Patient Group Direction For The Administration Of Shingles (Herpes
Zoster) Vaccine (Live) Zostavax® By Approved Healthcare
Professionals Working Within NHS Grampian, Highland, Orkney,
Shetland, Tayside And Western Isles

Lead Author:
Adapted from PHS
template by the Medicines
Management Specialist
Nurse NHSG

Consultation Group:
See relevant page in the
PGD

Approver:
NoS PGD Group

Authorisation:
NHS Grampian

Signature:

Signature:

NoS Identifier:
NoS/PGD/Zostavax/
MGPG1109

Review Date:
September 2021

Date Approved:
September 2020

Expiry Date:
September 2021

NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles have
authorised this Patient Group Direction to help individuals by providing them with
more convenient access to an efficient and clearly defined service within the NHS
Boards. This Patient Group Direction cannot be used until Appendix 1 and 2 are
completed.

Uncontrolled when printed

Version 2

(This Patient Group Direction has been adapted from the Public Health Scotland
Zostavax® PGD Template)
Revision History:

<table>
<thead>
<tr>
<th>Date of change</th>
<th>Summary of Changes</th>
<th>Section heading</th>
</tr>
</thead>
<tbody>
<tr>
<td>August 2020</td>
<td>NoS PGD adapted from the Public Health Scotland PGD.</td>
<td></td>
</tr>
<tr>
<td>August 2020</td>
<td>Route/Method of administration section updated to remove wording on co-administration with Yellow Fever vaccine aligned with Green Book chapter 11 (updated January 2020).</td>
<td>Route/Method of administration</td>
</tr>
</tbody>
</table>

NoS Identifier: NoS/PGD/Zostavax/MGPG1109
Keyword(s): PGD Patient Group Direction shingles herpes zoster vaccine live zostavax nurse

Policy Statement: It is the responsibility of the individual healthcare professional and their line managers to ensure that they work within the terms laid down in this PGD and to ensure that staff are working to the most up to date PGD. By doing so, the quality of the services offered will be maintained, and the chances of staff making erroneous decisions which may affect individual, staff or visitor safety and comfort will be reduced. Supervisory staff at all levels must ensure that staff using this PGD act within their own level of competence.

The lead author is responsible for the review of this PGD and for ensuring the PGD is updated in line with any changes in clinical practice, relevant guidelines, or new research evidence.

Review date: The review date for a PGD needs to be decided on a case-by-case basis in the interest of safety. The expiry date should not be more than 3 years, unless a change in national policy or update is required.

Document: Drafted: August 2020
Completed: August 2020
Approved: September 2020 (published – September 2020)
Amended:
Organisational Authorisations

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

PGD Developed/Reviewed by;

<table>
<thead>
<tr>
<th>Role</th>
<th>Name</th>
<th>Health Board</th>
<th>Title</th>
<th>Contact Email</th>
<th>Signature</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical practitioner</td>
<td>Dr Susan Laidlaw</td>
<td>NHSS</td>
<td>Consultant in Public Health</td>
<td><a href="mailto:susan.laidlaw@nhs.net">susan.laidlaw@nhs.net</a></td>
<td></td>
</tr>
<tr>
<td>Senior representative of the professional group who will provide care under the direction</td>
<td>Katrina Morrison</td>
<td>NHSG</td>
<td>Vaccination Programme Manager</td>
<td><a href="mailto:katrina.morrison@nhs.scot">katrina.morrison@nhs.scot</a></td>
<td></td>
</tr>
<tr>
<td>Lead author</td>
<td>Frances Adamson</td>
<td>NHSG</td>
<td>Medicines Management Specialist Nurse</td>
<td><a href="mailto:frances.adamson@nhs.scot">frances.adamson@nhs.scot</a></td>
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</tr>
<tr>
<td>Pharmacist</td>
<td>Liam Callaghan</td>
<td>NHSWI</td>
<td>Chief Pharmacist</td>
<td><a href="mailto:liam.callaghan@nhs.net">liam.callaghan@nhs.net</a></td>
<td></td>
</tr>
</tbody>
</table>
Management and Monitoring of Patient Group Direction

PGD Consultative Group

The consultative group is legally required to include a medical practitioner, a pharmacist and a representative of the professional group who will provide care under the direction.

