



**Patient Group Direction For The Administration of Inactivated Influenza Vaccine 2022/23 Season by Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles**

**Version 1.1 2022/23**

**Effective from 8<sup>th</sup> August 2022**

NoS/PGD/Influenza/MGPG1290

**Note:** Live Attenuated Intranasal Vaccine (LAIV) is not covered by this PGD – separate LAIV PGD will be available

This Patient Group Direction (PGD) has been adopted from the PGD template produced by Public Health Scotland on 5<sup>th</sup> August and 8<sup>th</sup> of August 2022.

## Most recent changes

Version	Date	Summary of changes
1.1	8 August 2022	<ul style="list-style-type: none"><li>Expiry date amended to 31 July 2023</li></ul>

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# Authorisation




## PGD administration of inactivated influenza vaccine

This specimen Patient Group Direction (PGD) template has been produced by Public Health Scotland to assist NHS Boards. NHS Boards should amend/adapt this PGD template and must ensure that the PGD is considered and approved in line with local clinical governance arrangements for PGDs

The qualified health professionals who may administer inactivated influenza vaccine under this PGD can only do so as named individuals. It is the responsibility of each professional to practice within the bounds of their own competence and in accordance with their own Code of Professional Conduct, and to ensure familiarity with the marketing authorisation holder's summary of product characteristics (SmPC) for all vaccines administered in accordance with this PGD.

NHS Board governance arrangements will indicate how records of staff authorised to operate this PGD will be maintained. Under PGD legislation there can be no delegation. Administration of the vaccine has to be by the same practitioner who has assessed the patient under the PGD.

This PGD template has been adopted by NoS for use across all 6 NoS Health Boards.

This PGD has been produced for NoS by				Date Signed
Doctor	Dr Jenny Wares	Signature		14/08/2022
Pharmacist	Russell Mackay	Signature		10/08/2022
Nurse	Jackie Donachie	Signature		10/08/2022

### Approved for use within NoS Boards by;

North of Scotland (NoS) PGD Group Chair	Signature	Date Signed
Lesley Coyle		16/08/2022

### Authorised and executively signed for use within NoS Boards by;

NHS Grampian Chief Executive	Signature	Date Signed
Professor Caroline Hiscox		19/08/2022

Version 1.1 effective from 8<sup>th</sup> August 2022 review date 31<sup>st</sup> July 2023

## Clinical situation

Category	Description
<b>Indication</b>	Active immunisation against disease caused by influenza virus in line with Scottish Government seasonal influenza immunisation programme 2022-23.
<b>Inclusion criteria</b>	<p>Influenza vaccine should be offered to individuals defined as eligible in accordance with Scottish Government's seasonal influenza vaccination programme 2022-23 as set out in <a href="#">Scottish Government seasonal influenza immunisation programme letter</a>. This includes:</p> <ul style="list-style-type: none"> <li>• Individuals aged 65 years or above by 31 March 2023.</li> <li>• Individuals aged 50 years to 64 years by 31 March 2023.</li> <li>• Individuals aged six months to under 50 years in clinical risk groups identified in Annex A of the <a href="#">Scottish Government seasonal influenza immunisation programme letter</a>.</li> <li>• Pregnant women at any stage of pregnancy (first, second or third trimester), irrespective if received influenza vaccine in a previous pregnancy</li> <li>• Individuals in whom live attenuated intranasal influenza vaccine is not suitable</li> <li>• Adult household contacts of immunosuppressed individuals</li> <li>• Individuals with an underlying disease where the risk from influenza infection may exacerbate their condition or result in serious illness from influenza itself.</li> <li>• Those 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 university halls of residence etc).</li> <li>• Those who are in receipt of carer's allowance or unpaid carers and young carers, defined as, someone who, without payment provides help and support to a partner, child, relative, friend or neighbour, who could not manage without their help. This could be due to age, physical or mental illness, addiction or disability. A young carer is a child or young person under the age of 18 carrying out significant caring tasks and assuming a level of responsibility for another person, which would normally be taken by an adult.</li> <li>• Health care workers who are in direct contact with patients and service users.</li> <li>• Social care workers who provide direct personal care in the following settings: residential care for adults; children's residential and secure care for children; or community care for persons at home including housing support and personal assistants.</li> <li>• NHS Independent contractors and support staff (GP, dental, optometry practices, community pharmacies and Non-NHS laboratory staff (if working on COVID-19 testing) and support staff).</li> <li>• Nursery, Primary and Secondary School Teachers and support staff</li> <li>• Prison population</li> </ul>

