Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Australian Public Assessment Report for Gardasil

Proprietary Product Name: Human Papillomavirus Quadrivalent Vaccine

Sponsor: Merck Sharp & Dohme (Australia) Pty Ltd

February 2011

TGA Health Safety Regulation

reported in up to 84% of low grade penile/perianal/perineal intraepithelial neoplasia (PIN) cases and in over 90% of PIN 3[2] cases, with HPV 16 the most common type detected.

The full indications Gardasil now read as:

> Gardasil is indicated in females aged 9 to 45 years* for the prevention of cervical, vulvar and vaginal cancer, precancerous or dysplastic lesions, genital warts and infection caused by Human Papilloma virus (HPV) types 6, 11, 16 and 18 (which are included in the vaccine).
>
> Gardasil is indicated in males aged 9 through 26 years for the prevention of external genital lesions and infection caused by Human Papilloma virus (HPV) types 6, 11, 16 and 18.
>
> *Immunogenicity studies have been conducted to link efficacy in females and males aged 16 to 26 years to the younger populations.

Regulatory Status

Details of Overseas Regulatory Status

Region/Country	Adult Women Submission Date	Review Milestones
USA	17 December 2008	Approved 16 October 2009
EU	Target Date for submission is 18 June 2010	The introduction and implementation of new regulatory procedures in the EU delayed the filing of the Men's data.
Canada	13 February 2009	Approved 22 February 2010

Product Information

The approved Product Information (PI) current at the time this AusPAR was prepared is at Attachment 1.

II. Quality Findings

There were no new quality data submitted with the current Australian submission.

III. Nonclinical Findings

Introduction

Overall quality of the nonclinical dossier

In order to support this extension of indication the sponsor has submitted a male fertility study. This study was Good Laboratory Practice (GLP) compliant and well-designed. Sufficient non clinical data are considered to have been submitted to support this application.

Pharmacology and Pharmacokinetics

There were no relevant studies submitted under these headings.

Toxicology

Male fertility

[2] PIN can be subdivided into different stages, based on the level of cell atypia. PIN was formerly classified as PIN 1, 2 or 3, in order of increasing cell irregularities. PIN 1 is referred to as low grade PIN, and PIN 2 and PIN 3 are grouped together as high grade PIN

Therapeutic Goods Administration

PO Box 100 Woden ACT 2606 Australia
Email: info@tga.gov.au Phone: 1800 020 653 Fax: 02 6232 8605
www.tga.gov.au