



PHE publications gateway number: GW-138

## PATIENT GROUP DIRECTION (PGD)

Administration of 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 shingles (herpes zoster, live) vaccine by registered healthcare practitioners identified in Section 3, subject to any limitations to authorisation detailed in Section 2.

Reference no: Shingles PGD  
Version no: v08.00  
Valid from: 01 April 2019  
Review date: 01 October 2020  
Expiry date: 31 March 2021

**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 [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.

**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:

<https://www.gov.uk/government/collections/immunisation-patient-group-direction-pgd>

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


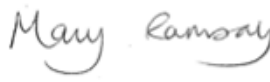

<sup>1</sup> This includes any relevant amendments to legislation (eg [2013 No.235](#), [2015 No.178](#) and [2015 No.323](#)).  
Shingles PGD v08.00 Valid from: 01/04/2019 Expiry: 31/03/2021

## 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	PHE Shingles PGD amended to: <ul style="list-style-type: none"> <li>• define eligible cohorts by age rather than age on 1 Sept, in the inclusion and exclusion criteria, as per service specification from April 2017</li> <li>• update transmission paragraph</li> </ul>	07 April 2017
Version 07.00	PHE Shingles PGD amended to: <ul style="list-style-type: none"> <li>• correct date in inclusion criteria to '2012' and add DOB note</li> </ul>	12 July 2017
Version 08.00	PHE Shingles PGD amended to: <ul style="list-style-type: none"> <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

## 1. PGD development

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

Developed by:	Name	Signature	Date
<b>Pharmacist</b> (Lead Author)	Elizabeth Graham Lead Pharmacist, Immunisation and Countermeasures, PHE		31/01/2019
<b>Doctor</b>	Mary Ramsay Consultant Epidemiologist and Head of Immunisation and Countermeasures, PHE		31/01/2019
<b>Registered Nurse</b> (Chair of Expert Panel)	David Green Nurse Consultant, Immunisations and Countermeasures, PHE		31/01/2019

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 Management Group and the PHE Quality and Clinical Governance Delivery Board.

### Expert Panel

Name	Designation
Gayatri Amirthalingam	Consultant Epidemiologist, Public Health England
Ed Gardner	Advanced Paramedic Practitioner / Emergency Care Practitioner, Medicines Manager, Proactive Care Lead
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 / NHS England South (South West)
Gill Marsh	Senior Screening and Immunisation Manager, Public Health England / NHS England Lancashire and South Cumbria
Lesley McFarlane	Screening and Immunisation Co-ordinator, NHS England / Public Health England Leicestershire, Lincolnshire and Northamptonshire
Sally Millership	Consultant in Communicable Disease Control, Public Health England, East of England Health Protection Team
Tushar Shah	Pharmacy Advisor, NHS England London Region
Sharon Webb	Programme Manager / Registered Midwife, NHS Infectious Diseases in Pregnancy Screening Programme, Public Health England
Helen Wilkinson	Principal Pharmacist, Bristol, North Somerset & South Gloucestershire Clinical Commissioning Group


## 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 Hampshire and Thames Valley (HTV)** authorises this PGD for use by the services or providers listed below:

<b>Authorised for use by the following organisations and/or services</b>
All NHS England HTV directly commissioned immunisation services.  In addition, the PGD may be adopted by provider organisations (providing NHS immunisation and vaccination services) working within the HTV geography. Where this occurs, provider organisations should have this PGD signed off by their governance lead prior to use. Provider organisation staff will be expected to follow local policies and procedures.
<b>Limitations to authorisation</b>
None stated.

