



## PHE publications gateway number: GOV-9518

# **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 <u>Section 3</u>, subject to any limitations to authorisation detailed in <u>Section 2</u>.

Zostavax PGD
v10.00
1 September 2021
1 March 2023
31 August 2023

# Public Health England has developed this PGD to facilitate the delivery of publicly funded immunisation 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 <u>HMR2012 Schedule 16 Part 2</u>.

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 PHE 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: <u>immunisation@phe.gov.uk</u>

Enquiries relating to the availability of organisationally authorised PGDs and subsequent versions of this PGD should be directed to: your local screening and immunisation team.

<sup>&</sup>lt;sup>1</sup> This includes any relevant amendments to legislation (such as <u>2013 No.235</u>, <u>2015 No.178</u> and <u>2015 No.323</u>). Zostavax PGD v10.00 Valid from: 01/09/2021 Expiry: 31/08/2023 Page 1 of 14

# Change history

Version number	Change details	Date
Final – revised 27 Aug 2013	New PHE PGD	Valid from 1 Sept 2013
Version 02.00	See earlier version of this PGD for change details.	4 June 2015
Version 03.00	See earlier version of this PGD for change details.	16 Nov 2015
Version 04.00	See earlier version of this PGD for change details.	3 Feb 2016
Version 05.00	See earlier version of this PGD for change details.	2 August 2016
Version 06.00	See earlier version of this PGD for change details.	07 April 2017
Version 07.00	See earlier version of this PGD for change details.	12 July 2017
Version 08.00	<ul> <li>PHE Shingles PGD amended to:</li> <li>include additional healthcare practitioners in Section 3</li> <li>refer to PHE Vaccine Incident Guidance in the off-label and storage sections</li> <li>move the exclusion following natural infection to the cautions section and refer to the 'Shingles vaccination: Guidance for healthcare professionals'</li> <li>include additional information in relation to the possible future availability of inactivated shingles vaccine</li> <li>update off-label status section</li> <li>include minor rewording, layout and formatting changes for clarity and consistency with other PHE PGD templates</li> </ul>	31 January 2019
Version 09.00	<ul> <li>PHE Shingles PGD amended to:</li> <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 monocloncal antibodies</li> <li>include minor rewording, layout and formatting changes for clarity and consistency with other PHE PGD templates</li> </ul>	18 February 2021
Version 10.00	<ul> <li>PHE Shingles PGD amended to:</li> <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 <u>Chapter 28a</u> and changes to the national shingles programme following the introduction of Shingrix<sup>®</sup> vaccine (see <u>PHE Shingrix PGD</u>) 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 <u>Chapter 28a</u></li> </ul>	22 August 2021

## 1. PGD development

This PGD has been developed by the following health professionals on behalf of Public Health England:

Developed by:	Name	Signature	Date
Pharmacist (Lead Author)	Elizabeth Graham Lead Pharmacist, Immunisation and Countermeasures, PHE	Elaha	25/08/2021
Doctor	Mary Ramsay Consultant Epidemiologist and Head of Immunisation and Countermeasures, PHE	Mary Ramony	25/08/2021
<b>Registered Nurse</b> (Chair of Expert Panel)	David Green Nurse Consultant, Immunisations and Countermeasures, PHE	DGieen.	25/08/2021

This PGD has been peer reviewed by the PHE Immunisations PGD Expert Panel in accordance with PHE PGD Policy. It has been ratified by the PHE Medicines Governance Group and the PHE Quality and Clinical Governance Delivery Board.

