

AFAO SUBMISSION TO PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE – 7 FEBRUARY 2011

1: What treatment (if any) are you using now?

Please describe what medicines you take to treat your health problem and how well this treatment works. 1340 characters/200 words

The Australian Federation of AIDS Organisations (AFAO) is the national federation for the HIV community response. Key constituents of AFAO are gay men, and other men who have sex with men (MSM), including those living with HIV. A recent study among Australian gay men indicates that the prevalence of HPV infection is very high. Our support for this Gardasil application to the PBS is based on the positive health impact that such a vaccination may have for all males, and in particular gay men and other MSM, including those living with HIV. Currently, there is no single preventative measure available to these groups to avoid HPV.

Treatment options for health problems that HPV can cause, such as genital warts and anal, penile and oropharyngeal cancers, have varying degrees of success. Genital warts can be treated with medicine, removed with surgery, or frozen off but can often come back within a few months, thus requiring several treatments. Recurrence of genital warts is common among gay men living with HIV, while treatment is less successful. Treating genital warts may not necessarily lower chances of transmission of HPV. Penile and anal cancers can be treated with new forms of surgery, radiation therapy, and chemotherapy.

2: What do you see as the benefits of this new medicine for you?

Please describe the benefits you think the new medicine could have for your health? Do you think the new medicine could have any disadvantages? 1340 characters/200 words

We see several benefits of Gardasil, including its effectiveness in preventing external genital lesions/genital warts and infection caused by Human Papilloma Virus (HPV) Types 6, 11, 16 and 18. A number of vaccine-preventable subtypes of HPV have also been associated with the development of several types of cancers, including anal cancer, penile cancer, and oropharyngeal cancers.

Preventing genital warts and HPV-related cancers is of particular significance for gay men and other MSM, including those living with HIV. Men who have sex with men are about 17 times more likely to develop anal cancer than men who only have sex with women. Further, men who have HIV have near-universal rates of HPV infection, are more likely to get severe cases of genital warts that are harder to treat, and have higher rates of anal cancer.

If HPV-negative gay men were able to access Gardasil/HPV vaccination at an affordable price under the PBS they would henceforth have protection from HPV. With lower prevalence of HPV there would be a reduction in the prevalence of warts. Research among Australian gay men has shown that the presence of genital warts increases the risk of HIV transmission; reducing the prevalence of warts would thus reduce HIV transmission and acquisition.

3: How will your life and that of your family and carers be improved by this new medicine? 1340 characters/200 words

Please describe how you think this medicine will affect your life and the lives of your family or carers. Please explain why you think this.

Gardasil has proven effective in providing immunity to girls to contracting HPV. Since its inclusion in the Australian National Immunisation Program in 2007, results have shown an encouraging fall in diagnoses of genital warts among young women. New data has also shown that vaccination has reduced the recurrence of HPV-related diseases in women with prior HPV infection. Due to the causal role of vaccine-preventable strains of HPV in anal cancers, vaccination is likely to be the best long-term approach for prevention of anal cancer and other HPV-related health problems.

Although some groups are at greater risk – gay men & other MSM - there are significant challenges in implementing targeted vaccination programs. Principally, it is impossible to positively identify all gay men and other MSM prior to sexual debut – the mean age being 16 – when vaccination is most effective. Australian data suggests MSM’s first disclosure of sexual identity to a health care professional is aged 20, by which time they are likely already exposed. For this reason we support the vaccination of all males prior to sexual-debut – as currently provided to 12-13 year old females. Approving Gardasil for the PBS would facilitate its inclusion in the National Immunisation Program Schedule, ensuring that boys and girls are equally protected from HPV.

4: What other benefits can you see from having this medicine on the PBS?

Please describe any other benefits you think will come from having this medicine listed on the PBS (for example: fewer hospital visits, reduced time off work and so on). 1340 characters/200 words

AFAO sees advantages in Gardasil being made available for men generally and thus supports a school-based vaccination program for males. Such a program would provide protection from HPV, leading to decreased incidence of genital warts and HPV-related cancers among men. It would also lead to improved herd immunity to HPV for unvaccinated females. Modelling has indicated that there would be significant reductions in HPV among females – vaccinated and unvaccinated – if 80% of boys were vaccinated.

The prevention of HPV promotes the aims of the *National STI Strategy 2010-2013* (the STI Strategy). One of the STI Strategy’s goals is to reduce transmission of and morbidity and mortality caused by sexually transmissible infections and minimise the personal and social impact of STIs. It also identifies HPV as a priority action, stating that “Emerging data regarding the efficacy of this vaccine in young men and in the prevention of the range of cancers associated with HPV could be reviewed to consider extending coverage to this cohort.”

Another positive is that vaccination may help prevent disease recurrence and/or reinfection/reactivation of infection among men. This is based on such a benefit being found among women. A study measuring benefit for males is currently being conducted. AFAO awaits these results with much interest.