



UKHSA Publications gateway number: GOV-15000

## Zostavax<sup>®</sup> vaccine Patient Group Direction (PGD)

This PGD is for the administration of Zostavax<sup>®</sup>, shingles (herpes zoster, live) vaccine, to individuals who are eligible for the national shingles immunisation programme for the prevention of herpes zoster ('zoster' or shingles) and herpes zoster-related post-herpetic neuralgia (PHN).

This PGD is for the administration of Zostavax<sup>®</sup> by registered healthcare practitioners identified in [Section 3](#), subject to any limitations to authorisation detailed in [Section 2](#).

Reference no: Zostavax PGD  
Version no: v11.00  
Valid from: 1 September 2023  
Expiry date: 30 June 2024

**UKHSA has developed this PGD to facilitate the delivery of publicly funded immunisation in England in line with national recommendations.**

Those using this PGD must ensure that it is organisationally authorised and signed in Section 2 by an appropriate authorising person, relating to the class of person by whom the product is to be supplied, in accordance with Human Medicines Regulations 2012 (HMR2012)<sup>1</sup>. **The PGD is not legal or valid without signed authorisation in accordance with [HMR2012 Schedule 16 Part 2](#).**

Authorising organisations must not alter, amend or add to the clinical content of this document (sections 4, 5 and 6); such action will invalidate the clinical sign-off with which it is provided. In addition, authorising organisations must not alter section 3 'Characteristics of staff'. Only sections 2 and 7 can be amended within the designated editable fields provided.

Operation of this PGD is the responsibility of commissioners and service providers. The final authorised copy of this PGD should be kept by the authorising organisation completing Section 2 for 8 years after the PGD expires as the PGD relates to adults only. Provider organisations adopting authorised versions of this PGD should also retain copies for 8 years.

**Individual practitioners must be authorised by name, under the current version of this PGD before working according to it.**

Practitioners and organisations must check that they are using the current version of the PGD. Amendments may become necessary prior to the published expiry date. Current versions of UKHSA PGD templates for authorisation can be found from: [Immunisation patient group direction \(PGD\) templates](#)

Any concerns regarding the content of this PGD should be addressed to: [immunisation@ukhsa.gov.uk](mailto:immunisation@ukhsa.gov.uk)

Enquiries relating to the availability of organisationally authorised PGDs and subsequent versions of this PGD should be directed to: Contacts listed on pages 4 & 5 of this PGD




<sup>1</sup> This includes any relevant amendments to legislation

## Change history

Version number	Change details	Date
Final – revised 27 Aug 2013	New PHE PGD	1 Sept 2013
V02.00	See earlier version of this PGD for change details.	4 June 2015
V03.00	See earlier version of this PGD for change details.	16 Nov 2015
V04.00	See earlier version of this PGD for change details.	3 Feb 2016
V05.00	See earlier version of this PGD for change details.	2 August 2016
V06.00	See earlier version of this PGD for change details.	07 April 2017
V07.00	See earlier version of this PGD for change details.	12 July 2017
V08.00	See earlier version of this PGD for change details.	31 January 2019
V09.00	<p>PHE Shingles PGD amended to:</p> <ul style="list-style-type: none"> <li>• reword inclusion criteria to remove catch-up cohort and define eligibility at 70 years and retention of eligibility until individuals 80<sup>th</sup> birthday</li> <li>• identify examples of biological therapy that are immunosuppressive monoclonal antibodies</li> <li>• include minor rewording, layout and formatting changes for clarity and consistency with other PHE PGD templates</li> </ul>	18 February 2021
V10.00	<p>PHE Shingles PGD amended to:</p> <ul style="list-style-type: none"> <li>• rename as the Zostavax PGD and replace 'shingles (herpes zoster, live) vaccine' with 'Zostavax<sup>®</sup>'</li> <li>• reflect recommendations in the revised Green Book <a href="#">Chapter 28a</a> and changes to the national shingles programme following the introduction of Shingrix<sup>®</sup> vaccine (see <a href="#">Shingrix<sup>®</sup> PGD</a>) with amendment to the criteria for exclusion, cautions, actions if excluded, drug interaction and additional information sections</li> <li>• include minor rewording, layout and formatting changes for clarity and consistency with other PHE PGD templates and the Green Book <a href="#">Chapter 28a</a></li> </ul>	22 August 2021
V11.00	<p>Zostavax<sup>®</sup> PGD amended to:</p> <ul style="list-style-type: none"> <li>• replace Public Health England and PHE with UKHSA, including branding and updated contact details</li> <li>• amend NHSEI to NHSE following completion of merger on 1 July 2022</li> <li>• include minor rewording of standard text, layout and formatting changes for clarity and consistency with other UKHSA PGDs</li> <li>• Addition of new eligibility cohorts to reflect policy change, effective as of 1 September 2023</li> </ul>	10 July 2023

