



NHS publishing approval reference: GOV-12991

## Inactivated influenza vaccine Patient Group Direction (PGD)

This PGD is for the administration of inactivated influenza vaccine to adults in accordance with the community pharmacy seasonal influenza vaccination advanced service and national influenza immunisation programme.

This PGD is for the administration of inactivated influenza vaccine by practitioners delivering the community pharmacy seasonal influenza vaccination advanced service.

Reference: Pharmacy Influenza Vaccination PGD  
Version no: 10.00  
Valid from: 1 September 2022  
Expiry date: 1 April 2023

**The UK Health Security Agency (UKHSA) has developed this PGD for authorisation by NHS England (NHSE) to facilitate delivery of the national immunisation programme in England.**

NHSE and community pharmacy contractors must not alter or amend the clinical content of this document (sections 3, 4, 5 and 6); such action will invalidate the clinical sign-off with which it is provided. Section 2 may be amended by NHSE only. [Section 7](#) is to be completed by the community pharmacy contractor providing the advanced service.

Operation of this PGD is the responsibility of NHSE as the commissioner and the community pharmacy contractor as the service provider. The final authorised copy of this PGD should be kept by NHSE and community pharmacy contractors for 8 years after the PGD expires.

**A practitioner must be authorised by name to work according to the current version of this PGD by signing [section 7](#). A manager with the relevant level of authority should also provide a counter signature.**

Providers must check that they are using the current version of the PGD. Amendments may become necessary prior to the published expiry date. The current version of the community pharmacy seasonal influenza vaccination advanced service PGD (Pharmacy Influenza Vaccination PGD) can be found at: [NHS England » Community Pharmacy Seasonal Influenza Vaccine Service](#)

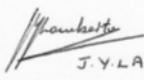


Any enquiries regarding this PGD should be addressed to:  
[ENGLAND.communitypharmacy@nhs.net](mailto:ENGLAND.communitypharmacy@nhs.net)

## Change History

Version number	Change details	Date
V01.00 – V06.00	See earlier version of this PGD for change details.	18 August 2015 – 8 May 2019
V07.00	Pharmacy Influenza Vaccination PGD amended to: <ul style="list-style-type: none"> <li>• add paragraph on document retention to the front page</li> <li>• include household contacts of those on the NHS Shielded Patient List, health and social care workers employed through Direct Payments or Personal Health Budgets, and potential in season extension of the programme to individuals from 50 years of age</li> <li>• update the table of recommended inactivated influenza vaccines for the 2020 to 2021 season</li> <li>• remove reference to Fluad® brand which will not be supplied to UK this season and remove black triangle from Fluarix® Tetra</li> <li>• remove reference to barium sulphate which is no longer listed in the adjuvanted trivalent influenza influenza vaccine SPC as a residue of the manufacturing process</li> <li>• include minor rewording, layout and formatting changes for clarity and consistency with other PHE PGDs</li> </ul>	24 August 2020
V08.00	Pharmacy Influenza Vaccination PGD amended to: <ul style="list-style-type: none"> <li>• include registered professionals who can legally supply and administer under a PGD</li> <li>• include eligible cohorts for the 2021 to 2022 season</li> <li>• include the inactivated influenza vaccines for the 2021 to 2022 season</li> <li>• include minor rewording, layout and formatting changes for clarity and consistency with other PHE PGDs</li> </ul>	27 July 2021
V09.00	Pharmacy Influenza Vaccination PGD amended to: <ul style="list-style-type: none"> <li>• include primary care contractors (primary medical services, pharmaceutical services, primary dental services or general ophthalmic services) and their frontline staff, including locums</li> <li>• mention consent or 'best-interests' decision in accordance with the Mental Capacity Act 2005</li> <li>• update additional information and drug interactions sections</li> <li>• update for change of organisation from PHE to UKHSA</li> <li>• web addresses hyperlinked into body text for clarity and consistency with other UKHSA PGDs</li> </ul>	12 October 2021
V10.00	Pharmacy Influenza Vaccination PGD amended to: <ul style="list-style-type: none"> <li>• include only eligible cohorts for the 2022 to 2023 influenza season</li> <li>• include the inactivated influenza vaccines for the 2022 to 2023 season</li> <li>• include minor rewording, layout and formatting changes for clarity and consistency with other UKHSA PGDs</li> </ul>	28 June 2022