<b>Organisational approval (legal requirement)</b>			
<b>Role</b>	<b>Name</b>	<b>Sign</b>	<b>Date</b>
Medical Director	Shahed Ahmad		19/2/19

<b>Additional signatories according to locally agreed policy</b>			
<b>Role</b>	<b>Name</b>	<b>Sign</b>	<b>Date</b>

Local enquiries regarding the use of this PGD may be directed to [england.southcentral-pgd.nhs.net](http://england.southcentral-pgd.nhs.net)

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

<p><b>Qualifications and professional registration</b></p>	<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 Limitations to authorisation</a> to confirm whether all practitioners listed above have organisational authorisation to work under this PGD.</p>
<p><b>Additional requirements</b></p>	<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</a> 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 (<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</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>THE INDIVIDUAL PRACTITIONER MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE WORKING ACCORDING TO IT.</b></p>
<p><b>Continued training requirements</b></p>	<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 Public Health England and/or 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>Shingles (herpes zoster, live) vaccine 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>Individuals who:</p> <ul style="list-style-type: none"> <li>• are aged 70 years (routine cohort)</li> <li>• are aged 78 years (catch-up cohort)</li> <li>• have existing eligibility for shingles (herpes zoster, live) vaccine under the national immunisation programme. This includes unimmunised individuals who turned 70 years of age after the 1 September 2012* (routine cohorts) and unimmunised individuals aged 79 years (catch-up cohorts). These individuals remain eligible for immunisation until their 80th birthday.</li> </ul> <p>*These individuals have attained 70 years of age and have a DOB on or after 2/9/1942</p>
<p><b>Criteria for exclusion<sup>2</sup></b></p> <p>Continued over page</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 of age</li> <li>• are 80 years of age or over, even if they were previously in an eligible cohort</li> <li>• are not and have not previously been in an eligible cohort for the national immunisation programme</li> <li>• have had a confirmed anaphylactic reaction to a previous dose of varicella vaccine or to any component of the vaccine, 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 active infection with shingles or post-herpetic neuralgia</li> <li>• have received systemic therapy with anti-viral medicines, such as aciclovir, in the last 48 hours</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 (Note: individual may be able to receive the vaccine under PSD following specialist advice)</li> <li>• have a primary or acquired immunodeficiency state (see <a href="#">overleaf</a>)</li> <li>• are on immunosuppressive or immunomodulating therapy (see <a href="#">overleaf</a>)</li> </ul> <p>Continued over page</p>

<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

<p><b>Criteria for exclusion<sup>3</sup></b> (continued)</p>	<p>Primary or acquired immunodeficiency states may be due to conditions such as:</p> <ul style="list-style-type: none"> <li>• acute and chronic leukaemias, lymphoma (including Hodgkin's lymphoma)</li> <li>• immunosuppression due to HIV/AIDS</li> <li>• cellular immune deficiencies</li> <li>• remaining under follow up for a lymphoproliferative disorder including haematological malignancies such as indolent lymphoma, chronic lymphoid leukaemia, myeloma and other plasma cell dyscrasias (Note: this list is not exhaustive)</li> <li>• solid organ or stem cell transplant (see <a href="#">Chapter 28a</a> for information on when vaccination may be indicated for these individuals under PSD)</li> </ul> <p>Immunosuppressive or immunomodulating therapy that would contraindicate shingles (herpes zoster, live) vaccination under this PGD includes:</p> <ul style="list-style-type: none"> <li>• those with renal failure, stage 4 or 5 CKD, who are receiving or have received in the past 3 months any immunosuppressive therapy (due to potential reduced clearance of immunosuppressive therapies)</li> <li>• those who are receiving or have received in the past 6 months immunosuppressive chemotherapy or radiotherapy for malignant disease or non-malignant disorders or who are not demonstrated to be in remission</li> <li>• those who are receiving or have received in the past 12 months biological therapy (eg anti-TNF therapy such as etanercept, infliximab, alemtuzumab, ofatumumab or rituximab)</li> <li>• those who are receiving or have received in the past 3 months immunosuppressive therapy (regardless of renal function) including: <ul style="list-style-type: none"> <li>i) high-dose corticosteroids (&gt;40mg prednisolone per day for more than 1 week);</li> <li>ii) lower dose corticosteroids (&gt;20mg to ≤40mg prednisolone per day for more than 14 days)</li> <li>iii) non-biological oral immune modulating drugs eg methotrexate &gt;25mg per week, azathioprine &gt;3.0mg/kg/day or 6-mercaptopurine &gt;1.5mg/kg/day</li> </ul> </li> </ul> <p>(see <a href="#">Chapter 28a</a> for information on when vaccination may be indicated for these individuals under PSD)</p> <p>Note: Shingles (herpes zoster, live) vaccine is not contraindicated for use in individuals who are receiving topical/inhaled corticosteroids or corticosteroid replacement therapy. Long term stable low dose corticosteroid therapy (defined as ≤20mg prednisolone per day for more than 14 days) either alone or in combination with low dose non-biological oral immune modulating drugs (eg methotrexate ≤25mg per week, azathioprine ≤3.0mg/kg/day or 6-mercaptopurine ≤1.5mg/kg/day) are not considered sufficiently immunosuppressive and these individuals can receive the vaccine under this PGD unless they also have impaired renal function (see <a href="#">above</a>).</p>
--	--

