**WRITTEN INSTRUCTION**

**Written instruction for registered nurses to administer inactivated seasonal influenza vaccine as part of an occupational health scheme, which may include peer to peer immunisation (2022/23).**

**For use within providers that are NOT an NHS Body\* or a Local Authority**

**Blue highlighted sections must be locally completed and the final written instruction signed by a doctor and approved through local governance processes prior to implementation *(remove yellow highlighted text from final approved document)***

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| **Organisation name:** | Text to be added by organisation |
| **Date of issue:** | Text to be added by organisation |
| **Date of review (not to exceed one year from date of issue):** | Text to be added by organisation |
| **Reference number:** | Text to be added by organisation |
| **Version number:** | Text to be added by organisation |
| **Details of local ratifying committee/governance approval or similar as appropriate:** | Text to be added by organisation or section removed as locally appropriate |

**Name and signature of the registered doctor authorising registered nurses, who declare themselves to have met the training and competency requirements defined in this written instruction, to operate under this written instruction on behalf of the named organisation.**

*Note in the absence of an Occupational Health Service (OHS) physician this written instruction can be signed by an organisation’s medical director or partner GP etc.* *The Doctor signing this written instruction on behalf of the organisation they are employed by must be working within their own competency when signing.*

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| **Name** | **GMC Registration Number** | **Job Title** | **Signature** | **Date** |
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**\* An NHS Body is defined in the Human Medicines Regulations 2012 (HMR 2012) as one of the following:**

* **the Common Services Agency**
* **a health authority**
* **a special health authority**
* **Integrated Care Board (formerly a Clinical Commissioning Group)**
* **an NHS trust**
* **an NHS foundation trust**

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| **Qualifications, registration, training and competency requirements** | |
| **Qualifications and professional registration** | Nurses registered with the Nursing and Midwifery Council (NMC). |
| **Training and competency** | The registered nurse must 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).  The registered nurse should be constantly alert to any subsequent recommendations from UK Health Security Agency (UKHSA) and/or NHS England and other sources of medicines information.  The registered nurse must have undertaken training appropriate to deliver influenza immunisation under this written instruction as required by local policy. This should be informed by the  [National Minimum Standards and Core Curriculum for Immunisation](https://www.gov.uk/government/publications/national-minimum-standards-and-core-curriculum-for-immunisation-training-for-registered-healthcare-practitioners) and tailored to the skills and competencies required for the safe and effective delivery of influenza immunisation services, including peer to peer immunisation.  The registered nurse must be competent in the handling and storage of vaccines, and management of the cold chain.  Insert details of and additional local training and competency requirements |
| **Competency assessment** | Insert details of local competency assessment.  Registered nurses operating under this written instruction are personally responsible for ensuring they remain up to date with the use of the vaccine/s included. If any training needs are identified these should be discussed with the senior individual responsible for authorising individuals to act under the Written Instruction and further training provided as required. |

