

Patient Group Direction For The Administration Of DTaP/IPV/Hib/HepB (Hexavalant) Vaccine By Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside And Western Isles

| Lead Author: Adapted from Public Health Scotland Administration of | Approver: NoS PGD Group |
|--|--------------------------------|
| DTaP/IPV/Hib/HepB vaccine Patient group direction (PGD) template Version 4.1 – PHS Publication date 1 st March 2024 | Authorisation: NHS Grampian |

| Signature: |
|------------|
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| NoS Identifier: NoS/PGD/Hexavalent/1458 | Review Date: 28 th February 2026 | Date Approved by NoS: 26th July 2024 |
|--|--|--------------------------------------|
| | Expiry Date: 28 th February 2026 | |

NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles 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 4.1

Revision History for NoS:

| NoS PGD that has | NoS/PGD/Hexavalent/1285, version 2.1 – Version 4.0 |
|------------------|--|
| superseded | unpublished |

Most recent changes NoS

| Version | Date of change | Summary of Changes | Section heading |
|---------|----------------|------------------------------------|-----------------------------------|
| 4.1 | March 2024 | Reference to NoS Appendix 1 and 2. | Authorisation |
| | | Training requirements for NoS. | Continuing education and training |
| 4.1 | July 2024 | Tayside only statements removed | Inclusion and frequency |

PHS recent changes

| Version | Date | Summary of changes |
|---------|--------------|--|
| 4.1 | 1 March 2024 | The following changes to version 4.0 of the PGD have been made: Inclusion criteria, frequency, is the use outwith the SmPC and additional reference sections updated to include reference to the Scottish Haematology Society schedule for the revaccination of individuals following haematopoietic stem cell transplant or CAR-T treatment. Observation following vaccination section updated to |
| | | include advice on driving post-immunisation. |

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.

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Patient Group Direction For Use Within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western isles

Authorisation

This specimen Patient Group Direction (PGD) template has been produced by Public Health Scotland and adapted by North of Scotland PGD Group (NoS) to assist NHS Boards. NHS Boards should ensure that the final PGD is considered and approved in line with local clinical governance arrangements for PGDs.

The qualified health professionals who may administer vaccine under this PGD can only do so as named individuals. It is the responsibility of each professional to practice within the bounds of their own competence and in accordance with their own Code of Professional Conduct and to ensure familiarity with the manufacturer's product information/Summary of Product Characteristics (SmPC) for all vaccines administered in accordance with this PGD.

NHS Board governance arrangements will indicate how records of staff authorised to operate this PGD will be maintained. Under PGD legislation there can be no delegation. Administration of the vaccine has to be by the same practitioner who has assessed the patient under the PGD.

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

A Certificate of Authorisation (<u>Appendix 2</u>) 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.

| This PGD h | as been produced | for NoS by: | | | |
|------------|------------------|-------------|-----------------|-------------|------------|
| Doctor | Dr Susan Laidlaw | Signature | S. Ceid | Date Signed | 02/07/2024 |
| Pharmacist | Findlay Hickey | Signature | tilles M. Likey | Date Signed | 19/06/2024 |
| Nurse | Pauline Merchant | Signature | Alland | Date Signed | 01/05/2024 |

Approved for use within NoS by:

| NoS Group Chair | Signature | Date Signed |
|-----------------|-----------|-------------|
| Lesley Coyle | -785 | 23/07/2024 |

Authorised and executively signed for use within NoS by:

| NHS Grampian Chief Executive | Signature | Date Signed |
|---|-----------|-------------|
| Adam Coldwells – Interim Chief Executive | Amus | 26/07/2024 |

Version 4.1 – Approved for NoS from 26th July 2024

1. Clinical situation

1.1 Indication

Active immunisation against diphtheria, tetanus, pertussis, poliomyelitis, Haemophilus influenzae type b and hepatitis B.

1.2 Inclusion criteria

Individuals from 6 weeks of age to under 10 years of age requiring primary vaccination as part of the routine immunisation schedule.

Individuals who have uncertain or incomplete primary vaccine history.