## 1. PGD Development

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

Developed by:	Name	Signature	Date
<b>Pharmacist</b> (Lead author)	Christina Wilson Lead Pharmacist, Immunisation and Vaccine Preventable Diseases Division, UKHSA		10 July 2023
<b>Doctor</b>	Dr Gayatri Amirthalingam Deputy Director of Public Health Programmes and Consultant Medical Epidemiologist, Immunisation and Vaccine Preventable Diseases Division, UKHSA		10 July 2023
<b>Registered Nurse</b> (Chair of Expert Panel)	David Green Nurse Consultant, Immunisation and Vaccine Preventable Diseases Division, UKHSA		10 July 2023

This PGD has been peer reviewed by the UKHSA Immunisations PGD Expert Panel in accordance with the UKHSA PGD Policy. It has been ratified by the UKHSA Medicines Governance Group.

### Expert Panel

Name	Designation
Nicholas Aigbogun	Consultant in Communicable Disease Control, Yorkshire and Humber Health Protection Team, UKHSA
Alison Campbell	Screening and Immunisation Coordinator, Clinical, NHSE Midlands
Sarah Dermont	Clinical Project Coordinator and Registered Midwife, NHS Infectious Diseases in Pregnancy Screening Programme, NHSE
Rosie Furner	Pharmacist, Medicines Governance, Patient Group Directions and Medicines Mechanisms, NHS Specialist Pharmacy Service
Ed Gardner	Advanced Paramedic Practitioner / Emergency Care Practitioner, Medicines Manager, Proactive Care Lead, Southbourne Surgery
Michelle Jones	Principal Medicines Optimisation Pharmacist, Bristol North Somerset and South Gloucestershire Integrated Care Board
Jacqueline Lamberty	Lead Pharmacist Medicines Governance, UKHSA
Elizabeth Lockett	Senior Screening and Immunisation Manager, NHSE South West
Vanessa MacGregor	Consultant in Communicable Disease Control, East Midlands Health Protection Team, UKHSA
Lesley McFarlane	Lead Immunisation Nurse Specialist, Immunisation and Vaccine Preventable Diseases Division, UKHSA
Nikki Philbin	Screening and Immunisation Manager, Vaccination and Screening Programmes, NHSE Midlands
Tushar Shah	Lead Pharmacy Adviser, NHSE London


## 2. Organisational authorisations


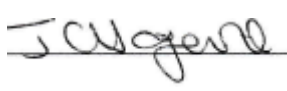
This PGD is not legally valid until it has had the relevant organisational authorisation.

It is the responsibility of the organisation that has legal authority to authorise the PGD, to ensure that all legal and governance requirements are met. The authorising body accepts governance responsibility for the appropriate use of the PGD.

NHSE North East and Yorkshire authorises this PGD for use by the services or providers listed below:

Authorised for use by the following organisations and/or services
NHS England (NHSE) commissioned immunisation services or NHS Trust providing immunisation services.
Limitations to authorisation
Authorisation is limited to those registered practitioners listed in Section 3 who are employed by organisations/providers commissioned by NHSE North East and Yorkshire (NEY) to deliver immunisation programmes within the whole of the NHSE region of North East and Yorkshire

Organisational approval (legal requirement)			
Role	Name	Sign	Date
Assistant Medical Director and Responsible Officer, NHS England –NEY	Dr James Gossow		4 <sup>th</sup> August 2023

