

Dear Colleague

## **IMPLEMENTATION OF IMMUNISATION PROGRAMME – HUMAN PAPILLOMA VIRUS (HPV) VACCINE**

### **FURTHER GUIDANCE ON IMPLEMENTATION**

This letter provides guidance for NHS professionals involved in immunising girls being offered the HPV vaccine, on the implementation of the national HPV immunisation programme.

**The official launch of the routine and catch-up HPV programmes will be on 1 September 2008.**

This letter on the implementation of the programme and associated priorities for NHS Boards is being sent to all Board Chief Executives. It follows Chief Executive Letters [17/2007](#) and [5/2008](#) issued on 13 November 2007 and 6 February 2008.

In particular this letter provides further information on –

- Programme start date and cohort to be immunised;
- The decision, now announced, on the vaccine manufacturer awarded the contract;
- Funding arrangements;
- HPV vaccination out with schools (GPs and community clinics);
- HPV vaccines;
- Consent;
- Communications;
- Local data management and monitoring vaccine uptake.

### **Routine and catch-up programme start dates and eligibility for immunisation**

The immunisation programme will officially begin on 1 September this year.

**From the Chief Medical Officer  
Chief Nursing Officer and  
Chief Pharmaceutical Officer**

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**Addresses**

For action

NHS Board Chief Executives  
NHS Board Immunisation  
Co-ordinators

For information

NHS Board Medical Directors  
CHP Managers  
NHS Board Communication Directors  
Directors of Public Health  
General Practitioners  
Chief Pharmacists  
NHS Board Nursing Directors  
Practice Nurses  
Health Visitors  
Health Scotland  
Health Protection Scotland  
NHS 24  
Local Authority Chief Executives and  
Directors of Education  
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**Further Enquiries**

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The routine programme will immunise all girls in school year S2 (or equivalent), beginning this year and continuing in future years as part of the routine childhood immunisation schedule.

The catch-up programme (for girls aged 13 to 17 inclusive) will also begin on 1 September this year and will be completed by August 2011. [CEL 5](#) issued on 6 February 2008 set out the details. The table which illustrates the phasing and timing of the catch-up over the next 3 years and the cohorts to be immunised is included below for ease of reference.

| <b>Phasing of HPV Immunisation Catch-up Campaign in Scotland:</b><br>(beginning September 2008, completing August 2011) |  |  |   |   |
|---|--|--|---|---|
| <b>Year</b>   | <b>School year at start of catch-up campaign: September 2008</b> | <b>Age at start of catch-up campaign: September 2008</b> | <b>School year when vaccination first offered</b> | <b>Age when vaccination first offered</b> |
| <b>Year 1</b><br>(September 2008 to August 2009)  | S5/S6/left school  | 16 - under 18 years                                      | S5/S6/left school                                 | 16 – under 18 years                       |
| <b>Year 2</b><br>(September 2009 to August 2010)  | S3/S4  | 13 -15 years   | S4/S5<br>Left school                              | 14 -16 years                              |
| <b>Year 3</b><br>(September 2010 to August 2011)  | “Mop up” of those with incomplete or no vaccination.             |  |   |   |

For the routine programme, girls aged around 12 to 13 years at 1 September in S2 at secondary school are eligible. S2 girls are **all** eligible for immunisation regardless of their actual age (ages may range from 11 to 13). Each course of immunisation requires three separate doses. Those who do not take up the offer of immunisation at this time or have not completed their course will remain eligible to complete their course until age 17 years and 364 days.

For the catch-up campaign the offer of immunisation will be time-limited, until August 2011. The catch-up campaign will be targeted initially over two years with the third year aimed at completing incomplete courses or undertaking a complete course of doses for those not taking up the offer of immunisation in the first two years.

## **Women aged 18 and over**

Having reviewed the cost effectiveness of immunising the whole female population at different ages the Joint Committee of Vaccination and Immunisation (JCVI) have not recommended a national programme of immunisation for women aged 18 years and over. CEL 5, issued on 6 February 2008, sets out the current position with regard to this age group. We will let you know if this position changes.

## **Funding Arrangements**

The Scottish Government will be funding the full cost of the HPV vaccine for this programme. This will include 3 doses for each girl who is eligible for immunisation. We are also funding a communications campaign for both health professionals and the public; amendments to the Child Health Systems Project School System (CHSP-S); and a programme to assess the impact of the immunisation programme.