Category	Description
	<ul style="list-style-type: none"> <li>• Prison officers/support staff delivering direct detention services</li> <li>• Valid consent has been given to receive the vaccine.</li> </ul>
<b>Exclusion criteria</b>	<p>Individuals who:</p> <ul style="list-style-type: none"> <li>• Are aged under 6 months.</li> <li>• Have had a confirmed anaphylactic reaction to a previous dose of influenza vaccine.</li> <li>• Have had a confirmed anaphylactic reaction to any component of influenza vaccine. Different brands may contain traces of neomycin, gentamicin, kanamycin, polymixin B, formaldehyde and other excipients – practitioners must check the marketing authorisation holder’s SmPC for the particular brand.</li> <li>• Have a history of confirmed anaphylactic reaction to eggs/egg product or chicken proteins such as ovalbumin where vaccine was produced using eggs.</li> <li>• Have a history of severe (i.e. anaphylactic) reaction to latex where vaccine is not latex free.</li> <li>• Are suffering from an acute febrile illness (the presence of a minor infection is not a contraindication for immunisation).</li> </ul> <p>Some influenza vaccines (inactivated) are restricted to use in particular age groups. Practitioners must be familiar with and refer to the marketing authorisation holder’s SmPC for the particular brand when administering vaccines:</p> <ul style="list-style-type: none"> <li>• Adjuvanted quadrivalent influenza vaccine ▼(aQIV) (Seqirus vaccine) is licensed from 65 years</li> <li>• Cell-based quadrivalent influenza vaccine ▼(QIVc) (Seqirus vaccine) is licensed from age 2 years</li> <li>• Quadrivalent influenza vaccine (Sanofi Pasteur) (egg grown QIV) (QIVe) is licensed from 6 months</li> </ul>
<b>Cautions/need for further advice/ circumstances when further advice should be sought from a doctor</b>	<p>The Green Book advises that there are very few individuals who cannot receive inactivated influenza vaccine. Where there is doubt, rather than withholding vaccination, appropriate advice should be sought from the relevant specialist, or from the local immunisation or health protection team.</p> <p>The presence of a neurological condition is not a contraindication to immunisation but if there is evidence of current neurological deterioration, deferral of vaccination may be considered, to avoid incorrect attribution of any change in the underlying condition. The risk of such deferral should be balanced against the risk of the preventable infection, and vaccination should be promptly given once the diagnosis and/or the expected course of the condition becomes clear.</p>

Category	Description
	<p>Syncope (fainting) can occur following, or even before, any vaccination especially in adolescents 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 if excluded</b>	<p>Specialist advice must be sought on the vaccine and circumstances under which it could be given. Immunisation using a patient specific direction may be indicated. The risk to the individual of not being immunised must be taken into account.</p> <p>Document the reason for exclusion and any action taken in accordance with local procedures</p> <p>Inform or refer to the clinician in charge at the clinic or GP as appropriate.</p> <p>In case of postponement due to acute severe febrile illness, advise when the individual can be vaccinated and ensure another appointment is arranged.</p>
<b>Action if patient declines</b>	<p>Advise the individual about the protective effects of the vaccine, the risks of infection and potential complications of disease.</p> <p>Advise how future immunisation may be accessed if they subsequently decide to receive the vaccine.</p> <p>Document advice given and decision reached. In NHS clinic setting.</p> <p>Inform or refer to the clinician in charge.</p>

## Description of treatment

### Name of medicine

Inactivated influenza vaccine suspension in a pre-filled syringe, including:

- Adjuvanted quadrivalent influenza vaccine ▼ (aQIV) (Seqirus vaccine)
- Cell-based quadrivalent influenza vaccine ▼ (QIVc) (Seqirus vaccine)
- Egg-grown quadrivalent influenza vaccine (QIVe) (Sanofi Pasteur)

