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## Shingrix® Herpes Zoster Vaccine Patient Group Direction (PGD)

This PGD is for the administration of Shingrix® Herpes Zoster Vaccine (recombinant, adjuvanted), for the prevention of herpes zoster ('zoster' or shingles) and herpes zoster-related post-herpetic neuralgia (PHN), to individuals who are eligible for the national shingles immunisation programme.

This PGD is for the administration of Shingrix® Herpes Zoster Vaccine (recombinant, adjuvanted) by registered healthcare practitioners identified in [Section 3](#), subject to any limitations to authorisation detailed in [Section 2](#).

Reference no: Shingrix PGD  
Version no: v02.00  
Valid from: 1 September 2023  
Review date: 31 March 2025  
Expiry date: 30 September 2025

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

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

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

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

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

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

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

Enquiries relating to the availability of organisationally authorised PGDs and subsequent versions of this PGD should be directed to: [enland.swvast@nhs.net](mailto:enland.swvast@nhs.net)


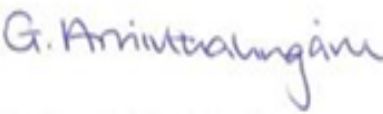

<sup>1</sup> This includes any relevant amendments to legislation

## Change history

Version number	Change details	Date
V01.00	New Shingrix® Herpes Zoster Vaccine PGD.	22 August 2021
V02.00	Shingrix Herpes Zoster Vaccine PGD amended to include: <ul style="list-style-type: none"><li data-bbox="277 365 1257 432">• addition of new eligibility cohorts to reflect policy change, effective as of 1 September 2023 (see <a href="#">Appendix 1</a> for summary)</li><li data-bbox="277 454 1257 521">• clarification of co-administration of Shingrix® with adjuvanted influenza vaccine</li></ul>	14 July 2023

## 1. PGD development

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

Developed by:	Name	Signature	Date
<b>Pharmacist</b> (Lead author)	Christina Wilson Lead Pharmacist, Immunisation and Vaccine Preventable Diseases Division, UKHSA		14 July 2023
<b>Doctor</b>	Dr Gayatri Amirthalingam Deputy Director of Public Health Programmes and Consultant Epidemiologist, Immunisation and Vaccine Preventable Diseases Division, UKHSA		14 July 2023
<b>Registered Nurse</b> (Chair of Expert Panel)	David Green Nurse Consultant, Immunisation and Vaccine Preventable Diseases Division, UKHSA		14 July 2023

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

### Expert Panel

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


## 2. Organisational authorisations

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

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

**NHS England (South West)** 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 <ul style="list-style-type: none"> <li>• Bath &amp; North East Somerset, Swindon, and Wiltshire</li> <li>• Bristol, North Somerset, and South Gloucestershire</li> <li>• Cornwall and the Isles of Scilly</li> <li>• Devon</li> <li>• Dorset</li> <li>• Gloucestershire</li> <li>• Somerset</li> </ul>
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 (South West) 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
Medical Director, System Improvement and Professional Standards, NHS England (South West)	Dr Kheelna Bavalia MRCGP MSc		26/07/2023

Additional signatories according to locally agreed policy			
Role	Name	Sign	Date

Local enquiries regarding the use of this PGD may be directed [england.swscreeningandimms@nhs.net](mailto:england.swscreeningandimms@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>Individual practitioners 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 UKHSA, NHS England and other sources of medicines information.</p> <p>Note: The most current national recommendations should be followed, but a Patient Specific Direction (PSD) may be required to administer the vaccine in line with updated recommendations that are outside the criteria specified in this PGD.</p>

