

**Service Level Agreement for Community Pharmacy Provision of
Seasonal Influenza Vaccination in 2014/15**
Service to commence on 1st September 2014

SLA between:

Service Provider:	Commissioners:
Community Pharmacies in Shropshire & Staffordshire	NHS England

Developed	July 2014	Endorsements		
Review date	March 2015			
Valid from	1st August 2014	Valid to	31st Mar 2015	

Background (with evidence of need):

Each year the DH recommends a national flu immunisation campaign to target those who may benefit.

This year NHS England Shropshire & Staffordshire have agreed to allow pharmacy to contribute towards the national flu immunisation programme targeting the following cohort of patients:

- those aged 65 years and over
- those aged from 18 years to under 65 in clinical risk groups
- pregnant women aged 18 years and over

Clinical risk groups include those with, chronic respiratory disease, chronic heart disease, chronic kidney disease, chronic liver disease, chronic neurological disease, diabetes, immunosuppression, and asplenia or dysfunction of the spleen

Contractual Obligation

The contractor shall submit to the commissioner a copy of the completed Service Level Agreement. The contractor must retain a copy of relevant signed Patient Group Directions (PGDs) for each pharmacist providing the service from that premise. The contractor must ensure that only Pharmacists who have completed the relevant training requirements detailed in this SLA offer the service. Competence to deliver the service should be recorded on PharmOutcomes.

Description of Enhanced Service:

The aims of this service are:

- To increase the uptake of seasonal influenza vaccine across Shropshire & Staffordshire in line with Department of Health recommendations
- To reduce the serious morbidity/mortality and hospitalisations from influenza by immunising those most likely to have a serious or complicated illness should they develop influenza.
- To improve access to seasonal influenza vaccine for eligible patients aged 18 years and over who are registered with a GP practice in Shropshire and Staffordshire

Patients eligible to be immunised as part of this enhanced service:

All patients must be registered with a GP practice within Shropshire & Staffordshire Area

Eligible Groups	Further Detail
All patients aged 65 years and over	"Sixty-five and over" is defined as those aged 65 years and over on 31 March 2015 (ie born on or before 31 March 1950).
Chronic respiratory disease aged 18 years and over	Asthma that requires continuous or repeated use of inhaled or systemic steroids or with previous exacerbations requiring hospital admission. Chronic obstructive pulmonary disease (COPD) including chronic bronchitis and emphysema; bronchiectasis, cystic fibrosis, interstitial lung fibrosis, pneumoconiosis and bronchopulmonary dysplasia (BPD).
Chronic heart disease aged 18 years and over	Congenital heart disease, hypertension with cardiac complications, chronic heart failure, individuals requiring regular medication and/or follow-up for ischaemic heart disease.
Chronic kidney disease aged 18 years and over	Chronic kidney disease at stage 3, 4 or 5, chronic kidney failure, nephrotic syndrome, kidney transplantation.
Chronic liver disease aged 18 years and over	Cirrhosis, biliary atresia, chronic hepatitis
Chronic neurological disease aged 18 years and over	Stroke, transient ischaemic attack (TIA). Conditions in which respiratory function may be compromised due to neurological disease (e.g. polio syndrome sufferers). Clinicians should consider on an individual basis the clinical needs of patients including individuals with cerebral palsy, multiple sclerosis and related or similar conditions; or hereditary and degenerative disease of the nervous system or muscles; or severe neurological or severe learning disability.
Diabetes aged 18 years and over	Type 1 diabetes, type 2 diabetes requiring insulin or oral hypoglycaemic drugs, diet controlled diabetes.
Immunosuppression aged 18 years and over	Immunosuppression due to disease or treatment, including patients undergoing chemotherapy leading to immunosuppression, bone marrow transplant, HIV infection at all stages, multiple myeloma or genetic disorders affecting the immune system (e.g. IRAK-4, NEMO, compliment deficiency). Individuals treated with or likely to be treated with systemic steroids for more than a month at a dose equivalent to prednisolone at 20mg or more per day. It is difficult to define at what level of