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| **Clinical criteria** | |
| **Clinical condition or situation to which this written instruction applies** | Inactivated influenza vaccine is indicated for the immunisation of staff for the prevention of influenza.  *Note: Staff refers to staff of the authorising organisation or staff members of another organisation the authorising organisation is commissioned to provide this vaccination service to.* |
| **Criteria for inclusion** | Inactivated influenza vaccine should be offered to the following staff:   * Employees aged 18 years and over including those in [clinical at-risk groups.](https://www.gov.uk/government/collections/annual-flu-programme) * Employees aged 16-17 years **not** in a clinical at-risk group. * Locally adapt to include staff group/s to be included in seasonal influenza vaccination scheme (e.g. consider if offering vaccination to contracted/commissioned staff including site workers, hospitality staff, volunteers and students. See advice in [Chapter 12](https://www.gov.uk/government/publications/immunisation-of-healthcare-and-laboratory-staff-the-green-book-chapter-12) of [‘The Green Book’](https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book)) |
| **Criteria for exclusion** | Individuals for whom no valid consent has been received (for further information on consent see [Chapter 2](https://www.gov.uk/government/publications/consent-the-green-book-chapter-2) of ‘[The Green Book](https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book)’).  Individuals who:   * aged under 16 years of age * employees aged 16-17 years in a clinical at-risk group –advise to attend their GP surgery to be immunised with LAIV. * have had a confirmed anaphylactic reaction to any component of the vaccine or residues from the manufacturing process[[1]](#footnote-2) (other than ovalbumin – see [Cautions](#Cautions)). * have received a dose of influenza vaccine for the current season * are suffering from acute severe febrile illness (the presence of a minor infection is not a contraindication for immunisation) * any additional locally agreed exclusion criteria |
| **Cautions including any relevant action to be taken** | **Increased bleeding risk:**   * Individuals with a bleeding disorder may develop a haematoma at the injection site. 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. * 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. The individual/carer should be informed about the risk of haematoma from the injection.   **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 [All influenza vaccines marketed in the UK for the 2022 to 2023 season](https://www.gov.uk/government/publications/influenza-vaccines-marketed-in-the-uk).  **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 (adapt to reflect local policy). |
| **Action to be taken if the client is excluded** | Where appropriate, such individuals should be referred to the Occupational Health Consultant (adapt to reflect local policy).  In case of postponement due to acute illness, advise when the individual can be vaccinated and how future vaccination may be accessed.  Document the reason for exclusion and any action taken in the individual’s Occupational Health records (adapt to reflect local policy). |
| **Action to be taken if the client declines treatment** | Advise the individual about the protective effects of the vaccine, the risks of infection to themselves, their families and the organisation’s service users and potential complications if not immunised.  Advise how future immunisation may be accessed if they subsequently decide to receive the inactivated influenza vaccine.  Document, in accordance with local policy, advice given and the decision reached.  Any additional locally agreed action to be taken |
| **Arrangements for referral for medical advice** | Insert details of local arrangements for referral to Occupational Health Consultant or GP. |

