



Patient Group Direction

for the administration of

Inactivated Influenza Vaccine

by pharmacists providing the NHS Wales Clinical Community Pharmacy Service for

Seasonal Influenza Vaccination and National Influenza Immunisation Programme

in _____

Operational from: 1st September 2022

Review Date: 1st July 2023

Version number: v1.0

PGD for the administration of Inactivated Influenza Vaccine by pharmacists delivering the Community Pharmacy seasonal influenza vaccination component of the clinical community pharmacy service

Reference: Pharmacy Influenza Vaccine PGD
 Version no: 01:00
 Valid from: 01 September 2022
 Review date: 01 July 2023
 Expiry date: 31 March 2023

Welsh Medicines Advice Service has developed this PGD for local authorisation

Those using this PGD must ensure that it is authorised by the Local Health Board in which they are operating and signed in section 2 by an appropriate authorising person, relating to the class of person by whom the product is to be supplied, in accordance with the Human Medicines Regulations 2012 (HMR2012)ⁱ. **THE PGD IS NOT LEGAL OR VALID WITHOUT SIGNED AUTHORISATION IN ACCORDANCE WITH HMR2012 SCHEDULE 16 Part 2.**

Authorising organisations must not *alter, amend* or *add* to the *clinical* content of this document such action will invalidate the *clinical sign-off* with which it is provided.

As operation of this PGD is the responsibility of service providers, the authorising organisation can decide which staff groups, in keeping with relevant legislation, can work to the PGD.

INDIVIDUAL PRACTITIONERS MUST BE LISTED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE WORKING ACCORDING TO IT.

Practitioners and organisations must check that they are using the current version of the PGD. Amendments may become necessary prior to the published expiry date.

Any queries regarding the clinical content of this PGD should be addressed to: welshmedicines.information@wales.nhs.uk

Change history

Version number	Change details	Date
v1.0	Pharmacy Influenza Vaccination PGD	1 st June 2022
v1.1	Hyperlinks moved to referencing in appendix	30 th August '22

ⁱ This includes any relevant amendments to legislation (e.g. [2013 No.235](#), [2015 No.178](#) and [2015 No.323](#)).

1. PGD development

This PGD has been developed and peer reviewed by an expert panel and approved by the Community Pharmacy Clinical Reference Group in accordance with the PGD Policy.

This section MUST REMAIN when a PGD is adopted by an organisation

Expert panel

Name	Designation
Expert Reviewer – James Couslon	Clinical Director All Wales Therapeutics and Toxicology Centre (AWTTC)
Main author – Dianne Burnett	National Lead Pharmacist Medicines Advice. Welsh Medicines Information Centre Cardiff and Vale UHB
Expert Reviewer - Anne McGowan	Nurse Consultant Health Protection Team Public Health Wales
Professional Group reviewer – Adam Mackridge	Chair of Community Pharmacy Clinical Reference Group and Strategic Lead Pharmacist for Community Pharmacy Betsi Cadwallader UHB

Date CPRG approval of PGD: 23/08/2022

2. Organisational authorisations

The PGD is not legally valid until it has had the authorisation of the Local Health Board in which the community pharmacy using it operates.

It is the responsibility of the Local Health Board, to ensure that all legal and governance requirements are met. The Local Health Board accepts governance responsibility for the appropriate use of the PGD.

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authorises this PGD for use by community pharmacies within its area that have been commissioned to provide the Seasonal Influenza Vaccination component of the Clinical Community Pharmacy Service. This authorisation is limited to those pharmacists that meet the requirements set out within the PGD

Local Health Board approval (legal requirement) as per health board policy			
Role	Name	Sign	Date

Local enquiries regarding the use of this PGD may be directed to welshmedicines.information@wales.nhs.uk

Appendix B provides a practitioner listing sheet. Individual practitioners must be listed by name to work to this PGD. Alternative practitioner listing sheets may be used where appropriate in accordance with local policy, but this should be an individual agreement or a multiple practitioner listing sheet as included at the end of this PGD.

