

This patient group direction (PGD) must only be used by registered health professionals who have been named and authorised by their organisation to practice under it. The most recent and in date final signed version of the PGD should be used.

## **Patient Group Direction (PGD)**

For the administration of

### **Inactivated influenza vaccine (Pharmacists)**

By registered health care professionals for

### **Inactivated influenza vaccine by practitioners delivering the community pharmacy seasonal influenza vaccination advanced service.**

Throughout Manx Care and those contracted by Manx Care where appropriate within practice

## **PGD NUMBER 161**

### **1. Change History**

<b>version number</b>	<b>Change Details</b>	<b>Date</b>
V01.0 – V05.00	See earlier version of this PGD for change details.	18/08/2015 – 10/08/2018

V06.00	Pharmacy Influenza Vaccination PGD amended to: <ul style="list-style-type: none"> <li>include vaccines for the 2019/20 season, including cell-based quadrivalent influenza vaccine (QIVc)</li> <li>update cautions for egg allergy and include use of QIVc which is egg free for individuals with a severe anaphylaxis to egg which has previously required intensive care</li> </ul>	08/05/2019
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 2020/21 season</li> <li>remove reference to Fludax<sup>®</sup> brand which will not be supplied to UK this season and remove black triangle from Fluarix<sup>®</sup> Tetra</li> <li>remove reference to barium sulphate which is no longer listed in the adjuvanted trivalent 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>	24/08/2020
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 2021/22 season</li> <li>include the inactivated influenza vaccines for the 2021/22 season</li> <li>include minor rewording, layout and formatting changes for clarity and consistency with other PHE PGDs</li> </ul>	27/07/2021
V 09.00	Pharmacy Influenza Vaccination PGD amended to: <ul style="list-style-type: none"> <li>include the inactivated influenza vaccines for the 2022/23 season</li> <li>include minor rewording, layout and formatting changes for clarity and consistency with other PGDs</li> </ul>	14/07/2022
V10.00	Inactivated Influenza PGD amended to: <ul style="list-style-type: none"> <li>mention consent or 'best-interests' decision in accordance with the Manx Care policy for Capacity, Best Interests Decision and Deprivation of Liberty</li> <li>Include recommendations as per JCVI regarding priority of flu vaccine to be offered to vulnerable patients and patients over 65 years</li> </ul>	14/10/2022
V11.00	Pharmacy Influenza Vaccination PGD amended to remove declaration of competence for vaccination services from additional requirements under staff characteristics	05/09/2022

V12.00	Community Pharmacy Influenza Vaccination PGD amended to: <ul style="list-style-type: none"> <li>• include eligible cohorts for the 2023 to 2024 season</li> <li>• include the recommended influenza vaccines for the 2023 to 2024 season</li> <li>• include updated advice on co-administration of aQIV with Shingrix® (shingles) vaccine</li> <li>• include minor rewording, layout and formatting changes for clarity and consistency with Manx Care PGDs, including acknowledgment of the change of PHE to UKHSA</li> </ul>	
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## 2. Medicines practice guideline 2: *Patient group directions*

Refer to the relevant sections of NICE medicines practice guideline 2: *Patient group directions* as stated in the blank template notes. For further information about PGD signatories, see the NHS and Manx Care [PGD website FAQs](#)

## 3. PGD development

Refer to the [NICE PGD competency framework for people developing PGDs](#)

Job Title & organisation	Name	Signature	Date
Author of the PGD			
Member of the PGD working group			

#### 4. PGD authorisation

Refer to the NICE PGD competency framework for people authorising PGDs

Job Title	Name	Signature	Date
Consultant (on behalf of Medical Director)			
Chief Pharmacist/ Pharmaceutical Adviser			
Senior Paramedic			
Director of Nursing			
GP Adviser			
Senior Microbiologist (if PGD contains antimicrobials)	N/A	N/A	N/A

#### 5. PGD adoption by the provider

Refer to the NICE PGD competency framework for people authorising PGDs

Job title and organisation	Signature	Date	Applicable or not applicable to area

## 6. Training and competency of registered healthcare professionals, employed or contracted by Manx Care, GP practice or Hospice

Refer to the [NICE PGD competency framework for health professionals using PGDs](#)

	Requirements of registered Healthcare professionals working under the PGD
<b>Qualifications and professional registration</b> (continued)	<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>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</li> <li>• must have undertaken appropriate training for working under PGDs for supply and administration of medicines as required by the community pharmacy advanced service specification: seasonal influenza vaccination</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 ('<a href="#">The 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 have undertaken training appropriate to this PGD as required by local policy and in line with the <a href="#">National Minimum</a></li> </ul>