Name: 

- Frances Adamson 
- Liam Callaghan 
- Dr Susan Laidlaw 
- Katrina Morrison 
- Mary McFarlane 
- Claire O'Brien 
- Russell Mackay 
- Fiona Thomson 
- Lynda Davidson 
- Fiona Browning 
- Tina McMichael 
- Alison Work

Title:

- **Lead Author:** Medicines Management Specialist Nurse NHSG
- **Pharmacist:** Chief Pharmacist NHSWI
- **Medical Practitioner:** Consultant in Public Health NHSS
- **Senior Representative:** Vaccination Programme Manager NHSG
- **Principal Pharmacist NHSS**
- **Lead Clinical Pharmacist NHST**
- **Specialist Clinical Pharmacist NHSO**
- **Argyll & Bute CHP Lead Pharmacist NHSH**
- **Health Protection Nurse Specialist NHSSH**
- **Health Protection Nurse Specialist NHSG**
- **Advanced Nurse Specialist (Health Protection) NHST**
- **Public Health Nurse Team Leader NHSG**
Patient Group Direction For The Administration Of Shingles (Herpes Zoster) Vaccine (Live) Zostavax® By Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside And Western Isles

Clinical indication to which this PGD applies

<table>
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<tr>
<th>Definition of situation/Condition</th>
<th>This Patient Group Direction (PGD) will authorise approved healthcare professionals as detailed in the characteristics of staff authorised to work under this PGD to administer Shingles (Herpes Zoster) Vaccine (Live) Zostavax® to individuals not previously vaccinated with Zostavax® included in age cohorts described by most current CMO letter. This PGD should be used in conjunction with the recommendations in the current British National Formulary (BNF), British National Formulary for Children (BNFC), The Green Book, TRAVAX, NaTHNaC and the individual Summary of Product Characteristics (SmPC).</th>
</tr>
</thead>
</table>
| Inclusion criteria               | • Individuals not previously vaccinated with Zostavax® included in age cohorts described by most current CMO letter.  

• From September 2020 eligible individuals are: Those who were 70 to 79 years of age on 1st September 2020. Prior to the administration of the vaccine, valid consent to receiving treatment under this PGD must be obtained. Consent must be in line with current individual NHS Boards consent policy. |
| Exclusion criteria               | N.B. There is a HPS Screening Tool for Contraindications for Shingles Vaccine available from the HPS website. N.B. The 2020/21 screening tool was not available at the time of publishing this PGD.  

• Primary or acquired immunodeficiency states due to conditions such as:  
  - current or previous treatment of malignant disease  
  - acute and chronic leukaemias; lymphoma (including Hodgkin’s lymphoma)  
  - those remaining under follow up for a chronic lymphoproliferative disorder including haematological malignancies such as indolent lymphoma, chronic lymphoid leukaemia, myeloma and other plasma cell dyscrasias (N.B. This list not exhaustive)  
  - immunosuppression due to HIV/AIDS  
  - cellular immune deficiencies |
| **o** those who have received an allogenic stem cell transplant (cells from a donor) in the past 24 months |
| **o** those who have received an allogenic stem cell transplant more 24 months ago and have evidence of ongoing immunosuppression or graft versus host disease (GVHD) |
| **o** those who have received an autologous (using their own stem cells) haematopoietic stem cell transplant in the past 24 months |
| **o** those who have received an autologous haematopoietic stem cell transplant more 24 months ago and are not in remission. |

- **Is on immunosuppressive or immunomodulating therapy including**
  - **o** those who are receiving or have received in the past 6 months immunosuppressive chemotherapy or radiotherapy for malignant disease or non-malignant disorders
  - **o** those who are receiving or have received in the past 6 months immunosuppressive therapy for a solid organ transplant
  - **o** those who are receiving or have received in the past 12 months biological therapy (e.g. anti-TNF therapy such as alemtuzumab, ofatumumab and rituximab)
  - **o** those who are receiving or have received in the past 3 months immunosuppressive therapy including:
    i) short term high-dose corticosteroids (>40mg prednisolone per day for more than 1 week);
    ii) long term lower dose corticosteroids (>20mg prednisolone per day for more than 14 days)
    iii) non-biological oral immune modulating drugs, e.g. methotrexate >25mg per week, azathioprine >3.0mg/kg/day or 6-mercaptopurine >1.5mg/kg/day.

