

4 August 2008

Dear Colleague

The purpose of this letter is to:

1. update you on the HPV Immunisation Programme
2. provide a factsheet for you to copy and give to parents and young women or girls who may have questions about the HPV vaccine (until resources are available).

The goal of the HPV Immunisation Programme is to implement an equitable, ongoing immunisation programme to provide protection against HPV infections which lead to most cervical cancers. DHBs are planning for the HPV Immunisation Programme and will be providing more information on local initiatives to achieve high immunisation coverage, particularly for Maori and Pacific young women.

This letter contains information about:

- HPV Immunisation Programme eligibility and when HPV vaccine can be given
- Ordering HPV vaccine
- Provider training
- Communications activities and resources
- Adverse event information
- Current issue with some PMS systems and scheduling HPV vaccine

### **1. Who is eligible for funded HPV vaccine?**

Girls and young women born on or after 1 January 1990 are eligible for funded HPV vaccine. HPV vaccine will be added to the National Immunisation Schedule for girls aged 12 (or school Year 8) with a catch up programme for girls born 1990 to 1996 inclusive. The vaccine will be introduced in stages, starting with the oldest girls first.

**From 1 September 2008 all girls born in 1990 and 1991 (whether in school or not) may be offered HPV vaccine.**

### **2. How will HPV vaccine be delivered?**

Through schools and primary care. To ensure high vaccine uptake, the Ministry recommends that most girls receive HPV vaccine through school-based programmes (where they are offered). School-based programmes for Years 8 to 13 will be phased in during 2009 and 2010. From 2011, school-based programmes will only immunise Year 8 girls. (See the table on the following page.)

HPV vaccine will also be available through primary care (which includes general practice, Māori and Pacific health providers, youth health services or other health clinics and settings) for girls and young women not in school or those who choose not to be vaccinated in schools. If a girl starts her immunisations in primary care, the Ministry's preference is for her to be actively recalled and complete her immunisations in primary care.

The table below shows how the programme will be rolled out, along with the proposed school based programme phasing. Note that programme delivery may vary in some DHBs. Programme rollout timeframes are explained further in points 3 and 4.

Date	Year at school	Age range	By birthdate	Delivery
1 September 2008	n/a	17-18	1990*	Primary care and community-based settings only
	n/a	16-17	1991*	
2009	8	11-13	1997	School-based programme begins
	13	16-18	1992	Primary care and community-based settings continue
	12	15-17	1993	
2010	8	11-13	1998	
	12	15-17	1994	
	11	14-16	1995	
	10	13-15	1996	
2011 and onwards	8	11-13	1999	

\* see points 3 and 4 below for exceptions to these age groups.

### 3. When can HPV vaccine be given to eligible girls?

#### a. Girls born during 1990 and 1991 – who are in school or not

From 1 September 2008 free HPV vaccine will be available from primary care to girls who were born during 1990 and 1991 (inclusive) regardless of whether they are in school or not. Active recall of these girls is recommended.

#### b. Girls born from 1992 onwards – who are still in school

Younger girls (born from 1992 onwards) who are still in school cannot receive HPV vaccine from 1 September 2008. These girls should wait until school programmes have started in their area (in 2009 and 2010). The Ministry's preference is for girls to receive HPV vaccine at the time scheduled for their DHB's school-based programme.

From January 2009 girls born from 1992 onwards who are still in school may receive free HPV vaccine through primary care only if they or their parents have determined they will not consent to school-based vaccination.

#### c. Girls born from 1992 onwards who are not in school

From 1 September 2008 any girl born from 1992 onwards who is not in school can receive free HPV vaccine through primary care. Active recall of these girls is recommended.

### 4. Are there any exceptions to the rules in question 3 above?

Yes. From 1 September 2008 girls and young women in the eligible age range who may benefit from receiving HPV vaccine (e.g. because of risk) may be immunised at the provider's discretion. However the provider will need to follow up and actively recall these girls to ensure that all 3 HPV vaccines doses are given.

### 5. Can eligible girls who paid for HPV vaccine prior to 1 September 2008 receive any remaining doses for free from 1 September 2008?

Yes. Eligible girls who paid for HPV vaccine can receive their remaining doses free from 1 September 2008 in primary care. As with other vaccines, the Ministry will not refund any privately-purchased HPV vaccine.

### 6. How long will HPV vaccine be available to eligible girls?

Girls born in 1990 and 1991 have until 31 December 2011 to start the immunisation programme. If they have not received dose 1 by 31 December 2011 they cannot start the programme. Girls born from 1992 onwards must start the programme by their 20<sup>th</sup> birthday.

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## 7. At what age can a girl give her own consent to HPV immunisation?