3. Characteristics of staff

Qualifications and professional registration	<p>Practitioners must only work under this PGD where they are competent to do so. This PGD is for use by pharmacists currently registered with the General Pharmaceutical Council (GPhC)</p>
Additional requirements	<p>Pharmacists must:</p> <ul style="list-style-type: none"> ➤ be employed by, or providing services on behalf of a pharmacy listed in the All Wales Pharmacy Database (AWPD) for the Seasonal Influenza Vaccination service. ➤ be authorised by name as an approved practitioner under the current terms of this Patient Group Direction before working to it (by completion of Appendix B) ➤ be familiar with the medicine and alert to changes in the Summary of Product Characteristics (SmPC)¹, prior to any administration. ➤ have access to the Patient Group Direction and associated resources and must be competent in the use of PGDs (see NICE Competency framework² for health professionals using PGDs) ➤ be named in the All Wales Pharmacy Database for the seasonal influenza vaccination service ➤ have met the training requirements for the service as set out by HEIW (Health Education and Improvement Wales)
Initial training	<p>Pharmacists must</p> <ul style="list-style-type: none"> ➤ have completed the HEIW Pharmacy Generic Skills and Competency assessment in line with the National Clinical Services Accreditation Process ➤ have completed the appropriate training as required by the Community Pharmacy Seasonal Influenza Vaccination Service Specification and the current HEIW Accreditation Flowchart for the Provision of NHS Influenza Vaccination Service ➤ Be familiar with the vaccine products and their British National Formulary (BNF³) and Summary of Product Characteristics (SmPC)¹ entries, Immunisation against Infectious Diseases ("The Green Book")⁴ and the National Immunisation Programme⁵. ➤ be competent to undertake immunisation and to discuss issues related to seasonal influenza immunisation. ➤ be competent in the handling and storage of vaccines, and management of the 'cold chain' as outlined in the Advisory document on ordering storage and handling of vaccines⁶. ➤ Be able to recognise the adverse drug reactions associated with each Influenza vaccine. ➤ be competent in the recognition and management of anaphylaxis <p>The pharmacist must be listed by name, under the current version of this PGD that has been issued by the Local Health Board in which area they are operating before working under its authority.</p>

<p>Ongoing training and competency</p>	<p>Pharmacists must:</p> <ul style="list-style-type: none"> ➤ Ensure they are up to date with relevant issues and clinical skills relating to immunisation and management of anaphylaxis, with evidence of appropriate Continuing Professional Development (CPD) ➤ Be aware of any updates to relevant national guidelines from Public Health Wales, NHS Wales, Welsh Government and other sources of medicines information. ➤ Be aware of any updates made to the product in its SmPC or BNF entries or in “The Green Book” ➤ As registered professionals, be professionally accountable and must work within their competence. A record of training and competence must be maintained ➤ Have demonstrated competence in Basic Life Support skills including resuscitation skills and the management of anaphylaxis within the community, in line with the published requirements for provision of this service. <p>Note: The most current national recommendations should be followed. However, if updated recommendations mean that to vaccinate the individual would be outside the scope of this PGD, the individual should be referred to their GP for vaccination</p>
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4. Clinical condition or situation to which this PGD applies

<p>Clinical condition or situation to which this PGD applies</p>	<p>Inactivated influenza vaccine is indicated for the active immunisation of adults for the prevention of influenza infection, in accordance with the community pharmacy seasonal influenza vaccination component of the clinical community pharmacy service, the national immunisation programme and recommendations given in Chapter 19 of the Immunisation Against Infectious Disease: “The Green Book”⁷ and Welsh Health Circular (WHC) 2022/010 2022/16⁸.</p>
<p>Criteria for inclusion</p>	<p>Individuals are included for vaccination under this PGD if they are included in one or more of the groups that are set out in the relevant Welsh Health Circulars relevant to current season (including WHC 2022/010/016 and any subsequent updates⁸ or other formal communication from Welsh Government or the relevant Local Health Board regarding eligibility</p> <p>For further information on eligible categories; refer to WHC (2022/010/016)⁸.</p>
<p>Criteria for exclusionⁱⁱ</p>	<ul style="list-style-type: none"> ➤ Individuals for whom no valid consent has been received (for further information on consent see Chapter 2 of ‘The Green Book’⁴). ➤ Individuals who: <ul style="list-style-type: none"> • are less than 18 years of age • have had a confirmed anaphylactic reaction to a previous dose of the vaccine • have had a confirmed anaphylactic reaction to any component of the vaccine or residues from the manufacturing process (other than ovalbumin – see Cautions) see Appendix C for table of vaccines and their potential residues • have received a complete dose of the recommended influenza vaccine for the current season • are suffering from acute severe febrile illness (the presence of a minor infection is not a contraindication for immunisation)
<p>Cautions</p>	<p>Please refer to the SmPC¹ for full details of special warnings and precautions for use.</p> <ul style="list-style-type: none"> ➤ Individuals with a thrombocytopenia or a bleeding disorder may develop a haematoma at the injection site (see Route of Administration). ➤ Syncope (fainting) can occur following, or even before, any vaccination as a psychogenic response to the needle injection. This can be accompanied by several neurological signs such as transient visual disturbance, paraesthesia and tonic-clonic limb