**Individuals:**
- With active untreated tuberculosis
- With current acute systemic or febrile illness
- Who have had an anaphylactic reaction to previous dose of the vaccine or to any of its excipients including neomycin or gelatine
- Who currently have shingles or have had shingles in the last year should have vaccination delayed for one year after shingles
- Who currently have postherpetic neuralgia (PHN) should wait until symptoms have ceased before being considered for shingles immunisation
- Being currently treated or are within 48 hours of cessation of treatment with oral or intravenous antivirals (such as acyclovir, the use of topical aciclovir is not an exclusion)
- Where there is no valid consent.

**Precautions and special warnings**

Zostavax® is a live attenuated vaccine. If there is any doubt of the individual’s suitability for vaccine do not vaccinate and seek further advice.

If the individual is under highly 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.

Specialists with responsibility for patients in the vaccine eligible cohorts should include a statement of their opinion on the patient’s suitability for Zostavax® in their correspondence with primary care. If primary healthcare professionals administering the vaccine have concerns about the nature of therapies (including biologicals) or the degree of immunosuppression they should contact the relevant specialist for advice.

Humoral deficiencies affecting IgG or IgA antibodies are not of themselves a contra-indication unless associated with T cell deficiencies. **If there is any doubt (e.g. common variable immune deficiency), immunological advice should be sought prior to administration.**

Many adults with chronic inflammatory diseases (e.g. rheumatoid arthritis, inflammatory bowel disease, psoriasis, glomerulonephritis) may be on stable long term low dose corticosteroid therapy (defined as ≤20mg prednisolone per day for more than 14 days) either alone or in combination with other immunosuppressive drugs including biological and non-biological therapies. 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 (e.g. methotrexate ≤25mg per week, azathioprine ≤3.0mg/kg/day or 6-mercaptopurine ≤1.5mg/kg/day) are not considered sufficiently immunosuppressive and these patients can receive the vaccine. **Specialist advice should be sought for other treatment regimes.**

The use of the vaccine is not excluded for use in individuals who are receiving topical/inhaled corticosteroids and in
people who are receiving corticosteroids as replacement therapy (e.g. for adrenal insufficiency).

The use of topical acyclovir is not an exclusion.

Minor illness without fever or systemic upset is not a valid reason to postpone immunisation. If an individual is acutely unwell, immunisation may be postponed until they have fully recovered.

**Action if excluded from treatment**

Medical advice must be sought – refer to relevant medical practitioner. If clarification is required about an individual meeting the exclusion criteria advice can be sought from the local Health Protection team.

The risk to the individual of not being immunised must be taken into account. Discussion of the risk and benefits of vaccination should take place. Discussions and decisions taken should be documented in clinical records.

In case of postponement due to acute severe febrile illness, advise when the individual can be vaccinated at a later date and ensure another appointment is arranged.

Document the reason for exclusion under the PGD and any action taken in the individual's appropriate clinical records.

**Action if treatment is declined**

Advise about the protective effects of the vaccine and the risk of infection and disease complications. Ensure they have additional reading material e.g. the Patient Information Leaflet (PIL) available to print here. Document advice given and decision reached.

Inform/refere to the relevant medical practitioner if individual declines treatment.

Document that the administration of the vaccine was declined, the reason and advice given in appropriate clinical records.