## 1. PGD Development

This PGD has been developed by the following health professionals on behalf of the UKHSA:

Developed by:	Name	Signature	Date
<b>Pharmacist</b> (Lead Author)	<b>Jacqueline Lamberty</b> Lead pharmacist Medicines Governance Health Equity and Clinical Governance Directorate, UKHSA	 J.Y. LAMBERTY	9 August 2022
<b>Doctor</b>	<b>Jamie Lopez-Bernal</b> Consultant Epidemiologist, Immunisation and Vaccine Preventable Diseases Division, UKHSA		9 August 2022
<b>Registered Nurse</b> (Chair of Expert Panel)	<b>David Green</b> Nurse Consultant for Immunisation, Immunisation and Vaccine Preventable Diseases Division, UKHSA		9 August 2022

This PGD has been peer reviewed by the UKHSA Immunisations PGD Expert Panel in accordance with the UKHSA PGD Policy. It has been approved by the UKHSA Medicines Governance Group and ratified by the UKHSA Clinical Quality and Oversight Board.

In addition to the signatories above the working group included:

Name	Designation
Jane Horsfall	Senior Policy Manager, Community Pharmacy, Strategy and Innovation Directorate, NHSE
Jill Loader	Deputy Director, Pharmacy Commissioning, NHSE
Sejal Parekh	Pharmacist, Pharmacy Commissioning, NHSE
Gul Root	Principal Pharmaceutical Officer, DHSC and National lead pharmacy public health, Office for Health Improvement and Disparities
Conall Watson	Consultant Epidemiologist, UKHSA

### Expert Panel

Name	Designation
Nicholas Aigbogun	Consultant in Communicable Disease Control, Yorkshire and Humber Health Protection Team, UKHSA
Sarah Dermont	Clinical Project Coordinator and Registered Midwife, NHS Infectious Diseases in Pregnancy Screening Programme, NHSE
Ed Gardner	Advanced Paramedic Practitioner/Emergency Care Practitioner, Medicines Manager, Proactive Care Lead
Michelle Jones	Principal Medicines Optimisation Pharmacist, Bristol North Somerset and South Gloucestershire Integrated Care Board
Elizabeth Lockett	Senior Screening and Immunisation Manager, NHSE South West
Vanessa MacGregor	Consultant in Communicable Disease Control, East Midlands Health Protection Team, UKHSA
Alison Mackenzie	Consultant in Public Health Medicine, Screening and Immunisation Lead, NHSE (South West)
Gill Marsh	Principal Screening and Immunisation Manager, NHSE North West
Lesley McFarlane	Lead Immunisation Nurse Specialist, Immunisation and Vaccine Preventable Diseases Division, UKHSA
Tushar Shah	Lead Pharmacy Advisor, NHSE London

## 2. Organisational Authorisations

NHSE accepts governance responsibility for this PGD. Any community pharmacy contractor providing the advanced service must work strictly within the terms of this PGD and The Pharmaceutical Services (Advanced and Enhanced Services) (England) Directions, covering the advanced service, published in the Drug Tariff. Any deviation will be treated as a serious contractual breach.

NHSE authorises this PGD for use by community pharmacy contractors delivering the community pharmacy seasonal influenza vaccination advanced service.

Organisational approval (legal requirement)			
Role	Name	Sign	Date
Deputy Medical Director of Primary Care, NHSE	Dr Raj Patel		

Enquiries regarding the use of this PGD may be directed to:

[ENGLAND.communitypharmacy@nhs.net](mailto:ENGLAND.communitypharmacy@nhs.net)

The community pharmacy contractor must complete the practitioner authorisation sheet included at the end of this PGD (see [Section 7](#)).

