Patient Group Directions
for the Administration of

Trivalent Seasonal Influenza Vaccine
to Adults
in Community Pharmacy

Issue Date: October 2011
To be reviewed: September 2012

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Patient Group Directions for the Administration of Trivalent Seasonal Influenza Vaccine to Adults in Community Pharmacy

Patient Group Directions (PGDs) are written instructions for the supply or administration of medicines to groups of patients who may not be individually identified before presentation for treatment.

<table>
<thead>
<tr>
<th>Date this PGD comes into effect:</th>
<th>1 November 2011</th>
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<tbody>
<tr>
<td>Expiry Date:</td>
<td>31 January 2012</td>
</tr>
<tr>
<td>For the administration of:</td>
<td>Trivalent seasonal influenza vaccine</td>
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**Class of health professional who may administer:**

**Rationale:**

To enable a pharmacist who has adequate knowledge of immunisations (Appendix 1) and is competent to administer immunisations in accordance with the following patient group directions. In line with: the GPhC standards of conduct, ethics and performance; the Review of Prescribing, Supply and Administration of Medicines (DH, 1998); the Health Service Circular 2000/026 (NHSE, 2000); and the amendments to the Medicines Act 1968 (2000).

**Staff authorised to administer vaccines under this direction:**

- Pharmacist with valid registration with the General Pharmaceutical Council (GPhC)

**Additional requirements:**

- Adequate training and competence in all aspects of immunisation as detailed in Appendix 1
- Responsibility for maintaining and updating professional knowledge as appropriate.
- Access to most recent edition of “Immunisation against Infectious Disease” and any updates; also access to latest issue of the BNF and CMO updates.
- Competence to recognise and treat anaphylaxis
  Immediate access to adrenaline 1:1000 injection, syringes and needles. Anaphylactic reactions to influenza vaccine are rare but can be fatal. **Adrenaline 1 in 1000 injection when administered for the purpose of saving a life in an emergency is exempt from the prescription only medicine requirement.** A PGD for adrenaline is therefore not required but pharmacists should have a protocol for the management of anaphylaxis in line with the recommendations from the Resuscitation Council (UK) available at: [http://www.resus.org.uk/](http://www.resus.org.uk/). See also Immunisation against Infectious Disease updated Chapter 8.
- Immediate access to a communication link whereby assistance could be summoned

**Note:** Pharmacists working under PGDs may not delegate administration to another health care professional or a dispensing assistant.
Reference to national / local policies or guidelines


For guidance on good practice in vaccine administration, consult:

Patient Group Directions for the Administration of Trivalent Seasonal Influenza Vaccine to Adults in Community Pharmacy

PGD Development and Approval

<table>
<thead>
<tr>
<th>Developed by:</th>
<th>Signature</th>
<th>Date</th>
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<tbody>
<tr>
<td><strong>Lead Doctor</strong></td>
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<tr>
<td>Dr Fiona Day</td>
<td>Day</td>
<td>5/10/11</td>
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<tr>
<td>Consultant in Public Health</td>
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<td>Medicine</td>
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<td>NHS Sheffield</td>
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<td><strong>Lead Pharmacist</strong></td>
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<td>Hilde Storkes</td>
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<td>Medicines Governance Pharmacist</td>
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<td>NHS Sheffield</td>
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<td><strong>Community Pharmacist</strong></td>
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<tr>
<td>Representative</td>
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<tr>
<td>Ravi Mohan</td>
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<td>Sheffield LPC Chair</td>
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<tr>
<td><strong>Reviewed &amp; Authorised on behalf of NHS Sheffield by:</strong></td>
<td>Signature</td>
<td>Date:</td>
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<tr>
<td>Dr Richard Oliver</td>
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<tr>
<td>Joint Clinical Director</td>
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<td>NHS Sheffield</td>
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<td><strong>Review date:</strong></td>
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<tr>
<td>September 2012</td>
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# PATIENT GROUP DIRECTION

