



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

www.dhsspsni.gov.uk

From The Chief Pharmaceutical Officer
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Our Ref: PHC/26/2011

Date: 24 October 2011

For Action: Assistant Director Pharmacy and Medicines Management,
HSC Board & BSO
Heads of Pharmacy and Medicines Management of
HSC Trusts
Regulation Quality Improvement Authority

DRUG ALERT MEDICINES RECALL

For immediate action

**Recall to general practitioner, clinic, hospital, community pharmacy and wholesaler level.
This information is relevant to influenza vaccinations**

Baxter Healthcare

Preflucel Vaccine

Split virion inactivated trivalent vaccine

PL 0016/0654

Batch number	Expiry date	Pack size	First distributed
VNV5L010C	31/07/2012	Single units	8 September 2011
VNV5L010A	31/07/2012	Single units	8 September 2011

This updated Drug Alert, PHC/26/2011 replaces the original alert issued on 21 October 2011, PHC/25/2011.

Baxter Healthcare has informed us that an additional affected batch with the batch number VNV5L010A has been identified in Northern Ireland only.

Baxter Healthcare is recalling all remaining stock of the above batches. The action is being taken as a precautionary measure because of a higher than expected frequency of reports of adverse reactions following administration of these batches.

The vaccine should no longer be used and any remaining stock should be returned to the original supplier for credit. **No further Preflucel of any batch should be administered at this time.**

Additional information is available as questions and answers in the attached appendix.

For medical information enquiries please contact Baxter Healthcare on 01635 206123.

For stock return enquiries please contact your original distributor.

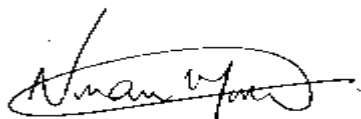
Suspected adverse reactions should be reported to the MHRA by use of a Yellow Card, which is available from MHRA, Freepost Yellow Card or electronically via <http://www.mhra.gov.uk/yellowcard>

Recipients of this drug alert are requested to forward this to recipients listed in the central title at the start of the document as promptly as possible.

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

Questions and answers

1. Can you provide more information about the adverse reactions?

The reports of reactions following use of these batches of vaccine have been mainly from other countries and have mostly been mild and short-lived. They are of the types usually associated with influenza vaccines. However, they have been reported more frequently with the implicated batches than with other batches. The cause is not known and is the subject of investigations by the manufacturer and regulatory authorities.

2. I have egg allergic patients who need vaccination – can I use alternative vaccines?

Yes. Any at risk patient who has an egg allergy should seek medical advice from their GP before receiving a replacement low-egg content product. Low egg-content flu vaccines are available and can be given safely to those with egg allergy, even severe egg allergy, as long as guidance is followed. Such patients should be referred to specialists for vaccination in hospital using vaccine with an ovalbumin content less than 0.12 mg/ml (ie containing less than 0.06mg per 0.5ml dose). A split dose schedule may be required at the discretion of the supervising physician. Further guidance is available in the influenza chapter of the [DH Green Book](#) (external link)

3. Will there be any shortages caused by the recall?

Adequate amounts of alternative products are available and no supply problems are foreseen.

4. Are there any concerns about the level of protection for patients who have been vaccinated?

No. There is no suggestion that the level is compromised or any revaccination is needed.

5. When will further batches of Preflucel be available for use?

This is not currently known. One further batch (VNV5L012C) is held in the supply chain. This has been quarantined pending investigations and no further Preflucel of any batch should be administered at this time.