ⁱⁱ Exclusion under this PGD does not necessarily mean the medication is contraindicated, but it would be outside its remit and another form of authorisation for administration of vaccine will be required

	<p>movements during recovery. It is important that procedures are in place to avoid injury from faints</p>
<p>Cautions continued</p>	<ul style="list-style-type: none"> ➤ Egg Allergy: Individuals with a severe anaphylaxis to egg which has previously required intensive care can be immunised in any setting using an egg-free vaccine, for instance QIVc or QIVr. Individuals with less severe egg allergy can be immunised in any setting using an egg-free vaccine or an inactivated influenza vaccine with an ovalbumin content less than 0.12 micrograms/mL (equivalent to 0.06 micrograms for 0.5 mL dose). For details of the influenza vaccines available for the 2022/23 season and their ovalbumin content see Influenza vaccines: 2022 to 2023 flu season⁹. ➤ Individuals with immunosuppression or taking immunosuppressant medication may have a reduced response to vaccination
<p>Action to be taken if the individual is excluded or declines</p>	<ul style="list-style-type: none"> ➤ Explain the reasons for exclusion and any action taken and document in the consultation record ➤ If the individual declines advise about the protective effects of the vaccine and the consequences of not receiving it ➤ The risk to the individual of not being immunised should be considered. The indications for flu vaccination are not exhaustive, and pharmacists should consider the risk of flu exacerbating any underlying disease that an individual may have, as well as the risk of serious illness from flu itself and refer individuals to their GP for immunisation where appropriate. ➤ All individuals under 18 years of age who are in a clinical risk group (including those who are pregnant) or otherwise eligible for influenza vaccination for the 2022/23 season should be referred to their GP or an appropriate local NHS service provider for immunisation. ➤ In case of postponement due to acute illness, advise when the individual can be vaccinated and ensure another appointment is arranged.
<p>Arrangements for referral for medical advice</p>	<ul style="list-style-type: none"> ➤ Refer to individual's GP ➤ If there is any doubt about the administration of the vaccine or a patient's suitability to receive the vaccine, a doctor should be consulted

5. Description of treatment

<p>Name, strength & formulation of drug</p>	<p>Influenza vaccine recommendations for Wales are published in WHC/2022/16⁸ and Public Health Link CEM/CMO/2022/</p> <p>Inactivated influenza vaccine suspension in a pre-filled syringe including:</p> <ul style="list-style-type: none"> • adjuvanted quadrivalent influenza vaccine (aQIV), Flud tetra Seqirus ▼ • cell-based quadrivalent influenza vaccine (QIVc), Flucelvax tetra Seqirus ▼ • egg-grown quadrivalent influenza vaccine (QIVe), Sanofi Pasteur split virion ▼ or Mylan Influvac sub-unit tetra ▼ • recombinant quadrivalent influenza vaccine (QIVr), Supemtek ▼ <p>Note: This PGD does not include high-dose quadrivalent influenza vaccine (QIV-HD) or trivalent influenza vaccines as these vaccines are not eligible for re-imburement under the NHS influenza vaccination programme in 2022/23⁵.</p> <p>The vaccines that are available for the 2022 to 2023 influenza immunisation programme are listed in the document Influenza vaccines: 2022 to 2023 flu season⁹.</p> <p>Some influenza vaccines are restricted for use in particular age groups. The SmPC for individual products should always be referred to</p> <p>Summary table of which influenza vaccines to offer (by age)</p> <table border="1" data-bbox="539 1115 1436 1646"> <thead> <tr> <th>Age</th> <th>Recommended influenza vaccine for adults</th> </tr> </thead> <tbody> <tr> <td>At risk adults 18 years to under 65 years including pregnancy</td> <td>Offer QIVc or QIVr. Or, if QIVc or QIVr are not available, offer QIVe.</td> </tr> <tr> <td>65 years and overⁱⁱⁱ</td> <td>Offer aQIV or QIVr If aQIV/QIVr not available offer QIVc It is recommended that aQIV is offered 'off-label' to those who become 65 years of age before 31 March 2023 (see Off-label use section).</td> </tr> </tbody> </table>	Age	Recommended influenza vaccine for adults	At risk adults 18 years to under 65 years including pregnancy	Offer QIVc or QIVr. Or, if QIVc or QIVr are not available, offer QIVe.	65 years and over ⁱⁱⁱ	Offer aQIV or QIVr If aQIV/QIVr not available offer QIVc It is recommended that aQIV is offered 'off-label' to those who become 65 years of age before 31 March 2023 (see Off-label use section).
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<p>Legal category</p>	<p>POM - Prescription Only Medicine</p>						
<p>Black triangle ▼</p>	<p>QIVc, QIVr and aQIV products are black triangle. QIVe vaccine from Viartis (formerly Mylan) is black triangle. This information was accurate at the time of writing. See product SPCs, available from the SmPC website, for indication of current black triangle status.</p>						