Eligible Groups (continued)	Further Detail
	<p>immunosuppression a patient could be considered to be at a greater risk of the serious consequences of influenza and should be offered influenza vaccination. This decision is best made on an individual basis and left to the patient's clinician.</p> <p>Some immunocompromised patients may have a suboptimal immunological response to the vaccine.</p>
<p>Asplenia or dysfunction of the spleen</p>	<p>This also includes conditions such as homozygous sickle cell disease and coeliac syndrome that may lead to splenic dysfunction.</p>
<p>Pregnant women aged 18 years and over</p>	<p>Pregnant women at any stage of pregnancy (first, second or third trimesters).</p>

Patients specifically EXCLUDED from this enhanced service agreement:

Patient Group	Recommended advice
<p>Patient not registered to a GP practice within Shropshire & Staffordshire Area</p>	<p>Refer to own GP</p>
<p>Patient already vaccinated in current vaccination period (August 2014 – March 2015)</p>	<p>Reassure the patient that they are already protected</p>
<p>Patient is less than 18 years of age</p>	<p>Refer to GP and give the appropriate flu information leaflet</p> <p>If the patient attends a school in Shropshire or Staffordshire and is in year 7 or 8 (11 to 13 year olds), advise that a free nasal spray vaccination will be offered this year in their school</p>
<p>Patient aged 18 years to 65 years who is not in the clinical risk group (see above)</p>	<p>Advise that free NHS flu immunisation is not available to them. (Offer private flu vaccination if available)</p>
<p>Patient who is currently suffering a febrile illness or acute infection</p>	<p>Advise them to return when recovered</p>
<p>Patient with history of severe local or general reaction to the vaccine</p>	<p>Refer to GP</p>
<p>Front line health and social care workers</p>	<p>Refer to own employer or Occupational Health Services. GPs are not allowed to immunise front line health and social care workers and so clients should not be referred to their GP.</p>
<p>Patients uncertain if they have been vaccinated in the current vaccination period (August 2014 – March 2015)</p>	<p>Refer to GP</p>

Caution:	
Patient with confirmed anaphylaxis to egg or chicken protein	To be offered egg-free influenza vaccine as per DH guidance. Refer to PGD.
Patient with egg allergy without anaphylaxis	To be offered a low ovalbumin inactivated influenza vaccine. Refer to PGD

Treatment Pathway:
The pharmacist must establish that the patient is eligible by taking the patient through the flowchart in Appendix 1 , and the inclusion criteria Appendix 2 . Pharmacy staff must have evidence of patient eligibility through GP invitation letter, pharmacy records, prescriptions or alternative methods that identify age (65 years and over only). Once satisfied that the patient is eligible, the Pharmacist must establish whether a flu vaccination from the participating pharmacy is the most suitable option by following the exclusion criteria in Appendix 3 .

Further information:

Documents providing background information on the seasonal influenza programme 2014/15 can be found here: <https://www.gov.uk/government/publications/flu-immunisation-programme-2014-to-2015>

Service description:

Eligibility of the Service Provider:
<ul style="list-style-type: none"> • The accredited pharmacist must have attended an approved flu vaccination training event or undertaken update training as specified below prior to delivery of the service. • The vaccination can only be provided by a Pharmacist who has completed appropriate immunisation training. All individuals requesting an influenza vaccination should be referred to the appropriately trained Pharmacist who will assess and vaccinate the patient following the agreed protocol. • The Pharmacist will ensure that all members of the pharmacy staff are aware of the operation of the scheme and full details must be made available to locum Pharmacists. • Locum pharmacists can offer flu immunisations if they meet all the other eligibility criteria in this SLA. It is the responsibility of the Pharmacy Contractor to ensure that the locum pharmacist has attended the training. • Ensure that the part of the pharmacy used for the provision of the service provides sufficient level of safety, privacy and meets infection control standards (please see Premises) • Ensure that pharmacists involved in the provision of the service have relevant knowledge and are appropriately trained in the operation of the service, including sensitive, client-centred communication skills. • The Pharmacy Contractor must be able to provide evidence on request of the training in administration of immunisations and anaphylaxis training for all pharmacists engaged by them for provision of this service. • Patient consent will need to be obtained for both the vaccination itself, and the sharing of information. This will need to be recorded electronically via PharmOutcomes. • Maintain appropriate records to ensure effective ongoing service delivery and audit. Records are confidential and should be stored securely and for a length of time in line with local NHS record retention policies. • Inform the registered General Practitioner of the influenza vaccination by PharmOutcomes (or fax if necessary) within 48 hours. • Advise the client of alternative provision if the qualified pharmacist is not present.