<b>Qualifications and professional registration</b> (continued)	<p><u>Standards and Core Curriculum for Immunisation Training</u>. For further information see <u>Flu immunisation training recommendations</u></p> <ul style="list-style-type: none"> <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>
<b>Initial training</b>	<ul style="list-style-type: none"> <li>• Knowledge of current guidelines and the administration of the drug specified in this PGD/BNF and of the inclusion and exclusion criteria</li> <li>• Training which enables the practitioner to make a clinical assessment to establish the need for the medication covered by this PGD</li> <li>• Training in the use of PGD's</li> </ul>
<b>Competency assessment</b>	Staff will be assessed on their knowledge of drugs and clinical assessment as part of the competency framework for registered health professionals using PGD's
<b>Ongoing training and competency</b>	<ul style="list-style-type: none"> <li>• The registered health care professionals should make sure they are aware of any changes to the recommendations for this medication; it is the responsibility of the registered health care professionals to keep up to date with continuing professional development. PGD updates will be held annually.</li> <li>• 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)</li> <li>• Practitioners should be constantly alert to any subsequent recommendations from UKHSA, NHSE and other sources of medicines information.</li> </ul> <p><b>Note:</b> 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>

## 7. Clinical Conditions

<b>Clinical condition or situation to which this PGD applies</b>	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 <u>Chapter 19</u> of the Immunisation Against Infectious Disease: 'The Green Book', annual flu letter and subsequent correspondence and publications from UKHSA and NHSE.
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<p><b>Inclusion criteria</b> (continued)</p>	<p>For the 2023 to 2024 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 2024)</li> <li>• adults aged from 18 years to under 65 years of age in a clinical risk group category listed in <u>Chapter 19</u> 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 chronic bronchitis</li> <li>○ chronic heart disease and vascular disease</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 for cancer)</li> <li>○ morbidly obese adults with a BMI of 40kg/m<sup>2</sup> and above</li> </ul> </li> </ul> <p>Adults aged from 18 years to under 65 years of age who are:</p> <ul style="list-style-type: none"> <li>• pregnant women (including those women who become pregnant during the influenza season)</li> <li>• household contacts 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>• 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>• carers: individuals 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 health and social care workers 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> </ul> </li> </ul>
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<b>Inclusion criteria</b> <i>(continued)</i>	<ul style="list-style-type: none"> <li>o 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> <li>o through Direct Payments (personal budgets) or Personal Health Budgets, such as Personal Assistants, to deliver domiciliary care to individuals</li> <li>o to deliver social care services and are in direct contact with those who are clinically vulnerable to flu, who receive care and support services from the social care provider</li> </ul>
<b>Exclusion criteria <sup>1</sup></b>	<ul style="list-style-type: none"> <li>• Individuals for whom valid consent, or ‘best-interests’ decision in accordance with the Manx Care policy for Capacity, Best Interest and Deprivation of Liberty, has not been obtained (for further information on consent see <a href="#">Chapter 2</a> of ‘<a href="#">The Green Book</a>’).</li> </ul> <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> <p><b>Note: This PGD covers NHS commissioned services only. It may not be used for the provision of inactivated influenza vaccine via occupational health schemes or peer-to-peer immunisation. A written instruction should instead be used</b></p>
<b>Cautions (including any relevant action to be taken)</b> <i>(continued)</i>	<ul style="list-style-type: none"> <li>• Facilities for management of anaphylaxis should be available at all vaccination premises (see <a href="#">Chapter 8</a> of the Green Book and advice issued by the <a href="#">Resuscitation Council UK</a>).</li> <li>• Individuals with a bleeding disorder may develop a haematoma at the injection site (see <a href="#">Route and method of administration</a>)</li> <li>• 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.</li> </ul>

<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.



<b>Cautions (including any relevant action to be taken)</b> <i>(continued)</i>	<ul style="list-style-type: none"> <li>• 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 2023/24 season and their ovalbumin content, visit <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>• 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</li> </ul>
<b>Arrangements for referral for medical advice</b>	Patient should be referred to a more experienced clinical practitioner for further assessment
<b>Action to be taken if patient excluded</b>	<ul style="list-style-type: none"> <li>• 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. Where appropriate, such individuals should be referred to their GP.</li> <li>• Individuals under 18 years of age who are in a clinical risk group or otherwise eligible for influenza vaccination for the 2023 to 2024 season, should be referred to their GP or an appropriate local NHS service provider.</li> <li>• In case of postponement due to acute illness, advise when the individual can be vaccinated and ensure another appointment is arranged</li> <li>• Communicate and document the reason for exclusion and any action taken in the individual's clinical records.</li> </ul>
<b>Action to be taken if patient declines treatment</b>	<ul style="list-style-type: none"> <li>• 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 Manx Care policy for Capacity, Best Interest and Deprivation of Liberty, a decision to vaccinate may be made in the individual's best interests</li> <li>• Advise the individual/carer about the protective effects of the vaccine, the risks of infection and potential complications if not immunised</li> <li>• Document advice given and decision reached and inform patient's GP as appropriate</li> </ul>