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

<p><b>Clinical condition or situation to which this PGD applies</b></p>	<p>Shingrix® Herpes Zoster Vaccine (recombinant, adjuvanted) is indicated for the prevention of herpes zoster ('zoster' or shingles) and herpes zoster-related post-herpetic neuralgia (PHN) for adults who are eligible for the national shingles immunisation programme 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><b>Immunocompetent individuals</b> who:</p> <ul style="list-style-type: none"> <li>• reach the age of 65 <b>or</b> 70 years of age during the period 1 September 2023 and 31 August 2028. These individuals should be vaccinated on or after (but not before) their 65<sup>th</sup> or 70<sup>th</sup> birthday</li> <li>• are aged between 70 years and 79 years old on or before 31 August 2023 <b>and</b> have never received a shingles vaccine</li> </ul> <p><b>and either</b></p> <ul style="list-style-type: none"> <li>(i) Zostavax® is no longer available</li> <li><b>or</b></li> <li>(ii) Zostavax® is not clinically appropriate for the individual</li> </ul> <ul style="list-style-type: none"> <li>• are currently aged 80 years or over, but received a first dose of Shingrix® before turning 80 years old and require a second Shingrix® dose to complete the course before their 81<sup>st</sup> birthday</li> </ul> <p><b>Severely immunosuppressed<sup>2</sup> individuals from 1 September 2023</b>, who:</p> <ul style="list-style-type: none"> <li>• are aged 50 years and above, and meet the definition of severe immunosuppression in the Box in <a href="#">Chapter 28a</a></li> <li>• are aged between 18 and 49 years and receiving a stem cell transplant</li> </ul> <p>See <a href="#">Appendix 1</a> for further information on cohort eligibility</p>
<p><b>Criteria for exclusion<sup>3</sup></b> (continued over page)</p>	<p>Individuals for whom no valid consent has been received.</p> <p><b>Immunocompetent individuals on or after 1 September 2023</b> who:</p> <ul style="list-style-type: none"> <li>• have not yet reached their 65<sup>th</sup> birthday</li> <li>• are between 65 to 69 years of age but reached their 65<sup>th</sup> birthday on or before 31 August 2023; these individuals must wait until they reach their 70<sup>th</sup> birthday</li> <li>• have not yet reached their 70<sup>th</sup> birthday</li> <li>• are 80 years of age or over, except those who have received a partial course of Shingrix® (who are no longer eligible from their 81<sup>st</sup> birthday)</li> <li>• have had their 70<sup>th</sup> birthday on or before 31 August 2023 <b>and</b> <ul style="list-style-type: none"> <li>(i) who have not yet been vaccinated against shingles <b>and</b></li> <li>(ii) do not have a clinical contraindication to Zostavax® <b>and</b></li> <li>(iii) Zostavax® is still routinely available at the time of assessment (refer to <a href="#">Zostavax® PGD</a>)</li> </ul> </li> </ul> <p><b>All individuals</b> who:</p> <ul style="list-style-type: none"> <li>• have had a confirmed anaphylactic reaction to a previous dose of varicella vaccine or to any component of the vaccine</li> <li>• are suffering from acute severe febrile illness (the presence of a minor infection is not a contraindication for immunisation)</li> <li>• have shingles infection with active lesions</li> </ul>

<sup>2</sup> Immunocompromised individuals in this PGD, are those defined as severely immunosuppressed, as outlined in the Box in [Chapter 28a](#)

<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

<p><b>Criteria for exclusion</b> (continued)</p>	<ul style="list-style-type: none"> <li>• are pregnant</li> <li>• have already received one dose of Zostavax® or two doses of Shingrix® prior to assessment</li> <li>• have received a dose of Shingrix® in the last 8 weeks</li> </ul>
<p><b>Cautions including any relevant action to be taken</b></p>	<p>Facilities for management of anaphylaxis should be available at all vaccination premises (see <a href="#">Chapter 8</a> of the Green Book and advice issued by the <a href="#">Resuscitation Council UK</a>).</p> <p>The immunogenicity of the vaccine could be reduced in immunosuppressed subjects. However, vaccination should proceed in accordance with the national recommendations.</p> <p>Shingrix® should be given with caution to individuals with thrombocytopenia or any coagulation disorder since bleeding may occur following intramuscular administration to these subjects (see <a href="#">Route and method of administration</a>).</p>
<p><b>Action to be taken if the patient is excluded</b></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. Refer to <a href="#">Appendix 1</a> for further information.</p> <p>Individuals aged between 70 to 79 years of age before 1 September 2023 who are in an eligible age group but do not have a clinical contraindication to receiving Zostavax®, shingles (herpes zoster, live), vaccine should be assessed to receive Zostavax®, if Zostavax® is still routinely available. This PGD does not cover the administration of Zostavax® (refer to <a href="#">Zostavax® PGD</a>).</p> <p>Individuals suffering from acute severe febrile illness should postpone immunisation until they have recovered. Advise when the individual may be vaccinated and ensure another appointment is arranged</p> <p>Individuals who present with a shingles infection with active lesions should postpone immunisation until recovered. As severely immunosuppressed individuals are at increased risk of recurrent zoster, Shingrix® can be given once any active shingles lesions have resolved.</p> <p>If clinically indicated, Shingrix® may be considered in pregnancy, following a discussion of the risks and benefits with the individual. In such cases, if the individual wishes to proceed with vaccination, Shingrix® may be given under a PSD.</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.</p> <p>If vaccination cannot be commenced before an immunocompetent individual is 80 years old, explain why vaccination will no longer be indicated.</p> <p>If required, seek advice from the local Screening and Immunisation Team, local Health Protection Team or the individual's clinician as deemed appropriate.</p> <p>The risk to the individual of not being vaccinated must be taken into account.</p> <p>Document the reason for exclusion and any action taken in the individual's clinical records.</p> <p>Inform or refer to the individual's GP or a prescriber as appropriate.</p>