Training:

It is mandated that all pharmacists undertaking seasonal influenza immunisations in this service level agreement will be appropriately trained.

- Training must cover the administration of immunisations in accordance with the Health Protection Agency Core Curriculum (2005) to include vaccine preventable disease, cold chain requirements, intramuscular immunisation technique, use of Patient Group Directions and specifically flu vaccine administration. An accredited training course must have been successfully completed
- The Area Team will maintain an approved list of accredited flu vaccination training courses. The following list includes those that have been approved as of 1st August 2014.
 - Novartis
 - Numark
 - Boots Flu Vaccination Training Programme
 - Morrisons Flu Vaccination Training Programme
- If pharmacists wish to attend training provided by organisations others than those listed above, then the Area Team will have to be contacted in advance to allow for verification checks to be undertaken.
- Training will include management of anaphylaxis including documentary evidence of anaphylaxis training undertaken since 1st April 2014
- All fully trained pharmacists wishing to provide the service will need to enter details of training undertaken (covering seasonal flu, injection technique and anaphylaxis) on PharmOutcomes.
- Pharmacists that have previously undertaken flu vaccination training in 2012 or 2013 will be required to complete a declaration on PharmOutcomes to confirm that they have had their annual update and confirm they have the relevant competencies to deliver the flu vaccination service as outlined in this SLA.

Each individual pharmacist will have to sign the relevant PGDs and maintain copies for inspection if required.

Premises:

- The service can only be provided in a pharmacy with a private consultation area that meets NHS infection control standards.
- The consultation area must have a chair for patients to sit in and facilities must be available for patients to be able to lie down in the event of a simple faint or an anaphylactic reaction.
- The pharmacy must have a pharmaceutical refrigerator (domestic refrigerators are not acceptable) and the temperature must be recorded on each working day. The records must be kept for audit purposes. An example template is shown in **Appendix 5** although providers can use their own templates.
- There will need to be dedicated hand washing facilities on the premises with liquid soap and disposable paper towels. Ideally this should be in the consultation room. Where it is not, infection control procedures must be followed rigorously.
- The pharmacy will need to have a vomit bowl available in the vaccination area.
- The pharmacy will also need to have a sharps bin and a sharps collection procedure in place. This will be provided by an Area Team commissioned waste contractor and it will be the responsibility of the Area Team to arrange for sharps generated as part of this service to be collected from accredited pharmacies on request or at the end of the service.
- The pharmacy will allow NHS England officers, or persons nominated by NHS England, to visit the pharmacy to assess adherence with the quality standards set out in this SLA and evidence of training. A check will be made to make sure all policies are in place. Non-compliance will result in the removal of the service.