In recognition of the additional pressures placed on NHS Board resources in relation to the delivery of the HPV programme the Minister for Public Health, Shona Robison, announced 8 April 2008, an allocation of £1.5 million to NHS Boards to help alleviate those pressures. NHS Boards have been asked to take this into account in their financial planning, including meeting any additional costs arising from community nursing resources and primary care teams from within their general allocations.

## **HPV vaccination out with schools (GPs and community clinics)**

The HPV immunisation programme is largely school based with four or five vaccine sessions each year. However, some girls will need HPV vaccine out with school premises, either because they have already left school or by way of catch-up.

NHS Boards may choose to engage GPs and/or arrange community clinics, and are expected to fund the cost of GP involvement and/or community HPV clinics from within existing resources.

- For the routine programme – Boards may decide to engage GPs in following up girls who have not presented for vaccination at school and/or who are harder to reach. Most Boards will offer girls five appointments at school for the three doses. If a girl does not take up the offer or does not complete the course her details may be passed to her GP for follow-up action.
- For the catch-up programme – Boards may decide to engage GPs in immunising girls who have left school or do not take an offer to complete the course at school. A list of those girls aged 16 and 17 years old who have left school will be provided to the local NHS Board.

Contractual arrangements for contracting GPs to carry out this work are currently being finalised and will be issued to all Boards before the end of this month.

## **HPV VACCINES**

There are two licensed vaccines in the UK – Cervarix (manufactured by GlaxoSmithKline - GSK) and Gardasil (manufactured by Sanofi Pasteur.)

## HPV Vaccine purchased for the UK national programme

The Department of Health has completed a UK wide procurement exercise for the HPV vaccine and announced, on 18 June 2008, that the contract for supply of HPV vaccine in the United Kingdom has been awarded to GlaxoSmithKline. The Scottish Government has entered into an agreement with the Department of Health to secure a sufficient supply of vaccine for Scotland.

The vaccine supplied for use in the HPV immunisation programme is therefore Cervarix™.

Cervarix™ is supplied as a turbid white suspension in a single dose 0.5ml pre-filled syringe with a blue needle (23g x 25mm). The vaccine may appear as a clear colourless supernatant with a fine white deposit after storage. The vaccine should be well shaken before use. A single syringe pack measures 42mm x 24mm x 133mm.

**Three doses of Cervarix™ are required. The second dose should be given one to two months after the first dose. The third dose should be given at least six months after the first dose. All three doses should be given within a 12-month period. Further information on scheduling is available in the new chapter for 'Immunisation against Infectious Disease 2006' ([www.dh.gov.uk/greenbook](http://www.dh.gov.uk/greenbook)).**

The administration of HPV vaccines, their adverse reactions, and their use in pregnancy are explained in detail in the new chapter for 'Immunisation against Infectious Disease 2006' ([www.dh.gov.uk/greenbook](http://www.dh.gov.uk/greenbook)).

### Vaccine Supply

HPV vaccine will be supplied by Movianto UK Ltd as part of the national childhood immunisation programme. Vaccine Holding Centres will be advised in due course of their indicative allocation of HPV vaccine. Orders for vaccine should be made against the indicative allocation. Requests for amounts over and above the allocated amounts should be made in advance to Margaret Johnston at NHS NSS National Procurement at email address [Margaret.johnston2@nhs.net](mailto:Margaret.johnston2@nhs.net)

NHS Boards can order HPV vaccines on a weekly basis. It is likely that each Board will have a unique HPV ordering identifier and ordering will be made via email. Details of this process if required will be advised before the first orders are made.

Invoices for the vaccine will be paid directly by the Scottish Government to the UK Government. The arrangements for NHS Boards to inform the Scottish Government of orders received will be communicated in the weeks ahead.

### Vaccine Storage

Vaccines should be stored in the original packaging at +2°C to +8°C and protected from light. All vaccines are sensitive to some extent to heat and cold. Freezing may cause increased reactogenicity and loss of potency for some vaccines. It can also cause hairline cracks in the container leading to contamination of the contents.

**NHS Board Vaccine Holding Centres should ensure sufficient fridge space is available for the new vaccine. Each Vaccine Holding Centre should review current stocks of all childhood vaccines. A review of available fridge space will be necessary to ensure adequate storage capacity at the start of the programme.**

## Reporting of adverse reactions

Cervarix<sup>TM</sup> carries a black triangle symbol (▼). This is a standard symbol added to the product information of a vaccine/medicine when it is under more intensive monitoring by the Medicines and Healthcare products Regulatory Authority (MHRA) and aims to encourage reporting of all suspected adverse reactions. If a doctor, nurse, pharmacist or patient/carer suspects that any adverse reaction to one of these vaccines has occurred they should report it to the MHRA using either the Yellow Card reporting form (e.g. in the BNF), the online reporting site for Yellow Cards on <http://yellowcard.mhra.gov.uk/>, or by telephoning 0800 100 3352.