## 8. Details of the medicine

<b>Name, form and strength of medicine</b>	<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 reimbursement under the NHS influenza vaccination programme for the 2023 to 2024 season (see <a href="#">Recommended vaccines</a>).</p> <p>Some influenza vaccines are restricted for use in particular age groups. Refer to the vaccine's SPC and the <a href="#">Off-label use</a> section for further information.</p> <p><b>Summary table of which influenza vaccines to offer (by age)</b></p> <table border="1"> <thead> <tr> <th>Age</th><th>Inactivated influenza vaccine to offer eligible individuals</th></tr> </thead> <tbody> <tr> <td>18 years to under 65 years</td><td>Offer QIVc or QIVr. If QIVc or QIVr are not available<sup>3</sup>, offer QIVe.</td></tr> <tr> <td>65 years<sup>4</sup> and over<sup>5</sup></td><td>Offer aQIV or QIVr. If aQIV or QIVr are not available<sup>6</sup>, offer QIVc. For those aged 64 who turn 65 years of age by 31 March 2024, aQIV may be offered off-label. <b>Note: QIVe is not recommended for those aged 65 years and over</b></td></tr> </tbody> </table>	Age	Inactivated influenza vaccine to offer eligible individuals	18 years to under 65 years	Offer QIVc or QIVr. If QIVc or QIVr are not available <sup>3</sup> , offer QIVe.	65 years <sup>4</sup> and over <sup>5</sup>	Offer aQIV or QIVr. If aQIV or QIVr are not available <sup>6</sup> , offer QIVc. For those aged 64 who turn 65 years of age by 31 March 2024, aQIV may be offered off-label. <b>Note: QIVe is not recommended for those aged 65 years and over</b>
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<b>Legal category</b>	Prescription Only Medicine (POM)						
<b>Black triangle ▼</b>	<p>QIVc, QIVr and aQIV vaccines are black triangle.</p> <p>This information was accurate at the time of writing. See product <a href="#">SPCs</a>, for indication of current black triangle status.</p>						

<sup>3</sup> QIVe should be offered only when every attempt to use QIVc or QIVr has been exhausted – evidence of this may be requested by the commissioner before reimbursement is agreed.

<sup>4</sup> Including those turning age 65 years by 31 March 2024.

<sup>5</sup> JCVI recommended use of QIV-HD in this age group but this is not currently available on the UK market.

<sup>6</sup> QIVc should be offered only when every attempt to use aQIV or QIVr has been exhausted – evidence of this may be requested by the commissioner before reimbursement is agreed.

<p><b>Indicate any <u>off-label use</u></b> (if relevant)</p>	<ul style="list-style-type: none"> <li>• Where a vaccine is recommended off-label, as part of the consent process, consider informing the individual or carer the vaccine is being offered in accordance with national guidance but this is outside the product licence.</li> <li>• 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 2024, in accordance with the recommendations for the national influenza immunisation programme for the 2023 to 2024 season (see the <u>annual flu letter</u>).</li> <li>• Vaccines should be stored according to the conditions detailed in the <u>Storage</u> section below. However, in the event of an inadvertent or unavoidable deviation of these conditions, refer to <u>Vaccine Incident Guidance</u>.</li> <li>• Where vaccines are assessed in accordance with these guidelines as appropriate for continued use, this would constitute off-label administration under this PGD.</li> </ul> <p><b>Note:</b> Different influenza vaccine products are licensed from different ages and should be administered within their license when working to this PGD, except where permitted off-label administration has been detailed above. Refer to product <u>SPCs</u> and <u>Flu vaccines for the 2023 to 2024 season</u> for more information.</p>
<p><b>Route/method of administration</b> (continued)</p>	<ul style="list-style-type: none"> <li>• Administer by intramuscular injection, preferably into the deltoid region of the upper arm</li> <li>• 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</li> <li>• 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</li> </ul>

