



PHE publications gateway number: 2015185

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 currently registered nurses or paramedics.

Reference no: Shingles PGD

Version no: v07.00

Valid from: 20 July 2017 Review date: 01 October 2018 Expiry date: 31 March 2019

Public Health England has developed this PGD template to facilitate the delivery of immunisations in the NHS 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)¹. 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.

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

Any concerns regarding the content of this PGD should be addressed to: immunisation@phe.gov.uk

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¹ This includes any relevant amendments to legislation (eg <u>2013 No235</u>, <u>2015 No.178</u> and <u>2015 No.323</u>). Shingles PGD v07.00 Valid from: 20/07/2017 Expiry: 31/03/2019 Page 1 of 14

Change history

Version number	Change details	Date
Final version – revised 27 Aug 2013	New PHE PGD	Valid from 1 Sept 2013
Version 02.00	PHE Shingles PGD transferred to new PHE PGD template and complete document review with multiple changes to text	4 June 2015
Version 03.00	 Changes include: exclusion criteria reworded to remove "Exclusions from PGD" paragraph and clarify non-biological therapy dose thresholds removing exclusion of low dose therapy exclusions added - individuals on long term low dose corticosteroids, transplant patients, higher dose non-biological therapies, those with renal failure exclusion removed – combination therapies, non-specific terminology now covered by other exclusions addition of paramedics to professional group following information that there are paramedics supporting this vaccines provision in general practice updated Competency Framework and BNF links revised Green Book chapter link header updated and minor style and formatting amendment 	16 Nov 2015
Version 04.00	 Changes include: exclusion criteria reworded to remove terms "short term" and "long term" corticosteroid therapy and lower dose corticosteroid therapy defined as ">20mg to ≤40mg prednisolone" rather than ">20mg prednisolone" name, strength & formulation of drug section, deletion of "in a prefilled syringe" to allow for either presentation route section, addition of intramuscular administration and green book text for subcutaneous administration for individuals with bleeding disorder. references, updated SPC and updated BNF link 	3 Feb 2016
Version 05.00	PHE Shingles PGD amended to: include 2016/17 programme eligible cohorts reference the protocol for ordering storage and handling of vaccines update wording regarding authorisation in line with agreed PHE PGD template changes include minor rewording, layout and formatting changes for clarity and consistency with other PHE PGD templates	2 August 2016
Version 06.00	PHE Shingles PGD amended to: • inclusion and exclusion criteria amended to define eligible cohorts by age rather than age on 1 Sept as per service specification from Apr 2017 • transmission paragraph amended	07 April 2017
Version 07.00	PHE Shingles PGD amended to: • correct date in inclusion criteria to "2012" and add DOB note	12 July 2017

1. PGD template development

This PGD template 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 Services, PHE	Cloha	20/07/2017
Doctor	Mary Ramsay Consultant Epidemiologist and Head of Immunisation, Hepatitis & Blood Safety Department, PHE	Mary Ramsony	20/07/2017
Registered Nurse (Chair of Expert Panel)	David Green Nurse Consultant – Immunisations, PHE	Daleen.	13/07/2017

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

Acknowledgements

Name	Designation
Gayatri Amirthalingam	Consultant Epidemiologist, Public Health England
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 Health Protection Nurse Practitioner, Cheshire & Merseyside Health Protection Team, Public Health England
Lesley McFarlane	Screening and Immunisation Co-ordinator (SIC) NHS England Leicestershire and Lincolnshire
Sally Millership	Consultant in Communicable Disease Control, Public Health England East of England
Sue Mulvenna	Pharmacist Lead, NHS England South West
Graham Munslow	Clinical Screening and Immunisation Manager, NHS England Lancashire & Greater Manchester / Public Health England
Matt Olley	Immunisation Manager, Public Health England / NHS England London Region
Lisa Rees	Medicines Management Pharmacist, Bristol Clinical Commissioning Group
Kelly Stoker	Senior Health Protection Nurse, North East Health Protection Team, Public Health England Centre North East

2. Organisational authorisations

The 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 London Region authorises this PGD for use by the services or providers listed below:

Authorised for use by the following organisations and/or services

This PGD must only be used by specified healthcare professionals working for providers that are directly commissioned by NHS England London Region, or who are administering vaccinations as part of a national immunisation programme, and who have been named and authorised to practice under it.