### Expert Panel

Name	Designation
Nicholas Aigbogun	Consultant in Communicable Disease Control, Yorkshire and Humber Health Protection Team, Public Health England
Gayatri Amirthalingam	Consultant Epidemiologist, Public Health England
Sarah Dermont	Clinical Project Coordinator and Registered Midwife, NHS Infectious Diseases in Pregnancy Screening Programme, Public Health England
Ed Gardner	Advanced Paramedic Practitioner / Emergency Care Practitioner, Medicines Manager, Proactive Care Lead
Michelle Jones	Senior Medicines Optimisation Pharmacist, NHS Bristol North Somerset and South Gloucestershire CCG
Jacqueline Lamberty	Lead Pharmacist Medicines Management Services, Public Health England
Vanessa MacGregor	Consultant in Communicable Disease Control, Public Health England, East Midlands Health Protection Team
Alison Mackenzie	Consultant in Public Health Medicine / Screening and Immunisation Lead, Public Health England (South West) / NHS England and NHS Improvement South (South West)
Gill Marsh	Principal Screening and Immunisation Manager, Public Health England / NHS England and NHS Improvement (North West)
Lesley McFarlane	Screening and Immunisation Manager: Clinical (COVID-19 and Influenza), Public Health England / NHS England and NHS Improvement (Midlands)
Tushar Shah	Lead Pharmacy Advisor, NHS England and NHS Improvement (London Region)

### 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.

NHS England & NHS Improvement (South East) authorises this PGD for use by the services or providers listed below:

Authorised for use by the following organisations and/or services All NHS England commissioned immunisation services within the NHS England and NHS Improvement South East Region.

Limitations to authorisation

This patient group direction (PGD) must only be used by the registered healthcare practitioners identified in Section 3 who have been named by their organisation to practice under it. The most recent in-date final version authorised by NHS England and NHS Improvement (South East) must be used.

This PGD includes vaccination of individuals across the national immunisation programme. Users of this PGD should note that where they are commissioned to immunise certain groups this PGD does not constitute permission to offer immunisation beyond the groups they are commissioned to immunise.

Organisational approval (legal requirement)			
Role	Name	Sign	Date
South East Regional Medical Director	Dr Vaughan Lewis	VGo	01 Sept 2021

Additional signatories according to locally agreed policy			
Role	Name	Sign	Date

Local enquiries regarding the use of this PGD may be directed to your local screening and immunisation team.

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

Qualifications and professional registration	<ul> <li>Registered professional with one of the following bodies:</li> <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> <li>The practitioners above must also fulfil the <u>Additional requirements</u> detailed below.</li> </ul>
	Check <u>Section 2 Limitations to authorisation</u> to confirm whether all practitioners listed above have organisational authorisation to work under this PGD.
Additional requirements	<ul> <li>Additionally, practitioners:</li> <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 <u>NICE Competency</u> <u>framework</u> for health professionals using PGDs)</li> <li>must be familiar with the vaccine product and alert to changes in the Summary of Product Characteristics (SPC), Immunisation Against Infectious Disease ('<u>The Green Book</u>'), 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 <u>National Minimum</u> <u>Standards and Core Curriculum for Immunisation Training</u></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> <li>The individual practitioner must be authorised by name, under the current version of this PGD before working according to it.</li> </ul>
Continued training requirements	<ul> <li>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).</li> <li>Practitioners should be constantly alert to any subsequent recommendations from Public Health England and/or NHS England and NHS Improvement and other sources of medicines information. 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.</li> </ul>

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

Clinical condition or situation to which this PGD applies Criteria for inclusion	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 <u>Chapter 28a</u> of Immunisation Against Infectious Disease: 'The Green Book'. Individuals who: • are aged 70 years (routine cohort) • have existing eligibility for Zostavax <sup>®</sup> under the national immunisation programme but remain unimmunised. Individuals from 70 years of age remain eligible for shingles immunisation
Criteria for exclusion <sup>2</sup>	until their 80th birthday. Individuals for whom no valid consent has been received
	<ul> <li>Individuals who:</li> <li>are under 70 years of age</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 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 Chapter 28a as a contraindication to Zostavax<sup>®</sup> administration</li> <li>are on immunosuppressive or immunomodulating therapy as defined in Chapter 28a as a 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 advice. Specialist advice should also be considered for individuals on combination immunosuppressive therapy.</li> </ul>