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| **Description of treatment** | |
| **Name, strength & formulation of drug** | Inactivated influenza vaccine suspension in a pre-filled syringe, including:   * adjuvanted quadrivalent influenza vaccine (aQIV) * cell-based quadrivalent influenza vaccine (QIVc) * egg-grown quadrivalent influenza vaccine (QIVe) * recombinant quadrivalent influenza vaccine (QIVr), Supemtek▼   **Summary table of which influenza vaccines to offer (by age)**  Some influenza vaccines are restricted for use in particular age groups. The SPC for individual products should always be referred to.   |  |  | | --- | --- | | 16-17 year olds NOT in a clinical at-risk group | Offer QIVc | | 18 years to under 65 years (including those in a clinical at- risk group) | Offer QIVc or QIVr.  Or, if QIVc or QIVr are not available, offer QIVe. | | 65 years and over[[2]](#footnote-3),[[3]](#footnote-4) | Offer aQIV or QIVr.  Or, if aQIV or QIVr is not available, offer QIVc.  For those who become 65 years of age before 31 March 2023, aQIV may be offered off-label.  **Additional notes (to be deleted by organisations depending on relevance due to vaccine offered):**   * aQIV or QIVr are the first line vaccines recommended for people aged 65 and over (or turning 65 years by 31 March 2023). If not available in OHS, the OH provider should advise that the patient can have these from a GP or community pharmacy if they wish. If QIVc is available in OHS this is the acceptable second-line vaccine for this age group and can be offered if the patient does not wish to attend a GP or community pharmacy for vaccination with aQIV or QIVr . * If the OH provider has only QIVe available, they should recommend that health and social care workers aged 65 years and over go to their GP or community pharmacy for vaccination with one of the JCVI-recommended products. | | Note – this template does not include high-dose quadrivalent influenza vaccine (QIV-HD) or trivalent influenza vaccines which are not part of the national programme. If these have been purchased by an OHS/organisation for administration, then this template should be adapted accordingly. | | |
| **Legal category** | Prescription only medicine (POM). |
| **Black triangleq** | * QIVc, QIVr and aQIV products are black triangle. * The QIVe vaccine from Viatris (formerly Mylan), Influvac sub-unit Tetra, is black triangle. * The QIVe vaccine from MASTA is black triangle.   This information was accurate at the time of writing. See product [SPCs](http://www.medicines.org.uk) for indication of current black triangle status. |
| **Off-label use** | Where a vaccine is recommended off-label, as part of the consent process, consider informing the individual that the vaccine is being offered in accordance with national guidance but that this is outside the product licence.  Note: Different influenza vaccine products are licensed from different ages and should be administered within their licence when working to this protocol, unless permitted off-label administration is detailed above. Refer to products’ [SPCs](http://www.medicines.org.uk), available from the [electronic medicines compendium](http://www.medicines.org.uk) website, and [All influenza vaccines marketed in the UK for the 2022 to 2023 season](https://www.gov.uk/government/publications/influenza-vaccines-marketed-in-the-uk) for more information.  The aQIV is licensed for administration to individuals aged 65 years and over. It may be administered under this protocol 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 [annual flu letter](https://www.gov.uk/government/publications/national-flu-immunisation-programme-plan)).  Vaccine should be stored according to the conditions detailed in the [Storage](#Storage) section below. However, in the event of an inadvertent or unavoidable deviation of these conditions refer to [Vaccine Incident Guidance](https://www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors). Where vaccine is assessed in accordance with these guidelines as appropriate for continued use this would constitute off-label administration under this protocol. |
| **Route / method of administration** | Administer by intramuscular injection, preferably into deltoid region of the upper arm.  Where the individual has been identified by the assessing registered professional as being at increased risk of bleeding, 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 should be informed about the risk of haematoma from the injection.  When administering at the same time as other vaccines care should be taken to ensure that the appropriate route of injection is used for all the vaccinations. The vaccines should be given at separate sites, preferably in different limbs. If given in the same limb, they should be given at least 2.5cm apart. The site at which each vaccine was given should be noted in the individual’s records. If aQIV needs to be administered at the same time as another vaccine, immunisation should be carried out on separate limbs.  The SPCs provide further guidance on administration and are available from the electronic medicines compendium website:  [www.medicines.org.uk](http://www.medicines.org.uk) |
| **Dose and frequency of administration** | Single 0.5ml dose for the current annual flu season (1 September 2022 to 31 March 2023). |
| **Vaccine preparation** | Vaccine supplied in single (0.5ml) dose pre-filled syringe.  Shake vaccine before administration.  Inspect visually prior to administration for foreign particulate matter and/or discoloration and ensure appearance is consistent with the description in the product’s [SPC](http://www.medicines.org.uk/). |
| **Storage** | Store at +2°C to +8°C. Do not freeze.  Store in original packaging in order to protect from light.  In the event of an inadvertent or unavoidable deviation of these conditions vaccine that has been stored outside the conditions stated above should be quarantined and risk assessed for suitability of continued off-label use or appropriate disposal. Refer to [Vaccine Incident Guidance](https://www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors) and Organisation Incident Policy. Contact the local pharmacy team for further advice.  Protocols for the ordering, storage and handling of vaccines should be followed to prevent vaccine wastage (see the Green Book [Chapter 3](https://www.gov.uk/government/publications/storage-distribution-and-disposal-of-vaccines-the-green-book-chapter-3)). |