## Patient Group Directions

The requirement for Patient Group Directions is described in HDL(2001)7 available from [http://www.sehd.scot.nhs.uk/mels/HDL2001\\_07.HTM](http://www.sehd.scot.nhs.uk/mels/HDL2001_07.HTM). The use of PGDs for administration of vaccines is described in detail in '*Immunisation against Infectious Disease 2006*' (pages 35 to 39, [www.dh.gov.uk/greenbook](http://www.dh.gov.uk/greenbook)

A specimen Patient Group Direction (PGD), for use with HPV vaccine Cervarix<sup>TM</sup> will be made available at [www.healthscotland.com/immunisation](http://www.healthscotland.com/immunisation) NHS Boards may choose to use this specimen as the basis of PGDs amended and approved for local use.

## Vaccine Wastage

Effective management of vaccines throughout the supply chain is essential to reduce vaccine wastage. The HPV vaccine will considerably increase the cost of the childhood immunisation programme. Vaccine wastage must be kept to a minimum - even small percentage reductions in vaccine wastage will have an important impact on the financing of vaccine supplies.

## Transporting and storing vaccine at immunisation sessions

Validated cool boxes and related items such as cool packs should be used when transporting and storing vaccine for use in situations such as school immunisation sessions. Cool boxes should be used in accordance with manufacturer's guidelines to ensure that vaccines are stored at the correct temperature.

A realistic calculation of how much vaccine is needed for a particular immunisation session should be made prior to transporting vaccine to a session. During the session care should be taken to remove only the required amount of vaccine from the cool box.

## Consent

As with all other forms of healthcare, consent must be obtained prior to the administration of the vaccine. Consent forms have been designed and can be viewed on the Health Protection Scotland HPV website <http://www.healthscotland.com/immunisation/hpv> Further guidance on consent is given in '*Immunisation against Infectious Disease 2006*', [www.dh.gov.uk/greenbook](http://www.dh.gov.uk/greenbook).

## Communication

All information and guidance in support of the HPV programme is being published on the NHS Health Scotland immunisation website as it becomes available – [www.healthscotland.com/immunisation](http://www.healthscotland.com/immunisation)

The following materials are available on the website –

- **Materials to support the training of health professionals: a Powerpoint presentation which can be used locally to deliver training**
- **Materials issued within the information pack for health professionals (see below) plus supporting materials**
- **Finalised versions of the public information leaflets as soon as they become available**

An information pack was sent to health professionals in hard copy format from 30 May. It contained the following items:

- Covering letter
- Draft information leaflet (for girls 12 to 13 years)
- Draft information leaflet (for girls 16 and 17 years)
- Draft Q&A booklet (parents and carers of girls aged 12 to 13 year olds)
- New HPV chapter for '*Immunisation against Infectious Disease 2006*' (the Green Book Chapter)
- Technical factsheet for health professionals
- Draft of the credit card sized information card which will direct the public to further sources of information

The information is also available online at [www.healthscotland.com/immunisation](http://www.healthscotland.com/immunisation) where the following additional items can be downloaded:

- Draft Q&A booklet (for girls 16 and 17 years)
- An A3 poster (when the final image becomes available)
- Example of the consent form (for use in schools)
- Specimen Patient Group Directions
- A data collection guide template
- A Health Rights Information Scotland booklet on consent
- Copies of previous CEL letters and this CMO letter
- The HPS Immunisation Newsletters

Elements of the above pack have been sent to the following professional groups (copies of the materials are also available on the website):

- Immunisation Co-ordinators, Directors of Public Health, NHS Chief Executives,
- GP surgeries, locum GPs, nurse specialists, LAAC nurses
- Nurses involved in HPV immunisation
- Community health practitioners
- Lead clinicians for colposcopy
- Directors of Pharmacy, Community Pharmacies, Vaccine Holding Centre Pharmacists, Pharmacist Bodies
- Professional Organisations – BMA, RCN, RCGP, RCOG, FPH, RCPCH, Scottish Health Council