### a. Primary care

In primary care, girls less than 16 years of age have the right to give consent for minor treatment, including immunisation, providing they understand fully the benefits and risks involved. For more information, see the *Immunisation Handbook 2006*, section 2.2.

### b. School-based programmes

Consent forms will be given to all girls in school based programmes to take home to their parents. Girls less than 16 years of age need written parental consent to receive HPV vaccine through school based programmes. Girls over 16 years of age may choose to self-consent to the HPV vaccine and will be required to sign the consent form.

## 8. Can non-resident girls in the eligible age range receive free HPV vaccine?

Non-resident girls under 16 years of age and who will be in New Zealand for 8 months or more (to ensure time to receive all 3 doses) may receive free HPV vaccine. If these girls have not received dose 1 by their 16<sup>th</sup> birthday they cannot start the programme.

Non-resident girls under 16 years of age and who will be in New Zealand for less than 8 months cannot receive free HPV vaccine. Non-resident girls 16 years and over cannot receive free HPV vaccine – regardless of their length of stay in New Zealand.

## 9. Ordering HPV vaccine

ProPharma vaccine order forms will be updated in August to include the HPV vaccine. Vaccine can be ordered from mid August 2008, for administration from 1 September 2008. See the *2008 National Immunisation Schedule Health Provider Booklet* page 21 for more information about the GARDASIL® box size and vaccine administration.

## 10. HPV vaccine provider training

The Ministry has contracted the Immunisation Advisory Centre (IMAC) to develop an HPV training package for vaccinators and information sharers. More information about these training sessions will be available soon from your DHB.

## 11. Communications and social marketing campaign

The Ministry is developing a social marketing campaign to support and promote the HPV Immunisation Programme. Resources are being developed for primary care including posters for clinics and practices, a fact sheet and a flipchart for immunisation providers to answer questions from the public and information sheets for young women and parents to take away. Primary care resources will be ready by mid to late August before the immunisation programme starts on 1 September.

## 12. Current sources of HPV information

Source	Available at	Audience
HPV Immunisation Programme – National Implementation Strategic Overview	<a href="http://www.moh.govt.nz/immunisation">www.moh.govt.nz/immunisation</a>	Health care providers
2008 National Immunisation Schedule – Health Provider Booklet (HP4575)	<a href="http://www.moh.govt.nz/immunisation">www.moh.govt.nz/immunisation</a> Hardcopies can be ordered from <a href="mailto:moh@wickliffe.co.nz">moh@wickliffe.co.nz</a> or phone (04) 496 2277 – quote HP number 4575	Health care providers
Ministry of Health website	<a href="http://www.moh.govt.nz/immunisation">www.moh.govt.nz/immunisation</a>	Health care providers Parents and young women
IMAC website	<a href="http://www.immune.org.nz">www.immune.org.nz</a>	Health care providers Parents and young women
Childhood Immunisation booklet (HE1323)	<a href="http://www.healthed.govt.nz">www.healthed.govt.nz</a> Hardcopies can be ordered from this website	Parents and young women

### 13. Recent media coverage regarding HPV vaccine and adverse events

Recent media coverage about HPV vaccine has focused on adverse events in the US and Australia. The majority of these were related to injection site pain, redness or swelling which can be expected reactions after any immunisation. Fainting has also been reported following immunisation.

Anaphylaxis has also been reported following GARDASIL® administration in Australian school programmes (see <http://www.tga.gov.au/alerts/medicines/gardasil.htm>). The current estimated rate of anaphylaxis based on doses given in Australia is 5.1 per million. Providers are reminded that vaccinees should remain under observation for 20 minutes following immunisation.

There have been reports of deaths in young women who have received GARDASIL® in the US – however a thorough investigation by the Center for Disease Control did not find any causal link between GARDASIL® and those deaths (see <http://www.cdc.gov/vaccinesafety/vaers/gardasil.htm>).

As with other medicines and vaccines, the Centre for Adverse Reaction Monitoring (CARM) will be recording adverse events following GARDASIL® immunisation. See section 2.4 of the Immunisation Handbook for more information about CARM and reporting adverse events. CARM will be providing regular reports to the Ministry regarding adverse events following GARDASIL® vaccine administration.

### 14. Current issue with some PMS systems and scheduling HPV vaccine

The Ministry is aware that some PMS systems have incorrectly coupled the HPV schedule to the Childhood Immunisation Schedule in the NIR and have also incorrectly scheduled the first HPV vaccine at age 11 (rather than age 12). This means that for affected practices, PMS systems are automatically scheduling 11 year old girls for HPV vaccine.

The HPV schedule should not be coupled to the Childhood Immunisation Schedule in the NIR, meaning PMS systems should not automatically schedule eligible girls. A change request is being made to vendors to correct this.