<sup>3</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  
Shingles PGD v08.00 Valid from: 01/04/2019 Expiry: 31/03/2021



<p><b>Cautions including any relevant action to be taken</b></p>	<p>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.</p> <p>Individuals who previously received immunosuppressive therapy should be carefully evaluated for the reconstitution of the immune system prior to receiving shingles (herpes zoster, live) vaccine.</p> <p>Immunocompetent individuals who present with a history of a recent shingles episode should ideally have their vaccination delayed for one year as boosting from natural infection is likely to offer protection at least until this time. For those aged between 79 and 80 years at the time of natural shingles infection, it is acceptable to reduce the interval from recovery to vaccination from one year to enable shingles (herpes zoster, live) vaccine to be administered as part of the national programme before the 80th birthday (see <a href="#">Shingles vaccination: Guidance for healthcare professionals</a>).</p> <p><b>Transmission</b></p> <p>There is a theoretical risk, in those who develop a rash following shingles (herpes zoster, live) vaccination, of transmitting the attenuated vaccine virus to a susceptible individual. However, vaccination will reduce the risk of developing natural shingles which is associated with a much higher risk of transmission, from the circulating wild type varicella zoster virus in the community. As a precautionary measure, individuals who develop a varicella-like rash after shingles (herpes zoster, live) vaccination 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 person with the vesicular rash is 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.</p> <p>In the event of a person developing a varicella (widespread) or shingles-like (dermatomal) rash post shingles (herpes zoster, live) vaccination, a vesicle fluid sample should be sent for analysis, to confirm the diagnosis and determine whether the rash is vaccine-associated. See <a href="#">Chapter 28a</a> for more details.</p>
<p><b>Action to be taken if the patient is excluded</b></p> <p>Continued over page</p>	<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.</p> <p>If in the eligible age group, but excluded on medical grounds as above, seek appropriate advice from the local Screening and Immunisation Team, local Health Protection Team or the individual's clinician, as immunisation under a PSD may be indicated or an alternative inactivated vaccine may be available (see <a href="#">Additional Information</a>).</p> <p>Individuals suffering acute severe febrile illness should postpone immunisation until they have recovered.</p> <p>Individuals who have received systemic anti-viral medicines should postpone shingles (herpes zoster, live) vaccination until at least 48</p>



<p><b>Action to be taken if the patient is excluded</b> (continued)</p>	<p>hours after any antiviral treatment is completed, as these medicines may reduce the response to the vaccine. The use of topical aciclovir is not a contraindication to vaccination.</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>The risk to the individual of not being vaccinated must be taken into account.</p> <p>Document the reason for exclusion and any action taken in individual's clinical records.</p> <p>In a GP practice setting, inform or refer to the 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/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>In a GP practice setting, inform or refer to the GP 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 &amp; formulation of drug</b>	<p>Shingles (herpes zoster, live) vaccine eg:</p> <ul style="list-style-type: none"> <li>• Zostavax<sup>®</sup>, shingles (herpes zoster, live) vaccine, powder and solvent for suspension for injection.</li> </ul> <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>	<p>Prescription only medicine (POM).</p>
<b>Black triangle ▼</b>	<p>No.</p>
<b>Off-label use</b>	<p>Vaccine should be stored according to the conditions detailed in the <a href="#">Storage section</a> below. However, in the event of an inadvertent or unavoidable deviation of these conditions refer to <a href="#">PHE 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/ carer that the vaccine is being offered in accordance with national guidance but that this is outside the product licence.</p>
<b>Route / method of administration</b>	<p>Following reconstitution, shingles (herpes zoster, live) vaccine is given as a single dose by intramuscular or subcutaneous injection, preferably in the deltoid region of the upper arm. Intramuscular administration is preferred due to comparable immune response and less frequent injection site adverse reactions than subcutaneous administration.</p> <p>For individuals with a bleeding disorder, vaccines normally given by an intramuscular route should be given by deep subcutaneous injection to reduce the risk of bleeding (see Green Book <a href="#">Chapter 4</a>).</p> <p>Shingles (herpes zoster, live) vaccine 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 the 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.</p> <p>When reconstituted, shingles (herpes zoster, live) vaccine 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>Continued over page</p>	

