

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 12 – CLASS 2

Please find attached drug safety information from the Medicines and Healthcare Products Regulatory Agency (MHRA) for onward transmission (see list below).

1. Please could Directors of Pharmacy forward this alert to:-
 - Hospital pharmacists
 - Chief Pharmacists to forward on to Medicines Information Pharmacists
 - Community pharmacists
2. Please could Medical Directors forward the message on to :-
 - General Practitioners
 - Dispensing Doctors
 - Chief Executives NHS Boards

Thank you for your co-operation.

Yours sincerely

IRENE FAZAKERLEY
Pharmacy Division

* NB: Drug alerts have the following classifications:

1. Action now (including out-of-hours); 2. Action within 48 hours; 3. Action within 5 days; 4 Caution in use

Safeguarding public health
Defective Medicines Report Centre
Market Towers
1 Nine Elms Lane
London
SW8 5NQ
Telephone: +44 (0)20 7084 2574

Fax: +44 (0)20 7084 2676

DRUG ALERT

CLASS 2 MEDICINES RECALL

Action Within 48 Hours

PHARMACY AND WHOLESALE LEVEL RECALL

Date: 12 May 2009

EL (09)A/12

Our Ref: MDR 69-04/09

Dear Healthcare Professional,

Allen and Hanburys

Seretide 250 Evohaler

PL 10949/0339

**25 micrograms of salmeterol xinafoate and 250
micrograms of fluticasone propionate per actuation**

| Batch Number | Expiry Date | Pack Size | First Distributed |
|---------------------|--------------------|---------------------------|--------------------------|
| 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 are 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

Contd/....

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

Market Towers 1 Nine Elms Lane London SW8 5NQ

T 020 7084 2000 F 020 7084 2353 www.mhra.gov.uk

An executive agency of the Department of Health

Date: 12 May 2009

EL (09)A/12

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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.

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

Yours faithfully

Ian Holloway
MHRA DMRC Manager