NHS Grampian NHS Highland NHS Orkney NHS Shetland NHS Tayside NHS Eileanan Siar Western Isles

VACCINE GROUP DIRECTION (VGD)

For The Administration Of Respiratory Syncytial Virus (RSV) Vaccine To Older Adults.
For use in NHS Grampian, Highland, Orkney, Shetland, Tayside And Western Isles.

This VGD has been authored by Public Health Scotland (PHS) and authorised by NOS PGD Group. PHS Publication date 1st April 2026, Version 1.0		**Approver:** NoS PGD Group **Authorisation:** NHS Grampian
		Signature:
NoS Identifier: NoS/VGD/RSV/1792	**Review Date:** March 2027 **Expiry Date:** March 2027	**Date Approved by NoS:** 8th April 2026

This VACCINE GROUP DIRECTION (VGD) has been authored by PHS and authorised by NoS PGD Group for use in NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles, as appropriate, to aid in the RSV vaccine delivery programme in Older Adults.

Annex B and C must be completed to comply with the requirements of this VGD.

Uncontrolled when printed

Version 1.0

Vaccine Group Direction: Administration of Respiratory Syncytial Virus (RSV) vaccine to older adults 2026/27

Publication date: 01 April 2026

Valid From: 01 April 2026

Expiry: 31 March 2027

Translations and other formats are available on request at:

phs.otherformats@phs.scot

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www.publichealthscotland.scot

Most recent changes

Version	Date	Summary of changes
1.0	01 April 2026	New Vaccine Group Direction (VGD) to support the 2026/27 RSV Older Adults programme.

NoS Document History:

NoS VGD that has been superseded	New PHS Authored VGD, Version 1.0

Contents

1. About the Vaccine Group Direction (VGD)

This VGD is for the supply and administration of RSV vaccine (Abrysvo®) to older adult individuals in accordance with the national RSV programme for older adults and residents in care homes for older adults.

This VGD is for the supply and administration of RSV vaccine by appropriately trained persons in accordance with regulation 235A of the Human Medicines Regulations 2012, as amended by **the Human Medicines (Amendment) Regulations 2026**.

Public Health Scotland, in the capacity of the Scottish public health agency, has produced and authored this VGD, for the purpose of providing protection against an infectious disease, namely RSV, as part of a vaccination programme which has been approved by Scottish Ministers.

In accordance with regulation 235A, this VGD must be authorised by a senior manager of a NHS Board prior to use in said NHS Board and be in effect at the time at which the medicinal product is administered.

This VGD will facilitate the delivery of the national RSV programme for older adults and residents in care homes for older adults vaccination programme by Health Boards in Scotland and any organisation a Health Board makes arrangements with to deliver such services on its behalf, referred to as “the provider”. Please note that in the context of this VGD, “the provider” means:

a. A Health Board,
b. a Health Board working with Armed Forces staff where Armed Forces staff are working in Health Board settings, or
c. an organisation delivering services on behalf of a Health Board.

This VGD may be followed wholly from assessment of an individual through to post-vaccination by a single appropriately specified registered healthcare professional as specified in the relevant parts of the Human Medicines Regulations 2012, as amended by **the Human Medicines (Amendment) Regulations 2026**.

Please note that nursing associates and operating department practitioners are not enabled to consent individuals under VGDs but may carry out non-registrant tasks provided they are supervised by a registered healthcare professional able to operate under Patient Group Directions. Alternatively, obtaining consent from, and assessment of, an individual may be undertaken by a registered healthcare professional with the processes of vaccine preparation, administration and recording undertaken by a non-registered professional or a non-registered Armed Forces staff member under clinical supervision by a registered healthcare professional.

Where multiple person models are used the provider must ensure that all elements of the VGD are complied with in the provision of the vaccination to each individual. **Please note that stages 2 and 3 (preparation and administration) must be undertaken by a single non-registered healthcare professional – where the**

non-registered healthcare professional is not authorised to undertake either stages 2 and/or 3, the registered healthcare professional must complete those stages, in addition to stage 1 activities.