ⁱⁱⁱ JCVI recommended use of QIV-HD in this age group but this is not currently available in the UK market.
PGD for the administration of Inactivated Influenza Vaccine by Community Pharmacist
 Valid from 1st September 2022 Expiry Date 31st March 2023

<p>Off-label use</p>	<ul style="list-style-type: none"> ➤ The aQIV (Adjuvanted QIV influenza vaccine ▼ Flud tetra Seqirus) is licensed for administration to individuals aged 65 years and over. It may be administered under this PGD to 64- year olds turning 65 years of age by 31 March 2023 in accordance with the recommendations for the national influenza immunisation programme for 2022/23. ➤ Vaccine should be stored according to the conditions detailed in the Storage section below. However, in the event of an inadvertent or unavoidable deviation of these conditions refer to section 5 (storage) and section 11 (incident) of Advisory document⁶ on ordering storage and handling of vaccines. Where vaccine is assessed in accordance with these guidelines as appropriate for continued use this would constitute off-label administration under this PGD. ➤ Where a vaccine is recommended off-label, as part of the consent process, consider informing the individual/carer that the vaccine is being offered in accordance with national guidance but that this is outside the product licence. <p>Note: Different influenza vaccine products are licensed from different ages and should be administered within their licence when working to this PGD, unless permitted off-label administration is detailed above. Refer to products' SmPCs¹ and the table of Influenza vaccines: 2022 to 2023⁹ flu season for more information.</p>
<p>Route/method of administration</p>	<ul style="list-style-type: none"> ➤ Administer by intramuscular injection, preferably into the deltoid region of the upper arm. ➤ Individuals on stable anticoagulation therapy, including individuals on warfarin who are up-to-date with their scheduled INR testing and whose latest INR was below the upper threshold of their therapeutic range, can receive intramuscular vaccination. A fine needle (equal to 23 gauge or finer calibre such as 25 gauge) should be used for the vaccination, followed by firm pressure applied to the site (without rubbing) for at least 2 minutes. If in any doubt, consult with the clinician responsible for prescribing or monitoring the individual's anticoagulant therapy. ➤ Individuals with bleeding disorders may be vaccinated intramuscularly if, in the opinion of a doctor familiar with the individual's bleeding risk, vaccines or similar small volume intramuscular injections can be administered with reasonable safety by this route. If the individual receives medication/treatment to reduce bleeding, for example treatment for haemophilia, intramuscular vaccination can be scheduled shortly after such medication/treatment is administered. A fine needle (equal to 23 gauge or finer calibre such as 25 gauge) should be used for the vaccination, followed by firm pressure applied to the site (without rubbing) for at least 2 minutes. The individual/carer should be informed about the risk of haematoma from the injection.