Individuals who have received a haematopoietic stem cell transplant or CAR-T therapy and who require revaccination, in accordance with the <u>Scottish Haematology</u> <u>Society Revaccination Schedule</u>.

Valid consent has been given to receive the vaccine.

1.3 Exclusion criteria

Individuals who:

- Are infants less than 6 weeks of age.
- Are individuals aged 10 years or above.
- Have had a confirmed anaphylactic reaction to a previous dose of Infanrix[®]-hexa or Vaxelis[®] vaccine.
- Have had a confirmed anaphylactic reaction to a previous dose of diphtheria, tetanus, pertussis, poliomyelitis, Haemophilus influenzae type b or hepatitis B containing vaccine, including any conjugate vaccines where diphtheria or tetanus toxoid is used in the conjugate.
- Have had a confirmed anaphylactic reaction to any component of the vaccine, including glutaraldehyde, formaldehyde, neomycin and polymyxin, streptomycin and bovine serum albumin. Practitioners must check the marketing authorisation holder's SmPC for details of vaccine components.
- Have received immunisation with combined diphtheria, tetanus, pertussis, poliomyelitis, Haemophilus influenza type b and hepatitis B containing vaccine in the preceding 3 weeks (there is no minimum gap required between DTaP/IPV/Hib/HepB vaccine and a previous dose of monovalent hepatitis B vaccine).
- Have a history of severe (i.e. anaphylactic reaction) to latex where the vaccine is not latex free.
- Are suffering from acute severe febrile illness (the presence of a minor infection is not a contraindication for immunisation).

1.4 Cautions/need for further advice/ circumstances when further advice should be sought from a doctor

The Green Book advises that there are very few individuals who cannot receive DTaP/IPV/Hib/HepB vaccine. Where there is doubt, rather than withholding vaccination, appropriate advice should be sought from the relevant specialist, or from the local immunisation or health protection team.

The presence of a neurological condition is not a contraindication to immunisation but if there is evidence of current neurological deterioration, deferral of vaccination may be considered, to avoid incorrect attribution of any change in the underlying condition. The risk of such deferral should be balanced against the risk of the preventable infection, and vaccination should be promptly given once the diagnosis and/or the expected course of the condition becomes clear.

If a child has experienced encephalopathy or encephalitis within 7 days of a previous immunisation with a pertussis-containing vaccine, it is unlikely these conditions will have been caused by the vaccine and they should have been investigated by a specialist. If a cause was identified or the child recovered within 7 days, immunisation should proceed as recommended. In children where no underlying cause was found and the child did not recover completely within 7 days, immunisation should be deferred until the condition has stabilized or the expected course of the condition becomes clear. If the child has not been investigated by a specialist, then immunisation should be deferred until a specialist opinion is obtained.

If a seizure associated with a fever occurred within 72 hours of a previous immunisation with any component of the vaccine, immunisation should continue as recommended if a cause is identified or the child recovers within 24 hours. However, if no underlying cause has been found and the child did not recover completely within 24 hours, further immunisation should be deferred until the condition is stable.

Co-administration of other vaccines

DTaP/IPV/Hib/HepB vaccine can be given at the same time as the other vaccines administered as part of the childhood immunisation programme including BCG. If the vaccine is given in the same limb as other vaccines, 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.

Syncope

Syncope (fainting) can occur following, or even before, any vaccination especially in adolescents as a psychogenic response to the needle injection. This can be accompanied by several neurological signs such as transient visual disturbance, paraesthesia and tonic-clonic limb movements during recovery. It is important that procedures are in place to avoid injury from faints.

1.5 Action if excluded

Specialist advice must be sought on the vaccine and circumstances under which it could be given. Immunisation using a patient specific direction may be indicated. The risk to the individual of not being immunised must be taken into account.

Document the reason for exclusion and any action taken in accordance with local procedures.

Inform or refer to the clinician in charge.

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

If aged less than 6 weeks advise to return for routine immunisation when the child is eight weeks old or over and give an appropriate appointment. Immunisation can be administered from six weeks of age if required, e.g. if travelling to an endemic country or at increased risk of hepatitis B virus and dose of Hep B vaccine is due.

