



From The Chief Pharmaceutical Officer
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For Action: Directors of Pharmaceutical Services of the HSC Board & BSO
Directors of Pharmaceutical Services of HSC Trusts
Regional Quality Improvement Authority

Our reference: PHC/12/09
Date: 6 April 2009

DRUG ALERT MEDICINES RECALL

Dear Healthcare Professional

GlaxoSmithKline UK

Engerix B 1.0ml Pre-filled Syringes

Hepatitis B surface antigen 20 micrograms/ml

PL 10592/0166

Batch number	Expiry date	Pack size	First distributed
AHBVB591BB	28/02/2011	10 syringes per carton	9/03/2009

GlaxoSmithKline UK (GSK) are recalling all remaining stock of the above batch due to exposure to unacceptably low temperatures during distribution which may render the vaccine ineffective.

Healthcare Professionals are requested to contact all known patients and recall them for revaccination. GSK have informed us that they are not aware of any safety concerns, apart from a possible lack of efficacy, with the affected batch or from revaccination.

All unused stock of the above batch should be quarantined and returned for credit. GSK plan to contact all customers and make arrangements for collection and replacement stocks. We understand there are adequate stocks of replacement syringes available.

Although there are no expected safety concerns from the affected batch or revaccination, any adverse events should be reported to GSK Safety Department on 0800 221 441.

For any general enquiries recipients are requested to contact GSK Customer Contact Centre on 0808 100 9997.

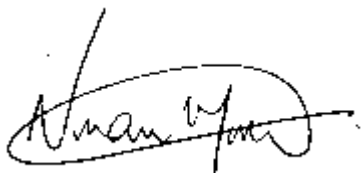
The marketing authorisation for this product is held by SmithKline Beecham plc but the package livery and contact information is GSK throughout.

Recipients of this Drug Alert should bring this to the attention of relevant contacts by copy of this letter.

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

A handwritten signature in black ink, appearing to read 'Norman Morrow', enclosed within a large, loopy oval shape.

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
NICPPET