<p><b>Action to be taken if the patient or carer declines treatment</b></p>	<p>Informed consent, from the individual or a person legally able to act on the individual's behalf, must be obtained prior to administration.</p> <p>Advise the individual or carer about the protective effects of the vaccine, the risks of infection and potential complications.</p> <p>Document advice given and the decision reached.</p> <p>Inform or refer to the individual's GP or a prescriber as appropriate.</p>
<p><b>Arrangements for referral for medical advice</b></p>	<p>As per local policy</p>



## 5. Description of treatment

<b>Name, strength and formulation of drug</b>	<p>Herpes zoster vaccine (recombinant, adjuvanted):</p> <ul style="list-style-type: none"> <li>• Shingrix<sup>®</sup>, powder and suspension for suspension for injection.</li> </ul> <p>After reconstitution, one dose (0.5ml) of Shingrix<sup>®</sup> contains varicella zoster virus glycoprotein E antigen 50 micrograms, adjuvanted with AS01<sub>B</sub>.</p>
<b>Legal category</b>	Prescription only medicine (POM).
<b>Black triangle ▼</b>	No.
<b>Off-label use</b>	<p>The Shingrix<sup>®</sup> <a href="#">SPC</a> advises an interval of 2 months between doses, which may be extended to between 2 and 6 months if flexibility is required. For individuals who are or about to become severely immunosuppressed and who might benefit from a shorter vaccination schedule, a 1 to 2 month interval between doses may be observed.</p> <p>The dose intervals advised in the Green Book and subsequently in this PGD are different to that outlined above; between 6 and 12 months for immunocompetent individuals and 8 weeks to 6 months for severely immunosuppressed individuals.</p> <p>Vaccine should be stored according to the conditions detailed in the <a href="#">Storage</a> section below. However, in the event of an inadvertent or unavoidable deviation of these conditions, refer to <a href="#">Vaccine Incident Guidance</a>. Where vaccine is assessed in accordance with these guidelines as appropriate for continued use this would constitute off-label administration under this PGD.</p> <p>Where a vaccine is recommended off-label, consider, as part of the consent process, informing the individual or carer that the vaccine is being offered in accordance with national guidance but that this is outside the product licence.</p>
<b>Route and method of administration</b>	<p>Shingrix<sup>®</sup> must be reconstituted in accordance with the manufacturer's instructions prior to administration.</p> <p>Following reconstitution, Shingrix<sup>®</sup> vaccine is given by intramuscular injection, preferably into the deltoid muscle of the upper arm.</p> <p>Subcutaneous administration is not recommended. Maladministration via the subcutaneous route may lead to an increase in transient local reactions.</p> <p>Individuals with bleeding disorders may be vaccinated intramuscularly if, in the opinion of a doctor familiar with the individual's bleeding risk, vaccines or similar small volume intramuscular injections can be administered with reasonable safety by this route. If the individual receives medication or other treatment to reduce bleeding, for example treatment for haemophilia, intramuscular vaccination can be scheduled shortly after such medication or treatment is administered. Individuals on stable anticoagulation therapy, including individuals on warfarin who are up to date with their scheduled INR testing and whose latest INR was below the upper threshold of their therapeutic range, can receive intramuscular vaccination. A fine needle (equal to 23 gauge or finer calibre such as 25 gauge) should be used for the vaccination, followed by firm pressure applied to the site (without rubbing) for at least 2 minutes. The individual or carer should be informed about the risk of haematoma from the injection.</p> <p>When administering at the same time as other vaccines, care should be taken to ensure that the appropriate route of injection is used for all vaccinations.</p> <p>The vaccines should be given at separate sites, preferably in different limbs. If given in the same limb, they should be given at least 2.5cm apart. The site at which each vaccine was given should be noted in the individual's records.</p>