Additional signatories according to locally agreed policy			
Role	Name	Sign	Date
Medicines Optimisation Pharmacist Lead, NHS NECS	Kurt Ramsden		4 <sup>th</sup> August 2023
Public Health Place Lead, Public Health Programme Team – Yorkshire and the Humber	Julie Hogarth		3 <sup>rd</sup> August 2023

Local enquiries regarding the use of this PGD may be directed to For North East and North Cumbria Area (i.e. Northumberland, Tyne & Wear, Durham Darlington and Tees and North Cumbria) use the following:

NHS England Screening and Immunisation Team: email [england.cane.screeningimms@nhs.net](mailto:england.cane.screeningimms@nhs.net) or NECS Medicine Optimisation Pharmacists: Kurt Ramsden: [kurtramsden@nhs.net](mailto:kurtramsden@nhs.net) or Sue White: [sue.white14@nhs.net](mailto:sue.white14@nhs.net)

Please note - All North East and North Cumbria PGDs can be found at:

<https://medicines.necsu.nhs.uk/resources/patient-group-directions/>

For Yorkshire and Humber Area use the following:

West Yorkshire - [england.wysit@nhs.net](mailto:england.wysit@nhs.net)

South Yorkshire and Bassetlaw - [england.sybsit@nhs.net](mailto:england.sybsit@nhs.net)

North Yorkshire and Humber ENGLAND.NYAHSIT@nhs.net or the Health Protection Team Acute Response Centre (ARC): Contact Number: 0113 3860 300.

Please note - All Yorkshire and Humber PGDs can be found at: <https://www.england.nhs.uk/north-east-yorkshire/our-work/information-for-professionals/pgds/>

[Section 7](#) provides a practitioner authorisation sheet. Individual practitioners must be authorised by name to work to this PGD. Alternative practitioner authorisation sheets may be used where appropriate in accordance with local policy but this should be an individual agreement or a multiple practitioner authorisation sheet as included at the end of this PGD.

### 3. Characteristics of staff

<b>Qualifications and professional registration required</b>	<p>Registered professional with one of the following bodies:</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) (Note: This PGD is not relevant to privately provided community pharmacy services)</li> <li>• paramedics and physiotherapists currently registered with Health and Care Professions Council (HCPC)</li> </ul> <p>The practitioners above must also fulfil the <a href="#">Additional requirements</a> detailed below.</p> <p>Check <a href="#">Section 2</a> (Limitations to authorisation) to confirm whether all practitioners listed above have organisational authorisation to work under this PGD.</p>
<b>Additional requirements</b>	<p>Additionally, practitioners:</p> <ul style="list-style-type: none"> <li>• must be authorised by name as an approved practitioner under the current terms of this PGD before working to it</li> <li>• must have undertaken appropriate training for working under PGDs for supply/administration of medicines</li> <li>• must be competent in the use of PGDs (see <a href="#">NICE Competency framework for health professionals using PGDs</a>)</li> <li>• must be familiar with the vaccine product and alert to changes in the Summary of Product Characteristics (SPC), Immunisation Against Infectious Disease ('<a href="#">The Green Book</a>'), and national and local immunisation programmes</li> <li>• must have undertaken training appropriate to this PGD as required by local policy and in line with the <a href="#">National Minimum Standards and Core Curriculum for Immunisation Training for Registered Healthcare Practitioners</a></li> <li>• must be competent to undertake immunisation and to discuss issues related to immunisation</li> <li>• must be competent in the handling and storage of vaccines, and management of the cold chain</li> <li>• must be competent in the recognition and management of anaphylaxis</li> <li>• must have access to the PGD and associated online resources</li> <li>• should fulfil any additional requirements defined by local policy</li> </ul> <p><b>Individual practitioners must be authorised by name, under the current version of this PGD before working according to it.</b></p>
<b>Continued training requirements</b>	<p>Practitioners must ensure they are up to date with relevant issues and clinical skills relating to immunisation and management of anaphylaxis, with evidence of appropriate Continued Professional Development (CPD).</p> <p>Practitioners should be constantly alert to any subsequent recommendations from UKHSA, NHS England and other sources of medicines information.</p> <p>Note: The most current national recommendations should be followed but a Patient Specific Direction (PSD) may be required to administer the vaccine in line with updated recommendations that are outside the criteria specified in this PGD.</p>