The provider is responsible for ensuring that persons are trained and competent to safely deliver the activity they are authorised to provide under this VGD. As a minimum, competence requirements stipulated in the VGD under 'Characteristics of staff' must be adhered to.

The provider must identify a clinical supervisor who has overall responsibility for provision of vaccinations under the VGD at all times. This includes overall responsibility for the activities of any Armed Forces staff working under the VGD.

The clinical supervisor must be a registered healthcare professional trained and competent in all aspects of the VGD and provide clinical supervision for the overall provision of clinical care provided under the VGD.

The clinical supervisor must be identifiable to individuals receiving vaccination. Whenever the VGD is used, the name of the clinical supervisor taking responsibility and all of the persons working under different activity stages of the VGD must be recorded for the session using the schedule in Annex C or maintaining an equivalent electronic record. The clinical supervisor has ultimate responsibility for safe care being provided under the terms of the VGD. Persons working under the VGD may be supported by additional registered healthcare professionals, but the clinical supervisor retains responsibility.

Persons working to the VGD must understand who the clinical supervisor for their practice is at any time and can only work under their authority. The clinical supervisor may withdraw this authority for all persons or individual persons at any time and has authority to stop and start service provision under the VGD as necessary. All members of staff have a responsibility to, and should, report immediately to the clinical supervisor any concerns they have about working under the VGD in general or about a specific individual, process, issue or event.

Individual practitioners must be designated by name to work to this VGD. Persons working in accordance with this VGD must ensure they meet the staff characteristics for the activity they are undertaking, make a declaration of competence and be authorised in writing by the provider. This can be done by completing Annex B of this VGD or maintaining an equivalent electronic record.

It is a Health Board's responsibility to adhere to this VGD. Where the Health Board is not the provider, it is the Health Board's responsibility to ensure that the provider adheres to this VGD. The final authorised copy of this VGD should be kept, by Health Boards for 8 years after the VGD expires. Providers adopting authorised versions of this VGD should also retain copies, along with the details of those authorised to work under it, for 8 years after the VGD expires.

It is Health Boards' responsibility to ensure they and any organisations they make arrangements with to deliver services on their behalf operate the specified

vaccination services in accordance with the VGD. Any provider administering RSV vaccines under VGD must work strictly within the terms of this VGD.

Authorising organisations must not alter, amend or add to the clinical content of this document; such action will invalidate the clinical sign-off with which it is provided in accordance with the regulations. The legal validity of this VGD is contingent on those authorising section 2 and Annex B complying with the above

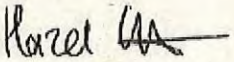
The national RSV programme for older adults and residents in care homes for older adults vaccination programme may also be provided under patient group direction, under written instruction for supply and administration in the course of an occupational health scheme, or on a patient specific basis, by or on the directions of an appropriate prescriber. Supply and administration in these instances are not related to this VGD.

Providers must check that they are using the current version of this VGD. Amendments may become necessary prior to the published expiry date. Current versions of VGDs authored by Public Health Scotland in accordance with regulation 235A of the Human Medicines Regulation 2012, as amended by **the Human Medicines (Amendment) Regulations 2026** can be requested by emailing phs.vaccination@phs.scot. Any concerns regarding the content of this VGD should also be sent to this email address.

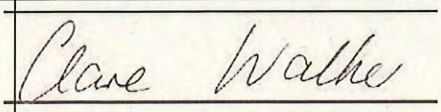
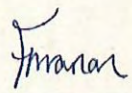
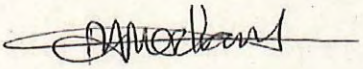
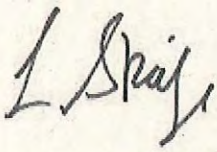
2. Approval and Clinical Authorisation

This VGD is not legally valid, in accordance with regulation 235A of the Human Medicines Regulations 2012, as amended by **the Human Medicines (Amendment) Regulations 2026**, until authored by Public Health Scotland and authorised by NHS Boards in Scotland.