**Description of vaccine available under the PGD**

<table>
<thead>
<tr>
<th>Name form and strength of vaccine</th>
<th>Shingles (herpes zoster) vaccine (live) Zostavax® powder and solvent for suspension for injection in a pre-filled syringe.</th>
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<tr>
<td>Legal status</td>
<td>Zostavax® is a Prescription-only Medicine (PoM).</td>
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</table>
N.B. The SmPC states that Zostavax® and 23-valent pneumococcal polysaccharide vaccine (PPV) should not be given concomitantly. This is superseded by the Green Book recommendation that the two vaccines may be given at the same time.

<table>
<thead>
<tr>
<th>Dosage/Maximum total dose</th>
<th>0.65mL</th>
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<tr>
<td>Frequency of dose/Duration of treatment</td>
<td>Single dose/administration</td>
</tr>
<tr>
<td>Maximum or minimum treatment period</td>
<td>N/A</td>
</tr>
<tr>
<td>Route/Method of administration</td>
<td>The vaccine should be administered via Intramuscular injection (IM) preferably in the deltoid region of the upper arm. Individuals with known bleeding disorders should receive the vaccine by deep subcutaneous route to reduce the risk of bleeding. Intramuscular administration is preferred due to comparable immune response and less frequent injection site adverse reactions than subcutaneous administration. This vaccine should not be given by the intravenous or intradermal routes under any circumstances. Zostavax® can be administered concomitantly with inactivated influenza vaccine as separate injections and at different body sites. Zostavax® can be given at the same time as the 23-valent pneumococcal polysaccharide vaccine (PPV). Zostavax® and MMR vaccine if not administered on the same day, then a four week minimum interval period should be observed. Apart from the above combination Zostavax® can be administered at any time before or after other live vaccines. When administering at the same time as other vaccines care should be taken to ensure that the appropriate route of injection is used for each of the vaccinations. The vaccines should be given when possible in different limbs to allow monitoring of local reactions to Zostavax®. If given in the same</td>
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</table>
limb they should be given at different sites at least 2.5cm apart. The site at which each vaccine was administered should be noted in the individual’s records.

To reconstitute the vaccine, use the solvent provided. When reconstituted, Zostavax® 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.

<table>
<thead>
<tr>
<th>Quantity to be administered</th>
<th>0.65mL</th>
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<tbody>
<tr>
<td>Storage requirements</td>
<td>Vaccine will be stored in a temperature controlled refrigerator between +2°C and +8°C. Refrigerators should have maximum and minimum temperatures recorded daily. Store in original packaging in order to protect from light. 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. Where vaccine is assessed in accordance with these guidelines as appropriate for continued use, administration under this PGD is allowed. Individual NHS Board guidance on the storage, handling and cold chain in relation to vaccines must be observed. Likewise, individual NHS Board guidance in relation to waste management and the disposal of all spent, partially spent or unused vaccines must also be observed.</td>
</tr>
<tr>
<td>Follow-up (if applicable)</td>
<td>Individuals should not leave if they are feeling unwell without speaking to the healthcare professional who administered the vaccine first. If necessary a doctor or the individuals GP should be contacted for advice.</td>
</tr>
<tr>
<td>Advice (Verbal)</td>
<td>Advise individual what to expect and what to do for minor and major reactions. If serious adverse or persistent effects occur, the individual should be advised to contact their GP/Accident and Emergency department/NHS24. Advise individual that if they develop a varicella-like rash after vaccination, they should avoid direct contact with a susceptible (chickenpox naïve) person until the rash is dry and crusted. Wherever possible vesicle fluid should be tested to determine...</td>
</tr>
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</table>
whether the rash is vaccine associated. (Please see Green book [Chapter 28a Page 11].)

When administration is postponed advise the individual when to return for vaccination.

| Advice (Written) | The PIL contained in the medicine(s) should be made available to the individual. Where this is unavailable, or unsuitable, sufficient information should be given in a language that they can understand.

More information regarding this vaccine can be found at: [https://www.nhsinform.scot/healthy-living/immunisation](https://www.nhsinform.scot/healthy-living/immunisation)

| Identifying and managing possible adverse reactions | The most commonly seen reactions are minor local injection site reactions such as hardening of the skin, oedema, pain and redness. A small painless nodule may form at the injection site.