If aged 10 years or over, assess for immunisation with Td/IPV as appropriate.

1.6 Action if patient declines

Advise the individual/parent/carer about the protective effects of the vaccine, the risks of infection and potential complications of disease.

Advise how future immunisation may be accessed if they subsequently decide to receive the vaccine.

Document advice given and decision reached.

Inform or refer to the clinician in charge.

2. Description of treatment

2.1 Name of medicine/form/strength

Diphtheria/tetanus/acellular pertussis/inactivated polio vaccine/H. influenzae type b/Hepatitis B (DTaP/IPV/Hib/HepB) vaccine, either:

DTaP/IPV/Hib/HepB vaccine, Hib powder and DTaP/IPV/HepB suspension for injection (Infanrix $^{\mbox{\tiny B}}$ -hexa).

DTaP/IPV/Hib/HepB vaccine suspension for injection (Vaxelis[®]).

2.2 Route of administration

DTaP/IPV/Hib/HepB vaccines should be administered by intramuscular (IM) injection preferably into the anterolateral aspect of the thigh in infants under 1 year of age. The deltoid region of the upper arm may be used in individuals over 1 year of age. Where administration into the deltoid is not possible the anterolateral thigh can be considered.

Patients with known bleeding disorders should receive the vaccine by deep subcutaneous route to reduce the risk of bleeding. However, the SmPC for Vaxelis[®] states that the Vaxelis[®] should only be administered by intramuscular injection. Therefore, where a deep subcutaneous injection is required, use Infanrix[®]-hexa.

If the only available vaccine is Vaxelis[®], 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.

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. If the individual receives medication/treatment to reduce bleeding, for example treatment for haemophilia, intramuscular vaccination can be scheduled shortly after such medication/treatment is administered. 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/parent/carer should be informed about the risk of haematoma from the injection.

The vaccine should be visually inspected for particulate matter and discoloration prior to administration. In the event of any foreign particulate matter and/or variation of physical aspect being observed, do not administer the vaccine.

2.3 Dosage

0.5mL

2.4 Frequency

The course consists of three doses with a recommended interval of at least 4 weeks between the doses, although one of these doses may be given up to one week early when required e.g. due to impending travel to an endemic country. No more than one dose should be given early in the three-dose schedule.

The routine childhood immunisation schedule recommends doses as follows:

- First primary immunisation at 8 weeks*.
- Second primary immunisation at 12 weeks.
- Third primary immunisation at 16 weeks.

*The first dose of primary immunisations can be given at 6 weeks of age if required in certain circumstances, e.g. travel to an endemic country.

If the primary course is interrupted it should be resumed but not repeated, allowing an interval of at least four weeks between the remaining doses.

Those individuals with uncertain or incomplete immunisation status should be vaccinated in accordance with the vaccination of individuals with uncertain or incomplete immunisation status flow chart.

Revaccination of individuals who have received a haemopoietic stem cell transplant or CAR-T treatment

In accordance with the schedule recommended by the Scottish Haematology Society <u>Revaccination of patients following haematopoietic stem cell transplant or CAR-T</u> <u>treatment</u>.

2.5 **Duration of treatment**

See frequency section.

2.6 Maximum or minimum treatment period

See frequency section.

2.7 Quantity to supply/administer

Single 0.5mL dose per administration.

2.8 ▼ black triangle medicines

No.

2.9 Legal category

Prescription only medicine (POM).

2.10 Is the use outwith the SmPC?

Administration of Infanrix[®]-hexa to individuals born before 24 weeks of gestational age and to individuals over 3 years of age is off label but is indicated until 10 years of age under this PGD in accordance with the Green Book recommendations.

Administration of DTaP/IPV/Hib/HepB to individuals who experienced an encephalopathy of unknown cause occurring within 7 days following previous vaccination with pertussis-containing vaccine is off-label. Individuals may be vaccinated under this PGD once the condition has stabilized or the expected course

of the condition becomes clear (see cautions), in line with the recommendations in the associated chapters of 'The Green Book'.