For those affected practices, the suggested fix is to reschedule the HPV vaccines that have been automatically scheduled at age 11 to a date well in the future (3-5 years). These 11-year-old girls should not be recalled (or pre-called) for HPV vaccine dose 1.

Management of HPV vaccine immunisation coverage on the NIR for each girl begins with her either receiving or declining HPV dose 1, in the school-based programme, or at primary care.

### 15. Who to contact for more information

Vaccine ordering	ProPharma: 0800 400 101
Immunisation benefit claiming	HealthPAC: 0800 458 448 <a href="http://www.moh.govt.nz/moh.nsf/indexmh/healthpac-faq-immunisation">www.moh.govt.nz/moh.nsf/indexmh/healthpac-faq-immunisation</a>
Technical advice	IMAC: 0800 IMMUNE or 0800 466 863 <a href="http://www.immune.org.nz">www.immune.org.nz</a>
Vaccine manufacturer	Merck Sharpe and Dohme – marketed in NZ by Commonwealth Serum Laboratories (CSL) Biotherapies Ltd. Ph (09) 579 8105 <a href="http://www.gardasil.co.nz">www.gardasil.co.nz</a>
HPV Immunisation Programme	HPV Immunisation Programme queries: <a href="mailto:hpv@moh.govt.nz">hpv@moh.govt.nz</a>

Yours sincerely

Rayoni Keith  
HPV Project Manager

## **Human Papillomavirus (HPV) Immunisation Programme - Factsheet**

This is an immunisation programme to protect girls and young women from HPV infection and from developing cervical cancer later in life.

### **Who is eligible?**

Girls born on or after 1 January 1990 will be eligible for free HPV vaccine (called GARDASIL<sup>®</sup>) beginning with the oldest girls first.

From 1 September 2008, GARDASIL<sup>®</sup> will be available to young women born in 1990 and 1991 from their family doctor, practice nurse, or health clinic. From 2009, girls aged 12 to 18 will be offered the vaccine. Most will receive it at school. Eligible girls or young women who paid for the first or second doses before the programme started can receive the vaccine free from September 1 2008. Your health care provider can tell you more about when eligible girls and young women can receive the free vaccine.

### **Why vaccinate?**

Every year in New Zealand about 160 women will be diagnosed with cervical cancer and 60 will die from it. More than 99 per cent of all cervical cancer is linked to infection with HPV.

### **About the vaccine**

GARDASIL<sup>®</sup> protects against the two HPV types that cause 7 out of 10 cervical cancers (types 16 and 18) and the two HPV types that cause 9 out of 10 genital warts (types 6 and 11). The vaccine contains virus like particles made from the outer shell of the virus, which are not live and cannot cause infection. GARDASIL<sup>®</sup> contains a small amount of aluminium - used in many vaccines to improve the body's immune response to the vaccine. The vaccine does not contain thiomersal.

The vaccine is injected into the upper arm. Three injections are given over a 6-month period at 0, 2 and 6 months.

For best protection girls need to be vaccinated before they are likely to be exposed to HPV, which means before they start having any sexual contact. It is recommended eligible women who are sexually active still have the vaccine as they are unlikely to have been exposed to all the HPV types the vaccine protects against.

### **How safe is the vaccine?**

GARDASIL<sup>®</sup> was shown to be safe during large clinical trials involving more than 20,000 girls and young women. The following reactions may be expected after vaccination - injection site pain, redness or swelling at the injection site, a general feeling of unwellness, mild fever. Very rarely people may have a severe allergic reaction (anaphylaxis). This usually happens in the first few minutes after vaccination, which is why people are asked to wait at their doctor's surgery or health clinic for 20 minutes after their vaccination.

As with other vaccines, New Zealand's Centre for Adverse Reactions Monitoring will record any reactions reported after HPV vaccination and provide regular reports to the Ministry of Health. There is also ongoing monitoring internationally of the girls and women involved in the clinical trials.

### **How effective is the vaccine?**

Results from studies at five years after vaccination report that protection remains good. The vaccine was effective at preventing infection with HPV in 96 per cent of women. These studies will continue to monitor the long term protection the vaccine provides. International experts do not expect that booster doses will be required but this will also be monitored.

### **Will young women still need to have smear tests?**

About 30 per cent of cervical cancers will not be prevented by this HPV vaccine, so immunised women should receive regular cervical smear tests, beginning from the age of twenty.

### **Why aren't boys being immunised as part of the free programme?**

The vaccine is licensed for use in boys aged 9 to 15 years, but is not funded for boys as part of this national cervical cancer prevention initiative. The Ministry is monitoring ongoing international research about the effectiveness of vaccinating boys.