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

<p><b>Clinical condition or situation to which this PGD applies</b></p>	<p>Zostavax<sup>®</sup> is indicated for vaccination of adults who are eligible for the national shingles immunisation programme for the prevention of herpes zoster ('zoster' or shingles) and herpes zoster-related post-herpetic neuralgia (PHN) in accordance with the recommendations given in <a href="#">Chapter 28a</a> of Immunisation Against Infectious Disease: 'The Green Book'.</p>
<p><b>Criteria for inclusion</b></p>	<p>Immunocompetent individuals who are:</p> <ul style="list-style-type: none"> <li>• aged between 70 and 79 before 1 September 2023</li> </ul> <p><b>and</b></p> <ul style="list-style-type: none"> <li>• who have never received a shingles vaccine</li> </ul> <p><b>and</b></p> <ul style="list-style-type: none"> <li>• in-date stocks of Zostavax<sup>®</sup> are available, either locally or to order via ImmForm</li> </ul>
<p><b>Criteria for exclusion<sup>2</sup></b></p>	<p>Individuals for whom no valid consent has been received</p> <p>Individuals who:</p> <ul style="list-style-type: none"> <li>• are under 70 years at the time of assessment; such individuals should be assessed against the <a href="#">Shingrix<sup>®</sup> vaccine PGD</a></li> <li>• are aged 70 years at the time of assessment, with a date of birth on or after 1 September 1953; such individuals should be assessed against the <a href="#">Shingrix<sup>®</sup> vaccine PGD</a></li> <li>• are 80 years of age or over, even if they were previously in an eligible cohort</li> <li>• have had a confirmed anaphylactic reaction to a previous dose of varicella vaccine or to any component of Zostavax<sup>®</sup>, including neomycin or gelatin</li> <li>• are suffering from acute severe febrile illness (the presence of a minor infection is not a contraindication for immunisation)</li> <li>• have active untreated tuberculosis</li> <li>• have shingles infection with active lesions</li> <li>• have received systemic therapy in the last 48 hours with anti-viral medicines known to be effective against varicella zoster virus, such as aciclovir</li> <li>• have been given intravenous immunoglobulin (IVIG) or varicella zoster immunoglobulin (VZIG) in the previous 6 weeks</li> <li>• have received MMR vaccine in the preceding 4 weeks</li> <li>• are pregnant</li> <li>• are within 14 days of commencement of immunosuppressive therapy</li> <li>• have a primary or acquired immunodeficiency state as defined in <a href="#">Chapter 28a</a> as a contraindication to Zostavax<sup>®</sup> administration</li> <li>• are on immunosuppressive or immunomodulating therapy as defined in <a href="#">Chapter 28a</a> as a contraindication to Zostavax<sup>®</sup> administration</li> </ul> <p>Note: Zostavax<sup>®</sup> is not contraindicated for use in individuals who are receiving topical or inhaled corticosteroids or corticosteroid replacement therapy. Individuals with low levels of immunosuppression can receive Zostavax<sup>®</sup>. If primary healthcare professionals administering the vaccine have concerns about the nature of therapies or the degree of immunosuppression, they should contact the relevant specialist for</p>

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<sup>2</sup> Exclusion under this PGD does not necessarily mean the medication is contraindicated, but it would be outside its remit and another form of authorisation will be required