### 3. Characteristics of Staff

<p><b>Qualifications and professional registration</b></p>	<p>Practitioners must only work under this PGD where they are competent to do so. Practitioners working to this PGD must also be one of the following registered professionals who can legally supply and administer under a PGD (see <a href="#">Patient Group Directions: who can administer them</a>):</p> <ul style="list-style-type: none"> <li>• nurses and midwives currently registered with the Nursing and Midwifery Council (NMC)</li> <li>• pharmacists currently registered with the General Pharmaceutical Council (GPhC)</li> <li>• chiropodists/podiatrists, dieticians, occupational therapists, orthoptists, orthotists/prosthetists, paramedics, physiotherapists, radiographers and speech and language therapists currently registered with the Health and Care Professions Council (HCPC)</li> <li>• dental hygienists and dental therapists registered with the General Dental Council</li> <li>• optometrists registered with the General Optical Council</li> </ul> <p>Practitioners must also fulfil all the <a href="#">Additional requirements</a>.</p>
<p><b>Additional requirements</b></p>	<p>Additionally, practitioners:</p> <ul style="list-style-type: none"> <li>• must be authorised by name as an approved practitioner under the current terms of this PGD before working to it (by completion of <a href="#">Section 7</a>)</li> <li>• must have undertaken appropriate training for working under PGDs for supply/administration of medicines as required by the community pharmacy seasonal influenza vaccination advanced service specification, the <a href="#">declaration of competence for vaccination services</a> and in line with the <a href="#">National Minimum Standards and Core Curriculum for Immunisation Training</a>. For further information see <a href="#">Flu immunisation training recommendations</a></li> <li>• must be competent in the use of PGDs (see <a href="#">NICE competency framework</a> for health professionals using PGDs)</li> <li>• must be familiar with the vaccine products and alert to changes in their Summary of Product Characteristics (SPC), Immunisation Against Infectious Disease (the '<a href="#">Green Book</a>'), and the national immunisation programme</li> <li>• must be competent to undertake immunisation and to discuss issues related to seasonal influenza immunisation</li> <li>• must be competent in the handling and storage of vaccines, and management of the 'cold chain' as outlined in the <a href="#">CPPE declaration of competence for vaccination services</a></li> <li>• must be competent in the recognition and management of anaphylaxis</li> <li>• must have access to the PGD and associated online resources</li> </ul> <p><b>The practitioner must be authorised by name, under the current NHSE authorised version of this PGD before working under its authority.</b></p>
<p><b>Continued training requirements</b></p>	<p>Practitioners should 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).</p> <p>Practitioners should be constantly alert to any subsequent recommendations from UKHSA and/or NHSE, and other sources of medicines information.</p> <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>

#### 4. Clinical condition or situation to which this PGD applies

<p><b>Clinical condition or situation to which this PGD applies</b></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 advanced service, the national immunisation programme and recommendations given in <a href="#">Chapter 19</a> of the Immunisation Against Infectious Disease: 'The Green Book', <a href="#">annual flu letter(s)</a> and subsequent correspondence/publications from UKHSA and/or NHSE.</p>
<p><b>Criteria for inclusion</b></p> <p>Continued over page</p>	<p>For the 2022 to 2023 influenza season, influenza vaccine should be offered at NHS expense to the following groups under the community pharmacy seasonal influenza vaccination advanced service:</p> <ul style="list-style-type: none"> <li>• individuals aged 65 years or over (including those becoming age 65 years by 31 March 2023)</li> <li>• healthy individuals aged 50 to 64 years (including those becoming age 50 years by 31 March 2023) eligible from 15 October 2022</li> <li>• adults aged from 18 years to under 50 years of age in a clinical risk group category listed in <a href="#">Chapter 19</a> of the Green Book such as those with:             <ul style="list-style-type: none"> <li>○ chronic (long-term) respiratory disease, such as asthma that requires continuous or repeated use of inhaled or systemic steroids or with previous exacerbations requiring hospital admission, chronic obstructive pulmonary disease (COPD) or bronchitis</li> <li>○ chronic heart disease and vascular disease, such as heart failure</li> <li>○ chronic kidney disease at stage 3, 4 or 5</li> <li>○ chronic liver disease</li> <li>○ chronic neurological disease, such as Parkinson's disease or motor neurone disease,</li> <li>○ learning disability</li> <li>○ diabetes and adrenal insufficiency</li> <li>○ asplenia or dysfunction of the spleen</li> <li>○ a weakened immune system due to disease (such as HIV/AIDS) or treatment (such as cancer treatment)</li> <li>○ morbidly obese adults with a BMI of 40kg/m<sup>2</sup> and above</li> </ul> </li> <li>• all pregnant women (including those women who become pregnant during the influenza season)</li> <li>• adult household contacts (aged 18 years and over) of immunocompromised individuals, specifically individuals who expect to share living accommodation on most days over the winter and, therefore, for whom continuing close contact is unavoidable</li> <li>• adults (aged 18 years and over) living in long-stay residential care homes or other long-stay care facilities where rapid spread is likely to follow introduction of infection and cause high morbidity and mortality. This does not include, for instance, prisons, young offender institutions, university halls of residence or boarding schools</li> <li>• adults (aged 18 years and over) who are in receipt of a carer's allowance, or those who are the main carer of an older or disabled person whose welfare may be at risk if the carer falls ill</li> <li>• frontline staff (aged 18 years and over) without employer led occupational health schemes, employed             <ul style="list-style-type: none"> <li>○ by a registered residential care or nursing home or registered domiciliary care provider, who are directly involved in the care of vulnerable individuals who are at increased risk from exposure to influenza</li> <li>○ by a voluntary managed hospice provider, who are directly involved in the care of vulnerable individuals who are at increased risk from exposure to influenza</li> </ul> </li> </ul>