Standard Operating Procedures (SOP)

The pharmacy will have a Standard Operating Procedure in place for this service. The pharmacy contractor must ensure that pharmacists and staff involved in the provision of the service are aware of and operate within national and locally agreed protocols. The following SOPs should be in place

- Infection control
- Sharps disposal
- Flu vaccination procedures
- Cold chain policy
- CPR policy – this must include:
 - At least one other person on site whenever immunisations are undertaken
 - Access to telephone to call emergency services
- Anaphylaxis
- Blood Spill Policy
- Chaperone policy
- Safeguarding policy

Specific Service criteria:

- The Pharmacist must ensure that the patient is aware that the details of the vaccination will be transferred to the registered GP practice.
- The Pharmacist must explain any potential side effects to the patient and what to do should they develop any side effects.
- Service providers must keep records of who has been vaccinated, ideally via the pharmacy PMR system. This is in addition to recording of information on PharmOutcomes. Client records must be kept by the accredited pharmacy contractor for 8 years following completion of treatment. This will include name of client, vaccine batch number, date of expiry, route of administration, site and date of vaccination (**Appendix 6**)
- To minimise the risk of patients receiving double immunisation, service providers must ensure that the details of vaccinations given are returned to the patient's registered GP by the next working day (within 48 hours if vaccination at weekend). If this is not undertaken by PharmOutcomes automated notification, a robust audit trail of notifications must be available.

Quality and Quality Monitoring:

- Any significant variation or deviation in the quality of the service provided as specified in the service specification must be notified in writing to NHS England as soon as identified, with proposed actions to rectify the performance.
- A number of mechanisms are currently in place for assessing the quality of service provided by Community Pharmacy. Contractors are required to demonstrate compliance with national and local clinical governance arrangements
- Pharmacies providing the service in Shropshire and Staffordshire will comply with the national clinical governance requirements as described in the National Health Service Pharmacy Regulations 2005.
- The Pharmacist and staff within the pharmacy should be trained to deal with anaphylaxis and will be required to have adrenaline (1:1000) available.
- In the event of an adverse incident or near miss, the pharmacist will contact the Immunisation and Screening Coordinator (SIC) by emailing phe.sssit@nhs.net with the details. The SIC will seek assurance from the pharmacist that the incident is being properly investigated in accordance with the [HPA vaccine incident guidance](#) and will offer further support as necessary. An adverse incident includes but is not limited to inappropriate immunisation (eg: unnecessary

extra dose given, incomplete dose given), anaphylaxis or post-vaccination incident requiring the emergency services

- All patients who wish to have a flu vaccination in a pharmacy must be informed of their right to have a chaperone. The patient has the right to bring a third party with them for the vaccination
- Pharmacists should ensure full patient confidentiality and compliance with data protection requirements.
- Analysis of data received will be carried out in order to determine the effectiveness of the service and the pharmacy must provide any information required to achieve this
- Adherence to this SLA will be monitored via a process agreed with the LPC, as part of the NHS England ongoing quality assurance process
- Pharmacies providing this service agree to participate in any evaluation process that may be undertaken by the commissioner

NHS England undertakes to:

- Provide the relevant fax numbers of all Shropshire & Staffordshire GP Practices and appropriate forms to those pharmacists participating in this enhanced service agreement. **(Contact details will be provided separately)**
- Arrange for an appropriate sharps bin to be provided to each pharmacy, and arrange for its collection and/or replacement on request.

Payment available:

£7.64 administration fee + NHS list price for the vaccine plus VAT

Submission of Claims information:

Claims for payment are made automatically through PharmOutcomes. The payment will be generated on 5th of each month

Method of Payment:

To be paid via the PPA and will be identified on the monthly statement as a local payment.

Acceptance of SLA – 1 form required per community pharmacy premises:

Please note that the NHS England has the right to withdraw this Service Level Agreement if the requirements are not being met, giving two weeks written notice. If the Pharmacy wishes to withdraw from the scheme, two weeks written notice is required.