<b>Route and method of administration</b> (continued)	<p>The vaccine should be inspected visually for particles and discolouration before preparation and administration. Should either occur, discard the vial in accordance with local procedures.</p> <p>The reconstituted vaccine is an opalescent, colourless to pale brownish liquid. Discard the vaccine if there is any foreign particulate matter or variation in appearance.</p> <p>After reconstitution, the vaccine should be used promptly (see <a href="#">Storage</a> section).</p> <p>The vaccine <a href="#">SPC</a> provides further guidance on reconstitution and administration.</p>
<b>Dose and frequency of administration</b>	<p>Single 0.5ml dose per administration. If the course is interrupted or delayed, it should be resumed as soon as possible, but not repeated.</p> <p><b>Eligible immunocompetent individuals</b></p> <ul style="list-style-type: none"> <li>• 2 doses of Shingrix<sup>®</sup>, with the second dose given 6 to 12 months after the first dose.</li> </ul> <p><b>Severely immunosuppressed individuals (includes stem cell transplant recipients):</b></p> <ul style="list-style-type: none"> <li>• 2 doses of Shingrix<sup>®</sup>, with the second dose given 8 weeks to 6 months after the first dose</li> </ul> <p>Severely immunosuppressed individuals who have already received 2 doses of Shingrix<sup>®</sup> do not require revaccination.</p>
<b>Duration of treatment</b>	<p>A 2 dose course (see <a href="#">Dose and frequency of administration</a>)</p>
<b>Quantity to be supplied and administered</b>	<p>Single 0.5ml dose per administration.</p>
<b>Supplies</b>	<p>Centrally purchased vaccines for the national immunisation programme can only be ordered via ImmForm and are provided free of charge.</p> <p>Protocols for the ordering, storage and handling of vaccines should be followed to prevent vaccine wastage (see Green Book <a href="#">Chapter 3</a>).</p>
<b>Storage</b>	<p>Store between +2°C to +8°C. Store in original packaging in order to protect from light. Do not freeze.</p> <p>Once reconstituted, any unused vaccine should be stored in a refrigerator at +2°C to +8°C if not immediately required.</p> <p>Though chemical and physical in-use stability has been demonstrated for 24 hours at +30°C, from a microbiological viewpoint, the reconstituted vaccine should be used as soon as possible. Any remaining vaccine should be discarded 6 hours following reconstitution.</p> <p>In the event of an inadvertent or unavoidable deviation of these conditions, vaccine that has been stored outside the conditions stated above should be quarantined and risk assessed for suitability of continued off-label use or appropriate disposal. Refer to <a href="#">Vaccine Incident Guidance</a>.</p>
<b>Disposal</b>	<p>Equipment used for immunisation, including used vials, ampoules, or discharged vaccines in a syringe or applicator, should be disposed of safely in a UN-approved puncture-resistant 'sharps' box, according to local authority arrangements and NHSE guidance (<a href="#">HTM 07-01: Management and disposal of healthcare waste</a>).</p>