<b>Criteria for exclusion</b> (continued)	advice. Specialist advice should also be considered for individuals on combination immunosuppressive therapy.
<b>Cautions including any relevant action to be taken</b>	<p>Facilities for management of anaphylaxis should be available at all vaccination premises (see <a href="#">Chapter 8</a> of the Green Book and advice issued by the <a href="#">Resuscitation Council UK</a>).</p> <p>Individuals who have previously received immunosuppressive therapy should be carefully evaluated for the reconstitution of the immune system prior to receiving Zostavax®.</p> <p><b>Transmission</b></p> <p>There is a theoretical risk, in those who develop a rash following Zostavax® vaccination, of transmitting the attenuated vaccine virus to a susceptible individual. This risk should be weighed against the reduced risk of developing natural shingles and much higher risk of transmission from the circulating wild-type varicella zoster virus in the community.</p> <p>As a precautionary measure, individuals who develop a vesicular rash after receiving Zostavax® should ensure the rash area is kept covered when in contact with a susceptible (chicken pox naïve) person until the rash is dry and crusted. If the individual with the vesicular rash is also severely immunosuppressed, they should avoid contact with susceptible people until the rash is dry and crusted, due to the higher risk of virus shedding. Prophylactic aciclovir can be considered in vulnerable individuals exposed to a varicella-like rash in a recent recipient of the vaccine.</p> <p>In the event of a person developing a varicella (widespread) or shingles-like (dermatomal) rash post-Zostavax®, a vesicle fluid sample should be sent for analysis, to confirm the diagnosis and determine whether the rash is vaccine-associated or wild-type. See <a href="#">Chapter 28a</a> for more details.</p>
<b>Action to be taken if the patient is excluded</b>	<p>Individuals who are not of eligible age for the national shingles immunisation programme should be advised when they will become eligible or why they are not eligible for immunisation. Individuals becoming 65 or 70 years of age on or after 1 September 2023 should be assessed against the <a href="#">Shingrix® vaccine PGD</a>.</p> <p>Individuals who have had a confirmed anaphylactic reaction to a previous dose of varicella vaccine or to any component of Zostavax®, should be assessed for suitability to Shingrix® instead, using the <a href="#">Shingrix® vaccine PGD</a>.</p> <p>Individuals suffering from acute severe febrile illness should postpone immunisation until they have recovered.</p> <p>Individuals with untreated tuberculosis should postpone immunisation until their tuberculosis has been treated.</p> <p>Zostavax® is not recommended for the treatment of shingles.</p> <p>Individuals who have shingles should wait until symptoms have ceased before being considered for shingles immunisation. The natural boosting that occurs following an episode of shingles, however, makes the benefit of offering Zostavax® immediately following recovery unclear.</p> <p>Individuals who have received systemic anti-viral medicines known to be effective against varicella zoster virus, such as aciclovir, should postpone Zostavax® vaccination until at least 48 hours after cessation of treatment, as these medicines may reduce the response to the vaccine. Individuals who have received intravenous immunoglobulin (IVIG) or varicella zoster</p>

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<p><b>Action to be taken if the patient is excluded</b> (continued)</p>	<p>immunoglobulin (VZIG) should wait 6 weeks before presenting for immunisation. The use of topical aciclovir is not a contraindication to vaccination.</p> <p>Individuals who have received MMR vaccine should postpone Zostavax® administration until a 4 week minimum interval period has been observed.</p> <p>Severely immunosuppressed individuals or individuals due to commence immunosuppressive therapy who are eligible for shingles vaccination but who are contraindicated to receiving Zostavax® as a live vaccine, in accordance with <a href="#">Chapter 28a</a> should be assessed for Shingrix® instead (see <a href="#">Shingrix® vaccine PGD</a>).</p> <p>If required, seek advice from the local Screening and Immunisation Team, local Health Protection Team or the individual's clinician as deemed appropriate.</p> <p>The risk to the individual of not being vaccinated must be taken into account.</p> <p>When administration is postponed arrange a future date for vaccination as appropriate, with due consideration of the individual's age to ensure they will meet the inclusion criteria for immunisation. If vaccination cannot be given before the individual is 80 years old explain why vaccination will no longer be indicated.</p> <p>Document the reason for exclusion and any action taken in the individual's clinical records.</p> <p>Inform or refer to the individual's GP or a prescriber as appropriate.</p>
<p><b>Action to be taken if the patient or carer declines treatment</b></p>	<p>Informed consent, from the individual or a person legally able to act on the individual's behalf, must be obtained prior to administration.</p> <p>Advise the individual or carer about the protective effects of the vaccine, the risks of infection and potential complications.</p> <p>Document advice given and the decision reached.</p> <p>Inform or refer to the individual's GP or a prescriber as appropriate.</p>
<p><b>Arrangements for referral for medical advice</b></p>	<p>As per local policy</p>