**Table showing current recommended influenza vaccine for national programme**

<b>Eligible Group</b>	<b>Current recommended influenza vaccine for national programme</b>
<b>6 months to less than 2 years</b>	Offer Sanofi Pasteur Quadrivalent influenza vaccine (egg based QIVe)
<b>2 years to under 18 years (unsuitable for LAIV)</b>	Offer Cell-based quadrivalent influenza vaccine ▼ (QIVc) (Seqirus vaccine)
<b>Aged 18 years to under 50 years in clinical risk group</b>	Offer Cell-based quadrivalent influenza vaccine ▼ (QIVc) (Seqirus vaccine),
<b>Aged 50-64 years (including those who are 50 years old by 31 March 2023)</b>	Offer Cell-based quadrivalent influenza vaccine ▼ (QIVc) (Seqirus vaccines)
<b>Aged 65 years and over (including those 64 year olds who are 65 years old by 31 March 2023)</b>	Offer Adjuvanted quadrivalent influenza vaccine ▼ (aQIV)
<b>Health and social care staff</b>	Offer Cell-based quadrivalent influenza vaccine ▼ (QIVc) (Seqirus vaccine)
<b>Carers/Unpaid/young carers</b>	Offer Cell-based quadrivalent influenza vaccine ▼ (QIVc) (Seqirus vaccine)
<b>Nursery, Primary and secondary School Teachers and support staff</b>	Offer Cell-based quadrivalent influenza vaccine ▼ (QIVc) (Seqirus vaccine)
<b>Prison population and Prison officers</b>	Offer Cell-based quadrivalent influenza vaccine ▼ (QIVc) (Seqirus vaccine)
<b>Independent contractors</b>	Offer Cell-based quadrivalent influenza vaccine ▼ (QIVc) (Seqirus vaccine)

**Note:** Adjuvanted quadrivalent influenza vaccine ▼ (aQIV) should preferably be used as appropriate for those aged 65 years and over.

**Note:** LAIV could be used as appropriate for those aged under 18 years – see Fluenz Tetra PGD



Category	Description
<b>Route of administration</b>	<p>Administer by Intramuscular injection.</p> <p>The preferred site for children older than 12 months or adults is deltoid area of upper arm. The preferred site for infants is anterolateral thigh.</p> <p>Adjuvanted quadrivalent influenza vaccine ▼ (aQIV), cell-based quadrivalent influenza vaccine ▼ (QIVc) (Seqirus vaccines) must only be administered via the intramuscular route.</p> <p>Influenza vaccines licensed for intramuscular or subcutaneous administration such as Sanofi Pasteur egg based quadrivalent influenza vaccine (QIVe) may alternatively be administered by the subcutaneous route.</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 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 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/parent/carer should be informed about the risk of haematoma from the injection.</p> <p>The vaccine should be visually inspected for particulate matter and discolouration prior to administration. In the event of any foreign particulate matter and / or variation of physical aspect being observed, do not administer the vaccine.</p>
<b>Dosage</b>	Single dose of 0.5mL
<b>Frequency</b>	Children aged six months to less than nine years who have not received influenza vaccine before should receive a second dose of vaccine at least four weeks later.
<b>Duration of treatment</b>	Not applicable.
<b>Maximum or minimum treatment period</b>	Not applicable.

Category	Description
<b>Quantity to supply/ administer</b>	Single dose of 0.5mL
<b>▼ Black triangle medicines</b>	<p>Yes, the following vaccines are ▼:</p> <p>Cell-based quadrivalent influenza vaccine ▼ (QIVc) (Seqirus vaccine) Adjuvanted quadrivalent influenza vaccine ▼ (aQIV) (Seqirus vaccine)</p> <p>This information was accurate at the time of writing. See product SmPCs at <a href="http://www.medicines.org.uk">www.medicines.org.uk</a> for indication of current black triangle status.</p>
<b>Legal category</b>	Prescription Only Medicine (POM)
<b>Is the use out with the SmPC?</b>	<p>Yes</p> <p>Adjuvanted quadrivalent influenza vaccine ▼ (aQIV) is licensed for administration to individuals aged 65 years and over. It may be administered under this PGD to those people who are 64 years old at the point of immunisation but are 65 years by 31 March 2023 in accordance with the Scottish Government seasonal influenza immunisation programme 2022/23.</p> <p>Where a vaccine is recommended off-label consider, as part of the consent process, informing the individual/parent/carer that the vaccine is being offered in accordance with national guidance but that this is outside the product licence.</p> <p>Vaccine should be stored according to the conditions detailed below. However, in the event of an inadvertent or unavoidable deviation of these conditions refer to NHS board guidance on storage and handling of vaccines or vaccine incident guidance. Where vaccine is assessed in accordance with these guidelines as appropriate for continued use, administration under this PGD is allowed.</p>
<b>Storage requirements</b>	<p>Vaccine should be stored at a temperature of +2° to +8°C.</p> <p>Store in the original packaging to protect from light. Do not freeze.</p> <p>NHS board guidance on storage and handling of vaccines should be observed.</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.</p>
<b>Additional information</b>	<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>