- Head teachers of state secondary schools, independent schools and faith schools
- Home education service providers
- Local Authority - Education Departments, Health Departments, Directors of Finance, Social Work Departments, Local Authority Directors of Childrens' services
- Universities and further education colleges
- Scottish Government
- Healthy living centres
- Faith group leaders
- Sexual health networks
- Cancer networks and voluntary organisations
- Care Commission
- Child and youth associations

## Public Information Campaign

The public information campaign to raise awareness of the HPV immunisation programme will include the following elements –

- Information leaflets and Q&A booklets for girls, and their parents or carers
- TV, radio, press advertising, cinema advertising and online media
- Public information website [www.fightcervicalcancer.org.uk](http://www.fightcervicalcancer.org.uk)
- NHS Helpline number 0800 22 44 88

The HPV information leaflets and Q&A booklets for girls and their parent or carer will be distributed to schools via local arrangements (see below) during July and August. Posters, leaflets, Q&A booklets and the credit card sized information cards will also be distributed to GPs, pharmacies and other relevant outlets during August. Copies of these resources can be ordered from local health promotion departments or from [publications@health.scot.nhs.uk](mailto:publications@health.scot.nhs.uk). They will also be available to view and download from [www.healthscotland.com/immunisation](http://www.healthscotland.com/immunisation).

The text in the leaflets and Q&A booklets will be translated into Bengali, Chinese, French, Lithuanian, Polish, Russian, Spanish and Urdu. These will be available online from the end of July 2008 at [www.healthscotland.com/immunisation](http://www.healthscotland.com/immunisation) and the public website [www.fightcervicalcancer.org.uk](http://www.fightcervicalcancer.org.uk).

Immunisation Coordinators who are delivering the schools-based programme have already ordered sufficient leaflets, Q&A booklets and posters for schools in their area through [publications@health.scot.nhs.uk](mailto:publications@health.scot.nhs.uk). Prior to the start of the immunisation programme schools should give a leaflet and consent form to each pupil to be immunised, to take home and share with their parent or carer

During August 2008, an advertising campaign will publicise the introduction of HPV immunisation. The media used will include TV, radio, local and regional press, cinema and on-line media. The advertising will run from 1 August to 14 September and will raise awareness of the immunisation programme in Scotland.

A DVD will be available in August for use in pre-immunisation talks in schools and will also be available to view on the public campaign website from August.

Information for professionals is already available at [www.healthscotland.com/immunisation](http://www.healthscotland.com/immunisation). A public information website ([www.fightcervicalcancer.org.uk](http://www.fightcervicalcancer.org.uk)) will launch at the end of June 2008. A mini version of this site is available already for parents, carers and girls who may seek information ahead of the advertising campaign starting in August. An NHS helpline is



also available (0800 22 44 88). All of the information materials and advertising will include the website and helpline number to direct girls and their parents and carers to more detailed information.

### **Local data management and monitoring vaccine uptake**

Maintenance of comprehensive and accurate data is a key factor determining the effective delivery of all immunisation programmes. To this effect, the Child Health Surveillance Programme- School (CHSP-S) has been specifically programmed to:

- provide call/recall,
- minimise duplicate vaccination,
- enable GP payments (where appropriate),
- support vaccine stock control, and
- measure uptake.

NHS Boards (working in partnership with their local education departments and independent schools) should use [CHSP-S](#) (or SIRS) to record all HPV vaccinations given under the programme, whether administered in school or in GP or community clinics.

Once the first round of school vaccination sessions is completed and data entered, CHSP-S reports should be generated to identify those needing HPV out with school. These reports, which list school leavers eligible for HPV and resident within an NHS Board area, can be produced by GP practice or as a download to run a community clinic. The reports should also be used to inform HPV vaccine stock control for GP and/or community clinics.

The preferred timescale for the initial reports is around October each year, after the first round of school based vaccinations and after school attendance has been updated following the summer break. Further CHSP-S reports may be run throughout the year to identify new school leavers, plus any HPV they may have had at school. These reports will be used in February when some older pupils leave school and, particularly, in July at the end of the school year.

As with other national immunisation programmes, ISD using data held within CHSP-S (or SIRS) will calculate and publish annual, quarterly and adhoc HPV immunisation uptake rates for the routine and catch-up arms of the programme for each NHS Board and nationally.

We recognise that the implementation of this programme is a major commitment for all of us and has already required significant time, energy and dedication. We would like to take this opportunity to thank you for your contributions.

Yours sincerely

*Harry Burns*

*Paul Martin*

*Bill Scott*

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Chief Medical Officer

**MR PAUL MARTIN**  
Chief Nursing Officer

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