhra.gov.uk/>. Telephone contact can be made (office hours only) on 0808 100 3352.

We understand that the quoted batch number (1183R) has only been distributed as an originator product to the UK market. If any parallel traders, importers or exporters have concerns about recent transactions with this, or any similar products, they are requested to call the DMRC on 0207 084 2574.

HSC Board/RQIA should bring this information to the attention of private hospitals/clinics registered with them, Out of Hours Centres 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  
CISSI  
SMO  
Director, Health Estates  
Public Health Branch  
DHSSPS, Library  
Extended nurse prescribers

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