Category	Description
	<p>Inactivated influenza vaccine can be given at the same time as other vaccines including COVID-19 vaccines.</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. 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.</p>

## Warnings

Category	Description
<b>Adverse reactions and management</b>	<p>Pain, swelling or redness at the injection site, low grade fever, malaise, shivering, fatigue, headache, aching muscles and joint pain are among the commonly reported symptoms after vaccination. A small painless nodule (induration) may also appear at the injection site. These symptoms usually disappear within one to two days without treatment.</p> <p>For full details/information on possible side effects, refer to the marketing authorisation holder's SmPC.</p> <p>As with all vaccines there is a very small possibility of anaphylaxis and facilities for its management must be available.</p> <p>In the event of a severe adverse reaction individual should be advised to seek medical advice.</p>
<b>Reporting procedure for adverse reactions</b>	<p>Healthcare professionals and individuals/carers should report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on <a href="http://yellowcard.mhra.gov.uk/">http://yellowcard.mhra.gov.uk/</a></p> <p>Any adverse reaction to a vaccine should be documented in accordance with locally agreed procedures in the individual's record and the individual's GP should be informed.</p>

Category	Description
<b>Advice to patient or carer including written information</b>	<p>Written information to be given to individual:</p> <ul style="list-style-type: none"> <li>• Provide manufacturer's consumer information leaflet/patient information leaflet (PIL) provided with the vaccine.</li> <li>• Immunisation promotional material may be provided as appropriate</li> </ul> <p>Individual advice / follow up treatment</p> <ul style="list-style-type: none"> <li>• Inform the individual/carer of possible side effects and their management.</li> <li>• The individual should be advised to seek medical advice in the event of a severe adverse reaction.</li> <li>• Inform the individual that they can report suspected adverse reactions to the MHRA using the Yellow Card reporting scheme on: <a href="https://yellowcard.mhra.gov.uk/">https://yellowcard.mhra.gov.uk/</a></li> <li>• Give general advice relating to good hygiene practice to prevent the spread of germs – always have tissues to hand, use a clean tissue to cover your mouth and nose when you cough and/or sneeze, bin any tissue after one use, wash your hands with soap and hot water or a sanitiser gel often.</li> <li>• When applicable, advise individual/parent/carer when the subsequent dose is due.</li> </ul>
<b>Observation following vaccination</b>	Following immunisation patients remain under observation in line with NHS board policy.
<b>Follow-up</b>	As above.
<b>Additional facilities</b>	A protocol for the management of anaphylaxis and an anaphylaxis pack must always be available whenever vaccines are given. Immediate treatment should include early treatment with intramuscular adrenaline, with an early call for help and further IM adrenaline every 5 minutes. The health professionals overseeing the immunisation service must be trained to recognise an anaphylactic reaction and be familiar with techniques for resuscitation of a patient with anaphylaxis.

## Characteristics of staff authorised under the PGD

Category	Description
<b>Professional qualifications</b>	<p>The following classes of registered healthcare practitioners are permitted to administer this vaccine</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> </ul>

