Patient Group Direction For The Administration Of Gardasil® Human Papillomavirus Vaccine (HPV) [Types 6, 11, 16, 18] (Recombinant, Adsorbed) By Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside And Western Isles

<table>
<thead>
<tr>
<th>Lead Author:</th>
<th>Consultation Group:</th>
<th>Approver:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medicines Management Specialist Nurse NHSG</td>
<td>See relevant page in the PGD</td>
<td>NoS PGD Group</td>
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<tr>
<td></td>
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<td>Authorisation:</td>
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<td></td>
<td>NHS Grampian</td>
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<thead>
<tr>
<th>NoS Identifier:</th>
<th>Review Date:</th>
<th>Date Approved:</th>
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<tbody>
<tr>
<td>NoS/PGD/Gardasil/ MGPG1015</td>
<td>March 2021</td>
<td>March 2019</td>
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<td>Expiry Date:</td>
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<td>March 2022</td>
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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 1.2 (Amended February 2020)
## Revision History:

<table>
<thead>
<tr>
<th>Date of change</th>
<th>Summary of Changes</th>
<th>Section heading</th>
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<tbody>
<tr>
<td>November 2018</td>
<td>NHSG 880 &amp; 844 PGDs amalgamated and NHSH, NHST and NHSWI added to PGD.</td>
<td>Throughout</td>
</tr>
<tr>
<td>March 2019</td>
<td>Child protection information added.</td>
<td>Inclusion criteria</td>
</tr>
<tr>
<td>August 2019</td>
<td>New HPS PGD released, NoS PGD amended according to changes in the National PGD as detailed below.</td>
<td>Throughout</td>
</tr>
<tr>
<td>August 2019</td>
<td>Inclusion criteria updated to reflect inclusion of males in immunisation programme in schools.</td>
<td>Inclusion criteria</td>
</tr>
<tr>
<td>August 2019</td>
<td>Inclusion criteria updated to reflect the policy change to include individuals up to age 25 years.</td>
<td>Inclusion criteria</td>
</tr>
<tr>
<td>August 2019</td>
<td>Age range amended to 11-13 years for vaccination from school year S1.</td>
<td>Inclusion criteria</td>
</tr>
<tr>
<td>August 2019</td>
<td>Age increased from 13 to 14 years in accordance with changes to SmPC and release of HPS National PGD.</td>
<td>Legal status</td>
</tr>
<tr>
<td>August 2019</td>
<td>Additional statement added in regard to off-label use in the case of the potential use of vaccines out with stated storage conditions, as included in HPS National PGD.</td>
<td>Storage Requirements</td>
</tr>
<tr>
<td>August 2019</td>
<td>Wording of 3rd bullet point amended to allow clearer interpretation.</td>
<td>Inclusion criteria</td>
</tr>
<tr>
<td>February 2020</td>
<td>The term ‘females’ replaced with individuals in the second bullet point.</td>
<td>Inclusion Criteria</td>
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</table>

**NoS Identifier:** NoS/PGD/Gardasil/MGPG1015  
**Keyword(s):** PGD Patient Group Direction nurses HPV human papillomavirus gardasil vaccine 6 11 16 18 recombinant men sex
Policy Statement: It is the responsibility of 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.
Organisational Authorisations

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

PGD Developed/Reviewed by;

| Medical Practitioner | Name: Dr Louise Wilson  
Health Board: NHSO  
Title: Director of Public Health  
Contact email: louise.wilson2@nhs.net  
Signature ................................ |
|----------------------|--------------------------------------------------|
| Senior Representative of the professional group who will provide care under the direction | Name: Fiona Browning  
Health Board: NHSG  
Title: Health Protection Specialist Nurse  
Contact email: fiona.browning@nhs.net  
Signature ................................ |
| Lead Author | Name: Frances Adamson  
Health Board: NHSG  
Title: Medicines Management Specialist Nurse  
Contact email: f.adamson@nhs.net  
Signature ................................ |
| Pharmacist | Name: Liz Kemp  
Health Board: NHSG  
Title: Principal Pharmacist  
Contact email: e.kemp@nhs.net  
Signature ................................ |
Patient Group Direction For Use Within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles

Approved for use within NoS Boards by;

<table>
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<tr>
<th>North of Scotland (NoS) PGD Group Chair</th>
<th>Signature</th>
<th>Date Signed</th>
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<tr>
<td>Lesley Thomson</td>
<td></td>
<td>March 2019</td>
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Authorised and executively signed for use within NoS Boards by;

<table>
<thead>
<tr>
<th>NHS Grampian Chief Executive</th>
<th>Signature</th>
<th>Date Signed</th>
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<tr>
<td>Professor Amanda Croft</td>
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<td>March 2019</td>
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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.

Frances Adamson  Lead Author: Medicines Management Specialist Nurse, NHSG
Dr Louise Wilson  Medical Professional: Director of Public Health, NHSO
Liz Kemp          Pharmacist: Principal Pharmacist, NHSG
Fiona Browning    Senior Representative: Health Protection Nurse Specialist, NHSG
Dr Ambreen Butt   Consultant Sexual Health and HIV, NHSG
Susan Caldwell    Senior Medicines Information Pharmacist, NHSH
Tina McMichael    Advanced Nurse Specialist (Health Protection), NHST
Lorraine McKee    Health Protection Nurse Specialist, NHSH
Patient Group Direction For The Administration Of Gardasil® Human Papillomavirus Vaccine (HPV) [Types 6, 11, 16, 18] (Recombinant, Adsorbed) By Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside And Western Isles

Clinical indication to which this PGD applies

| Definition of situation/Condition | 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 Gardasil® Human Papillomavirus Vaccine (HPV) [Types 6, 11, 16, 18] (recombinant, adsorbed) in line with the Scottish Government Health Directorate HPV immunisation programme.

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 Chapter 18a, TRAVAX, NaTHNaC and the individual Summary of Product Characteristics (SmPC). |
| Inclusion criteria | • Individuals aged 11 years to under 25 years of age
• Individuals from school year S1, aged around 11-13 years, including those not in school (although licensed for individuals aged 9 years, for the purposes of the Immunisation Programme, Gardasil® is recommended as listed in this inclusion)
• Individuals from eligible cohorts who do not commence HPV immunisation in S1 remain eligible until they reach 25 years of age
• Men who have Sex with other Men (MSM) aged up to and including 45 years of age attending sexual health or HIV clinics
• Prisoners up to and including 45 years of age who identify as MSM.

N.B. Child protection procedures should be followed for individuals under the age of 16 who report engaging in sexual activity as per each individual Boards policy/protocol.

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 | Individuals:
• 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 |
• Who are pregnant
• Where there is no valid consent.

Precautions and special warnings

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.

**Individuals with a Bleeding Disorder** - An individual risk assessment should be undertaken prior to vaccination. As with any intramuscular (IM) vaccination, the injection should be given with caution to individuals with thrombocytopenia or any coagulation disorder, as bleeding may occur following IM administration. Therefore, individuals with known bleeding disorders or taking anticoagulant therapy should receive the vaccine by deep subcutaneous injection route to reduce the risk of bleeding. Individuals should be informed of the risk of developing haematoma and what to do if this occurs.

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. Patient Information Leaflet (PIL) available to print here. Document advice given and decision reached.

Inform/refer to the relevant medical practitioner if individual/person with parental responsibility declines treatment.

Document refusal, advice given and if possible the reason for refusal in appropriate clinical records.
### Description of vaccine available under the PGD