Administration by deep subcutaneous injection to individuals with a bleeding disorder is off-label administration in line with advice in Green Book <u>Chapter 4</u>.

Revaccination of individuals following haematopoietic stem cell transplant of CAR-T treatment is considered off-label but is in accordance with the <u>Scottish Haematology</u> <u>Society schedule.</u>

Vaccine should be stored according to the conditions detailed in the Storage section below. However, in the event of an inadvertent or unavoidable deviation of these conditions refer to NHS Board guidance on the storage and handling of vaccines or National Vaccine Incident Guidance. Where vaccine is assessed in accordance with these guidelines as appropriate for continued use this would constitute off-label administration under this PGD.

2.11 Storage requirements

General requirements

Vaccine should be stored at a temperature of +2° to +8°C.

Do not freeze.

During storage it is recommended that the vials are stored in the original packaging/cartons, away from direct sunlight to protect from light and kept upright.

NHS Board guidance on Storage and Handling of vaccines should be observed.

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 use or appropriate disposal.

2.12 Additional information

Minor illnesses without fever or systemic upset are not valid reasons to postpone immunisation. If an individual is acutely unwell, immunisation should be postponed until they have fully recovered.

Very premature infants (born less than or equal to 28 weeks of gestation) who are in hospital should have respiratory monitoring for 48 to 72 hours when given their first routine immunisations, particularly those with a previous history of respiratory immaturity. If the child has apnoea, bradycardia or desaturations after the first routine immunisations, the second immunisation should also be given in hospital, with respiratory monitoring for 48 to 72 hours.

The immunogenicity of the vaccine could be reduced in immunosuppressed individuals. However, vaccination should proceed in accordance with national recommendations.

Infants born to a hepatitis B surface antigen positive mother will require additional doses of paediatric hepatitis B vaccine at 0 and 4 weeks of age and at 12 months.

3. Adverse reactions

3.1 Warnings including possible adverse reactions and management of these

Fever, and pain, swelling or redness at the injection site commonly occurs and are seen more frequently following subsequent doses. A small, painless nodule may form at the injection site; this usually disappears and is of no consequence. Other common adverse reactions include fever, abnormal crying, irritability, restlessness, appetite loss, fatigue, diarrhoea, vomiting and nervousness.

Studies have shown that when hepatitis B vaccine is added to DTaP/IPV/Hib vaccine, the frequency and type of adverse reactions experienced are similar to those seen when the DTaP/IPV/Hib vaccine is given alone or with monovalent hepatitis B vaccine.

Hypersensitivity reactions, such as bronchospasm, angioedema, urticaria, and anaphylaxis can occur but are very rare and facilities for its management must be available.

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

In the event of a severe adverse reaction individuals should be advised to seek medical advice.

For full details/information on possible adverse reaction, refer to manufacturer's product literature or SmPC.

3.2 Reporting procedure for adverse reactions

Healthcare professionals and individuals/carers should report all suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on <u>http://www.mhra.gov.uk/yellowcard.</u>

Any adverse reaction to a vaccine should be documented in accordance with locally agreed procedures in the individual's record and the individual's GP should be informed.

3.3 Advice to patient or carer including written information

Written information to be given to individual:

- Provide manufacturer's consumer information leaflet/patient information leaflet (PIL) provided with the vaccine.
- Supply immunisation promotional material as appropriate.

Individual advice / follow up treatment:

- Inform the individual/parent/carer of possible side effects and their management.
- When applicable, advise parent/carer when the subsequent dose is due.
- Complete certificate of vaccination, if required.
- The individual should be advised to seek medical advice in the event of a severe adverse reaction.
- Immunosuppressed individuals should be advised that they may not make a full immune response to the vaccine and they should continue to take appropriate measures to protect themselves against this infection.
- Inform the individual that they can report suspected adverse reactions to the MHRA using the Yellow Card reporting scheme on: <u>http://www.mhra.gov.uk/yellowcard</u>
- When administration is postponed advise the individual how future vaccination may be accessed.

