

To: General Practitioners  
NHS Trusts – Medical Director  
NHS Foundation Trusts – Medical Director  
PCT Medical Directors  
PCT Immunisation Co-ordinators  
SHA Immunisation Leads  
SHA Flu Leads  
Chief Pharmacists/Pharmaceutical Advisers of PCTs  
Practice Nurses  
All Pharmacists

cc: SHA Directors of Public Health  
Consultants in Communicable Disease Control  
Accident and Emergency Departments  
Regional Directors of Public Health  
Royal College of Paediatrics and Child Health  
Royal College of Physicians  
Royal College of General Practitioners

Gateway reference number: 16791

21 October 2011

Dear Colleague

### **VOLUNTARY RECALL – PREFLUCEL® INFLUENZA VACCINE**

Baxter Healthcare Ltd has today begun a voluntary recall of one specific batch of the influenza vaccine, Preflucel®. This a precautionary measure taken because of a higher than expected frequency of reports of adverse reactions following use of vaccine from this particular batch.

All Preflucel® that has been supplied so far in the UK comes from the implicated batch with the batch number: VNV5L010C. The company is writing to its distributors (TPS and MASTA) with details about the recall, who will in turn communicate with their customers. This vaccine should no longer be used and all stocks should be returned via the distributors to the manufacturer.

All return and re-supply questions should be directed to the distributors. Any medically related questions about the recall should be directed to Baxter on 01635 206123.

The reports of reactions following use of this batch of vaccine have been mainly from other countries and have mostly been mild and of the types usually associated with influenza vaccines. However, they have been reported more frequently with the implicated batch than with other batches. The cause is not known and is being investigated by the manufacturer and regulatory authorities.

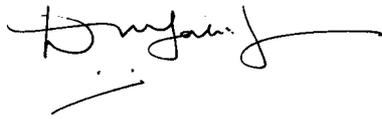
As this vaccine accounts for a very small proportion of the total UK supply of influenza vaccine, this recall will not significantly affect the availability of influenza vaccine.

Whilst it is the only egg-free vaccine available, low-egg content influenza vaccines are available that can be used safely in those with severe egg allergy as described in guidance already available in the influenza chapter of the Green Book. The Green Book chapter will shortly be updated to take account of the recall. The chapter is at: [http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_079917](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_079917)

As patients may ask questions about the recall, some questions and answers have been provided (Annex A).

Please report any suspected adverse reactions associated with this vaccine via the Yellow Card Scheme ([www.yellowcard.gov.uk](http://www.yellowcard.gov.uk)).

Yours sincerely

A handwritten signature in black ink, appearing to read 'D M Salisbury', with a horizontal line underneath.

**Professor D M SALISBURY CB FRCP FRCPCH FFPHM**  
**Director of Immunisation**

## **ANNEX A**

### **Should I be concerned if I've already received Preflucel?**

No. Most of the side effects are those usually associated with flu vaccines, have started shortly after the vaccination and have been mild and short-lived. However, for this particular batch of vaccine they have occurred more frequently than expected.

### **Why wasn't this picked up earlier?**

The safety of Preflucel® has been tested in clinical trials. The implicated batch passed all the quality checks in place before it was released. However, following a higher than expected number of reports of side effects when this batch of vaccine has been used, the manufacturer voluntarily instigated a recall of the batch. The cause is being investigated by the manufacturer and regulatory authorities.

### **What about the safety of alternative vaccines? What if I'm allergic to eggs?**

Alternative flu vaccines are available for which there are no safety concerns.

Low egg-content flu vaccines are available and can be given safely to those with egg allergy, even severe egg allergy, following guidance in the influenza chapter of the Green Book:

[http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_079917](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_079917)

Egg allergy is relatively rare with prevalence estimated at 2% in children and 0.1% in adults. It is most commonly first noticed in infancy following the ingestion of egg-containing foods. Severe reactions involving narrowing of the airway are uncommon.

Egg allergy should not prevent flu vaccination.