



Australian Government

Department of Health and Ageing

CHIEF MEDICAL OFFICER

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Dear Ms Wilyman

Thank you for your emails of 18 March 2013, 21 March 2013 and 5 April 2013, in which you raise a number of concerns about vaccination policies in general and more specifically about the safety and efficacy of human papillomavirus (HPV) vaccine. I note that your public stance against immunisation has not varied over the last few years, even following comprehensive responses to your previous communications with the Department of Health and Ageing, the Therapeutic Goods Administration (TGA) and present and former Health Ministers.

Following the marketing of Gardasil, its safety has been closely monitored by the TGA through the Adverse Drug Reaction System, periodic safety update reporting from the sponsor, study reports and adverse event analysis in the literature, and liaising with other regulators. In common with the United States Food and Drug Administration and the European Medicines Agency, the TGA continues to be of the opinion that Gardasil is safe and effective and the benefits of the vaccine outweigh its risks.

Gardasil protects against HPV genotypes 6, 11, 16 and 18. HPV genotypes 16 and 18 are the causative agents in 70 to 80 per cent of all cervical cancers, and also account for about 90 per cent of all HPV attributable cancers in men. HPV genotypes 6 and 11 are associated with more than 90 per cent of genital warts in males and females. There are a number of controlled studies continuing internationally with long term follow up of safety as well as immunogenicity and efficacy outcomes. There are no signals to date that would indicate any change in the safety profile of Gardasil. The prevalence of vaccine preventable HPV genotypes 6, 11, 16 and 18 in women aged 18 to 24 years significantly decreased from 28.7% to 6.7% four years after the introduction of the HPV vaccination program. There has also been a reduction in the diagnosis rate for genital warts in both females and males.

Vaccination is not compulsory in Australia, and your claim that vaccination policies are infringing upon the individual's right to choose, is not accurate. The Australian Government strongly encourages immunisation because it has been repeatedly demonstrated to be one of the most effective medical