Other common reactions reported in at least one in 100 people were haematoma, itching or pruritus, induration and warmth at the injection site, pain in arm or leg and headache.

As with all vaccines there is a very small possibility of anaphylaxis and facilities for its management must be available.

**This list is not exhaustive. Please also refer to current BNF and manufacturers SmPC for details of all potential adverse reactions.**

**BNF:** [https://www.bnf.org/products/bnf-online/](https://www.bnf.org/products/bnf-online/)

**SmPC/PIL/Risk Minimisation Material:** [https://www.medicines.org.uk/emc/](https://www.medicines.org.uk/emc/)
[https://www.medicines.org.uk/emc/rmm-directory](https://www.medicines.org.uk/emc/rmm-directory)

If an adverse reaction does occur give immediate treatment and inform relevant medical practitioner as soon as possible.

Report any severe reactions using the MHRA using the Yellow Card System [https://yellowcard.mhra.gov.uk/](https://yellowcard.mhra.gov.uk/).
<table>
<thead>
<tr>
<th>Facilities and supplies required</th>
<th>The following are to be available at sites where the vaccine is to be administered:</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>• Pharmaceutical refrigerator (or a validated cool box for storing vaccine if mobile unit)</td>
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<tr>
<td></td>
<td>• An acceptable level of privacy to respect individual’s right to confidentiality and safety</td>
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<td></td>
<td>• Basic airway resuscitation equipment (e.g. pocket mask, bag valve mask, supraglottic airway)</td>
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<tr>
<td></td>
<td>• Immediate access to Epinephrine (Adrenaline) 1 in 1000 injection</td>
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<tr>
<td></td>
<td>• Access to a working telephone</td>
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<td></td>
<td>• Another competent adult, who can summon urgent emergency support if required should ideally be present</td>
</tr>
<tr>
<td></td>
<td>• Access to medical support (this may be via the telephone)</td>
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<tr>
<td></td>
<td>• Approved equipment for the disposal of used materials</td>
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<tr>
<td></td>
<td>• Clean and tidy work areas, including access to hand washing facilities or alcohol hand gel</td>
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<tr>
<td></td>
<td>• A copy of this PGD in print or electronically.</td>
</tr>
</tbody>
</table>

**Characteristics of staff authorised to administer vaccine under PGD**

<table>
<thead>
<tr>
<th>Professional qualifications</th>
<th>Registered Nurses as recognised by the Nursing and Midwifery Council (NMC).</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specialist competencies</td>
<td>Approved by the organisation as:</td>
</tr>
<tr>
<td></td>
<td>• Competent to assess the individual’s capacity to understand the nature and purpose of vaccination in order to give or refuse consent</td>
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<td></td>
<td>• Competent to undertake administration of the vaccine and discuss issues related to vaccination</td>
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<tr>
<td></td>
<td>• Competent in the handling and storage of vaccines, and management of the “cold chain”</td>
</tr>
<tr>
<td></td>
<td>• Competent to work under this PGD.</td>
</tr>
</tbody>
</table>
### Ongoing training and competency

**All professionals working under this PGD must:**

- Have undertaken PGD training as required/set out by each individual Health Board
- Have undertaken immunisation training where available
- Have attended basic life support training which is required to be updated annually
- Have undertaken NHS e-anaphylaxis training or equivalent (including annual updates) which covers all aspects of the identification and management of anaphylaxis
- Maintain their skills, knowledge and their own professional level of competence in this area according to their Code of Professional Conduct
- Have knowledge and familiarity of the following:
  - Current edition of the [Green Book](#)
  - [SmPC](#) for the vaccine to be administered in accordance with this PGD
  - Relevant policy relating to vaccine storage and immunisation procedures for use within their Health Board
  - Relevant Scottish Government Health Directorate advice including the relevant CMO letter(s).

### Responsibilities of professional manager(s)

**Professional manager(s) will be responsible for:**

Ensuring that the current PGD is available to all staff providing care under this direction.