<sup>&</sup>lt;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 Zostavax PGD v10.00 Valid from: 01/09/2021 Expiry: 31/08/2023 Page 6 of 14

relevant action to be i taken i	The decision to administer shingles vaccine to immunosuppressed individuals should be based on a clinical risk assessment. If the individual is under specialist care, and it is not possible to obtain full information on that individual's treatment history, then vaccination should not proceed until the advice of the specialist or a local immunologist has been sought.
	Individuals who have previously received immunosuppressive therapy should be carefully evaluated for the reconstitution of the immune system prior to receiving Zostavax <sup>®</sup> .
-	Transmission
	There is a theoretical risk, in those who develop a rash following Zostavax <sup>®</sup> 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.
	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 are themselves 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 patients exposed to a varicella like rash in a recent vaccinee.
	In the event of a person developing a varicella (widespread) or shingles-like (dermatomal) rash post-Zostavax <sup>®</sup> , 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 <u>Chapter 28a</u> for more details.
patient is excluded i	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.
	For individuals who have had a confirmed anaphylactic reaction to a previous dose of varicella vaccine or to any component of Zostavax <sup>®</sup> there is as an alternative inactivated vaccine Shingrix <sup>®</sup> . However, supply of Shingrix <sup>®</sup> is currently, at the time of writing, limited such that under the national shingles vaccination programme it is only recommended to be offered to immunosuppressed individuals (see <u>Chapter 28a</u> for current recommendations).
	Individuals suffering acute severe febrile illness should postpone immunisation until they have recovered.
	Individuals with untreated tuberculosis should postpone immunisation until their tuberculosis has been treated.
	Zostavax <sup>®</sup> is not recommended for the treatment of shingles 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 <sup>®</sup> immediately
	following recovery unclear.

Action to be taken if the patient is excluded (continued)	Individuals who have received systemic anti-viral medicines known to be effective against varicella zoster virus, such as aciclovir, should postpone Zostavax <sup>®</sup> vaccination until at least 48 hours after cessation of treatment, as these medicines may reduce the response to the vaccine. The use of topical aciclovir is not a contraindication to vaccination.
	Individuals who have received MMR vaccine should postpone Zostavax <sup>®</sup> administration until a four-week minimum interval period has been observed.
	Individuals within 14 days of commencement of immunosuppressive therapy are not currently, at the time of writing, eligible for pre- treatment vaccination with Shingrix <sup>®</sup> . Supply of Shingrix <sup>®</sup> is currently, at the time of writing, limited and so vaccine supplied via the national programme should not be used for this indication. Eligible individuals who have not received Zostavax <sup>®</sup> are recommended to receive a single dose of vaccine at the earliest opportunity and at least 14 days before starting immunosuppressive therapy, although leaving one month would be preferable if a delay is possible (see <u>Chapter 28a</u> for current recommendations).
	Immunosuppressed individuals who are eligible for shingles vaccination but who are contraindicated to the receipt of the live vaccine Zostavax <sup>®</sup> , in accordance with <u>Chapter 28a</u> should be offered Shingrix <sup>®</sup> instead (see <u>PHE Shingrix PGD</u> ). If there is any doubt, individual patients should be discussed with their specialist.
	The risk to the individual of not being vaccinated must be taken into account.
	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.
	Document the reason for exclusion and any action taken in individual's clinical records.
	Inform or refer to the GP or a prescriber as appropriate.
Action to be taken if the patient or carer declines	Informed consent, from the individual or a person legally able to act on the individual's behalf, must be obtained prior to administration.
treatment	Advise the individual/carer about the protective effects of the vaccine, the risks of infection and potential complications.
	Document advice given and the decision reached.
	Inform or refer to the GP or a prescriber as appropriate.
Arrangements for referral for medical advice	As per local policy