<table>
<thead>
<tr>
<th>Name form and strength of vaccine</th>
<th>Gardasil® Human Papillomavirus Vaccine (HPV) [Types 6, 11, 16, 18] (Recombinant, adsorbed) suspension for injection in a pre-filled syringe. 1 dose (0.5 mL) contains approximately:</th>
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<tr>
<td></td>
<td>Human Papillomavirus Type 6 L1 protein 20 micrograms</td>
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<tr>
<td></td>
<td>Human Papillomavirus Type 11 L1 protein 40 micrograms</td>
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<tr>
<td></td>
<td>Human Papillomavirus Type 16 L1 protein 40 micrograms</td>
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<tr>
<td></td>
<td>Human Papillomavirus Type 18 L1 protein 20 micrograms.</td>
</tr>
<tr>
<td>Legal status</td>
<td>Gardasil® Vaccine is a Prescription-only Medicine (PoM). <strong>N.B.</strong> The administration of this vaccine by subcutaneous injection to individuals with a bleeding disorder is outside the terms of the marketing authorisation and constitutes an off-label use of the vaccine. However, the use of the vaccine in this way is in-line with recommendations in the Green Book Chapter 4. The individual or the person with parental responsibility should be informed prior to the administration that the use is off-label. The SmPC for Gardasil® states the two dose schedule should be used in individuals 9 years of age up to and including 14 years of age. This is superseded by Scottish Government policy based on JCVI recommendation/advice in Green Book. (See Frequency of dose/Duration of treatment section below).</td>
</tr>
<tr>
<td>Dosage/Maximum total dose</td>
<td>Single dose of 0.5mL per administration. Maximum 2-3 doses dependent on age – see Frequency of dose/Duration of treatment section below.</td>
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| Frequency of dose/Duration of treatment | The frequency depends on the age the individual receives their first dose and whether the individual is immunocompromised at the time of vaccination. **Individuals aged below 15 years when receiving the first dose** The course consists of two doses;  
  - First dose.  
  - Second dose at least six months after the first dose. Both doses should ideally be given with a 24 month period. If the course is interrupted, it should be resumed but not repeated. |
Individuals aged 15 years or above receiving the first dose or individuals of any age who are known to be HIV positive (including those on antiretroviral therapy) or are immunocompromised at the time of vaccination

The course consists of three doses;
- First dose.
- Second dose at least one month after the first dose.
- Third dose at least three months after the second dose.

All three doses should be ideally given within a 12-month period. If the course is interrupted, it should be resumed but not repeated, ideally allowing the appropriate interval between the remaining doses.

There is no clinical data on whether the interval between doses two and three can be reduced below three months. Where the second dose is given late, and there is a high likelihood that the individual will not return for a third dose after three months, or if for practical reasons it is not possible to schedule a third dose within this time-frame, then a third dose of Gardasil® Vaccine can be given at least one month after the second dose.

Maximum or minimum treatment period
See Frequency of dose/Duration of treatment section above.

Route/Method of administration
Administration of Gardasil® Vaccine should be by Intramuscular (IM) Injection and the preferred site is the deltoid area of the upper arm. It can also be administered in the anterolateral area of the thigh.

This vaccine should not be given by the intravenous or intradermal routes under any circumstances.

Individuals with known bleeding disorders should receive the vaccine by deep subcutaneous route to reduce the risk of bleeding.

The vaccine's normal appearance is a clear liquid with a white precipitate prior to agitation. **Shake the prefilled syringe or reconstituted mixture well** to uniformly distribute the suspension to a cloudy white liquid before administering the vaccine. The reconstituted vaccine should be inspected visually for any foreign particulate matter and/or variation of physical aspect prior to administration. In the event of either being observed, do not use the vaccine.
When administering at the same time as other vaccines such as Td/IPV, MMR, influenza, Men ACWY and hepatitis B, care should be taken to ensure that the appropriate route of injection is used for all the vaccinations. The vaccines should be given when possible in different limbs to allow monitoring of local reactions to Gardasil®. If given in the same limb they should be given at different sites at least 2.5cm apart (American Academy of Paediatrics 2003). The site at which each vaccine was administered should be noted in the individual’s records.

<table>
<thead>
<tr>
<th>Quantity to be administered</th>
<th>0.5mL per dose for a maximum of three doses according to vaccination schedule. See Frequency of dose/Duration of treatment section above.</th>
</tr>
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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. Data from stability studies demonstrate that the vaccine components are stable for 72 hours when stored at temperatures from +8°C to +42°C. These data are intended to guide healthcare professionals in case of temporary temperature excursion only. This PGD may be used to administer vaccine that has not exceeded these stability data parameters. 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/person with parental responsibility what to expect and what to do for minor and major reactions.</td>
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</table>
If serious adverse or persistent effects occur, the individual/person with parental responsibility should be advised to contact their GP/Accident and Emergency department/NHS24.