<b>Route/method of administration</b> (continued)	<ul style="list-style-type: none"> <li>Influenza vaccines licensed for both intramuscular and subcutaneous administration may alternatively be administered by the subcutaneous route. Note: QIVc, QIVr and aQIV are not licensed for subcutaneous administration so should only be administered intramuscularly under this PGD.</li> <li>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</li> <li>The SPC for each vaccine provides further guidance on administration and is available from the <a href="#">electronic medicines compendium</a> website.</li> </ul>
<b>Dose and frequency</b>	Single 0.5ml dose to be administered for the current annual flu season (1 September 2023 to 31 March 2024)
<b>Quantity to be administered</b>	Single 0.5ml dose for the current annual flu season
<b>Maximum or minimum treatment period</b>	Single dose of 0.5ml per administration
<b>Storage</b>	<ul style="list-style-type: none"> <li>Store at +2°C to +8°C.</li> <li>Do not freeze</li> <li>Store in original packaging to protect from light.</li> <li>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="#">PHE Vaccine Incident Guidance</a></li> </ul>
<b>Adverse effects</b> (continued)	<ul style="list-style-type: none"> <li>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</li> <li>Immediate reactions such as urticaria, angio-oedema, bronchospasm and anaphylaxis can occur</li> <li>A higher incidence of mild post-immunisation reactions has been reported with adjuvanted compared to non-adjuvanted influenza vaccines</li> <li>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</li> <li>A detailed list of adverse reactions associated with inactivated influenza vaccine is available in the SPC for each vaccine, which</li> </ul>

<b>Adverse effects</b> <i>(continued)</i>	<p>are available from the electronic Medicines Compendium website: <a href="http://www.medicines.org.uk">www.medicines.org.uk</a></p> <p><b>Reporting procedure of adverse reactions</b></p> <ul style="list-style-type: none"> <li>Healthcare professionals, individuals and 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 by searching for MHRA Yellow Card in the Google Play or Apple App Store.</li> <li>QIVc, QIVr and aQIV are black triangle vaccines. All suspected adverse reactions to these products should be reported via the Yellow Card reporting scheme, as these particular vaccines are newer to market.</li> <li>Any adverse reaction to a vaccine should be documented in the individual's record and the individual's GP should be informed as appropriate.</li> </ul>
<b>Records to be kept</b>	<p>The administration of any medication given under a PGD must be recorded within the patients' medical records</p> <p>Please see Appendix C for more details.</p>

## 9. Patient information

<b>Verbal/Written information to be given to patient or carer</b>	<ul style="list-style-type: none"> <li>Verbal information must be given to patients and or carers for all medication being administered under a PGD</li> <li>Where medication is being supplied under a PGD, written patient information leaflet must also be supplied</li> <li>Offer the marketing authorisation holder's patient information leaflet (PIL) provided with the vaccine</li> </ul>
<b>Follow-up advice to be given to patient or carer</b> <i>(continued)</i>	<ul style="list-style-type: none"> <li>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</li> <li>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</li> <li>Inform the individual/carers of possible side effects and their management</li> <li>The individual or carer should be advised when and where to seek appropriate advice in the event of an adverse reaction and encouraged to report this via the Yellow Card reporting scheme.</li> <li>In case of postponement due to acute illness, advise when the individual can be vaccinated and how future vaccination may</li> </ul>

<b>Follow-up advice to be given to patient or carer</b> <i>(continued)</i>	<p>be accessed</p> <ul style="list-style-type: none"> <li>• Advise the individual/carers when a subsequent vaccine dose is due, such as a single immunisation for each annual influenza season</li> <li>• If the individual is eligible for another vaccine on the NHS and has not received it, such as the COVID-19 vaccine, PPV23 or shingles vaccine, they should be signposted to their GP or an appropriate NHS provider.</li> </ul>
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## 10. Appendix A

References
<ol style="list-style-type: none"> <li>1. British National Formulary (BNF) available online: <a href="https://bnf.nice.org.uk">https://bnf.nice.org.uk</a></li> <li>2. Nursing and Midwifery “The code” available online: <a href="https://www.nmc.org.uk">https://www.nmc.org.uk</a></li> <li>3. Current Health Care Professions Council standards of practice</li> <li>4. General Pharmaceutical Council standards</li> <li>5. Electronic medicines compendium available online: <a href="https://www.medicines.org.uk">https://www.medicines.org.uk</a></li> </ol> <p><b>Inactivated influenza vaccination</b></p> <ul style="list-style-type: none"> <li>• Immunisation Against Infectious Disease: The Green Book, Chapter 19. Published 16 September 2022 <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 <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 Advanced Service Specification: Seasonal Influenza <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 2023 to 2024: supporting letter. <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>• All influenza vaccines marketed in the UK for the 2023 to 2024 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>• Flu vaccines for the 2023 to 2024 season, updated 25 May 2023 <a href="https://www.gov.uk/government/publications/flu-vaccines-for-the-current-season">https://www.gov.uk/government/publications/flu-vaccines-for-the-current-season</a></li> <li>• Competency assessment tools 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>• Flu immunisation training recommendations. Updated 12 August 2022. <a href="https://www.gov.uk/government/publications/flu-immunisation-training-recommendations">https://www.gov.uk/government/publications/flu-immunisation-training-recommendations</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>• NHSE Health Technical Memorandum 07-01: Safe Management of Healthcare Waste. Updated 7 March 2023 <a href="https://www.england.nhs.uk/publication/management-and-disposal-of-healthcare-waste/">https://www.england.nhs.uk/publication/management-and-disposal-of-healthcare-waste/</a></li> </ul>