Limitations to authorisation

None

Organisational approval (legal requirement)			
Role	Name	Sign	Date
Director of Nursing / Deputy Regional Chief Nurse NHS England (London Region)	Jane Clegg	The state of the s	17/10/2017

Role	Name	Sign	Date
Interim Director of Nursing (South London) NHS England London Region	Gwen Kennedy	J4 Larredy	13/10/2017
Pharmacy Advisor, NHS England London Region	Tushar Shah	Toonah	11/10/2017

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	 Registered professional with one of the following bodies: nurses currently registered with the Nursing and Midwifery Council (NMC). paramedics currently registered with the Health and Care Professions Council (HCPC)
Additional requirements	 Additionally practitioners: must be authorised by name as an approved practitioner under the current terms of this Patient Group Direction before working to it must have undertaken appropriate training for working under PGDs for supply/administration of medicines must be competent in the use of PGDs (see NICE Competency framework for health professionals using patient group directions) must be familiar with the vaccine product and alert to changes in the Summary of Product Characteristics, Immunisation Against Infectious Disease ("The Green Book"), and national and local immunisation programmes must have undertaken training appropriate to this PGD as required by local policy and in line with the National Minimum Standards for Immunisation Training (2005) must be competent to undertake immunisation and to discuss issues related to immunisation must be competent in the handling and storage of vaccines, and management of the "cold chain" must be competent in the recognition and management of anaphylaxis must have access to the Patient Group Direction and associated online resources should fulfil any additional requirements defined by local policy THE INDIVIDUAL PRACTITIONER MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE WORKING ACCORDING TO IT.
Continued training requirements	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). Practitioners should be constantly alert to any subsequent recommendations from Public Health England and/or NHS England 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.

4. Clinical condition or situation to which this PGD applies

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Clinical condition or situation to which this PGD applies	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 Chapter 28a of Immunisation Against Infectious Disease: The Green Book.
Criteria for inclusion	 Individuals who: are aged 70 years (routine cohort) are aged 78 years (catch-up cohort) have existing eligibility for shingles 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. *These individuals have attained 70 years of age and have a DOB on or after 2/9/1942
Criteria for exclusion ²	Individuals for whom no valid consent has been received Individuals who: • are under 70 years of age • are 80 years of age or over, even if they were previously in an eligible cohort • are not and have not previously been in an eligible cohort for the national immunisation programme • have had a confirmed anaphylactic reaction to a previous dose of varicella vaccine • have had a confirmed anaphylactic reaction to any component of the vaccine, including neomycin or gelatin • have active untreated tuberculosis • have active infection with shingles or post-herpetic neuralgia • are pregnant • are within 14 days of commencement of immunosuppressive therapy (Note: individual may be able to receive the vaccine under PSD following specialist advice) • have primary or acquired immunodeficiency state due to conditions such as: • acute and chronic leukaemias, lymphoma (including Hodgkin's lymphoma) • immunosuppression due to HIV/AIDS • cellular immune deficiencies • remaining under follow up for a lymphoproliferative disorder including haematological malignancies such as indolent lymphoma, chronic lymphoid leukaemia, myeloma and other
Continued over page	plasma cell dyscrasias (Note: this list is not exhaustive) o solid organ or stem cell transplant (see "The Green Book" for information on when vaccination may be indicated for these individuals under PSD) • are on immunosuppressive or immunomodulating therapy

² Exclusion under this Patient Group Direction 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 v07.00 Valid from: 20/07/2017 Expiry: 31/03/2019 Page 6 of 14

Criteria for exclusion³ (continued)

including:

- 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)
- 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
- those who are receiving or have received in the past 12 months biological therapy (e.g. anti-TNF therapy such as etanercept or infliximab)
- those who are receiving or have received in the past 3 months immunosuppressive therapy (regardless of renal function) including:
 - high-dose corticosteroids (>40mg prednisolone per day for more than 1 week);
 - ii) lower dose corticosteroids (>20mg to ≤40mg prednisolone per day for more than 14 days)
 - iii) non-biological oral immune modulating drugs eg methotrexate >25mg per week, azathioprine >3.0mg/kg/day or 6-mercaptopurine >1.5mg/kg/day

(see "The Green Book" for information on when vaccination may be indicated for these individuals under PSD)

Note: Shingles 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 above).

Temporary exclusions are:

- acute severe febrile illness postpone administration until completely recovered
- immunocompetent individuals who have developed shingles in the last 12 months defer vaccination
- systemic therapy with anti-viral medicines, such as aciclovir, administration of shingles vaccine should be delayed until at least
 48 hours after treatment is completed, as these medicines may
 reduce the response to the vaccine. The use of topical aciclovir is
 not a contraindication to vaccination.
- MMR vaccine administered less than 4 weeks ago defer vaccination until 4 weeks or more post MMR vaccination

Cautions including any relevant action to be taken

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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.