| **Disposal** | Equipment used for immunisation, including used vials, ampoules, or discharged vaccines in a syringe or applicator, should be disposed of safely in a UN-approved puncture-resistant ‘sharps’ box, according to local authority arrangements and guidance in the [technical memorandum 07-01](https://www.england.nhs.uk/publication/management-and-disposal-of-healthcare-waste-htm-07-01/): Safe management of healthcare waste (Department of Health, 2013). |
| **Drug interactions** | Immunological response may be diminished in those receiving immunosuppressive treatment, but it is important to still immunise this group.  Because of the absence of data on co-administration of Shingrix® vaccine with adjuvanted influenza vaccine, it should not be routine to offer appointments to give this vaccine at the same time as the adjuvanted influenza vaccine. Based on current information, scheduling should ideally be separated by an interval of at least 7 days to avoid incorrect attribution of potential adverse events. Where individuals attend requiring both vaccines, however, and require rapid protection or are considered likely to be lost to follow up, co-administration may still be considered.  Inactivated influenza vaccine may be given at the same time as other vaccines (See [Route / method of administration](#RouteOfAdministration)).  All of the current COVID-19 vaccines are considered inactivated (including the non-replicating adenovirus vaccine)..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.  where individuals in an eligible cohort present having recently received COVID-19 vaccination, influenza vaccination should still be given.  A detailed list of drug interactions is available in the [SPC](http://www.medicines.org.uk) for each vaccine, which are available from the [electronic medicines compendium](http://www.medicines.org.uk) website. |
| **Identification & management of adverse reactions** | 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.  Immediate reactions such as urticaria, angio-oedema, bronchospasm and anaphylaxis can occur.  A higher incidence of mild post-immunisation reactions has been reported with adjuvanted compared to non-adjuvanted influenza vaccines.  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 at the same visit.  A detailed list of adverse reactions is available in the [SPC](http://www.medicines.org.uk) for each vaccine, which are available from the [electronic medicines compendium](http://www.medicines.org.uk) website. |
| **Management of and reporting procedure for adverse reactions** | Healthcare professionals and individuals are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the [Yellow Card reporting scheme](http://yellowcard.mhra.gov.uk) or search for MHRA Yellow Card in the Google Play or Apple App Store.  QIVe vaccines from Viatris (formerly Mylan) and MASTA, QIVc, QIVr and aQIV are black triangle. Therefore, any suspected adverse reactions should be reported via the Yellow Card Scheme.  Any adverse reaction to a vaccine should be documented in the individual’s record and the individual’s GP should be informed as appropriate.  Any adverse reaction to a vaccine should be documented in the individual’s occupational health record and the individual’s GP should be informed. |
| **Written information to be given to client** | Offer marketing authorisation holder's patient information leaflet (PIL) provided with the vaccine. |
| **Client advice / follow up treatment** | 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.  Immunosuppressed individuals should be advised that they may not make a full immune response to the vaccine. Therefore, consideration should be given to the influenza vaccination of their household contacts.  Inform the individual of possible side effects and their management.  The individual should be advised when to seek medical advice in the event of an adverse reaction.  When applicable, advise the individual when to return for vaccination.  Individuals in a clinical risk group recommended seasonal influenza vaccine should be encouraged to inform their GP (and midwife if relevant) once they have received influenza vaccine for the current season so their medical records (and maternity records if relevant) can be updated accordingly. Individuals who decline immunisation from their OHS provider and who are immunised elsewhere should be encouraged to inform their employer of their immunisation status as per local policy.  Resources to share with clients are available at: <https://www.gov.uk/government/collections/annual-flu-programme> |
| **Special considerations / additional information** | Ensure there is immediate access to adrenaline (epinephrine) 1 in 1,000 injection and easy access to a telephone at the time of vaccination.  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.  Individuals with learning disabilities may require reasonable adjustments to support vaccination (see [Flu vaccinations for people with learning disabilities)](https://www.gov.uk/government/publications/flu-vaccinations-for-people-with-learning-disabilities). A PSD may be required.  The licensed ages for the 2022 to 2023 season influenza vaccines are:   * QIVe licensed from 6 months of age * QIVc licensed from 2 years of age * QIVr licensed from 18 years of age * aQIV licensed from 65 years of age (see [Off-label](#OffLabelUse) section) |
| **Records** | Record in line with local procedure:   * that valid informed consent was given * name of individual, address, date of birth and GP with whom the individual is registered * name of immuniser * name and brand of vaccine * date of administration * dose, form and route of administration of vaccine * quantity administered * batch number and expiry date * anatomical site of vaccination * advice given, including advice given if excluded or declines immunisation * details of any adverse drug reactions and actions taken * administered under written instruction   Records should be signed and dated (or password-controlled immuniser’s record on e-records).  All records should be clear, legible and contemporaneous.  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.  It is important that vaccinations given within Occupational Health settings are recorded according to OH principles and ethics and in a timely manner.  Local policy should be followed to encourage information sharing with the individual’s General Practice where the individual would be eligible for immunisation under the national influenza programme to allow appropriate clinical follow up, improve data capture of vaccination status and to avoid duplicate vaccination.  A record of all individuals receiving treatment under this written instruction should also be kept for audit purposes in accordance with local policy. |