**PATIENT GROUP DIRECTION** for the administration of **Trivalent Seasonal Influenza Vaccine**

## 1. Clinical conditions or situation to which the direction applies

<table>
<thead>
<tr>
<th>Indication</th>
<th>For the prevention of seasonal influenza</th>
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</table>
| **Criteria for inclusion** | ➢ All patients aged 18 years to under 65 years in a clinical risk group. This includes patients suffering from:  
• Chronic respiratory disease, including asthma requiring continuous or repeated use of inhaled or systemic steroids or with previous exacerbation requiring hospital admission.  
• Chronic heart disease.  
• Chronic renal disease.  
• Chronic liver disease.  
• Chronic neurological disease e.g. stroke/TIA.  
• Diabetes requiring insulin or oral hypoglycaemic drugs or diet controlled.  
• Immunosuppression due to disease or treatment, including asplenia or splenic dysfunction. These patients may show a reduced antibody response but vaccination is recommended  
➢ All patients aged 18 years to under 65 years who are pregnant. The vaccine may be administered at any stage of pregnancy.  
Valid consent should be obtained and the NHS Sheffield checklist/consent form completed and signed by the patient. |
| **Criteria for exclusion** | ➢ Lack of valid consent  
➢ Acute febrile illness or systemic upset.  
➢ Known sensitivity to any component of the vaccine being administered. Consult the individual SPC for details of excipients and residues of substances such as formaldehyde, gentamcin, kanamycin, neomycin and thiomersal.  
➢ Confirmed anaphylactic reaction to a previous dose of influenza vaccine.  
➢ Severe general or local reaction to previous dose of influenza vaccine.  
➢ Severe latex allergy (i.e. anaphylaxis). Consult the SPC to determine suitability of vaccine as some pre-filled syringes may contain latex proteins in the tip cap and/or rubber plunger of the syringe. For further advice regarding latex allergy see Immunisation against Infectious Disease updated Chapter 6.  
➢ Presence of any contraindication as detailed in the product’s SPC. |
• Egg allergy. These patients may be given PrefluCel® as this is egg free, otherwise refer to GP.
• Bleeding disorder, including receiving oral or parenteral anticoagulants.
• Drug interactions: patients taking theophylline or phenytoin may occasionally experience an enhancement of their effects with influenza vaccine (BNF Appendix 1). The benefits of immunisation outweigh the effects of the interactions.
• Has received a seasonal influenza vaccine in the past 6 months

Arrangements for referral or for seeking further advice

Refer to GP if patient excluded or declines treatment.
If patient is excluded as acutely unwell, vaccination may be given when they have fully recovered

2. Description of treatment

<table>
<thead>
<tr>
<th>Name of Medicine</th>
<th>Trivalent Seasonal Influenza Vaccine</th>
<th>All influenza vaccines are supplied as suspensions of inactivated vaccines in pre-filled syringes.</th>
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<tr>
<td>POM/P/GSL</td>
<td>POM</td>
<td></td>
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<tr>
<td>Dose</td>
<td>Adult 18 years and over: 0.5 ml</td>
<td>Shake vaccine well before use.</td>
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<tr>
<td>Route Method</td>
<td>Influenza vaccine is routinely given by intramuscular injection into the deltoid muscle.</td>
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<tr>
<td>Frequency</td>
<td>Adults: annual single dose.</td>
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<tr>
<td>Adverse reactions and reporting procedure</td>
<td>Common reactions: injection site reactions, low grade fever, malaise, shivering, fatigue, headache, myalgia and arthralgia. These reactions usually disappear within 1 to 2 days without treatment. Immediate reactions such as urticaria, angio-oedema, bronchospasm and anaphylaxis may occur, most likely due to hypersensitivity to residual egg protein. See Green Book updated chapter 19 influenza for information on rarely reported adverse reactions and Guillain-Barre syndrome. Any adverse reaction should be recorded in the patient’s medication record (PMR) and the GP informed. Report to the CHM all serious suspected reactions to established vaccines including those that are fatal, life-threatening, disabling, or which result in hospitalisation by completing the yellow card found at the back of BNF or online (<a href="http://yellowcard.mhra.gov.uk/">http://yellowcard.mhra.gov.uk/</a>).</td>
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<tr>
<td>Patient Advice/Follow up</td>
<td>Advise the patient to remain seated for 15 minutes following the injection and observe for an immediate adverse reaction</td>
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Patients should be warned that as the vaccine is administered intramuscularly, the time of onset of anaphylaxis is variable and may be delayed for up to 72 hours. They should seek immediate medical advice if unexpected symptoms develop after immunisation.