³ Exclusion under this Patient Group Direction 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 v07.00 Valid from: 20/07/2017 Expiry: 31/03/2019 Page 7 of 14

Cautions including any Individuals who previously received immune suppressive therapy relevant action to be should be carefully evaluated for the reconstitution of the immune system prior to receiving shingles vaccine. taken continued **Transmission** There is a theoretical risk, in those who develop a rash following shingles 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 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. In the event of a person developing a varicella (widespread) or shingles-like (dermatomal) rash post shingles vaccination, a vesicle fluid sample should be sent for analysis, to confirm the diagnosis and determine whether the rash is vaccine-associated. Please see Chapter 28a of Immunisation Against Infectious Disease: The Green Book for more details. Action to be taken if the If in the eligible age group, but excluded on medical grounds as above, seek appropriate advice from the local Screening and patient is excluded Immunisation Team. local Health Protection Team or the individual's clinician, as a PSD may be indicated. The risk to the individual of not being vaccinated must be taken into account. Document reason for exclusion and any action taken in individual's clinical records. In a GP practice setting, inform or refer to the GP. **Temporary exclusion** 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. Action to be taken if the Informed consent, from the individual or a person legally able to act patient or carer declines on the individual's behalf, must be obtained prior to administration. treatment Advise individual/carer about the protective effects of the vaccine, the risks of infection and potential complications. Document advice given and decision reached. In a GP practice setting, inform or refer to the GP. Arrangements for referral As per local policy for medical advice

5. Description of treatment

Name, strength & formulation of drug Shingles (herpes zoster), live) vaccine eg: Zostavax®, shingles (herpes zoster) vaccine (live), powder and solvent for suspension for injection. After reconstitution, Zostavax® 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 Yes, only with respect to concomitant use of pneumococcal vaccine, see section on drug interactions below. Route / method of administration Following reconstitution, shingles 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. 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 Chapter 4). Shingles vaccine 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 reconstituted vaccine if it is not used within 30 minutes. Note: • the product must not be mixed with other medicinal products in the same syringe • a avoid contact with disinfectants • when reconstituted, shingles vaccine is a semi-hazy to translucent, off-white to pale yellow liquid. Discard the vaccine if there is any particulate matter present or the appearance of solvent or reconstituted vacc		T
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further guidance on administration and is available from the electronic Medicines Compendium website: http://www.medicines.org.uk Dose and frequency of administration Single dose of 0.65ml of reconstituted shingles vaccine.		 the product must not be mixed with other medicinal products in the same syringe avoid contact with disinfectants when reconstituted, shingles vaccine is a semi-hazy to translucent, off-white to pale yellow liquid. Discard the vaccine if there is any particulate matter present or the appearance of
administration		further guidance on administration and is available from the electronic Medicines Compendium website:
Duration of treatment Single dose		Single dose of 0.65ml of reconstituted shingles vaccine.
	Duration of treatment	Single dose

Quantity to be supplied / administered	Single 0.65ml dose of reconstituted shingles vaccine
Supplies	Centrally purchased vaccines for the national immunisation programme for the NHS can only be ordered via ImmForm and are provided free of charge to NHS organisations.
	Protocols for the ordering, storage and handling of vaccines should be followed to prevent vaccine wastage (see protocol for ordering storage and handling of vaccines and Green Book Chapter 3).
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.
	Shelf life is 18 months
	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.
Disposal	Equipment used for immunisation, including used vials, ampoules, or discharged vaccines in a syringe or applicator, should be disposed of at the end of a session by sealing in a UN-approved puncture-resistant 'sharps' box, according to local authority regulations and guidance in the technical memorandum 07-01 (Department of Health, 2013).
Drug interactions ⁴	None reported.
	Shingles vaccine can be given at the same time as inactivated influenza vaccine.
	Shingles vaccine can also be given at the same time as 23-valent pneumococcal vaccine; Such administration is off-label but recommended in 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 vaccine.
	There is no data on concomitant use with anti-viral medications but it is likely that these will reduce the response to shingles vaccine - see exclusions.
	A detailed list of drug interactions is available in the Summary of Product Characteristics, which is available from the electronic Medicines Compendium website: www.medicines.org.uk

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⁴ Refer to British National Formulary (BNF) and Summary of Product Characteristics (SPC) for complete list Shingles PGD v07.00 Valid from: 20/07/2017 Expiry: 31/03/2019 Page 10 of 14