Pharmacy details:

NHS England details:

<i>Pharmacist Signature (signing on behalf of the pharmacy):</i>	<i>NHS Signature:</i>
<i>Pharmacist Name:</i>	<i>Position of signatory:</i>
<i>Position of pharmacist signatory:</i>	<i>Date:</i>
<i>Date of acceptance:</i>	

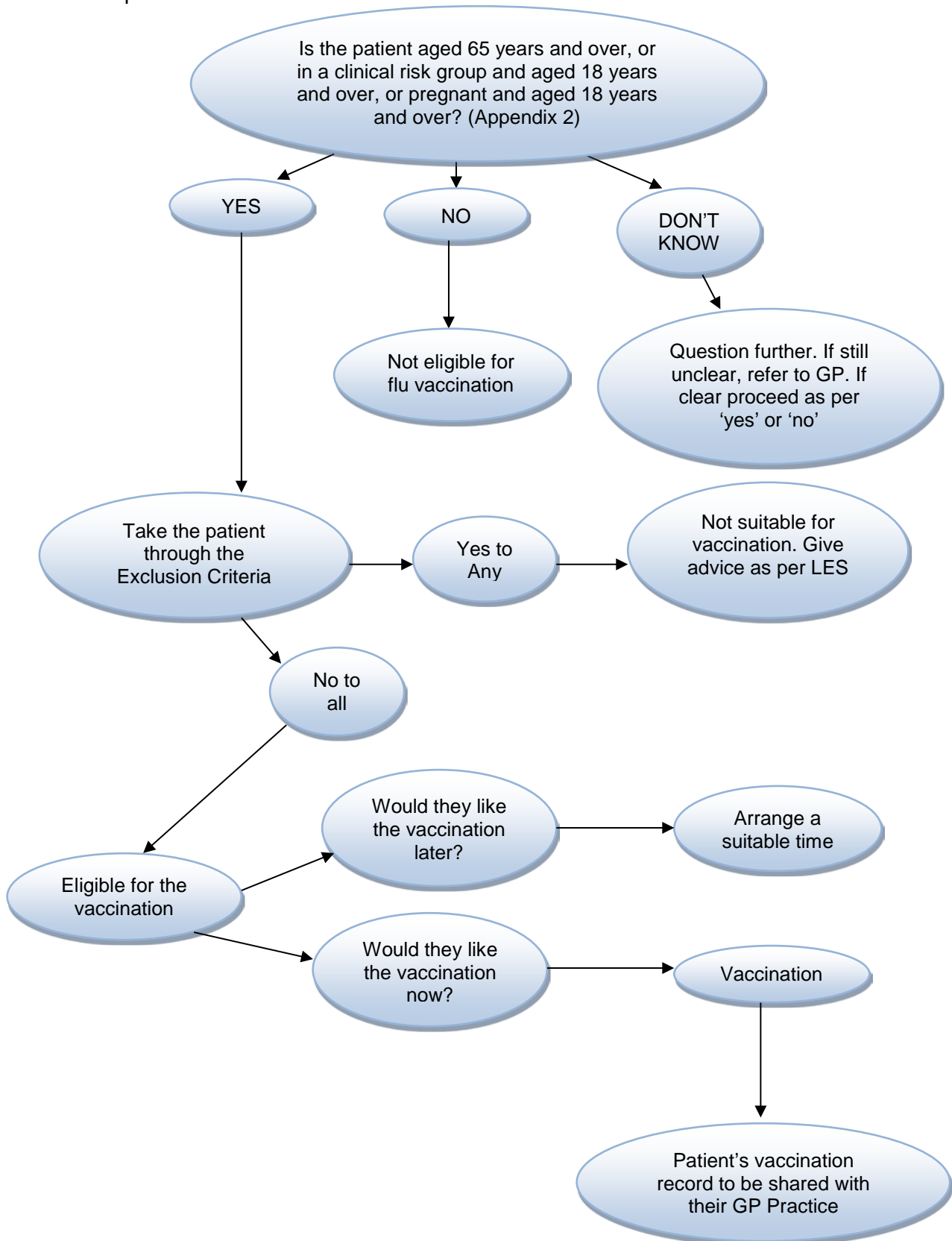
A signed copy of this agreement will be kept by the Pharmacy and NHS England

Pharmacy Details	
To be completed and returned with signed Service Level Agreement	
Pharmacy name	
Pharmacy address	
Pharmacy OCS code (PPA code)	
Phone number	
Fax number	
Email address	
Pharmacist GPhC registration number	
Named contact at pharmacy	

The responsible pharmacist is responsible for ensuring that any pharmacist offering this service is appropriately trained in the administration of flu vaccinations and in anaphylaxis

Appendix 1

Vaccination process flow chart



Appendix 2

Patient groups eligible for Pharmacy Service.