<b>Criteria for inclusion</b> continued	<ul style="list-style-type: none"> <li>○ through Direct Payments (personal budgets) and/or Personal Health Budgets, such as Personal Assistants, to deliver domiciliary care to individuals</li> </ul>
<b>Criteria for exclusion<sup>1</sup></b>	<p>Individuals for whom valid consent, or ‘best-interests’ decision in accordance with the <a href="#">Mental Capacity Act 2005</a>, has not been obtained (for further information on consent see <a href="#">Chapter 2</a> of ‘<a href="#">The Green Book</a>’).</p> <p>Individuals who:</p> <ul style="list-style-type: none"> <li>• are less than 18 years of age</li> <li>• have had a confirmed anaphylactic reaction to a previous dose of the vaccine</li> <li>• have had a confirmed anaphylactic reaction to any component of the vaccine or residues from the manufacturing process<sup>2</sup> (other than ovalbumin – see <a href="#">Cautions</a>)</li> <li>• have received a complete dose of the recommended influenza vaccine for the current season</li> <li>• are suffering from acute severe febrile illness (the presence of a minor infection is not a contraindication for immunisation)</li> </ul>
<b>Cautions including any relevant action to be taken</b>	<p>Individuals with a bleeding disorder may develop a haematoma at the injection site (see <a href="#">Route of Administration</a>).</p> <p>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 to 2023 season and their ovalbumin content see <a href="#">All influenza vaccines marketed in the UK for the 2022 to 2023 season</a>.</p> <p>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 movements during recovery. It is important that procedures are in place to avoid injury from faints.</p>
<b>Action to be taken if the patient is excluded</b>	<p>The risk to the individual of not being immunised should be taken into account. The indications for flu vaccination are not exhaustive, and the practitioner should take into account 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.</p> <p>Individuals under 18 years of age who are in a clinical risk group or otherwise eligible for influenza vaccination for the 2022 to 2023 season should be referred to their GP or an appropriate local NHS service provider for immunisation.</p> <p>In case of postponement due to acute illness, advise when the individual can be vaccinated and ensure another appointment is arranged.</p> <p>Document the reason for exclusion and any action taken in the individual’s clinical records.</p>

<sup>1</sup> 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

<sup>2</sup> Residues from the manufacturing process may include beta-propiolactone, cetyltrimethylammonium bromide (CTAB), formaldehyde, gentamicin, hydrocortisone, kanamycin, neomycin, octoxinol-9, octylphenol ethoxylate, polysorbate 80, sodium deoxycholate. Check the vaccine products SPC for details.

