



**Australian Government**  
**Department of Health and Ageing**

**FACT SHEET**

**Australian Government funding of GARDASIL®**  
**Updated 28 November 2006**

**What is human papillomavirus (HPV) and how is it linked to cervical cancer?**

HPV is a sexually transmitted infection, mostly affecting women 20 to 24 years of age. Almost all abnormal Pap smear results are caused by HPV. In 98 per cent of cases, HPV clears by itself. In rare cases, if the virus persists and if left undetected, it can lead to cervical cancer. This usually takes about 10 years.

For more information on HPV, see:

[http://www.cancerscreening.gov.au/internet/screening/publishing.nsf/Content/cv-hpv/\\$File/hpv.pdf](http://www.cancerscreening.gov.au/internet/screening/publishing.nsf/Content/cv-hpv/$File/hpv.pdf)

**What can be done to prevent cervical cancer?**

Early detection is the best protection from cervical cancer. Australia has one of the best national cervical screening programs in the world.

Every year the Australian Government and the state and territory governments invest more than \$90 million in the National Cervical Screening Program. This investment has cut deaths from cervical cancer by around 60 per cent since 1985 and has halved the number of cases of cervical cancer.

Australia currently has the second-lowest incidence of cervical cancer and the lowest mortality rate from cervical cancer in the world.

**Are there vaccines available to protect people from HPV?**

There are many strains of HPV, only some of which can cause cancer. HPV strains 16 and 18 cause around 70 per cent of all cervical cancers. There is one vaccine (GARDASIL) which has been approved for use in Australia. This vaccine prevents infection from HPV strains 16 and 18 if individuals are vaccinated before they are infected with them.

For more on HPV vaccines, see [http://www.ncirs.usyd.edu.au/facts/hpv\\_oct\\_2006.pdf](http://www.ncirs.usyd.edu.au/facts/hpv_oct_2006.pdf)

**How does GARDASIL work?**

GARDASIL is administered as a series of three injections over a period of seven months. To ensure that some girls do not miss out, an immunisation program needs to run over a whole school year.

All medicines and vaccines considered for funding by the Australian Government must first be approved by the Therapeutic Goods Administration (TGA) for use in Australia. This guarantees they are safe and clinically effective, but it does not assess their cost-effectiveness. The TGA approved GARDASIL on 16 June 2006 for females aged 9 to 26 years and males aged 9 to 15 years.

### **The Government subsidises many vaccines – is it going to subsidise GARDASIL?**

Yes. The Government has agreed with the recommendation of its expert advisory committee, the Pharmaceutical Benefits Advisory Committee (PBAC), that GARDASIL should be funded under the National Immunisation Program, commencing in the 2007 school year, for three cohorts:

- An ongoing target group of 12 and 13 year old girls in a school-based program, generally delivered in the first year of high school
- A catch-up group of 13-18 year old girls in a largely school-based program
- A further catch-up group of women up to and including 26 years of age in a community-based program generally delivered through general practice.

### **Why is the vaccine not available to women older than 26 years?**

GARDASIL is not registered for use in women older than 26 years as there is no evidence to support its efficacy or safety in these women. For these women, the best way to avoid cervical cancer is to participate in cervical screening through regular Pap smears.

### **How much will the vaccine cost the Government?**

The expected cost of the vaccine is \$436 million over the four year period 2006-07 to 2009-10. This includes vaccine costs for the two-year catch-up programs for girls and women aged 13 to 26. Once these catch ups are complete, the ongoing cost of the vaccine for girls in the first year of high school is under \$50 million a year. As well as buying the vaccine, there are costs associated with its administration. Discussions with the states and territories need to occur before these costs are finalised.

### **What is the PBAC?**

Before a vaccine can be part of the National Immunisation Program or put on the Pharmaceutical Benefits Scheme, it needs to be evaluated to assess whether it is clinically- and cost-effective. This evaluation is performed by the PBAC. The PBAC comprises men and women experts, including health professionals, health economists and a consumer advocate.

The PBAC seeks advice from the Australian Technical Advisory Group on Immunisation (ATAGI) whenever it considers a vaccine. There are two immunisation experts on the PBAC, one of whom is a member of ATAGI. In making its recommendation on GARDASIL, the PBAC sought additional advice from experts in the fields of immunology and sexual health.

### **Didn't the PBAC initially reject GARDASIL? Why has it changed its mind?**

Following feedback and negotiations on its original application, CSL submitted a revised application to the PBAC in which a reduced price and other favourable conditions of supply were offered. The PBAC found that the vaccine was cost-effective at the new price and conditions offered.

### **Why did the PBAC consider this application so quickly?**

To avoid as many cases of cervical cancer as possible, it is important that a vaccine program starts as soon as possible.

As the sponsor company showed a willingness to listen to the feedback of the PBAC and to revise its application quickly, it was possible to consider a revised application out of the normal schedule of meetings to support a commencement within the 2007 school year. This is a very unusual circumstance as, in this case, vaccination would need to commence by April at the latest to ensure the full dose is administered before the school year finishes.

The PBAC agreed to accelerate its processes in this instance to support a 2007 roll-out, in the event of a positive recommendation.

**When could a school-based HPV vaccine program commence?**

It should be possible to introduce a school-based vaccination program in April 2007. This will require strong collaboration between the Commonwealth, state and territory governments and the vaccine supplier.

**How will girls and their parents gain access to the HPV vaccine?**

The HPV vaccine will be provided to the majority of girls through a school-based program. To receive full protection, each girl requires three doses of the vaccine within a seven-month period. The best way to make sure that each girl has all three doses is to deliver the vaccine through schools. The Commonwealth Government will fund the purchase of the vaccine. State and territory governments will run the program, that is, administer the vaccine, in their schools.

**What about young women up to and including 26 years of age who are no longer at school?**

These young women will be able to obtain the vaccine through their general practitioner. Some states and territories may also make the vaccine available at no cost through local programs. If the vaccine is delivered by a GP, there will be no charge for the vaccine but there could be a charge for the GP consultation. The vaccine should be available through GPs from mid-2007.

**If I am vaccinated, will I still have to have Pap smears?**

Yes. Being vaccinated does **not** mean that women will be able to stop having regular Pap smears. HPV vaccination will not prevent all cases of cervical cancer, nor pre-cancerous cervical lesions.

This means that all women aged 18 to 69 who have ever been sexually active, whether vaccinated or unvaccinated, should have regular cervical screening by Pap smears.

For more information on cervical screening, see: [www.cancerscreening.gov.au](http://www.cancerscreening.gov.au)

**Can I get access to the vaccine now?**

Yes. You can talk to your doctor about the vaccine. If you want to go ahead with vaccination you will have to pay the full vaccine price. The cost for a three-injection course is about \$460.

It is important though that you continue to have regular Pap smears and to keep informed about whether you need a booster vaccination in the future.