Please note that this list is based on DH recommendations but has been modified for community pharmacy

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Eligible Groups	Further Detail
All patients aged 65 years and over	"Sixty-five and over" is defined as those aged 65 years and over on 31 March 2015 (ie born on or before 31 March 1950).
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Eligible Groups (continued)	Further Detail
	<p>deficiency).</p> <p>Individuals treated with or likely to be treated with systemic steroids for more than a month at a dose equivalent to prednisolone at 20mg or more per day. It is difficult to define at what level of immunosuppression a patient could be considered to be at a greater risk of the serious consequences of influenza and should be offered influenza vaccination. This decision is best made on an individual basis and left to the patient's clinician.</p> <p>Some immunocompromised patients may have a suboptimal immunological response to the vaccine.</p>
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Pregnant women aged 18 years and over	<p>Pregnant women at any stage of pregnancy (first, second or third trimesters).</p>

Appendix 3

Patients specifically **EXCLUDED** from this enhanced service agreement

Patient Group	Recommended advice
Patient not registered to a GP practice within Shropshire & Staffordshire Area	Refer to own GP
Patient already vaccinated in current vaccination period (August 2014 – March 2015)	Reassure the patient that they are already protected
Patient is less than 18 years of age	Refer to GP and give the appropriate flu information leaflet If the patient attends a school in Shropshire or Staffordshire and is in year 7 or 8 (11 to 13 year olds), advise that a free nasal spray vaccination will be offered this year in their school
Patient aged 18 years to 65 years who is not in the clinical risk group (see above)	Advise that free NHS flu immunisation is not available to them. (Offer private flu vaccination if available)
Patient who is currently suffering a febrile illness or acute infection	Advise them to return when recovered
Patient with history of severe local or general reaction to the vaccine	Refer to GP
Front line health and social care workers	Refer to own employer or Occupational Health Services. GPs are not allowed to immunise front line health and social care workers and so clients should not be referred to their GP.
Patients uncertain if they have been vaccinated in the current vaccination period (August 2014 – March 2015)	Refer to GP

Caution

Caution:	
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Appendix 4: Sample fax/ letter to inform GP contractor of flu vaccination for registered patient

Dear Practice Manager,

This letter is to inform you that your patient received an influenza vaccination from this pharmacy as detailed below. Please record this in their patient records.

Pharmacy stamp

Name:	
Date of birth:	
Address:	
GP name:	
GP address:	

To be completed by pharmacist:

Date of administration:	Expiry date:	Brand and batch number:	Site of vaccination e.g. Left arm	Clinical Risk Group –please state	Signature

Appendix 5

Temperature Recording and Checking Sheet

PHARMACY:	
MONTH:	YEAR:
Appliance ID Number:	Location:

The temperature must be maintained between +2°C to +8°C

Date	Time	ACTUAL Temperature	MINIMUM Temperature	MAXIMUM Temperature	Tick if within specification, write details if not. Note other factors e.g. cleaning, addition of new stock	Tick max/min thermometer reset	Signature
1 st							
2 nd							
3 rd							
4 th							
5 th							
6 th							
7 th							
8 th							
9 th							
10 th							
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26 th							
27 th							
28 th							
29 th							
30 th							
31 st							

If the temperature is outside of the recommended range, please refer to your Cold Chain SOP and follow GPhC standards.

Expiry date check done: _____ **Date:** _____ **Signature:** _____

RECORDINGS FOR THE MONTH REVIEWED: **Date:** _____ **Signature:** _____