## 5. Description of treatment

<b>Name, strength and formulation of drug</b>	<p>Zostavax<sup>®</sup>, shingles (herpes zoster, live) vaccine, powder and solvent for suspension for injection.</p> <p>After reconstitution, Zostavax<sup>®</sup> lyophilised suspension (0.65ml) contains shingles (herpes zoster) vaccine, consisting of live attenuated virus derived from varicella zoster virus.</p>
<b>Legal category</b>	Prescription only medicine (POM).
<b>Black triangle</b>	No.
<b>Off-label use</b>	<p>Vaccine should be stored according to the conditions detailed in the <a href="#">Storage</a> section below. However, in the event of an inadvertent or unavoidable deviation of these conditions, refer to <a href="#">Vaccine Incident Guidance</a>. Where vaccine is assessed in accordance with these guidelines as appropriate for continued use, this would constitute off-label administration under this PGD.</p> <p>Where a vaccine is recommended off-label consider, as part of the consent process, informing the individual or carer that the vaccine is being offered in accordance with national guidance but that this is outside the product licence.</p>
<b>Route and method of administration</b>	<p>Following reconstitution, Zostavax<sup>®</sup> is given as a single dose by intramuscular or subcutaneous injection, preferably in the deltoid muscle of the upper arm. Intramuscular administration is preferred as injection-site adverse reactions were significantly less frequent in those who received the vaccine via this route.</p> <p>For individuals with a bleeding disorder, Zostavax<sup>®</sup> should be given by deep subcutaneous injection to reduce the risk of bleeding.</p> <p>Zostavax<sup>®</sup> should NOT be injected intravascularly.</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 vaccinations.</p> <p>The vaccines should be given at separate sites, preferably in different limbs. If given in the same limb, they should be given at least 2.5cm apart. The site at which each vaccine was given should be noted in the individual's records.</p> <p>It is recommended that the vaccine be administered immediately after reconstitution, to minimise loss of potency. Discard reconstituted vaccine if it is not used within 30 minutes.</p> <p>Avoid contact with disinfectants, as they may inactivate the vaccine virus.</p> <p>When reconstituted, Zostavax<sup>®</sup> is a semi-hazy to translucent, off-white to pale yellow liquid. Discard the vaccine if there is any foreign particulate matter present or the appearance of the reconstituted vaccine differs from this description.</p> <p>The vaccine <a href="#">SPC</a> provides further guidance on reconstitution and administration.</p>
<b>Dose and frequency of administration</b>	Single dose of 0.65ml of reconstituted Zostavax <sup>®</sup> .
<b>Duration of treatment</b>	Single dose

<b>Quantity to be supplied and administered</b>	Single 0.65ml dose of reconstituted Zostavax®.
<b>Supplies</b>	Centrally purchased vaccines for the national immunisation programme can only be ordered via ImmForm and are provided free of charge.  Protocols for the ordering, storage and handling of vaccines should be followed to prevent vaccine wastage (see Green Book <a href="#">Chapter 3</a> ).
<b>Storage</b>	Store between +2°C to +8°C. Store in original packaging in order to protect from light. Do not freeze.  Avoid contact with disinfectants.  After reconstitution the vaccine should be used immediately. However, in-use stability has been demonstrated for 30 minutes when stored at +20°C to +25°C.  In the event of an inadvertent or unavoidable deviation of these conditions, vaccine that has been stored outside the conditions stated above should be quarantined and risk assessed for suitability of continued off-label use or appropriate disposal. Refer to <a href="#">Vaccine Incident Guidance</a> .
<b>Disposal</b>	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 NHSE guidance ( <a href="#">HTM 07-01: Management and disposal of healthcare waste</a> ).
<b>Drug interactions</b>	None reported.  See the <a href="#">Additional information</a> section and <a href="#">SPC</a> for information on co-administration with antivirals and other vaccines.
<b>Identification and management of adverse reactions</b>	The most common adverse reactions observed after administration of Zostavax® are injection-site reactions, including redness, swelling, pain and itching. Other common reactions include bruising, hardening (induration) and warmth at the injection site, headache and pain in the relevant limb. Very rarely, a varicella (chickenpox)-like illness has been reported.  In the event of a person developing a varicella (widespread) or shingles-like (dermatomal) rash post-Zostavax® vaccination, a vesicle fluid sample should be sent for analysis, to confirm the diagnosis and determine whether the rash is vaccine-associated or wild-type (see <a href="#">Chapter 28a</a> ).  A detailed list of adverse reactions is available in the <a href="#">SPC</a> .