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Identification & management of adverse reactions ⁵	The most common adverse reactions observed after administration of shingles 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.
	In the event of a person developing a varicella (widespread) or shingles-like (dermatomal) rash post shingles vaccination, a vesicle fluid sample should be sent for analysis, to confirm the diagnosis and determine whether the rash is vaccine-associated.
	A detailed list of adverse reactions is available in the Summary of Product Characteristics, which is available from electronic Medicines Compendium website: www.medicines.org.uk
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 Yellow Card reporting scheme on: http://yellowcard.mhra.gov.uk
	Any adverse reaction to the vaccine should be documented in the individual's record.
	The individual's GP should also 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 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 shingles vaccination so that their clinician may test vesicle fluid from the rash to confirm the diagnosis and determine whether the rash is vaccine-associated.
	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.

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⁵ Refer to British National Formulary (BNF) and Summary of Product Characteristics (SPC) for complete list Shingles PGD v07.00 Valid from: 20/07/2017 Expiry: 31/03/2019 Page 11 of 14

Special considerations / additional information

Immediate access to adrenaline (epinephrine) 1 in 1000 injection and access to a telephone.

Minor illnesses without fever or systemic upset are NOT valid reasons to postpone immunisation. In cases of acute severe febrile illness, postpone administration until completely recovered.

Please note:

- 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
- all immunosuppressed individuals who are <u>inadvertently</u> administered shingles 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.

Please see <u>Chapter 28a</u> of *Immunisation Against Infectious Disease:* The Green Book for more details.

Records

Record:

- that valid informed consent was given
- name of individual, address, date of birth and GP with whom the individual is registered
- name of immuniser
- name and brand of vaccine
- date of administration
- dose, form and route of administration of vaccine
- quantity administered
- batch number and expiry date
- anatomical site of vaccination
- advice given, including advice given if excluded or declines immunisation
- details of any adverse drug reactions and actions taken
- supplied via Patient Group Direction (PGD)

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 eg 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

- Zostavax[®] Summary of Product Characteristics. MSD Ltd. Updated 01 Mar 2017 http://www.medicines.org.uk/emc/medicine/25927
- Immunisation Against Infectious Disease: The Green Book, <u>Chapter 28a</u> Updated 26 February 2016.
 https://www.gov.uk/government/publications/shingles-herpes-zoster-the-green-book-chapter-28a
- Vaccination against shingles: 2015/16. Information for healthcare professionals. 24 February 2016 https://www.gov.uk/government/publications/vaccination-against-shingles-for-adults-gas-for-healthcare-professionals
- Enhanced Service Specification: Shingles (catch-up) vaccination programme 2017/18. Published March 2017 https://www.england.nhs.uk/publication/enhanced-service-specifications/
- Shingles: Guidance and Vaccination Programme. Updated 30 June 2016 https://www.gov.uk/government/collections/shingles-vaccination-programme
- Revised recommendations for the administration of more than one live vaccine. Public Health England. 24 April 2015 https://www.gov.uk/government/publications/revised-recommendations-for-administering-more-than-1-live-vaccine

General

- PHE Immunisation Collection Accessed 30 June 2016 https://www.gov.uk/government/collections/immunisation
- British National Formulary (BNF) July 2016 <u>www.BNF.org</u> <u>http://www.evidence.nhs.uk/formulary/bnf/current</u>
- National Minimum Standards for Immunisation Training (2005) https://www.gov.uk/government/publications/immunisation-training-national-minimum-standards
- NICE Medicines Practice Guideline 2 (MPG2): Patient Group Directions. Published August 2013. https://www.nice.org.uk/guidance/mpg2
- NICE MPG2 Patient group directions: competency framework for health professionals using patient group directions. January 2014. https://www.nice.org.uk/guidance/mpg2/resources
- Immunisation knowledge and skills competence assessment tool. Royal College of Nursing (RCN)
 2015. https://www.rcn.org.uk/professional-development/publications/pub-005336
- Protocol for ordering storage and handling of vaccines. April 2014. https://www.gov.uk/government/publications/protocol-for-ordering-storing-and-handling-vaccines
- Health Technical Memorandum 07-01: Safe Management of Healthcare Waste. Department of Health 20 March 2013 https://www.gov.uk/government/publications/guidance-on-the-safe-management-of-healthcare-waste

7. Multiple practitioner authorisation sheet

Shingles PGD v07.00 Valid from: 20/07/2017 Expiry: 31/03/2019

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 the following organisation				
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.