On 01 April 2026 Public Health Scotland approved and authored this VGD in accordance with regulation 235A of the Human Medicines Regulations 2012, as amended by **the Human Medicines (Amendment) Regulations 2026**. Approval of clinical information in Annex A is via the Clinical Governance and Oversight Group of the Scottish Vaccination and Immunisation Programme on behalf of Public Health Scotland for the delivery of the national RSV vaccination programme for older adults and residents in care homes for older adults, with defined limitations to authorisation that may be updated from time to time as may be required.

Clinical author signatories – Public Health Scotland			
Role	**Name**	**Signature**	**Date**
Medical	Sam Ghebrehewet		01/04/2026
Pharmacy	Hazel Close		01/04/2026
Nursing	Jill Madden		01/04/2026

Authorised for use by the following organisations and/or services
NoS Boards
Limitations to authorisation
This authorisation applies to the supply and administration of the RSV vaccine, Abrysvo®, only under the conditions set out in the authorisation for supply or license set out by the Medicines and Healthcare products Regulatory Agency.

Clinical authorisation acting as a senior manager for NoS Boards			
Role	**Name**	**Sign**	**Date**
Medical	Clare-Louise Walker		08/04/2026
Pharmacy	Fiona Marion		07/04/2026
Nursing	Pauline Merchant		03/04/2026
NoS PGD Group Chair	Lesley Coyle		08/04/2026
Authorised & Executive Approval for NoS – Chief Executive NHS Grampian	Laura Skaife-Knight		08/04/2026

This RSV VGD Version 1.0 is Authorised and Approved for NoS From 8th April 2026

3. Characteristics of staff

Characteristics of staff

The provider is responsible for the designation and authorisation of persons within the classes set out below permitted to administer medicinal products under this VGD. In doing so the provider must establish that those persons:

a) demonstrate appropriate knowledge and skills to work under the Vaccine Group Direction for the supply/administration of RSV vaccine.
b) have met the requirements of the relevant Public Service Delivery (PSD) Scotland, formally NHS Education for Scotland (NES), Vaccination Proficiency document as appropriate at https://learn.nes.nhs.scot/82079

Classes of persons permitted to administer medicinal products under this VGD		
This VGD may be adhered to wholly from assessment through to post-vaccination by a single appropriately specified registered healthcare professional. Alternatively, multiple persons may undertake specific activity stages in the vaccination pathway in accordance with this VGD. Activity stages of the vaccination pathway under this VGD:		
Stage 1	a) Assessment of the individual presenting for vaccination b) Provide information and obtain informed consent c) Provide advice to the individual	Registered Healthcare Professionals Only
Stage 2	Vaccine Preparation **Delegation of this stage must be to the same practitioner as stage 3***	Registered Healthcare Professionals, non- registered professionals or non-registered Armed Forces staff
Stage 3	Vaccine Administration **Delegation of this stage must be to the same practitioner as stage 2***	Registered Healthcare Professionals, non- registered professionals or non-registered Armed Forces staff
Stage 4	Record keeping	Registered Healthcare Professionals, non- registered professionals or non-registered Armed Forces staff
***From 1 April 2026, only the person administering a vaccine may carry out reconstitution or dilution. Therefore, vaccine preparation and administration must be completed by the same practitioner, where these steps have been delegated by the practitioner working under stage 1.**		

Providers are responsible for assessing the competency of, designating and recording the names of, all those persons permitted to supply and administer under this VGD.

The following specified registered healthcare professionals are permitted to administerunder the VGD subject to the requirements set out below:

- Nurses and midwives currently registered with the Nursing and Midwifery Council(NMC).
- Pharmacists currently registered with the General Pharmaceutical Council (GPhC).
- Pharmacy technicians currently registered with the General Pharmaceutical Council (GPhC).
- Chiropodists/podiatrists, dieticians, occupational therapists, operating departmentpractitioners, orthoptists, orthotists/prosthetists, paramedics, physiotherapists, radiographers and speech and language therapists currently registered with the Health and Care Professions Council (HCPC).
- Dental hygienists and dental therapists currently registered with the General Dental Council.
- Optometrists currently registered with the General Optical Council.