<b>Reporting procedure of adverse reactions</b>	<p>Healthcare professionals, individuals and carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the <a href="#">Yellow Card reporting scheme</a> or by searching for MHRA Yellow Card in the Google Play or Apple App Store.</p> <p>Any adverse reaction to the vaccine should be documented in the individual's record and the individual's GP should be informed.</p>
<b>Written information to be given to patient or carer</b>	<p>Offer the marketing authorisation holder's patient information leaflet (PIL) provided with the vaccine.</p> <p>Immunisation promotional material may be provided as appropriate: <a href="#">Vaccination against shingles guide</a></p> <p>For resources in accessible formats and alternative languages, please visit <a href="#">Home – Health Publications</a>.</p> <p>Where applicable, inform the individual or carer that large print, Braille or audio CD PILs may be available from emc accessibility (freephone 0800 198 5000) by providing the medicine name and product code number, as listed on the <a href="#">electronic Medicines Compendium</a>.</p>
<b>Patient advice and follow-up treatment</b>	<p>Inform the individual or carer of possible side effects and their management.</p> <p>Give advice regarding normal reaction to the injection, for example redness and pain at the injection site.</p> <p>The individual or carer should be advised to seek medical advice in the event of a severe adverse reaction and report this via the <a href="#">Yellow Card Scheme</a>.</p> <p>Individuals should be advised to seek medical attention if they develop a varicella (widespread) or shingles-like (dermatomal) rash post-Zostavax<sup>®</sup> vaccination.</p> <p>If administration is postponed, advise the individual or carer when to return for vaccination with due consideration of the individual's age to ensure they will meet the inclusion criteria for immunisation. If vaccination cannot be commenced before an immunocompetent individual is 80 years old, explain why vaccination will no longer be indicated (there is no upper age limit for severely immunocompromised individuals).</p>
<b>Special considerations and additional information</b>          (continued over page)	<p><b>Individuals identified as eligible under the inclusion criteria remain so for as long as Zostavax<sup>®</sup> remains available and clinic stock is in date. When locally-held stocks are depleted and Zostavax<sup>®</sup> is no longer available from ImmForm, the authorising manager (as per section 7) should retire this PGD and revert to using the <a href="#">Shingrix<sup>®</sup> vaccine PGD</a> to vaccinate individuals against shingles.</b></p> <p>Ensure there is immediate access to adrenaline (epinephrine) 1 in 1000 injection and easy access to a telephone at the time of vaccination.</p> <p>All severely immunosuppressed individuals who are inadvertently administered Zostavax<sup>®</sup> require urgent assessment and may need to receive prophylactic aciclovir. Severely immunosuppressed individuals who develop a varicella rash following inadvertent vaccination should be urgently assessed and offered prompt treatment with IV high-dose aciclovir, given the risks and severity of disseminated zoster.</p>

<b>Special considerations and additional information</b> (continued)	<p>Zostavax® can be given at the same time as inactivated influenza vaccine (includes aQIV) and 23-valent pneumococcal polysaccharide vaccine (PPV) for those who are eligible for both vaccines.</p> <p>In the rare event that MMR vaccine is indicated in this age group it should be administered on the same day, or a four-week minimum interval period should be observed. Other live vaccines can be administered at any time before or after Zostavax®.</p> <p>Though a 7 day gap between administration of Zostavax® and COVID-19 vaccine is preferred, where individuals attend requiring both vaccines and require rapid protection or are considered likely to be lost to follow up, co-administration may still be considered. In such circumstances, patients should be informed about the likely timing of potential adverse events relating to each vaccine.</p> <p>There is no data on concomitant use with anti-viral medications known to be effective against varicella zoster virus but it is likely that these will reduce the response to Zostavax® - see <a href="#">Criteria for exclusion</a>.</p> <p>See <a href="#">Chapter 28a</a> for more details.</p>
<b>Records</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 immuniser</li> <li>• name and brand of vaccine</li> <li>• date of administration</li> <li>• dose, form and route of administration of vaccine</li> <li>• quantity administered</li> <li>• batch number and expiry date</li> <li>• anatomical site of vaccination</li> <li>• advice given, including advice given if the individual is excluded or declines immunisation</li> <li>• details of any adverse drug reactions and actions taken</li> <li>• supplied via PGD</li> </ul> <p>Records should be signed and dated (or password controlled on e-records).</p> <p>All records should be clear, legible and contemporaneous.</p> <p>This information should be recorded in the individual's GP record and any other appropriate medical records, such as care or nursing records.</p> <p>A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.</p>