When administration is postponed advise the individual/person with parental responsibility when to return for vaccination.

If appropriate, advise the individual/person with parental responsibility when subsequent doses are due and if any follow up is required.

### Advice (Written)

The PIL contained in the vaccine should be made available to the individual/person with parental responsibility. Where this is unavailable, or unsuitable, sufficient information should be given in a language that they can understand.

Provide/refer girls to national leaflet [A guide to the HPV vaccine](https://www.nhsinform.scot/healthy-living/immunisation).

If the individual is aged, 12 to under 18 years of age provide/refer to “What to expect after immunisation: Teenagers”.

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

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.

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 reactions commonly reported are headache, myalgia, fatigue and low grade fever.

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 BNFC/BNF and manufacturers SmPC for details of all potential adverse reactions.**

**BNFC/BNF:**
[https://www.bnf.org](https://www.bnf.org)
SmPC/PIL/Risk Minimisation Material:
https://www.medicines.org.uk/emc/
http://www.mhra.gov.uk/spc-pil/index.htm
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 or reactions to any ▼ vaccines using the MHRA using the Yellow Card System
https://yellowcard.mhra.gov.uk/.

Facilities and supplies required

The following are to be available at sites where the vaccine is to be administered:

- Pharmaceutical refrigerator (or a validated cool box for storing vaccine if mobile unit)
- An acceptable level of privacy to respect individual’s right to confidentiality and safety
- Resuscitation equipment
- Immediate access to Epinephrine (Adrenaline) 1 in 1000 injection
- Access to a working telephone
- Another competent adult, who can summon urgent emergency support if required should ideally be present
- Access to medical support (this may be via the telephone)
- Approved equipment for the disposal of used materials
- Clean and tidy work areas, including access to hand washing facilities or alcohol hand gel
- A copy of the current PGD for the medicine specified in the PGD.

Characteristics of staff authorised to administer medicine under PGD

<table>
<thead>
<tr>
<th>Professional qualifications</th>
<th>Registered Nurses as recognised by the Nursing and Midwifery Council (NMC). Pharmacists as registered with the GPhC.</th>
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<tr>
<td>Specialist competencies</td>
<td>Approved by the organisation as:</td>
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<td></td>
<td>• Competent to assess the individual/person with parental responsibilities capacity to understand the nature and purpose of vaccination in order to give or refuse consent</td>
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<td>• Competent to undertake administration of the vaccine and discuss issues related to vaccination</td>
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<td>• Competent in the handling and storage of vaccines, and management of the “cold chain”</td>
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<td>• Competent to work under this PGD.</td>
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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 individual 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 Nurse Manager/Consultant/Practice GP.

Pharmacists working in **NHS Tayside only** can be authorised to administer the vaccine specified in this PGD by their Director of Pharmacy.

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 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
- NaSH – Sexual Health Electronic Patient Record
- Child Health Information Services if appropriate
- 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

Electronic Medicines Compendium
[http://www.medicines.org.uk](http://www.medicines.org.uk) Gardasil® suspension for injection in a pre-filled syringe – Date of revision of text 07/05/19, accessed 01/08/19.

| Department of Health (2006): Immunisation against Infectious Disease [Green Book]  
Immunisation against Infectious Disease [Green Book] chapter 18a (Human papillomavirus)  
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 Gardasil® Human Papillomavirus Vaccine (HPV) [Types 6, 11, 16, 18] (Recombinant, Adsorbed) 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 ______________________________________
## Healthcare Professionals Authorisation to Administer Vaccine Under Patient Group Direction

### The Lead manager/Professional
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
The Senior Nurse/Professional 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.

### The Healthcare Professional
The Healthcare Professional 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.

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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>
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