The following professionals (who are in the main non-registered) are permitted to administer under the VGD, with appropriate supervision as set out below, subject to the requirements set out below:

- Healthcare support workers
- Pre-registration pharmacists and other pharmacy support practitioners
- Retired clinical practitioners such as doctors, dentists, pharmacists, nurses, optometrists, chiropodists/podiatrists, dieticians, occupational therapists, orthoptists,orthotists/prosthetists, paramedics, pharmacy technicians, physiotherapists, radiographers, speech and language therapists, dental hygienists and dental therapists not currently registered
- Student doctors, dentists, pharmacists, nurses, midwives, optometrists, chiropodists/podiatrists, dieticians, occupational therapists, orthoptists, orthotists/prosthetists, paramedics, physiotherapists, radiographers, speech and language therapists, dental hygienists and dental therapists not currently registered
- Healthcare Scientists
- Dental nurses
- Physician's assistants
- Nursing associates
- Operating department practitioners
- Scottish Ambulance Service Ambulance Technicians

The following non-registered Armed Forces staff are permitted to administer under the VGD with appropriate supervision as set out below, subject to the requirements set out below:

- Combat Medical Technician – Class 1,2 &3 (CMT)
- Royal Navy Medical Assistant (RN MA)
- Royal Air Forces Medic

- Defence Medic
- Healthcare Assistant (HCA)
- Military General Duties Vaccinators

Requirements
All those working under this VGD must have undertaken training, be assessed as competent and receive supervision appropriate to the stage of activity they are undertaking. Where multiple person models are used, the provider must ensure that all elements of the VGD are complied with in the provision of vaccination to each individual. The provider is responsible for ensuring that persons are trained and competent to safely deliver the activity they are employed to provide under this VGD. As a minimum, competence requirements stipulated in the VGD must be adhered to.

All persons must be designated by name by the provider as an approved person under the current terms of this VGD before working to it, and listed on the practitioner authorisation sheet in Annex B. All staff listed on the sheet will be covered by NHS indemnity extended by the Health Board who is responsible for the RSV vaccination programme in that locality. VGDs do not remove inherent obligations or accountability.

All practitioners operating under this VGD must work within their terms of employment at all times; registered healthcare professionals should also abide by their professional code of conduct.

There are three underpinning principles to which every person undertaking activities under the remit of this VGD must adhere.

Training
- They must have undertaken training appropriate to this VGD and relevant to their role, as required by local policy and health board standard operating procedures and in line with the training recommendations for persons vaccinating for RSV.
- They must have met the requirements set out in the relevant NES Vaccination Proficiency document.

Competency
- Those providing clinical supervision to those administering the vaccine must be competent to assess individuals for suitability for vaccination, identify any contraindications / exclusions or precautions, discuss issues related to vaccination and obtain informed consent from the individuals being vaccinated.
- All persons must be one of above noted registered professionals. Those that are not registered professionals, and those returning to immunisation after a prolonged interval (more than 12 months), should be assessed and signed off as meeting the requirements of the relevant NES Vaccination Proficiency document. They should be observed administering the vaccine until both they, and their supervisor or trainer, feel confident that they have the necessary knowledge and skills to administer vaccines safely and competently.

- Experienced persons should use the relevant NES Vaccination Proficiency document to self-assess that they are able to meet all the competencies listed and confirm that they have the knowledge and skills necessary to administer RSV vaccine. They must have completed local Infection Prevention and Control (IPC) training and comply with the vaccination guidance.