# 5. Description of treatment

Name, strength and formulation of drug	Zostavax <sup>®</sup> , shingles (herpes zoster, live) vaccine, powder and solvent for suspension for injection.
	After reconstitution, Zostavax <sup>®</sup> lyophilised suspension (0.65ml) contains shingles (herpes zoster) vaccine, consisting of live attenuated virus derived from varicella zoster virus.
Legal category	Prescription only medicine (POM).
Black triangle▼	No.
Off-label use	Vaccine should be stored according to the conditions detailed in the <u>Storage section</u> below. However, in the event of an inadvertent or unavoidable deviation of these conditions refer to <u>PHE Vaccine</u> <u>Incident Guidance</u> . Where vaccine is assessed in accordance with these guidelines as appropriate for continued use this would constitute off-label administration under this PGD.
	Where a vaccine is recommended off-label consider, as part of the consent process, informing the individual/carer that the vaccine is being offered in accordance with national guidance but that this is outside the product licence.
Route / method of administration	Following reconstitution, Zostavax <sup>®</sup> is given as a single dose by intramuscular or subcutaneous injection, preferably in the deltoid region 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.
	For individuals with a bleeding disorder, Zostavax <sup>®</sup> should be given by deep subcutaneous injection to reduce the risk of bleeding.
	Zostavax <sup>®</sup> should NOT be injected intravascularly.
	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.
	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.
	Avoid contact with disinfectants.
	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.
	The <u>SPC</u> for the vaccine provides further guidance on reconstitution and administration.
Dose and frequency of administration	Single dose of 0.65ml of reconstituted Zostavax <sup>®</sup> .

Duration of treatment	Single dose
Quantity to be supplied / administered	Single 0.65ml dose of reconstituted Zostavax <sup>®</sup> .
Supplies	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 <u>Chapter 3</u> ).
Storage	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, the 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 <u>PHE</u> <u>Vaccine Incident Guidance</u> .
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 <u>technical</u> <u>memorandum 07-01</u> (Department of Health, 2013).
Drug interactions	None reported.
	See the <u>Additional information</u> section and <u>SPC</u> for information on co-administration with anti-virals and other vaccines.
Identification and management of adverse reactions	The most common adverse reactions observed after administration of Zostavax <sup>®</sup> are injection site reactions, including redness, swelling, pain and itching. Other relatively 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 <sup>®</sup> 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 <u>Chapter 28a</u> ).
	A detailed list of adverse reactions is available in the <u>SPC</u> .

Reporting procedure of adverse reactions	As with all vaccines, healthcare professionals and individuals/carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the <u>Yellow Card reporting scheme</u> or search for MHRA Yellow Card in the Google Play or Apple App Store.				
	Any adverse reaction to the vaccine should be documented in the individual's record and the individual's GP should be informed.				
Written information to be given to patient or carer	Offer marketing authorisation holder's patient information leaflet (PIL) provided with the vaccine.				
Patient advice / follow up treatment	Inform the individual/carer of possible side effects and their management.				
	Give advice regarding normal reaction to the injection, for example redness and pain at the injection site.				
	The individual/carer should be advised to seek medical advice in the event of a severe adverse reaction.				
	Individuals should be advised to seek medical attention if they develop a varicella (widespread) or shingles-like (dermatomal) rash post-Zostavax <sup>®</sup> vaccination.				
Special considerations / additional information	Ensure there is immediate access to adrenaline (epinephrine) 1 in 1000 injection and easy access to a telephone at the time of vaccination.				
	The risk and severity of shingles is much higher in immunosuppressed individuals so ideally those eligible should receive Zostavax <sup>®</sup> preferably one month and at least 14 days before commencing immunosuppressive therapy.				
	An inactivated shingles vaccine, Shingrix <sup>®</sup> , is now available. However, supply of Shingrix <sup>®</sup> is currently, at the time of writing, limited such that under the national shingles vaccination programme it is only recommended to be offered to immunosuppressed individuals contraindicated to the live vaccine. Inactivated shingles vaccine cannot be administered under this PGD (see <u>PHE Shingrix</u> <u>PGD</u> ) and current national guidance should be referred to (see <u>Chapter 28a</u> for current recommendations).				
	All immunosuppressed individuals who are inadvertently administered Zostavax <sup>®</sup> require urgent assessment and may need to receive prophylactic aciclovir. Immunosuppressed individuals who develop a varicella rash following inadvertent vaccination should be urgently assessed and offered prompt treatment with IV high-dose aciclovir, give the risks and severity of disseminated zoster.				
	Zostavax <sup>®</sup> can be given at the same time as inactivated influenza vaccine.				
	Zostavax <sup>®</sup> vaccine can also be given at the same time as 23-valent pneumococcal polysaccharide vaccine for those who are eligible for both vaccines.				
Continued over page	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 <sup>®</sup> .				

