

6th November 2012

TGA Response Re HPV Vaccine not in the public's best interest

Dear Judy

Thank you for your letter in which you expressed your concern about the efficacy and safety of Gardasil, a HPV vaccine.

You should be reassured that prior to the decision to register and to market Gardasil in Australia, a thorough review of its quality, safety, and efficacy had been undertaken by the TGA and has been considered by the Australian Committee for Prescription Medicines.

The detailed Gardasil efficacy and safety information can be found in the TGA-approved Product Information (PI) which can be found by searching TGA website:
<https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2010-PI-05714-3From>

It should be acknowledged that there are always adverse reactions or risks associated with the use of any medicine or vaccine, and the decision to approve the use of medicines or vaccines is based on a positive benefits and risks balance.

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

Yours sincerely

Debbie

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