In addition and where indicated as relevant to the role:

- They must be familiar with the vaccine product and alert to any changes in the manufacturers summary of product characteristics (SmPC) and familiar with the national recommendations for the use of this vaccine.
- They must be familiar with, and alert to changes in relevant chapters of **The Green Book Respiratory syncytial virus (RSV) chapter.**
- They must be familiar with, and alert to changes in the relevant provider's standard operating procedures (SOPs) and provider's arrangements for the national RSV vaccination programme.
- They must be competent in the correct handling and storage of vaccines and management of the cold chain if receiving, responsible for, or handling the vaccine.
- They must be competent in the recognition and management of anaphylaxis, have completed basic life support training and be able to respond appropriately to immediate adverse reactions.
- They must have access to the provider's VGDs and relevant RSV vaccination programme online resources.
- For those preparing and administering the vaccine, they must be competent in the handling of the vaccine product and use of the correct technique for drawing up the correct dose.
- For those preparing and administering the vaccine, they must be competent in the intramuscular injection technique, this should include a practical element
- For those in record keeping roles, they must understand the importance of making sure vaccine information is recorded on the vaccination management app.
- They should fulfil any additional requirements defined by local policies developed in accordance with any national guidance.

Supervision

- A period of supervised practice to allow observation of, and development of skills in vaccine administration and application of knowledge to practice is essential.
- Supervision for new immunisers and support for all immunisers is critical to the safe and successful delivery of the RSV immunisation programme.
- Non-registered professionals and non-registered Armed Forces staff must be supervised and supported by a registered healthcare professional at all times.
- The clinical supervisor must be a registered healthcare professional trained and competent in all aspects of the VGD and provide clinical supervision for the overall provision of clinical care provided under the VGD.

Annex A: Clinical Information

This Annex provides information about the clinical situation or condition and treatment in relation to the Vaccine Group Direction

Clinical condition or situation to which this Vaccine Group Direction applies

Category	Description
Inclusion Criteria	Active immunisation of older individuals against respiratory syncytial virus (RSV) in accordance with **Scottish Government RSV immunisation programme**, Joint Committee on Vaccination and Immunisation (JCVI) advice/recommendations given in **The Green Book Respiratory syncytial virus chapter** and subsequent correspondence/publications from Scottish Government. Specifically, this includes individuals who: • are turning 75 years of age between 01/08/26 – 31/07/27. • are 75 years of age and over. • are resident in a care home for older adults including those under 75 years of age. Valid consent has been given to receive the vaccine.
Exclusion criteria	Individuals who: • have had a confirmed anaphylactic reaction to any components of the vaccine (refer to relevant SmPC). • are suffering from acute severe febrile illness (the presence of a minor infection is not a contraindication for immunisation). • Individuals who have received a previous dose of RSV vaccine in accordance with the older adults NHS programme.
Cautions/ needfor further advice/ circumstances when further advice should be sought from a doctor	The Green Book advises that there are very few individuals who cannot receive RSV vaccines. A number of cases of Guillain-Barre syndrome (GBS) have been reported following vaccination with Pfizer Pre-F and GSK adjuvanted pre-F vaccines. Individuals who have a history of GBS can be vaccinated as recommended for their age. There is evidence to suggest that having had a prior diagnosis of GBS does not predispose an individual to further episodes of GBS when immunised with other vaccines. Although there is no current indication for revaccination, those who are diagnosed with GBS within six weeks of a dose of RSV vaccine, should be advised to seek medical advice before accepting a future offer of revaccination, on a precautionary basis. Where there is doubt, rather than withholding vaccination, appropriate advice should be sought from the local immunisation coordinator or health protection team.