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| **Key references** |
| **Inactivated influenza vaccination**   * Immunisation Against Infectious Disease: The Green Book, [Chapter 19](https://www.gov.uk/government/publications/influenza-the-green-book-chapter-19). Published 29 October 2020.   <https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book>   * Collection: Annual Flu Programme. Updated 26 July 2022   <https://www.gov.uk/government/collections/annual-flu-programme>   * The national flu immunisation programme 2022 to 2023: supporting letter. Published 22 April 2022. <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> * Enhanced Service Specification, Seasonal influenza and vaccination programme 2022 to 2023. <https://www.england.nhs.uk/gp/investment/gp-contract/> * All influenza vaccines marketed in the UK for the 2022 to 2023 season   <https://www.gov.uk/government/publications/influenza-vaccines-marketed-in-the-uk>   * Live attenuated influenza vaccine (LAIV) PGD   <https://www.gov.uk/government/publications/influenza-vaccine-fluenz-tetra-patient-group-direction-pgd-template>   * Written instruction for the administration of seasonal ‘flu vaccination. NHS Specialist Pharmacy Service. 22 June 2022 <https://www.sps.nhs.uk/articles/written-instruction-for-the-administration-of-seasonal-flu-vaccination/> * Summary of Product Characteristics   [www.medicines.org.uk](http://www.medicines.org.uk)   * Flu immunisation training recommendations. Updated 27 July 2021.   <https://www.gov.uk/government/publications/flu-immunisation-training-recommendations>   * Flu Vaccinations: Supporting people with learning disabilities. Updated 25 September 2018.   <https://www.gov.uk/government/publications/flu-vaccinations-for-people-with-learning-disabilities>   * The national influenza immunisation programme 2022 to 2023 Information for healthcare practitioners Published 10 August 2022 <https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1097483/Flu-information-for-HCPs-2022-to-2023.pdf> * UKHSA Inactivated influenza vaccine Patient Group Direction 2022-23 <https://www.gov.uk/government/collections/immunisation-patient-group-direction-pgd#:~:text=UKHSA%20immunisation%20PGD%20templates%20require,Medicines%20Regulations%202012%20(HMR)>.   **General**   * Health Technical Memorandum 07-01: Safe Management of Healthcare Waste. Department of Health 20 March 2013   <https://www.england.nhs.uk/publication/management-and-disposal-of-healthcare-waste-htm-07-01/>   * 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>   * Patient Group Directions: who can use them. Medicines and Healthcare products Regulatory Agency. 4 December 2017.   <https://www.gov.uk/government/publications/patient-group-directions-pgds/patient-group-directions-who-can-use-them>   * 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> |

**Vaccinator authorisation sheet**

*Example – other recording forms, including electronic may be used in line with local policies*

**Details of the approved vaccinator\*\* working for ……………..*Insert name of organisation*………………who have completed the required training and been assessed as competent (as detailed in the relevant section of the Written Instruction and confirmed by line manager/clinical supervisor signing below) who are authorised and willing to administer inactivated influenza vaccine in accordance with this written instruction as part of the named organisation’s occupational health scheme, which may include peer to peer immunisation:**

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| **Name** | **Profession and Professional Registration Number** | **Signature** | **Date** | **Clinical Supervisor/Line manager name** | **Clinical supervisor/line manager signature** | **Date** |
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1. 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. [↑](#footnote-ref-2)
2. Including those becoming age 65 years by 31 March 2023 [↑](#footnote-ref-3)
3. JCVI recommended use of QIV-HD in this age group but this is not currently available in the UK market. [↑](#footnote-ref-4)