Category	Description
	<ul style="list-style-type: none"> <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>
<b>Specialist competencies or qualifications</b>	<p>Persons must only work under this PGD where they are competent to do so.</p> <p>All persons operating this PGD:</p> <ul style="list-style-type: none"> <li>• must be authorised by name by their employer as an approved person under the current terms of this PGD before working to it</li> <li>• must be familiar with the vaccine product and alert to changes in the manufacturers product information/summary of product information,</li> <li>• must be competent to undertake immunisation and to discuss issues related to immunisation to assess patients for vaccination and obtain consent</li> <li>• must be competent in the correct storage of vaccines and management of the cold chain if receiving, responsible for, or handling the vaccine</li> <li>• must be competent in the recognition and management of anaphylaxis or under the supervision of persons able to respond appropriately to immediate adverse reactions</li> <li>• must have access to the PGD and associated online resources</li> <li>• should fulfil any additional requirements defined by local policy</li> </ul> <p>Employer</p> <p>The employer is responsible for ensuring that persons have the required knowledge and skills to safely deliver the activity they are employed to provide under this PGD.</p> <p>As a minimum, competence requirements stipulated in the PGD must be adhered to.</p>
<b>Continuing education and training</b>	<p>All practitioners operating under the PGD are responsible for ensuring they remain up to date with the use of vaccines included.</p> <p>If any training needs are identified these should be discussed with the individuals in the organisation responsible for authorising individuals to act under this PGD.</p>

## Audit trail

Category	Description
<b>Record/audit trail</b>	<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 person that undertook assessment of individual's clinical suitability for vaccine and subsequently administered the vaccine</li> <li>• name and brand of vaccine</li> <li>• date of administration</li> <li>• dose, form and route of administration of vaccine</li> <li>• batch number</li> <li>• where possible 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 under PGD</li> </ul> <p>Records should be kept line with local procedures. Local policy should be followed to encourage information sharing with the individual's General Practice. All records should be clear, legible and contemporaneous and in an easily retrievable format.</p>
<b>Additional references</b>	<p>Practitioners operating the PGD must be familiar with:</p> <ul style="list-style-type: none"> <li>• <a href="#">Immunisation against Infectious Disease [Green Book]</a></li> <li>• <a href="#">Immunisation against Infectious Disease [Green Book] chapter 19</a></li> <li>• Current edition of British National Formulary (BNF) and BNF for children</li> <li>• Marketing authorisation holder's Summary of Product Characteristics</li> <li>• <a href="#">Educational resources for registered professionals produced by National Education for Scotland</a></li> <li>• All relevant Scottish Government advice including the relevant CMO letter(s)</li> <li>• <a href="#">Professional Guidance on the Administration of Medicines in Healthcare Settings 2019</a></li> <li>• <a href="#">Professional Guidance on the Safe and Secure Handling of Medicines</a></li> </ul>

**Healthcare Professional Agreement to Administer Vaccine Under Patient Group Direction**

I: \_\_\_\_\_ (Insert name)

Working within: \_\_\_\_\_ e.g. Health Board, Area Practice

Agree to administer the vaccine contained within the following Patient Group Direction:

**Patient Group Direction For The Administration of Inactivated Influenza Vaccine 2022/23 Season by Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles (Version 1.1 – Valid from 8<sup>th</sup> August 2022)**

I have completed the appropriate training to my professional standards enabling me to administer the vaccine under the above direction. I agree not to act beyond my professional competence, nor out with the recommendations of the direction. **PGDs do not remove inherent professional obligations or accountability.**

Signed: \_\_\_\_\_

Print Name: \_\_\_\_\_

Date: \_\_\_\_\_

Profession: \_\_\_\_\_

Professional Registration number/PIN \_\_\_\_\_

**Healthcare Professionals Authorisation to Administer Vaccine Under Patient Group Direction**

<p><b>The Lead manager/Professional</b> of each clinical area is responsible for maintaining records of all clinical areas where this PGD is in use, and to whom it has been disseminated.</p>					
<p><b>The Senior Nurse/Professional</b> who approves a healthcare professional to administer the vaccine under this PGD is responsible for ensuring that they are competent, qualified and trained to do so, and for maintaining an up-to-date record of such approved persons.</p>					
<p><b>The Healthcare Professional</b> that is approved to administer the vaccine under this PGD is responsible for ensuring that they understand and are qualified, trained and competent to undertake the duties required. The approved person is also responsible for ensuring that administration is carried out within the terms of the direction, and according to their individual code of professional practice and conduct.</p>					
<p><b>Patient Group Direction For The Administration of Inactivated Influenza Vaccine 2022/23 Season by Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles (Version 1.1 – Valid from 8<sup>th</sup> August 2022)</b></p>					
<p><b>Local clinical area(s) where the listed healthcare professionals will operate under this PGD:</b></p>					
<b>Name of Healthcare Professional</b>	<b>Signature</b>	<b>Date</b>	<b>Name of Manager</b>	<b>Signature</b>	<b>Date</b>