	Individuals who are immunosuppressed may not make a full antibody response. 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. **Individuals with a bleeding history** Individuals with a bleeding disorder may develop a haematoma at the injection site (see Route of Administration). **Co-administration with other vaccines** RSV vaccines can be safely co-administered with Shingrix shingles vaccine, COVID-19 and pneumococcal vaccines. It is recommended that RSV vaccine is not routinely scheduled to be given to an older adult at the same appointment or on the same day as an influenza vaccine. No specific interval is required between administering the vaccines. If it is thought that the individual is unlikely to return for a second appointment or immediate protection is necessary, Abrysvo® can be administered at the same time as influenza vaccination. Reactogenicity for co-administered vaccines is expected to be consistent with the profiles of the individual products. 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. **Syncope** 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.
Action if excluded	Specialist advice must be sought on the vaccine and circumstances under which it could be given as immunisation using a patient specific direction may be indicated. The risk to

	the individual not being immunised must be taken into account. Document the reason for exclusion and any action taken in accordance with local procedures. Inform or refer to the clinician in charge. Advise individuals of preventative measures to reduce exposure to RSV such as covering coughs and sneezes, washing or sanitising hands often, and cleaning frequently touched surfaces. **Temporary exclusion** In case of postponement due to acute severe febrile illness, advise when the individual can be vaccinated and ensure another appointment is arranged.
Action if person declines	Advise the individual about the protective effects of the vaccine, the risks of infection and potential complications of disease. Advise how future immunisation may be accessed if they subsequently decide to receive the vaccine. Advise individuals of preventative measures to reduce exposure to RSV such as covering coughs and sneezes, washing or sanitising hands often, and cleaning frequently touched surfaces. Document advice given and decision reached. Inform or refer to the clinician in charge.

4.1 Description of treatment

Category	Description
Name of medicine	Respiratory syncytial virus vaccine (bivalent, recombinant): Abrysvo® powder and solvent for solution for injection
Form	Powder and solvent for solution for injection.
Route of administration	Abrysvo ® vaccine is for intramuscular injection, preferably in the deltoid muscle. The vaccine should not be mixed with any other vaccines or medicinal products. Individuals with bleeding disorders may be immunised intramuscularly if, in the opinion of a doctor familiar with the individual's bleeding risk, immunisations 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 immunisation 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 International Normalised Ration (INR) testing and whose latest INR is below the upper level of the therapeutic range, can receive intramuscular vaccination. A fine needle (23 or 25 gauge) should be used for the immunisation, 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. For individuals with an unstable bleeding disorder or where the intramuscular route is otherwise deemed unsuitable, vaccines normally given by the intramuscular route may be given by deep subcutaneous injection to reduce the risk of bleeding (see **The Green Book chapter 4**). The vaccine must not be given via the intradermal or intravascular route. The vaccine should be visually inspected for particulate matter and discoloration prior to administration. In the event of any foreign particulate matter and/or variation of physical aspect being observed, do not administer the vaccine.
Dosage	Vaccine dose is 0.5ml.
Frequency	Single dose.
Duration of treatment	See frequency section.
Maximum or minimum treatment period	See frequency section.
Quantity to supply/administer	See frequency section
▼ black triangle medicines	Yes. 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 **http://www.mhra.gov.uk/yellowcard**
Legal category	Prescription Only Medicine (POM)

Is the use out with the SPC?	Yes Administration of Abrysvo® by deep subcutaneous injection to individuals with a bleeding disorder is off-label, but appropriate where the intramuscular route is unsuitable and is in line with advice in **Chapter 4 of The Green Book**. Abrysvo SmPC states that administration is by intramuscular injection into the deltoid region of the upper arm, this is the preferred site of administration according to **The Green Book Respiratory syncytial virus chapter**. 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. 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 VGD is allowed.
Storage requirements	Vaccine should be stored at a temperature of +2° to +8°C. Store in the original packaging to protect from light. Do not freeze. Abrysvo® should be administered immediately after reconstitution or within 4 hours if stored at room temperature. NHS Board guidance on Storage and Handling of vaccines should be observed. 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 use or appropriate disposal.
Additional information	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.