<b>Drug interactions</b>	<p>Immunological response may be diminished in individuals receiving immunosuppressant treatment. Vaccination is recommended even if the antibody response may be limited.</p> <p>See the <a href="#">Additional information</a> section for information on co-administration with other vaccines.</p> <p>A detailed list of drug interactions is available in the <a href="#">SPC</a>.</p>
<b>Identification and management of adverse reactions</b>	<p>The most common adverse reactions observed after administration of Shingrix® are injection-site reactions (such as pain, redness and swelling) myalgia and headache. Most of these reactions are not long-lasting (median duration of 2 to 3 days). Other very common side-effects include gastrointestinal symptoms (including nausea, vomiting, diarrhoea and abdominal pain), chills and fever.</p> <p>A detailed list of adverse reactions is available in the <a href="#">SPC</a>.</p> <p>In the event of a person developing a varicella (widespread) or shingles-like (dermatomal) rash post-Shingrix® vaccination, a vesicle fluid sample should be sent for analysis, to confirm the diagnosis and determine whether the rash is vaccine-associated or wild-type (see <a href="#">Chapter 28a</a>).</p>
<b>Reporting procedure of adverse reactions</b>	<p>Healthcare professionals, individuals and carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the <a href="#">Yellow Card reporting scheme</a> or by searching for MHRA Yellow Card in the Google Play or Apple App Store.</p> <p>Any adverse reaction to the vaccine should be documented in the individual's record and the individual's GP should be informed.</p>
<b>Written information to be given to patient or carer</b>	<p>Offer marketing authorization holder's patient information leaflet (PIL) provided with the vaccine.</p> <p>Immunisation promotional material may be provided as appropriate.</p> <p><a href="#">Shingles vaccination guide</a></p> <p><a href="#">Shingrix® vaccine for people with weakened immune systems</a></p> <p>For resources in accessible formats and alternative languages, please visit <a href="#">Home-Health Publications</a>.</p> <p>Where applicable, inform the individual or carer that large print, Braille or audio CD PILs may be available from emc accessibility (freephone 0800 198 5000) by providing the medicine name and product code number, as listed on the <a href="#">electronic Medicines Compendium</a>.</p>
<b>Patient advice and follow-up treatment</b>	<p>Inform the individual or carer of possible side effects and their management.</p> <p>Give advice regarding normal reactions to the injection, for example redness and pain at the injection site.</p> <p>The individual or carer should be advised to seek medical advice in the event of a severe adverse reaction and report this via the <a href="#">Yellow Card Scheme</a>.</p> <p>When administration is postponed, advise the individual or carer when to return for vaccination with due consideration of the individual's age to ensure they will meet the inclusion criteria for immunisation. If vaccination cannot be commenced before an immunocompetent individual is 80 years old, explain why vaccination will no longer be indicated (there is no upper age limit for severely immunocompromised individuals).</p> <p>Individuals should be advised to seek medical attention if they develop a varicella (widespread) or shingles-like (dermatomal) rash post-Shingrix® vaccination.</p>

<p><b>Special considerations and additional information</b></p>	<p>Ensure there is immediate access to adrenaline (epinephrine) 1 in 1000 injection and easy access to a telephone at the time of vaccination.</p> <p>Individuals anticipated to commence immunosuppressive treatment should, where feasible, complete the course of Shingrix® before treatment is scheduled to begin, with a dose interval of 8 weeks. Under no circumstances should there be a delay in commencing immunosuppressive treatment in order to complete the vaccine schedule. The first dose of Shingrix® should be given at least 2 weeks before treatment starts, though 1 month prior is preferred. If immunosuppressive treatment is subsequently commenced after the first dose of Shingrix® is given, the second dose may be given 8 weeks to 6 months later.</p> <p>Shingrix® can be given at the same time as unadjuvanted inactivated influenza vaccine or 23-valent pneumococcal vaccine (PPV23). The vaccines should be administered at different injection sites. The adverse reactions of fever and shivering are more frequent when PPV23 vaccine is co-administered with Shingrix®.</p> <p>In line with general advice about co-administration of inactivated vaccines, Shingrix® can be given concomitantly with inactivated influenza vaccine. Initially, a 7 day interval was recommended between Shingrix® and adjuvanted influenza vaccine because the potential reactogenicity from 2 adjuvanted vaccines may reduce tolerability in those being vaccinated. Interim data from a US study on co-administration of Shingrix® with adjuvanted seasonal influenza vaccine is reassuring. Therefore, an appointment for administration of the seasonal influenza vaccine can be an opportunity to also provide shingles vaccine, although the latter should be offered all year round, rather than purely as a seasonal programme.</p> <p>A 7 day gap between administration of Shingrix® and COVID-19 vaccine is no longer required. As Shingrix® is an inactivated vaccine, where individuals in an eligible cohort present having received another inactivated or live vaccine, Shingrix® vaccination should still be considered. In most cases, vaccination should proceed to avoid any further delay in protection and to avoid the risk of the patient not returning for a later appointment. In such circumstances, patients should be informed about the likely timing of potential adverse events relating to each vaccine.</p>
<p><b>Record</b></p> <p>(continued over page)</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 the individual is excluded or declines immunisation</li> <li>• details of any adverse drug reactions and actions taken</li> <li>• supplied via PGD</li> </ul> <p>Records should be signed and dated (or password-controlled on e-records).</p> <p>All records should be clear, legible and contemporaneous.</p> <p>This information should be recorded in the individual's GP record and any other appropriate medical records, such as care or nursing records.</p>

<b>Record</b> (continued)	A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.
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## 6. Key references