3.4. Observation following vaccination

As syncope (fainting) can occur following vaccination, all vaccinees should either be driven by someone else or should not drive for 15 minutes after vaccination.

Following immunisation, patients remain under observation in line with NHS Board policy.

3.5. Follow up

See frequency section.

3.6. Additional facilities

A protocol for the management of anaphylaxis and an anaphylaxis pack must always be available whenever vaccines are given. Immediate treatment should include early treatment with intramuscular adrenaline, with an early call for help and further IM adrenaline every 5 minutes.

The health professionals overseeing the immunisation service must be trained to recognise an anaphylactic reaction and be familiar with techniques for resuscitation of a patient with anaphylaxis.

4. Characteristics of staff authorised under the PGD

4.1 **Professional qualifications**

The following classes of registered healthcare practitioners are permitted to administer this vaccine:

- Nurses and midwives currently registered with the Nursing and Midwifery Council (NMC).
- Pharmacists currently registered with the General Pharmaceutical Council (GPhC).
- Chiropodists/podiatrists, dieticians, occupational therapists, orthoptists, orthotists/prosthetists, paramedics, physiotherapists, radiographers and speech and language therapists currently registered with the Health and Care Professions Council (HCPC).
- Dental hygienists and dental therapists registered with the General Dental Council.
- Optometrists registered with the General Optical Council.

4.2. Specialist competencies or qualifications

Persons must only work under this PGD where they are competent to do so. All persons operating this PGD:

- Must demonstrate appropriate knowledge and skills to work under this PGD.
- Must be authorised by name by their employer as an approved person under the current terms of this PGD before working to it.
- Must be familiar with the vaccine product and alert to changes in the manufacturer's product information/summary of product characteristics information.
- Must be competent to undertake immunisation and to discuss issues related to immunisation to assess patients for vaccination and obtain consent.
- Must be competent in the correct storage of vaccines and management of the cold chain if receiving, responsible for, or handling the vaccine.
- Must be competent in the recognition and management of anaphylaxis or under the supervision of persons able to respond appropriately to immediate adverse reactions.
- Must have access to the PGD and associated online resources.
- Should fulfil any additional requirements defined by local policy.

Employer

- The employer is responsible for ensuring that persons have the required knowledge and skills to safely deliver the activity they are employed to provide under this PGD.
- As a minimum, competence requirements stipulated in the PGD must be adhered to.

4.3 **Continuing education and training**

All practitioners operating under the PGD are responsible for ensuring they remain up to date with the use of vaccines included. If any training needs are identified these should be discussed with the individuals in the organisation responsible for authorising individuals to act under this PGD.

- Have undertaken NoS PGD module training on <u>TURAS Learn</u>
- Have attended basic life support training either face to face or online and updated in-line with individual Board requirements.
- Have undertaken immunisation training where available.
- Have undertaken NHS e-anaphylaxis training or equivalent which covers all aspects of the identification and management of anaphylaxis updated in-line with individual Board requirements.
- Maintain their skills, knowledge and their own professional level of competence in this area according to their individual Code of Professional Conduct.

5. Audit trail

Record the following information:

- valid informed consent was given
- name of individual, address, date of birth and GP with whom the individual is registered if possible
- name of person that undertook assessment of individual's clinical suitability and subsequently administered the vaccine
- name and brand of vaccine
- date of administration
- dose, form and route of administration of vaccine
- batch number
- where possible 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
- administered under PGD.

Records should be kept in line with local procedures.

Local policy should be followed to encourage information sharing with the individual's General Practice.

All records should be clear, legible and contemporaneous and in an easily retrievable format.

6. Additional references

Practitioners operating the PGD must be familiar with:

• Immunisation against Infectious Disease [Green Book].