<b>Route / method of administration</b> (continued)	The SPC for the vaccine provides further guidance on administration and is available from the electronic Medicines Compendium website: <a href="http://www.medicines.org.uk">http://www.medicines.org.uk</a>
<b>Dose and frequency of administration</b>	Single dose of 0.65ml of reconstituted shingles (herpes zoster, live) vaccine.
<b>Duration of treatment</b>	Single dose
<b>Quantity to be supplied / administered</b>	Single 0.65ml dose of reconstituted shingles (herpes zoster, live) vaccine
<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 <a href="#">protocol for ordering storage and handling of vaccines</a> and 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, the in-use stability has been demonstrated for 30 minutes when stored at 20°C - 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="#">PHE 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 regulations and guidance in the <a href="#">technical memorandum 07-01</a> (Department of Health, 2013).
<b>Drug interactions</b>	None reported.  Shingles (herpes zoster, live) vaccine can be given at the same time as inactivated influenza vaccine.  Shingles (herpes zoster, live) vaccine can also be given at the same time as 23-valent pneumococcal vaccine. Such administration is recommended in <a href="#">Chapter 28a</a> of 'The Green Book' following assessment of the evidence, concluding that there is no reduction in the effectiveness of Zostavax®.  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 shingles (herpes zoster, live) vaccine.  There is no data on concomitant use with anti-viral medications but it is likely that these will reduce the response to shingles (herpes zoster, live) vaccine - see <a href="#">Criteria for exclusion</a> .

Continued over page

<b>Drug interactions</b> (continued)	A detailed list of drug interactions is available in the SPC, which is available from the electronic Medicines Compendium website: <a href="http://www.medicines.org.uk">www.medicines.org.uk</a>
<b>Identification &amp; management of adverse reactions</b>	<p>The most common adverse reactions observed after administration of shingles (herpes zoster, live) vaccine 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.</p> <p>In the event of a person developing a varicella (widespread) or shingles-like (dermatomal) rash post shingles (herpes zoster, live) vaccination, a vesicle fluid sample should be sent for analysis, to confirm the diagnosis and determine whether the rash is vaccine-associated.</p> <p>A detailed list of adverse reactions is available in the SPC, which is available from electronic Medicines Compendium website:  <a href="http://www.medicines.org.uk">www.medicines.org.uk</a></p>
<b>Reporting procedure of adverse reactions</b>	<p>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 Yellow Card reporting scheme at:  <a href="http://yellowcard.mhra.gov.uk">http://yellowcard.mhra.gov.uk</a></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 marketing authorisation holder's patient information leaflet (PIL) provided with the vaccine.</p>
<b>Patient advice / follow up treatment</b>	<p>Inform the individual/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/carer should be advised to seek medical advice in the event of a severe adverse reaction.</p> <p>Individuals should be advised to seek medical attention if they develop a varicella (widespread) or shingles-like (dermatomal) rash post shingles (herpes zoster, live) vaccination so that their clinician may test vesicle fluid from the rash to confirm the diagnosis and determine whether the rash is vaccine-associated.</p> <p>When administration is postponed advise the individual 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 given before the individual is 80 years old explain why vaccination will no longer be indicated.</p>
<b>Special considerations / additional information</b>  Continued over page	<p>Ensure there is immediate access to adrenaline (epinephrine) 1 in 1000 injection and access to a telephone at the time of vaccination.</p> <p>The risk and severity of shingles is much higher in immunosuppressed individuals so ideally those eligible should receive shingles vaccine preferably one month and at least 14 days before commencing immunosuppressive therapy.</p>