## 6. Key references

<b>Key references</b>	<p><b>Shingles</b></p> <ul style="list-style-type: none"><li>• Zostavax® Summary of Product Characteristics. MSD Ltd. Updated 8 September 2021. <a href="https://www.medicines.org.uk/emc/product/6101">https://www.medicines.org.uk/emc/product/6101</a></li><li>• Immunisation Against Infectious Disease: The Green Book, <a href="#">Chapter 28a</a>. Updated July 2023. <a href="https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book">https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book</a></li><li>• Shingles: Guidance and Vaccination Programme. Updated 4 July 2023. <a href="https://www.gov.uk/government/collections/shingles-vaccination-programme">https://www.gov.uk/government/collections/shingles-vaccination-programme</a></li><li>• UKHSA: Vaccination against shingles – information for healthcare practitioners. Updated 6 July 2023. <a href="https://www.gov.uk/government/publications/shingles-vaccination-guidance-for-healthcare-professionals">https://www.gov.uk/government/publications/shingles-vaccination-guidance-for-healthcare-professionals</a></li></ul> <p><b>General</b></p> <ul style="list-style-type: none"><li>• NHSE Health Technical Memorandum 07-01: Safe Management of Healthcare Waste. Updated 7 March 2023. <a href="https://www.england.nhs.uk/publication/management-and-disposal-of-healthcare-waste-hm-07-01">https://www.england.nhs.uk/publication/management-and-disposal-of-healthcare-waste-hm-07-01</a></li><li>• National Minimum Standards and Core Curriculum for Immunisation Training. Published February 2018. <a href="https://www.gov.uk/government/publications/national-minimum-standards-and-core-curriculum-for-immunisation-training-for-registered-healthcare-practitioners">https://www.gov.uk/government/publications/national-minimum-standards-and-core-curriculum-for-immunisation-training-for-registered-healthcare-practitioners</a></li><li>• NICE Medicines Practice Guideline 2 (MPG2): Patient Group Directions. Updated March 2017. <a href="https://www.nice.org.uk/guidance/mpg2">https://www.nice.org.uk/guidance/mpg2</a></li><li>• NICE MPG2 Patient group directions: competency framework for health professionals using patient group directions. Updated March 2017. <a href="https://www.nice.org.uk/guidance/mpg2/resources">https://www.nice.org.uk/guidance/mpg2/resources</a></li><li>• UKHSA Immunisation Collection. <a href="https://www.gov.uk/government/collections/immunisation">https://www.gov.uk/government/collections/immunisation</a></li><li>• Vaccine Incident Guidance: responding to errors in vaccine storage, handling and administration. Updated 7 July 2022. <a href="https://www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors">https://www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors</a></li></ul>
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## 7. Practitioner authorisation sheet

**Zostavax PGD v011.00 Valid from: 1 September 2023 Expiry: 30 June 2024**

Before signing this PGD, check that the document has had the necessary authorisations in section 2. Without these, this PGD is not lawfully valid.

### Practitioner

By signing this PGD you are indicating that you agree to its contents and that you will work within it. PGDs do not remove inherent professional obligations or accountability. It is the responsibility of each professional to practise only within the bounds of their own competence and professional code of conduct.

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

### Authorising manager

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

### Note to authorising manager

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

This authorisation sheet should be retained to serve as a record of those practitioners authorised to work under this PGD.