Special considerations / additional information continued	Immunisation with Zostavax <sup>®</sup> should ideally be delayed for seven days after COVID-19 vaccination and vice versa. Neither vaccine has been tested for routine co-administration; there may be a reduced response to Zostavax <sup>®</sup> . 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 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 <sup>®</sup> - see <u>Criteria for</u> <u>exclusion</u> . See <u>Chapter 28a</u> for more details.		
Records	<ul> <li>Record:</li> <li>that valid informed consent was given</li> <li>name of individual, address, date of birth and GP with whom the individual is registered</li> <li>name of immuniser</li> <li>name and brand of vaccine</li> <li>date of administration</li> <li>dose, form and route of administration of vaccine</li> <li>quantity administered</li> <li>batch number and expiry date</li> <li>anatomical site of vaccination</li> <li>advice given, including advice given if excluded or declines immunisation</li> <li>details of any adverse drug reactions and actions taken</li> <li>supplied via PGD</li> </ul>		
	Records should be signed and dated (or a password controlled immuniser's record on e-records).		
	All records should be clear, legible and contemporaneous.		
	This information should be recorded in the individual's GP record and any other appropriate medical records, such as care or nursing records.		
	A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.		

# 6. Key references

Key references	Shingles
	<ul> <li>Zostavax<sup>®</sup> Summary of Product Characteristics. MSD Ltd. Updated 8 May 2021. <u>https://www.medicines.org.uk/emc/product/6101</u></li> </ul>
	Immunisation Against Infectious Disease: The Green Book, <u>Chapter 28a.</u> Updated 23 August 2021. <u>https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book</u>
	<ul> <li>Shingles: Guidance and Vaccination Programme. Updated 18 August 2021. <u>https://www.gov.uk/government/collections/shingles-vaccination-</u></li> </ul>
	programme
	<ul> <li>Shingles vaccination: Guidance for healthcare professionals. Public Health England. Published March 2018.</li> <li><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>
	General
	Health Technical Memorandum 07-01: Safe Management of Healthcare Waste. Department of Health. 20 March 2013. <u>https://www.gov.uk/government/publications/guidance-on-the-safe-management-of-healthcare-waste</u>
	National Minimum Standards and Core Curriculum for Immunisation Training. Published February 2018. <u>https://www.gov.uk/government/publications/national-minimum-standards-and-core-curriculum-for-immunisation-training-for-registered-healthcare-practitioners</u>
	<ul> <li>NICE Medicines Practice Guideline 2 (MPG2): Patient Group Directions. Published March 2017. <u>https://www.nice.org.uk/guidance/mpg2</u></li> </ul>
	<ul> <li>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</li> </ul>
	<ul> <li>PHE Immunisation Collection. <u>https://www.gov.uk/government/collections/immunisation</u></li> </ul>
	PHE Vaccine Incident Guidance. <u>https://www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors</u>

## 7. Practitioner authorisation sheet

#### Zostavax PGD v010.00 Valid from: 01/09/2021 Expiry: 31/08/2023

Before signing this patient group direction (PGD), check that the document has had the necessary authorisations in section two. 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.