<p><b>Special considerations / additional information</b> (continued)</p>	<p>An inactivated shingles vaccine has now been developed. This vaccine was not available to the UK market at the time this PGD was written but may become available in the future as an option for the immunisation of immunosuppressed individuals. Inactivated shingles vaccine cannot be administered under this PGD and current national guidance should be referred to.</p> <p>All immunosuppressed individuals who are inadvertently administered shingles (herpes zoster, live) vaccine require urgent assessment and may need to receive prophylactic aciclovir. Immunosuppressed individuals who develop a varicella rash following inadvertent vaccination can be offered prompt treatment with IV high-dose aciclovir.</p> <p>See <a href="#">Chapter 28a</a> for more details.</p>
<p><b>Records</b></p>	<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 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 a password controlled immuniser's record 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 eg 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

<p><b>Key references</b></p> <p>Continued over page</p>	<p><b>Shingles</b></p> <ul style="list-style-type: none"><li>• Zostavax® Summary of Product Characteristics. MSD Ltd. Updated 28 January 2019. <a href="http://www.medicines.org.uk/emc/medicine/25927">http://www.medicines.org.uk/emc/medicine/25927</a></li><li>• Immunisation Against Infectious Disease: The Green Book, Chapter 28a. Updated 26 February 2016. <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>• NHS public health functions agreement 2018-19, Service Specification No.14. Shingles (herpes zoster) immunisation programme. Published September 2018. <a href="https://www.england.nhs.uk/publication/public-health-national-service-specifications/">https://www.england.nhs.uk/publication/public-health-national-service-specifications/</a></li><li>• Enhanced Service Specification: Shingles (catch-up) vaccination programme 2018/19. Published June 2018. <a href="https://www.england.nhs.uk/publication/gp-contract-2017-18-enhanced-service-specifications/">https://www.england.nhs.uk/publication/gp-contract-2017-18-enhanced-service-specifications/</a></li><li>• Shingles: Guidance and Vaccination Programme. Updated 26 October 2018. <a href="https://www.gov.uk/government/collections/shingles-vaccination-programme">https://www.gov.uk/government/collections/shingles-vaccination-programme</a></li><li>• Shingles vaccination: Guidance for healthcare professionals. Public Health England. Published March 2018. <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><li>• Revised recommendations for the administration of more than one live vaccine. Public Health England. 24 April 2015. <a href="https://www.gov.uk/government/publications/revised-recommendations-for-administering-more-than-1-live-vaccine">https://www.gov.uk/government/publications/revised-recommendations-for-administering-more-than-1-live-vaccine</a></li></ul> <p><b>General</b></p> <ul style="list-style-type: none"><li>• Health Technical Memorandum 07-01: Safe Management of Healthcare Waste. Department of Health. 20 March 2013. <a href="https://www.gov.uk/government/publications/guidance-on-the-safe-management-of-healthcare-waste">https://www.gov.uk/government/publications/guidance-on-the-safe-management-of-healthcare-waste</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. Published 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>• PHE Immunisation Collection. <a href="https://www.gov.uk/government/collections/immunisation">https://www.gov.uk/government/collections/immunisation</a></li><li>• PHE Vaccine Incident Guidance.</li></ul>
---	--

<b>Key references</b> (continued)	<p><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></p> <ul style="list-style-type: none"><li>• Protocol for ordering storage and handling of vaccines. April 2014. <a href="https://www.gov.uk/government/publications/protocol-for-ordering-storing-and-handling-vaccines">https://www.gov.uk/government/publications/protocol-for-ordering-storing-and-handling-vaccines</a></li></ul>
--------------------------------------	--



## 7. Practitioner authorisation sheet

**Shingles PGD v08.00 Valid from: 01/04/2019 Expiry: 31/03/2021**

Before signing this 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 patient group direction you are indicating that you agree to its contents and that you will work within it.

Patient group directions 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 Patient Group Direction 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 <b>NHS England HTV</b> 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.