<p><b>Action to be taken if the patient or carer declines treatment</b></p>	<p>Informed consent, from the individual or a person legally able to act on the person's behalf, must be obtained for each administration. Where a person lacks the capacity, in accordance with the <a href="#">Mental Capacity Act 2005</a>, a decision to vaccinate may be made in the individual's best interests. For further information on consent see <a href="#">Chapter 2</a> of the '<a href="#">Green Book</a>'.</p> <p>Advise the individual/carer about the protective effects of the vaccine, the risks of infection and potential complications if not immunised.</p> <p>Document advice given and decision reached and inform individual's GP as appropriate.</p>
<p><b>Arrangements for referral for medical advice</b></p>	<p>Refer to individual's GP.</p>



## 5. Description of Treatment

<p><b>Name, strength and formulation of drug</b></p>	<p>Inactivated influenza vaccine suspension in a pre-filled syringe including:</p> <ul style="list-style-type: none"> <li>• adjuvanted quadrivalent influenza vaccine (aQIV)</li> <li>• cell-based quadrivalent influenza vaccine (QIVc)</li> <li>• egg-grown quadrivalent influenza vaccine (QIVe)</li> <li>• recombinant quadrivalent influenza vaccine (QIVr), Supemtek ▼</li> </ul> <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 for the 2022 to 2023 season see <a href="#">All influenza vaccines marketed in the UK for the 2022 to 2023 season</a>..</p> <p>Some influenza vaccines are restricted for use in particular age groups. The SPC for individual products should always be referred to.</p> <p><b>Summary table of which influenza vaccines to offer (by age)</b></p> <table border="1" data-bbox="497 696 1444 1099"> <thead> <tr> <th data-bbox="497 696 700 763">Age</th> <th data-bbox="700 696 1444 763">Recommended influenza vaccine for adults</th> </tr> </thead> <tbody> <tr> <td data-bbox="497 763 700 898">18 years to under 65 years</td> <td data-bbox="700 763 1444 898">Offer QIVc or QIVr If QIVc or QIVr are not available, offer QIVe</td> </tr> <tr> <td data-bbox="497 898 700 1099">65 years<sup>3</sup> and over<sup>4</sup></td> <td data-bbox="700 898 1444 1099">Offer aQIV or QIVr If aQIV or QIVr are not available, offer QIVc  For those aged 64 who turn 65 years of age by 31 March 2023, aQIV may be offered off-label</td> </tr> </tbody> </table>	Age	Recommended influenza vaccine for adults	18 years to under 65 years	Offer QIVc or QIVr If QIVc or QIVr are not available, offer QIVe	65 years <sup>3</sup> and over <sup>4</sup>	Offer aQIV or QIVr If aQIV or QIVr are not available, offer QIVc  For those aged 64 who turn 65 years of age by 31 March 2023, aQIV may be offered off-label
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65 years <sup>3</sup> and over <sup>4</sup>	Offer aQIV or QIVr If aQIV or QIVr are not available, offer QIVc  For those aged 64 who turn 65 years of age by 31 March 2023, aQIV may be offered off-label						
<p><b>Legal category</b></p>	<p>Prescription only medicine (POM).</p>						
<p><b>Black triangle ▼</b></p>	<p>QIVc, QIVr and aQIV products are black triangle.</p> <p>The QIVe vaccine from Viatrix (formerly Mylan), Influvac® sub-unit Tetra, is black triangle.</p> <p>This information was accurate at the time of writing. See product SPCs, available from the <a href="#">electronic medicines compendium</a> website, for indication of current black triangle status.</p>						
<p><b>Off-label use</b></p> <p>Continued over page</p>	<p>Where a vaccine is recommended off-label, as part of the consent process, consider informing the individual/carer the vaccine is being offered in accordance with national guidance but this is outside the product licence.</p> <p>The aQIV is licensed for administration to individuals aged 65 years and over. It may be administered under this PGD to those aged 64 years and turning 65 years of age by 31 March 2023 in accordance with the recommendations for the national influenza immunisation programme for the 2022 to 2023 season (see Appendix C of the <a href="#">annual flu letter</a> dated 22 April 2022).</p> <p>Vaccine should be stored according to the conditions detailed in the <a href="#">Storage section</a> below. However, in the event of an inadvertent or unavoidable deviation of these conditions refer to <a href="#">Vaccine Incident Guidance</a>. Where vaccine is assessed in accordance with these</p>						

<sup>3</sup> Including those turning age 65 years by 31 March 2023

<sup>4</sup> JCVI recommended use of QIV-HD in this age group but this is not currently available in the UK market.