<p>Route/method of administration continued</p>	<ul style="list-style-type: none"> ➤ Influenza vaccines licensed for intramuscular or subcutaneous administration may alternatively be administered by the subcutaneous route. Subcutaneous administration is covered by this PGD where the pharmacist is trained and competent in administration via this route. Note: <p>QIVe (Sanofi Pasteur split virion inactivated) and QIVe (Mylan Influvac▼® sub-unit tetra) are licensed for sub-cutaneous administration</p> <p>QIVr (Supemtek▼®), aQIV Flud Tetra (Seqirus adjuvanted quadrivalent influenza vaccine▼®) and QIVc Flucelvax Tetra (Seqirus cell based quadrivalent influenza vaccine▼®) are not licensed for subcutaneous administration and should only be administered intramuscularly under this PGD</p> <p><u>Administration:</u></p> <ul style="list-style-type: none"> ➤ If administering the Sanofi Pasteur split virion QIVe vaccine or the Mylan Influvac▼® sub unit vaccine, the vaccine should be allowed to reach room temperature before administration ➤ Gently shake vaccine before administration. (excluding QIVr Supemtek▼®) ➤ Inspect visually prior to administration and ensure appearance is consistent with the description in the SmPC for the vaccine being administered <p><u>Co-administration:</u></p> <ul style="list-style-type: none"> ➤ Inactivated influenza vaccination may be given at the same time as other vaccines. ➤ When administering at the same time as other vaccines, care should be taken to ensure that the appropriate route of injection is used for all the vaccinations. ➤ The vaccines should be given at separate sites, preferably in different limbs. ➤ If given in the same limb, they should be given at least 2.5cm apart. ➤ The site at which each vaccine was given should be noted in the individual's records. ➤ If aQIV or QIVc needs to be administered at the same time as another vaccine, immunisation should be carried out on separate limbs.
<p>Dose and frequency of administration</p>	<p>Single 0.5mL dose to be administered for the current annual flu season (1 September 2022 to 31 March 2023).</p>
<p>Duration of treatment</p>	<p>See dosage schedule above. This PGD only allows for the duration stated in the dosage schedule above.</p>
<p>Quantity to be supplied</p>	<ul style="list-style-type: none"> ➤ Providers should order influenza vaccines for adults from the influenza vaccine manufacturers or pharmaceutical wholesalers as in previous years. ➤ Should centrally procured vaccines for patients aged 18 years and over be made available, they should be ordered and used in accordance with any related guidance.

Storage	<ul style="list-style-type: none"> ➤ Store between +2°C to +8°C. ➤ Do not freeze ➤ Store in original packaging in order to protect from light ➤ In the event of an inadvertent or unavoidable deviation of these conditions, vaccine that has been stored outside the conditions stated above should be quarantined and risk assessed for suitability of continued off-label use or appropriate disposal. Refer to the Advisory document on ordering storage and handling of vaccines section 5 (storage)⁶ and Green Book Chapter 3⁴.
Disposal	<ul style="list-style-type: none"> ➤ Equipment used for immunisation, including discharged vaccines in a syringe, should be disposed of safely in a UN-approved puncture-resistant 'sharps' box, according to guidance in the Welsh Health Technical Memorandum 07-01 Safer management of healthcare waste¹⁰.
Drug interactions	<p>No interaction studies have been performed with QIV. Any reaction thought to be due to a drug interaction should be reported to a medical professional and a yellow card completed</p> <p>Inactivated influenza vaccines can be given at the same time as other vaccines, preferably at separate injection sites on different limbs</p> <p>The immunological response maybe diminished in those individuals receiving immunosuppressive therapy.</p>
Identification & management of adverse reactions	<p>The most frequently reported adverse effects (affecting between 1 in 10 people and 1 in 100 people) include:</p> <ul style="list-style-type: none"> ➤ Pain at injection site ➤ Fatigue ➤ Generally feeling unwell ➤ Headache ➤ Joint and/or muscle pain ➤ Diarrhoea ➤ Shivering ➤ Nausea ➤ Loss of appetite ➤ Cough, mouth and throat pain ➤ Reactions at injection site: skin irritation, redness, hardening, bruising, itching, warmth, rash ➤ Flu like symptoms ➤ Hot flush ➤ Swelling of the glands in neck, armpit or groin ➤ Vomiting ➤ Fever ($\geq 38^{\circ}\text{C}$)