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- Immunisation Against Infectious Disease: The Green Book, Chapter 2. Updated 18 June 2021  
<https://www.gov.uk/government/publications/consent-the-green-book-chapter-2>
- National Minimum Standards and Core Curriculum for Immunisation Training. Published February 2018  
<https://www.gov.uk/government/publications/national-minimum-standards-and-core-curriculum-for-immunisation-training-for-registered-healthcare-practitioners>
- NICE Medicines Practice Guideline 2 (MPG2): Patient Group Directions. Published March 2017  
<https://www.nice.org.uk/guidance/mpg2>
- NICE MPG2 Patient group directions: competency framework for health professionals using patient group directions. Updated March 2017  
<https://www.nice.org.uk/guidance/mpg2/resources>
- UKHSA Immunisation Collection  
<https://www.gov.uk/government/collections/immunisation>
- Vaccine Incident Guidance  
<https://www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors>

## 11. Appendix B

### Health professionals agreed to practice

- Each registered healthcare professional will hold their own Competency framework which will be signed and agreed by their mentor
- A mentor is defined within the Manx Care policy as any ward/area managers, sisters, senior nurses, GPs, pharmacists or senior paramedics who has completed the PGD training themselves

## 12. Appendix C

<b>Special considerations/ additional information</b>	<ul style="list-style-type: none"><li>• The practitioner should have immediate access to adrenaline (epinephrine) 1 in 1,000 injection and access to a telephone at the time of vaccination.</li><li>• 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.</li><li>• 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.</li></ul>
<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 local arrangements and NHSE

Reference number: 161

Valid from: 01/09/23. Review date: n/a. Expiry date: 01/04/2024

Version: 12.00

	guidance in (HTM 07-01): Management and disposal of healthcare waste
<b>Drug interactions</b>	<ul style="list-style-type: none"> <li>Immunological response may be diminished in those receiving immunosuppressive treatment, but it is important to still immunise this group</li> <li>Influenza vaccines can be co-administered with other vaccines including COVID-19 and shingles vaccines (see Route and method of administration). Initially, a seven day interval was recommended between Shingrix®(shingles) vaccine and adjuvanted influenza vaccine (aQIV) because the potential reactogenicity from two adjuvanted vaccines may reduce the tolerability in those being vaccinated. Interim data from a US study on co-administration of Shingrix® with adjuvanted seasonal influenza vaccine is reassuring. Therefore, an appointment for administration of the seasonal influenza vaccine can be an opportunity to also provide shingles vaccine (see Shingrix® PGD).</li> <li>Where aQIV is given with other vaccines, including other adjuvanted vaccines, the adverse effects of both vaccines may be additive and should be considered when informing the recipient. Individuals should also 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.</li> <li>A detailed list of drug interactions is available in the SPC for each vaccine, which are available from the electronic medicines compendium website.</li> </ul>
<b>Supplies</b>	<ul style="list-style-type: none"> <li>Providers should order influenza vaccines for adults from the influenza vaccine manufacturers or pharmaceutical wholesalers as in previous years</li> </ul>
<b>Records</b> (continued)	<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 with whom the individual is registered</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 excluded or declines immunisation</li> <li>details of any adverse drug reactions and actions taken</li> <li>administered via PGD</li> </ul>
<b>Records</b>	<ul style="list-style-type: none"> <li>Records should be signed and dated or if using electronic records,</li> </ul>



<i>(continued)</i>	<p>the immuniser's account should be password protected such as to provide an electronic signature to the vaccination record</p> <ul style="list-style-type: none"> <li>• All records should be clear, legible, contemporaneous and in line with the community pharmacy seasonal influenza immunisation advanced service specification</li> <li>• 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</li> <li>• 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</li> <li>• For pregnant women, also record immunisation in the hand-held maternity record (if available)</li> <li>• Records of all individuals receiving treatment under this PGD should also be kept for audit purposes and post payment verification</li> </ul>
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