<p><b>Off-label use</b> (continued)</p>	<p>guidelines as appropriate for continued use this would constitute off-label administration under this PGD.</p> <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' SPCs, available from the <a href="#">electronic medicines compendium</a> website, and <a href="#">All influenza vaccines marketed in the UK for the 2022 to 2023 season</a> for more information.</p>
<p><b>Route / method of administration</b></p>	<p>Administer by intramuscular injection, preferably into the deltoid region of the upper arm.</p> <p>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 (23 gauge or 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.</p> <p>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 (23 gauge or 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> <p>Influenza vaccines licensed for both intramuscular or subcutaneous administration may alternatively be administered by the subcutaneous route. Subcutaneous administration is covered by this PGD where the practitioner is trained and competent in administration via the subcutaneous route. Note: QIVc, QIVr and aQIV are not licensed for subcutaneous administration so should only be administered intramuscularly under this PGD.</p> <p>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.</p> <p>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 needs to be administered at the same time as another vaccine, immunisation should be carried out on separate limbs.</p> <p>Shake vaccine before administration.</p> <p>Inspect visually prior to administration and ensure appearance is consistent with the description in the SPC for the vaccine being administered.</p> <p>The SPC for each vaccine provides further guidance on administration and is available from the <a href="#">electronic medicines compendium</a> website.</p>

<b>Dose and frequency of administration</b>	Single 0.5ml dose to be administered for the current annual flu season (1 September 2022 to 31 March 2023).
<b>Duration of treatment</b>	Single 0.5ml dose for the current annual flu season.
<b>Quantity to be supplied / administered</b>	Single dose of 0.5ml per administration.
<b>Supplies</b>	Providers should order influenza vaccines for adults from the influenza vaccine manufacturers or pharmaceutical wholesalers as in previous years.
<b>Storage</b>	<p>Store between +2°C to +8°C. Do not freeze. Store in original packaging in order to protect from light.</p> <p>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 <a href="#">Vaccine Incident Guidance</a>.</p>
<b>Disposal</b>	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 <a href="#">technical memorandum 07-01: Safe management of healthcare waste</a> (Department of Health, 2013).
<b>Drug interactions</b>	<p>Immunological response may be diminished in those receiving immunosuppressive treatment, but it is important to still immunise this group.</p> <p>Because of the absence of data on co-administration of Shingrix<sup>®</sup> vaccine with adjuvanted influenza vaccine, administration should ideally be separated by an interval of at least 7 days to avoid incorrect attribution of potential adverse events. Where individuals require rapid protection or are likely to be lost to follow up, administration at an interval of less than 7 days may still be considered, which may include coadministration at clinical services that offer both vaccines.</p> <p>Inactivated influenza vaccination may be given at the same time as other vaccines (see <a href="#">Route / method of administration</a>).</p> <p>Where co-administration does occur, individuals should be informed about the likely timing of potential adverse events relating to each vaccine. If the vaccines are not given together, they can be administered at any interval, although separating the vaccines by a day or two will avoid confusion over systemic side effects.</p> <p>As all of the early COVID-19 vaccines are considered inactivated (including the non-replicating adenovirus vaccine), where individuals in an eligible cohort present having recently received COVID-19 vaccination, influenza vaccination should still be given.</p> <p>A detailed list of drug interactions associated with inactivated influenza vaccine is available in the SPC for each vaccine, which are available from the <a href="#">electronic medicines compendium</a> website.</p>
<b>Identification and management of adverse reactions</b>  Continued over page	Pain, swelling or redness at the injection site, low-grade fever, malaise, shivering, fatigue, headache, myalgia and arthralgia are among the commonly reported symptoms after intramuscular vaccination. A small painless nodule (induration) may also form at the injection site. These symptoms usually disappear within 1 to 2 days without treatment.