## Version history

Version	Date	Summary of changes
1.0	05 August 2022	<p>New national specimen PGD for 2022/23 season. The following changes from the PGD used in 2021-22 have been made:</p> <ul style="list-style-type: none"><li>• Removal of Recombinant quadrivalent influenza vaccine ▼ (QIVr) (Sanofi Pasteur) throughout</li><li>• Indication section updated for dates for 2022-23 season</li><li>• Inclusion criteria section updated to include cohorts eligible in 2022-23 season</li><li>• Name of medicine section updated to reflect vaccines procured for 2022-23 programme</li><li>• Use out with SmPC section updated for dates for 2022-23 season</li><li>• Advice to patient section updated to remove advice about COVID-19</li></ul>
1.1	08 August 2022	<ul style="list-style-type: none"><li>• Expiry date amended to 31 July 2023</li></ul>

### Appendix 3: Seasonal Influenza Vaccine PGDs 2022-23 - UK Licensed Influenza Vaccines

Manufacturer/ supplier	Name of product	Vaccine type	Age indication	Ovalbumin content per 0.5ml dose	Latex Formaldehyde Other	Amino- glycosides
Astra Zeneca UK Ltd	Fluenz Tetra® LAIV	Quadrivalent live attenuated influenza vaccine – nasal spray suspension	From 24 months to less than 18 years of age	Less than 0.024 micrograms per 0.2mL dose	Latex free <sup>1</sup> Contains gelatin (porcine) Formaldehyde free	Gentamicin <sup>3</sup>
Sanofi Pasteur	Quadrivalent Influenza Vaccine QIVe	Standard egg grown quadrivalent influenza vaccine – split virion inactivated	From 6 months	Equal to or less than 0.05 micrograms per 0.5 mL dose	Latex free Risk of formaldehyde residue	Neomycin <sup>2</sup>
Seqirus	Cell-based Quadrivalent Influenza Vaccine (Surface Antigen, Inactivated) Seqirus suspension (QIVc) Flucelvax Tetra ®▼	Cell grown quadrivalent influenza vaccine – surface antigen inactivated prepared in cell cultures	From 2 years	Not applicable – egg free	Latex free <sup>2</sup> Formaldehyde free	Not applicable
	Adjuvanted Quadrivalent Influenza Vaccine (Surface Antigen, Inactivated) Seqirus suspension for injection (aQIV) Fluad Tetra ®▼	Adjuvanted quadrivalent influenza vaccine – surface antigen, inactivated – adjuvanted with MF59C.1	From 65 years	Equal to or less than 1 micrograms per 0.5 mL dose	Latex free <sup>2</sup> Risk of formaldehyde residue	Kanamycin <sup>3</sup> Neomycin <sup>3</sup>

## Notes

None of the influenza vaccines for the 2022 to 2023 season contain thiomersal as an added preservative.

1. No latex is present in the product but manufacturer is unable to confirm if latex has come into contact with the product during the manufacturing process.
2. None of the components of the staked needle prefilled syringe presentation that are in direct contact with the vaccine (syringe barrel, plunger and rubber stopper) are made with natural rubber latex. The needle shield contains natural rubber latex.

Chapter 6 of the Green Book states it is theoretically possible that latex protein from these tip caps, plungers or vial stoppers may cause allergic reactions when the vaccines are administered to latex-sensitive individuals. There is little evidence that such a risk exists and any such risk would be extremely small. The Green Book chapter states as a precaution, if an individual has a history of severe (i.e. anaphylactic) allergy to latex, vaccines supplied in vials or syringes that contain latex should not be administered, unless the benefit of vaccination outweighs the risk of an allergic reaction to the vaccine. Where possible, an alternative latex-free vaccine that covers the same disease should be administered.

3. Cross sensitivity to aminoglycosides is common, assume potential reaction for all, if allergic response to one has been demonstrated.

Ovalbumin, Ovalbumin, latex and aminoglycoside content for vaccines are correct as at **01 August 2022**, however, these may be subject to change in manufacturing practice at any time.

Acknowledgement - this appendix has been produced based on a previous version produced by NHS Greater Glasgow and Clyde.