Adverse reactions

Category	Description
Warnings including possible adverse reactions and	For full details/information on possible side effects, refer to the marketing authorisation holder's SmPC. A clinical trial of older adults receiving Abrysvo® found that the most common adverse events following immunisation was pain

	at the vaccination site (11% of recipients). Redness and swelling at the injection site were the next most commonly reported reactions. A small number of cases of Guillain-Barré syndrome (GBS) were detected in phase 3 clinical trials and in post-marketing surveillance of older adults. Surveillance studies over the first few seasons of vaccination in the USA, England and Scotland suggested that RSV vaccines were associated with an increased risk of GBS in the six weeks following administration. The risk is estimated at around 10 to 25 cases of GBS for every million doses of the vaccine administered to older people. This compares to a background rate of GBS which is 20 per million per year in those aged 70-79 years. MHRA have advised health professionals to be attentive to signs and symptoms of GBS in all recipients of Abrysvo to ensure early and correct diagnosis, and to initiate treatment and supportive care; noting that early medical care can reduce severity and improve outcomes. The Commission on Human Medicines advises that overall the benefit of vaccination in preventing hospitalisation and death from RSV remains highly favourable relative to the risk of older adults developing GBS. As with all vaccines there is a very small possibility of anaphylaxis and facilities for its management must be available. In the event of a severe adverse reaction individuals should be advised to seek medical advice.
agement ofthese	Healthcare professionals and individuals/carers should report all suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on **http://www.mhra.gov.uk/yellowcard.** 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. Anaphylaxis is a very rare, recognised side effect of most vaccines and suspected cases should be reported via the MHRA Yellow Card Scheme. The Green Book **Vaccine safety and adverse events following immunisation chapter (8)** gives detailed guidance on distinguishing between faints, panic attacks and the signs and symptoms of anaphylaxis. If a case of suspected anaphylaxis meets the clinical features described in The Green Book **Vaccine safety and adverse events following immunisation chapter (8)** , this should be reported via the Yellow Card Scheme as a case of 'anaphylaxis' (or if appropriate 'anaphylactoid reaction'). Cases of less severe allergic reactions (i.e. not including the clinical

	features of anaphylaxis) should not be reported as anaphylaxis but as 'allergic reaction'.
Reporting procedure for adverse reactions	Healthcare professionals and individuals/carers should report suspected adverse reactions to the Medicines and Healthcareproducts Regulatory Agency (MHRA) using the Yellow Card reporting scheme on **http://www.mhra.gov.uk/yellowcard.** 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. Programmatic Adverse Events should be recorded in line with local procedures and where appropriate escalated in accordance with the national framework.
Advice to patient or carer including written information	**Written information to be given to individual** • Provide manufacturer's consumer information leaflet/patient information leaflet (PIL) provided with the vaccine. • Supply immunisation promotional material as appropriate. **Individual advice / follow up treatment:** • Inform the individual/carer of possible side effects and their management. • The individual should be advised to seek medical advice in the event of a severe adverse reaction. Healthcare professionals should advise all recipients of Abrysvo that they should be alert to signs and symptoms of Guillain-Barré syndrome. This may include symptoms such as tingling, numbness, weakness, sharp pain or pins and needles in the hands, feet, arms or legs. If they occur, individuals should be advised to seek immediate medical attention as it requires urgent treatment in hospital. • The individual should be advised to seek medical advice in the event of a severe adverse reaction. • As with all vaccines, immunisation may not result in protection in all individuals. The individual, parent or carer should be advised that immunosuppressed individuals may not make a full immune response to the vaccine. • Inform the individual that they can report suspected adverse reactions to the MHRA using **Yellow Card reporting scheme**.
Observation following vaccination	Following immunisation individuals remain under observation in line with NHS Board policy. As syncope (fainting) can occur following vaccination, all vaccinees should either be driven by someone else or should not drive for 15 minutes after vaccination.

Follow up	As above
Additional facilities	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 professional overseeing the immunisation service must be trained to recognise an anaphylactic reaction and be familiar with techniques for resuscitation of an individual with anaphylaxis.

4. Audit Trail/Records

Name	Description
Record/ audit trail	Record: • that valid informed consent was given • name of individual, address, date of birth and GP with whom the individual is registered • name of person that undertook assessment of individual's clinical suitability • name of person that administered the vaccine • name and brand of vaccine • date of administration • dose, form and route of administration of vaccine • batch number • where possible 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 vaccine group direction. 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 contemporaneousand in an easily retrievable format.