<p>Identification & management of adverse reactions continued</p>	<p>Most side effects are mild to moderate in severity and resolve within 3 days of appearing</p> <p>During and following vaccination individuals can experience severe allergic reactions. Symptoms include difficulty breathing, shortness of breath, swelling of the face, tongue, lips and throat, cold and/or clammy skin, palpitations, feeling dizzy, feeling weak, fainting, rash or itching. If signs or symptoms of a clinically significant hypersensitivity reaction or anaphylaxis occurs, initiate appropriate medication and or supportive care</p> <p>If individuals are concerned about their health at any time, they should seek advice from their GP or NHS 111 Wales.</p> <p>A detailed list of adverse reactions is available in the Summary of Product Characteristics¹.</p>
<p>Reporting procedure of adverse reactions</p>	<p>Any adverse reaction to the product should be documented in the medical records.</p> <p>Alert a doctor in the event of a serious adverse reaction.</p> <p>Report ALL suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) or by using the Yellow Card¹¹ reporting scheme.</p>
<p>Written information to be given to patient or their carer</p>	<p>Supply the marketing authorisation holder's patient information leaflet (PIL).</p>
<p>Patient or carer advice /follow up</p>	<p>Inform the individual or their carer:</p> <ul style="list-style-type: none"> • of any possible side effects and their management • that the inactivated vaccine cannot cause influenza • it will take 14 days to provide protection against influenza • it does not protect against other respiratory viruses that often circulate at the same time during the flu season • if they have a weakened immune system that they may not make a full immune response to the vaccine and that they may need to consider vaccination of their household contacts • when they can be vaccinated another time if they have to postpone because of illness • if they get any side effects, to talk to their doctor, or pharmacist, including side effects not listed in the leaflet. • to seek medical advice in the event of a severe adverse reaction • to seek advice from their doctor, pharmacist or NHS Wales111 if common side effects do not spontaneously resolve 3 days after vaccination • that the PIL will be provided • to visit the NHS 111 Wales¹² website for more information

<p>Special considerations / additional information</p>	<p>The practitioner should have immediate access to adrenaline (epinephrine) 1 in 1,000 injection and access to a telephone at the time of vaccination.</p> <p>See Chapter 8 of the Green Book⁴ and advice issued by the Resuscitation Council¹³.</p> <p>Minor illnesses without fever or systemic upset are not valid reasons to postpone immunisation. If an individual is acutely unwell, immunisation may be postponed until they have fully recovered.</p> <p>Individuals who are not registered with a GP practice may be vaccinated at the professional discretion of the practitioner, weighing up risks and benefits for the individual. They should be encouraged to register with a GP as appropriate to their circumstances or be referred to appropriate alternative medical services as required.</p>
<p>Records</p>	<p>The consultation details must be recorded in Choose Pharmacy as prompted at the time of consultation (where the Choose Pharmacy platform is not available records must be made to document the vaccination, using the paper-based consultation record. Paper based records must be transferred onto the Choose Pharmacy Flu module as soon as practically possible and by the end of the next working day</p> <ul style="list-style-type: none"> ➤ All records, electronically or otherwise must be kept in accordance with NHS record keeping and Community Pharmacy Information Governance requirements. See: Information Governance Alliance (IGA) - NHS Digital¹⁴. ➤ All records should be clear, legible and contemporaneous. <p>A record of all individuals receiving treatment under this Patient Group Direction should also be kept for audit purposes in accordance with local policy.</p> <p>As a wide variety of influenza vaccines are available on the UK market each year, it is especially important that the exact brand of vaccine, batch number and site at which each vaccine is given is accurately recorded in the individual's records.</p> <p>It is important that vaccinations administered are recorded in a timely manner. A record of the vaccination should be returned to the individual's GP practice (as specified in the service specification) to allow clinical follow up and to avoid duplicate vaccination.</p> <p>For pregnant women, also record immunisation in the hand-held maternity record (if available).</p>

Appendices

Appendix A: References

1. Electronic Medicines Compendium (emc). <https://www.medicines.org.uk/emc/>.
2. NICE. Tools and resources | Patient group directions | Guidance | NICE. <https://www.nice.org.uk/guidance/mpg2/resources> (2017).
3. NICE. BNF. <https://bnf.nice.org.uk/>.
4. UK Health Security Agency. Immunisation Against Infectious Disease. *GOV.UK* <https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book> (2020).
5. Welsh Government. The national influenza immunisation programme 2022 to 2023 (WHC/2022/16). *GOV.WALES* <https://gov.wales/national-influenza-immunisation-programme-2022-2023-whc202216>.
6. Welsh Government. Advisory Document on Ordering, Storage and Handling of Vaccines. (2017).
7. *GOV.UK. Influenza: the green book, chapter 19.* (2020).
8. Welsh Government. Health circulars. *GOV.WALES* <https://gov.wales/health-circulars>.
9. UK Health Security Agency. Influenza vaccines marketed in the UK. *GOV.UK* <https://www.gov.uk/government/publications/influenza-vaccines-marketed-in-the-uk> (2022).
10. NHS Wales. Welsh Health Technical Memorandum - Safe management of healthcare waste. (2013).
11. Medicines & Healthcare products Regulatory Agency. Yellow Card. <https://yellowcard.mhra.gov.uk/>.
12. NHS Wales. NHS 111 Wales - Contact Us. <https://111.wales.nhs.uk/contactus/>.
13. Resuscitation Council UK. Anaphylaxis guidance for vaccination settings. *Resuscitation Council UK* <https://www.resus.org.uk/about-us/news-and-events/anaphylaxis-guidance-vaccination-settings> (2021).
14. NHS UK. Information Governance Alliance (IGA). *NHS Digital* <https://digital.nhs.uk/data-and-information/looking-after-information/data-security-and-information-governance/information-governance-alliance-iga>.