Ensuring that staff have received adequate training in all areas relevant to this PGD and meet the requirements above.

Maintain up to date record of all staff authorised to administer the vaccine specified in this direction.

### Documentation

#### Authorisation of administration

Nurses working within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles can be authorised to administer the vaccine specified in this PGD by their Professional Line Manager/Consultant/Practice GP.

All authorised staff are required to read the PGD and sign the Agreement to Administer Medicines Under PGD (Appendix 1).

A Certificate of Authorisation (Appendix 2) signed by the authorising professional/manager should be supplied. This should be held in the individual health professional's records, or as agreed within the individual Health Board.
### Record of administration

An electronic or paper record for recording the screening of individuals and the subsequent administration, or not of the vaccine specified in this PGD must be completed in order to allow audit of practice. This should include as a minimum:

- Date and time of vaccine administration
- Individuals name and CHI
- Exclusion criteria, record why the vaccine was not administered (if applicable)
- Record that valid consent to treatment under this PGD was obtained
- The name, brand, dose, form, batch number, expiry date, route/site of the vaccination administered
- Advice given, including advice given if excluded or declined treatment under this PGD
- Signature and name in capital letters of the healthcare professional who administered the vaccine
- Record of any adverse effects (advise individuals GP/relevant medical practitioner).

Depending on the clinical setting where administration is undertaken, the information should be recorded manually or electronically on the individual service specific system, as appropriate.

- Consent forms
- Secondary Care Medical Notes
- Individual’s GP records if appropriate
- Individual service specific systems.

### Audit

All records of the vaccine specified in this PGD will be filed with the normal records of medicines in each practice/service. A designated person within each practice/service where the PGD will be used will be responsible for annual audit to ensure a system of recording medicines administered under a PGD.

### References


| | Immunisation against Infectious Disease [Green Book] chapter 28a shingles (herpes zoster)

Appendix 1

Healthcare Professional Agreement to Administer Vaccine Under Patient Group Direction

I: ____________________________________________ (Insert name)

Working within: ________________________________ e.g. Area, Practice

Agree to administer the vaccine contained within the following Patient Group Direction:

Patient Group Direction For The Administration Of Shingles (Herpes Zoster) Vaccine (Live) Zostavax® By Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside And Western Isles

I have completed the appropriate training to my professional standards enabling me to administer the vaccine under the above direction. I agree not to act beyond my professional competence, nor out with the recommendations of the direction.

Signed: __________________________________________________________________________

Print Name: _______________________________________________________________________

Date: ____________________________________________________________________________

Profession: ________________________________________________________________________

Professional Registration number/PIN _______________________________________________________________________

Appendix 2

Healthcare Professionals Authorisation to Administer Vaccine Under Patient Group Direction

<table>
<thead>
<tr>
<th>The Lead manager/Professional</th>
<th>of each clinical area is responsible for maintaining records of all clinical areas where this PGD is in use, and to whom it has been disseminated.</th>
</tr>
</thead>
<tbody>
<tr>
<td>The Senior Nurse/Professional</td>
<td>who approves a healthcare professional to administer the vaccine under this PGD is responsible for ensuring that he or she is competent, qualified and trained to do so, and for maintaining an up-to-date record of such approved persons.</td>
</tr>
<tr>
<td>The Healthcare Professional</td>
<td>that is approved to administer the vaccine under this PGD is responsible for ensuring that he or she understands and is qualified, trained and competent to undertake the duties required. The approved person is also responsible for ensuring that administration is carried out within the terms of the direction, and according to his or her individual code of professional practice and conduct.</td>
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Patient Group Direction For The Administration Of Shingles (Herpes Zoster) Vaccine (Live) Zostavax® By Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside And Western Isles

Local clinical area(s) where the listed healthcare professionals will operate under this PGD:

<table>
<thead>
<tr>
<th>Name of Healthcare Professional</th>
<th>Signature</th>
<th>Date</th>
<th>Name of Manager</th>
<th>Signature</th>
<th>Date</th>
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