<b>Key references</b>	<p><b>Shingles</b></p> <ul style="list-style-type: none"><li>• Shingrix® Summary of Product Characteristics. GlaxoSmithKline UK. Updated 15 June 2023. <a href="https://www.medicines.org.uk/emc/product/12054/smpc">https://www.medicines.org.uk/emc/product/12054/smpc</a></li><li>• Immunisation Against Infectious Disease: The Green Book, <a href="#">Chapter 28a</a>. Updated July 2023. <a href="https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book">https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book</a></li><li>• Shingles: Guidance and Vaccination Programme. Updated 4 July 2023. <a href="https://www.gov.uk/government/collections/shingles-vaccination-programme">https://www.gov.uk/government/collections/shingles-vaccination-programme</a></li><li>• UKHSA: Vaccination against shingles- information for healthcare practitioners. Updated 6 July 2023. <a href="https://www.gov.uk/government/publications/shingles-vaccination-guidance-for-healthcare-professionals">https://www.gov.uk/government/publications/shingles-vaccination-guidance-for-healthcare-professionals</a></li></ul> <p><b>General</b></p> <ul style="list-style-type: none"><li>• NHSE Health Technical Memorandum 07-01: Safe Management of Healthcare Waste. Update 7 March 2023. <a href="https://www.england.nhs.uk/publication/management-and-disposal-of-healthcare-waste-hm-07-01">https://www.england.nhs.uk/publication/management-and-disposal-of-healthcare-waste-hm-07-01</a></li><li>• National Minimum Standards and Core Curriculum for Immunisation Training. Published February 2018. <a href="https://www.gov.uk/government/publications/national-minimum-standards-and-core-curriculum-for-immunisation-training-for-registered-healthcare-practitioners">https://www.gov.uk/government/publications/national-minimum-standards-and-core-curriculum-for-immunisation-training-for-registered-healthcare-practitioners</a></li><li>• NICE Medicines Practice Guideline 2 (MPG2): Patient Group Directions. 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>• UKHSA Immunisation Collection. <a href="https://www.gov.uk/government/collections/immunisation">https://www.gov.uk/government/collections/immunisation</a></li><li>• Vaccine Incident Guidance: responding to errors in vaccination storage, handling and administration. Updated 7 July 2022. <a href="https://www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors">https://www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors</a></li></ul>
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## 7. Practitioner authorisation sheet

**Shingrix® PGD v02.00 Valid from: 1 September 2023 Expiry: 30 September 2025**

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

### Practitioner

By signing this PGD, you are indicating that you agree to its contents and that you will work within it.

PGDs do not remove inherent professional obligations or accountability.

It is the responsibility of each professional to practise only within the bounds of their own competence and professional code of conduct.

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

Name	Designation	Signature	Date

### Authorising manager

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

Name	Designation	Signature	Date

### Note to authorising manager

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

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

**Appendix 1: Immunocompetent patients and phased implementation of Shingrix® during Stage 1 (1 September 2023 to 31 August 2028)**

<b>Implementation stage</b>	<b>Age attained (years) within first programme year (1 Sept 2023 to 31 Aug 2024)</b>	<b>Dates of birth</b>	<b>Programme year offered</b>		<b>Age offered at</b>
Previously eligible cohorts:	70 to 79	before 1 Sept 1953	those in the cohort previously eligible for the Zostavax® programme prior to 1 Sept 2023 remain eligible for Zostavax® until stocks deplete, after which time they become eligible for Shingrix®		
Stage 1:	70	1 Sept 1953 to 31 Aug 1954	Year 1	1 Sept 2023 to 31 Aug 2024	70
	69	1 Sept 1954 to 31 Aug 1955	Year 2	1 Sept 2024 to 31 Aug 2025	70
	68	1 Sept 1955 to 31 Aug 1956	Year 3	1 Sept 2025 to 31 Aug 2026	70
	67	1 Sept 1956 to 31 Aug 1957	Year 4	1 Sept 2026 to 31 Aug 2027	70
	66	1 Sept 1957 to 31 Aug 1958	Year 5	1 Sept 2027 to 31 Aug 2028	70
	65	1 Sept 1958 to 31 Aug 1959	Year 1	1 Sept 2023 to 31 Aug 2024	65
	64	1 Sept 1959 to 31 Aug 1960	Year 2	1 Sept 2024 to 31 Aug 2025	65
	63	1 Sept 1960 to 31 Aug 1961	Year 3	1 Sept 2025 to 31 Aug 2026	65
	62	1 Sept 1961 to 31 Aug 1962	Year 4	1 Sept 2026 to 31 Aug 2027	65
	61	1 Sept 1962 to 31 Aug 1963	Year 5	1 Sept 2027 to 31 Aug 2028	65