<p><b>Identification and management of adverse reactions</b> (continued)</p>	<p>Immediate reactions such as urticaria, angio-oedema, bronchospasm and anaphylaxis can occur.</p> <p>A higher incidence of mild post-immunisation reactions has been reported with adjuvanted compared to non-adjuvanted influenza vaccines.</p> <p>The frequency of injection site pain and systemic reactions may be higher in individuals vaccinated concomitantly with inactivated influenza vaccine and pneumococcal polysaccharide vaccine (PPV23) compared to vaccination with influenza vaccine alone and similar to that observed with PPV23 vaccination alone. Influenza vaccine and PPV23 may be administered on the same day or at any interval from each other.</p> <p>A detailed list of adverse reactions associated with inactivated influenza vaccine is available in the SPC for each vaccine, which are available from the <a href="#">electronic medicines compendium</a> website.</p>
<p><b>Reporting procedure of adverse reactions</b></p>	<p>Healthcare professionals and individuals/carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the <a href="#">Yellow Card reporting scheme</a> or search for MHRA Yellow Card in the Google Play or Apple App Store.</p> <p>QIVe vaccine from Viatrix (formerly Mylan), QIVc, QIVr and aQIV are black triangle. Therefore, any suspected adverse reactions to these products should be reported via the Yellow Card Scheme.</p> <p>Any adverse reaction to a vaccine should be documented in the individual's record and the individual's GP should be informed.</p>
<p><b>Written information to be given to patient or carer</b></p>	<p>Offer the marketing authorisation holder's patient information leaflet (PIL) provided with the vaccine.</p>
<p><b>Patient advice / follow up treatment</b></p>	<p>Individuals should be advised regarding adverse reactions to vaccination and reassured that the inactivated vaccine cannot cause influenza. However, the vaccine will not provide protection for about 14 days and does not protect against other respiratory viruses that often circulate during the flu season.</p> <p>Immunosuppressed individuals should be advised that they may not make a full immune response to the vaccine. Therefore, consideration should be given to the vaccination of household contacts of immunocompromised individuals.</p> <p>Inform the individual/carer of possible side effects and their management.</p> <p>The individual/carer should be advised when and where to seek appropriate advice in the event of an adverse reaction.</p> <p>In case of postponement due to acute illness, advise when the individual can be vaccinated and how future vaccination may be accessed.</p> <p>Advise the individual/carer when a subsequent vaccine dose is due, such as a single immunisation for each annual influenza season.</p> <p>If the individual is eligible for another vaccine on the NHS and has not received it, such as a COVID-19 vaccine, PPV23 or shingles vaccine, they should be signposted to their GP or an appropriate provider to receive the vaccine on the NHS.</p>
<p><b>Special considerations / additional information</b> Continued over page</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><b>Special considerations / additional information</b> (continued)</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>For 50 to 64 year olds, the <a href="#">advice of JCVI</a> is the most vulnerable cohorts should be prioritised over the otherwise healthy 50 to 64 year olds and given the most effective vaccines available first, QIVr or QIVc where possible, while QIVe should be reserved for otherwise healthy 50 to 64 year olds. However, QIVe is suitable to offer as a second option for vulnerable cohorts.</p>
<p><b>Records</b></p>	<p>Record:</p> <ul style="list-style-type: none"> <li>• that valid informed consent was given</li> <li>• name of individual, address, date of birth and GP practice with whom the individual is registered (or record where an individual is not registered with a GP and that appropriate advice has been given)</li> <li>• eligible/clinical risk group indication for immunisation</li> <li>• name of immuniser</li> <li>• name and brand of vaccine</li> <li>• date of administration</li> <li>• dose, form and route of administration of vaccine</li> <li>• quantity administered</li> <li>• batch number and expiry date</li> <li>• anatomical site of vaccination</li> <li>• advice given, including advice given if not vaccinated</li> <li>• details of any adverse drug reactions and actions taken</li> <li>• supplied via PGD</li> </ul> <p>Records should be signed and dated or if using electronic records, the immuniser's account should be password protected such as to provide an electronic signature to the vaccination record.</p> <p>All records should be clear, legible, contemporaneous and in line with the community pharmacy seasonal influenza immunisation advanced service specification.</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> <p>Records of all individuals receiving treatment under this PGD should also be kept for audit purposes and post payment verification.</p>