- Professional Guidance on the Safe and Secure Handling of Medicines
- <u>Professional Guidance on the Administration of Medicines in Healthcare Settings</u> 2019
- <u>Educational resources for registered professionals produced by National</u> <u>Education for Scotland</u>
- Marketing authorisation holder's Summary of Product Characteristics
- <u>Scottish Haematology Society advice on the revaccination of patients following</u>
 <u>haematopoietic stem cell transplant or CAR-T treatment</u>

7. PHS Version history

| Version | Date | Summary of changes |
|---------|--------------------|--|
| 1.0 | July 2017 | Version 1.0 New PGD |
| 2.0 | March 2019 | This PGD has undergone minor rewording, layout, formatting changes for clarity and consistency with other PHS national specimen PGDs |
| 3.0 | 1 December 2021 | Version 3.0 produced following expiry of Version 2.0 This PGD has undergone minor rewording, layout, formatting changes for clarity and consistency with other PHS national specimen PGDs. The following changes have been made: Cautions section updated to include information on encephalopathy or encephalitis within 7 days of a previous immunisation with a pertussis-containing vaccine or a seizure associated with a fever occurred within 72 hours of a previous immunisation with any component of the vaccine. Use outwith SmPC section updated to include administration to individuals born before 24 weeks of gestational age and to individuals who experienced an encephalopathy of unknown cause occurring within 7 days following previous vaccination with pertussis-containing vaccine. Use out-with SmPC section updated to include administration of Vaxelis[®] to individuals over 15 months of age. Exclusion criteria updated to include anaphylaxis of components of Vaxelis[®] vaccine. Name of medicine section updated to include Vaxelis[®] vaccine. Route of administration section updated to include Vaxelis[®] vaccine to be given by IM injection only. Adverse reactions section updated to include other common adverse effects. |
| 4.0 | 1 December 2023 | This PGD has undergone minor rewording, layout, formatting changes for clarity and consistency with other PHS national specimen PGDs. Updated section 2.10: Is the use outwith the SmPC to align with updates to SmPC. |

| 4.1 | 1 March 2024 | The following changes to version 4.0 of the PGD have been made: |
|-----|-----------------|--|
| | | Inclusion criteria, frequency, is the use outwith the SmPC and additional reference sections updated to include reference to the Scottish Haematology Society schedule for the revaccination of individuals following haematopoietic stem cell transplant or CAR-T treatment. Observation following vaccination section updated to include advice on driving post-immunisation. |

NoS Version History

| Version | Date of change | Summary of Changes | Section heading |
|---------|--------------------------------|--|-----------------------------------|
| 4.0 | December 2023 (Unpublished) | Reference to NoS Appendix 1 and 2. | Authorisation |
| | | Training requirements for NoS | Continuing education and training |
| | | Children requiring booster post chemotherapy (NHST only) added. | Inclusion criteria |
| | | Further information added in regard to NHST only inclusion for post chemotherapy boosters. | Frequency |
| 4.1 | March 2024 | Reference to NoS Appendix 1 and 2. | Authorisation |
| | | Training requirements for NoS. | Continuing education and training |
| 4.1 | July 2024 | Tayside only statements removed | Inclusion and frequency |



Appendix 1 - Healthcare Professional Agreement to Administer Medicine(s) Under Patient Group Direction

| l: | (Insert name) |
|----|---------------|
| | |

Working within: e.g. Area, Practice

Agree to administer the medicine(s) contained within the following Patient Group Direction:

Patient Group Direction For The Administration Of DTaP/IPV/Hib/HepB (Hexavalant) Vaccine By Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside And Western Isles, Version 4.1

I have completed the appropriate training to my professional standards enabling me to administer the medicine(s) 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 Medicine(s) Under Patient Group Direction

The Lead manager/Professional 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.

The Senior Nurse/Professional who approves a healthcare professional to administer the medicine(s) under this PGD is responsible for ensuring that they are competent, qualified and trained to do so, and for maintaining an up-to-date record of such approved persons.

The Healthcare Professional that is approved to administer the medicine(s) under this PGD is responsible for ensuring that they understand and are 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 their individual code of professional practice and conduct.

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

| Name of Healthcare Professional | Signature | Date | Name of Manager | Signature | Date |
|---------------------------------------|-----------|------|--------------------|-----------|------|
| | | | | | |
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|---------------------------------------|-----------|------|--------------------|-----------|------|
| Name of Healthcare Professional | Signature | Date | Name of Manager | Signature | Date |
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