5. References

Name	Description
Additional references	• Immunisation against Infectious Disease [Green Book] • Immunisation against infectious disease - Respiratory syncytial virus • Current edition of British National Formulary • Educational resources for registered professionals produced by Public Services Delivery Scotland, formerly NES • All relevant JCVI statements • All relevant Scottish Government advice including the relevant CMO letter(s) • Marketing authorisation holders Summary of Product Characteristics. • Professional Guidance on the Administration of Medicines in Healthcare Settings 2019 • Professional Guidance on the Safe and Secure Handling of Medicines • Scottish Government Section 47 certificate of incapacity • NES adults with incapacity

Annex B: Practitioner authorisation sheet

RSV vaccine for older adults programme VACCINE GROUP DIRECTION

Valid from: 8th April 2026
Expiry: March 2027

Before signing this VGD, check that the document has had the necessary authorisations. Without these, this VGD is not lawfully valid.

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

VGDs do not remove inherent professional obligations or accountability.

It is the responsibility of each practitioner to practice only within the bounds of their own competence and any appropriate professional code of conduct.

I confirm that I have read and understood the content of this VGD and that I am willing and competent to work to it within my professional code of conduct.			
Name	Designation	Signature	Date

Person authorising on behalf of the Provider

I confirm that the practitioners named above have declared themselves suitably trained and competent to work under this VGD. I give authorisation on behalf of **insert name of organisation** for the above named health care professionals who have signed the VGD to work under it.			
Name	Designation	Signature	Date

Note to person authorising on behalf of Provider
Score through unused rows in the list of practitioners to prevent practitioner additions post managerial authorisation. This authorisation sheet should be retained to serve as a record of those practitioners authorised to work under this VGD.

Annex C: Clinical Supervision sheet

RSV vaccine for older adults programme VACCINE GROUP DIRECTION

Valid from: 8th April 2026
Expiry: March 2027

This sheet must record the name of the clinical supervisor taking responsibility and all of the people working under different activity stages of the VGD.

Activity stages of the vaccination pathway under this VGD:

Stage 1	a) Assessment of the individual presenting for vaccination b) Provide information and obtain informed consent c) Provide advice to the individual	Registered Healthcare Professionals Only
Stage 2	Vaccine Preparation **Delegation of this stage must be to the same practitioner as stage 3***	Registered Healthcare Professionals, non-registered professionals or non-registered Armed Forces staff
Stage 3	Vaccine Administration **Delegation of this stage must be to the same practitioner as stage 2***	Registered Healthcare Professionals, non-registered professionals or non-registered Armed Forces staff
Stage 4	Record Keeping	Registered Healthcare Professionals, non-registered professionals or non-registered Armed Forces staff

***From 1 April 2026, only the person administering a vaccine may carry out reconstitution or dilution. Therefore, vaccine preparation and administration must be completed by the same practitioner, where these steps have been delegated by the practitioner working under stage 1.**

The clinical supervisor has ultimate responsibility for safe care being provided under the terms of the VGD. Persons working under the VGD may be supported by additional registered healthcare professionals, but the clinical supervisor retains responsibility.

Before signing this VGD, check that the document has had the necessary authorisations. Without these, this VGD is not lawfully valid.

Clinical Supervisor

Name	Designation	Signature	Date

Practitioner(s) and Activity Stages

Name	Activity Stage(s)	Signature	Date	Clinical Supervisor Initials

Note to Clinical Supervisor

Score through unused rows in the list of practitioners to prevent practitioner additions post managerial authorisation. This authorisation sheet should be retained to serve as a record of clinical supervision arrangements for those working under this VGD.

6. Version history

Version	Date	Summary of changes
1.0	01 April 2026	New Vaccine Group Direction (VGD) to support the 2026/27 RSV Older Adults programme.