## 6. Key References

<b>Key references</b>	<p><b>Inactivated influenza vaccination</b></p> <ul style="list-style-type: none"><li>• Immunisation Against Infectious Disease: The Green Book, Chapter 19. Published 29 October 2020 <a href="https://www.gov.uk/government/publications/influenza-the-green-book-chapter-19">https://www.gov.uk/government/publications/influenza-the-green-book-chapter-19</a></li><li>• Collection: Annual Flu Programme. Updated 26 July 2022 <a href="https://www.gov.uk/government/collections/annual-flu-programme">https://www.gov.uk/government/collections/annual-flu-programme</a></li><li>• Community Pharmacy Seasonal Influenza Vaccine Service <a href="https://www.england.nhs.uk/publication/community-pharmacy-seasonal-influenza-vaccine-service/">https://www.england.nhs.uk/publication/community-pharmacy-seasonal-influenza-vaccine-service/</a></li><li>• The national flu immunisation programme 2022 to 2023: supporting letter. Published 22 April 2022 <a href="https://www.gov.uk/government/publications/national-flu-immunisation-programme-plan">https://www.gov.uk/government/publications/national-flu-immunisation-programme-plan</a></li><li>• Statement of amendments to annual flu letter – 21 July 2022 <a href="https://www.gov.uk/government/publications/national-flu-immunisation-programme-plan/statement-of-amendments-to-annual-flu-letter-21-july-2022">https://www.gov.uk/government/publications/national-flu-immunisation-programme-plan/statement-of-amendments-to-annual-flu-letter-21-july-2022</a></li><li>• All influenza vaccines marketed in the UK for the 2022 to 2023 season <a href="https://www.gov.uk/government/publications/influenza-vaccines-marketed-in-the-uk">https://www.gov.uk/government/publications/influenza-vaccines-marketed-in-the-uk</a></li><li>• Declaration of competence for vaccination services <a href="https://www.cppe.ac.uk/services/declaration-of-competence">https://www.cppe.ac.uk/services/declaration-of-competence</a></li><li>• Summary of Product Characteristics <a href="http://www.medicines.org.uk">www.medicines.org.uk</a></li></ul> <p><b>General</b></p> <ul style="list-style-type: none"><li>• Health Technical Memorandum 07-01: Safe Management of Healthcare Waste. Department of Health. 20 March 2013 <a href="https://www.england.nhs.uk/publication/management-and-disposal-of-healthcare-waste-hm-07-01/">https://www.england.nhs.uk/publication/management-and-disposal-of-healthcare-waste-hm-07-01/</a></li><li>• Immunisation Against Infectious Disease: The Green Book. Chapter 2. Updated 18 June 2021 <a href="https://www.gov.uk/government/publications/consent-the-green-book-chapter-2">https://www.gov.uk/government/publications/consent-the-green-book-chapter-2</a></li><li>• National Minimum Standards and Core Curriculum for Immunisation Training. Published February 2018 <a href="https://www.gov.uk/government/publications/national-minimum-standards-and-core-curriculum-for-immunisation-training-for-registered-healthcare-practitioners">https://www.gov.uk/government/publications/national-minimum-standards-and-core-curriculum-for-immunisation-training-for-registered-healthcare-practitioners</a></li><li>• NICE Medicines Practice Guideline 2 (MPG2): Patient Group Directions. Published March 2017 <a href="https://www.nice.org.uk/guidance/mpg2">https://www.nice.org.uk/guidance/mpg2</a></li><li>• NICE MPG2 Patient group directions: competency framework for health professionals using patient group directions. Updated March 2017 <a href="https://www.nice.org.uk/guidance/mpg2/resources">https://www.nice.org.uk/guidance/mpg2/resources</a></li><li>• UKHSA Immunisation Collection <a href="https://www.gov.uk/government/collections/immunisation">https://www.gov.uk/government/collections/immunisation</a></li><li>• Vaccine Incident Guidance <a href="https://www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors">https://www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors</a></li></ul>
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## 7. Practitioner authorisation sheet

### Pharmacy Influenza Vaccination PGD v10.00

Valid from: 1 September 2022 Expiry: 1 April 2023

#### Practitioner

By signing this PGD you are indicating that you agree to its contents and that you will work within it.

PGDs do not remove inherent professional obligations or accountability.

It is the responsibility of each professional to practise only within the bounds of their own competence and professional code of conduct.

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

Name	Designation	Signature	Date

#### Authorising manager

I confirm that the practitioners named above have declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of insert name of organisation for the above named practitioners who have signed the PGD to work under it.

Name	Designation	Signature	Date

#### Note to authorising manager

Score through unused rows in the list of practitioners to prevent practitioner additions post managerial authorisation.

A copy of this PGD with completed practitioner authorisation sheet should be retained and available at the pharmacy premises as a record of those practitioners authorised to work under this PGD.