Appendix B: Healthcare Professionals Agreement to Practice

Authorisation for the use of the Patient Group Direction for the Administration of:
 Inactivated influenza vaccine in adults by community pharmacists under the Clinical
 Community Pharmacy Service: Seasonal Influenza Vaccination service commissioned by

Patient Group Directions do not remove inherent professional obligations or accountability.

Once completed and approved, health professionals wishing to use the PGD must sign up to the PGD for the LHB in which they will be providing services. Only pharmacists who are accredited in line with the National Service Specification can operate under the PGD.

This Patient Group Direction is to be read, agreed and signed by all pharmacists authorised to operate the PGD. By signing this document, the pharmacist operating the PGD confirms that they have read and understood the content of this PGD and are willing and competent to work under it within their professional code of conduct. One copy should be given to each named pharmacist and a signed copy must be kept within the pharmacy by the nominated member of staff with responsibility for PGDs. This will usually be the Superintendent Pharmacist or Responsible Pharmacist.

Name and address of Pharmacy:

For registered professionals

I confirm that I have read and understood the content of this PGD and that I am willing and competent to work under it within my professional code of conduct.

Name of registered pharmacist	Signature	GPhC number	Date

A signed copy of this form must also be returned to:
 Primary Care Services
 Floor 3, Matrix House
 Northern Boulevard
 Matrix Park
 Swansea Enterprise Park
 Swansea
 SA6 8BX
 E-mail: nwssp-primarycareservices@wales.nhs.uk

Fax: 01792 860481

Appendix C: Table to show the excipients and residues from manufacturing for the influenza vaccines

Vaccine name	Potential residues from manufacturing	Vaccine Excipients
Cell based quadrivalent influenza vaccine ▼ (surface antigen inactivated) Seqirus Flucelvax Tetra Seqirus UK Limited QIVc	Beta-propilactone Cetyltrimethylammonium bromide (CTAB) Polysorbate 80	Sodium chloride Potassium chloride Magnesium chloride hexahydrate Disodium phosphate dihydrate Potassium dihydrogen phosphate Water for injections
Adjuvanted Quadrivalent influenza vaccine ▼ (Surface antigen inactivated) Seqirus Fluad Tetra Seqirus UK Ltd aQUIV Adjuvant MF59C.1 containing squalene, polysorbate, sorbitan trioleate, sodium citrate and citric acid	Kanamycin sulphate Neomycin sulphate Formaldehyde Hydrocortisone CTAB	Sodium chloride Potassium chloride Potassium dihydrogen phosphate Disodium phosphate dihydrate Magnesium chloride hexahydrate Calcium chloride dihydrate Water for injection
Supemtek ▼® solution for injection Quadrivalent Influenza vaccine recombinant Sanofi Pasteur QIVr	Octylphenol ethoxylate	Polysorbate 20 (E432) Sodium chloride Sodium phosphate monobasic, monohydrate Sodium phosphate dibasic, dodecahydrate Water for injections
Quadrivalent influenza vaccine (split virion inactivated influenza vaccine) Sanofi Pasteur QIVe	Neomycin Formaldehyde Octoxinol-9	Sodium chloride Potassium chloride Disodium phosphate dihydrate Potassium dihydrogen phosphate Water for injections
Quadrivalent Influvac sub unit tetra ▼ Viatris formerly Mylan QIVe	Formaldehyde CTAB Polysorbate 80 gentamicin	Potassium chloride Potassium dihydrogen phosphate Disodium phosphate dihydrate Sodium chloride Calcium chloride dihydrate Magnesium chloride hexahydrate Water for injections