- Inform the patient on the management of minor local and generalised reactions. This should include the use of simple methods such as a cold flannel for local reactions and paracetamol for the management of pain and fever. They should be advised to seek medical advice if they are concerned about any reaction to an immunisation.

- Patients should be informed that many other organisms cause respiratory infections similar to influenza and influenza vaccine will not protect against these diseases.

### Records

Name and dose of vaccine given, date and time of administration, batch number, expiry, route and site of vaccination to be recorded in the PMR along with the name of the pharmacist working under the PGD.

The completed NHS Sheffield checklist / consent form for influenza immunisation should be faxed to the patient’s GP and the original kept in the pharmacy for 2 years.

### Storage

Vaccines should be stored at 2° to 8° C in original packaging and protected from light. Adequate cold chain procedures should be followed.

- Do not freeze.

(See Immunisation against Infectious Disease Chapter 3 and the PCT’s vaccine transport and storage guidelines).

The vaccine should be allowed to reach room temperature before administration to reduce pain on injection.

Discard used vaccine in the sharps bin in line with the PCT’s healthcare waste management policy.

### Additional information

Some seasonal influenza vaccines may contain traces of thiomersal that are left over from the manufacturing process. There is no evidence of risk from thiomersal-containing vaccines and based on the current evidence, JCVI does not recommend the preferential use of non-thiomersal containing vaccines routinely in any group including pregnant women.
Appendix 1

Competence in Immunisation

Aim: to ensure safe practice in the administration of influenza vaccine by community pharmacists.

Before undertaking immunisation, the pharmacist must have undertaken training in the administration of influenza vaccine and should have achieved competence in the following areas of practice. Proof of completion of a vaccination and immunisation training programme must be returned to NHS Sheffield with the individual authorisation form.

1. Storage, distribution and disposal of vaccines, including maintenance of the cold chain
2. Understanding of the principles of valid consent. Consent is discussed in more detail in “Immunisation against Infectious Disease” (2006) chapter 2 Consent
3. Indications and contraindications of influenza vaccines
4. Inclusions and exclusions of this PGD
5. Adverse reactions and reporting requirements.
6. Anaphylaxis and resuscitation
7. Disposal of sharps and clinical waste
8. Needle stick injury
9. Record keeping requirements

All pharmacists involved in immunisation have a professional responsibility to reinforce and update their knowledge and skills in this area, with particular reference to recent and current changes in practice.
Authorisation for the Administration of Trivalent Seasonal Influenza Vaccine under PGD.

A separate authorisation form must be completed for each individual pharmacist.

Note to pharmacist: in signing this document, you are stating your competence in immunisation as detailed in Appendix 1 and agreeing to accept professional responsibility for any immunisations you undertake.

Note to authorising manager: in signing this form you are authorising the named pharmacist to undertake trivalent seasonal influenza immunisations in the community pharmacy.

<table>
<thead>
<tr>
<th>Name</th>
<th>Signature</th>
<th>Date</th>
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<tbody>
<tr>
<td>Pharmacist</td>
<td>Print name of pharmacist</td>
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<tr>
<td>Authorising Manager</td>
<td>Print name of authorising manager</td>
<td></td>
</tr>
<tr>
<td>Community Pharmacy name and address:</td>
<td>Print or stamp:</td>
<td></td>
</tr>
</tbody>
</table>

1. All pharmacists: keep original copy of authorisation form and send one copy to:

    Jo Tsoneva,
    Community Pharmacy Improvement & Development Manager
    NHS Sheffield, 722 Prince of Wales Road, Sheffield S9 4EU

2. Append proof of completion of a vaccination and immunisation training programme to this form before return to NHS Sheffield