Commonwealth of Australia Gazette

Published by the Commonwealth of Australia

GOVERNMENT NOTICES

Australian Government

Department of Health

Office of the Gene Technology Regulator

24 April 2015

Invitation to comment on draft assessment for a genetically modified (GM) virus for cancer therapy

Australia's gene technology regulatory system is designed to protect the health and safety of people and the environment by identifying risks posed by, or as a result of, gene technology and managing those risks.

The Gene Technology Regulator is assessing licence application DIR 132 from Amgen Australia Pty Ltd for dealings with a GM herpes simplex virus 1. The GM virus is proposed to be used as a prescription-only treatment for skin cancer and other solid tumours not suitable for surgical removal. Amgen also need approval from the Therapeutic Goods Administration (TGA) before this GM virus can be used as a therapeutic product. The TGA, who have regulatory responsibility for assessing quality, safety and efficacy of medicines, is also considering an application from Amgen.

A consultation Risk Assessment and Risk Management Plan (RARMP) has been prepared, which concludes that the proposed dealings associated with the proposed commercial supply would pose negligible risk to human health and safety or to the environment. Draft licence conditions are proposed to ensure ongoing oversight of these activities.

The Regulator welcomes written submissions to inform the decision on whether or not to issue a licence. The consultation RARMP and related documents can be obtained from the OGTR website under 'What's New' or by contacting the Office. Please quote application DIR 132 in any correspondence.

Submissions should be received by close of business on **19 June 2015**.

Office of the Gene Technology Regulator, MDP 54, GPO BOX 9848 CANBERRA ACT 2601
Telephone: 1800 181 030 Facsimile: 02 6271 4202 E-mail: ogtr@health.gov.au
Website: http://www.ogtr.gov.au