Australian Government
Department of Health
Office of the Gene Technology Regulator

12 August 2015

Issue of licence DIR-132 to the Amgen Australia Pty Ltd (Amgen) for the commercial supply of a tumour-selective genetically modified virus for cancer therapy

On 22 April 2015, the Gene Technology Regulator invited submissions on the consultation version of the Risk Assessment and Risk Management Plan (RARMP) for licence application DIR-132 from Amgen.

The Regulator has now issued a licence in response to application DIR-132, authorising import, transport, storage and disposal of the genetically modified virus, known as Talimogene laherparepvec, for the purpose of commercial supply as a therapeutic.

Before the GMO can be used as a human therapeutic, Amgen also needs approval from the Therapeutic Goods Administration (TGA). Medicines and other therapeutic goods for sale in Australia are required to be assessed for quality, safety and efficacy under the *Therapeutic Goods Act 1989* and must be included in the Australian Register of Therapeutic Goods (ARTG).

Subject to TGA approval, the GMO would be used as a prescription only treatment for patients with skin cancer (metastatic melanoma) and other suitable solid tumours that are unable to be removed by surgery. The GMO will be administered to patients at appropriate clinical facilities by injection directly into the tumour.

The decision to issue the licence was made after extensive consultation on the RARMP with the public, State and Territory governments, Australian Government agencies, the Minister for the Environment, the Gene Technology Technical Advisory Committee, and local councils, as required by the *Gene Technology Act 2000* and the corresponding State and Territory legislation.

Issues raised relating to the health and safety of people and the protection of the environment were considered in the context of current scientific information in reaching the conclusions in the finalised RARMP and in making the decision to issue the licence.

The finalised RARMP concludes that this commercial supply poses negligible risks to people and the environment and does not require specific risk treatment measures. However, general licence conditions have been imposed to ensure ongoing oversight of the release.

Appendix A and B of the RARMP summarise the advice received from prescribed experts, agencies and authorities, and indicate how issues raised relating to risks to human health and safety or the environment were considered in the document. One submission was received from the public on the application and the issues raised, and their consideration, are summarised in Appendix C of the RARMP.

The finalised RARMP, together with a summary of the RARMP, a set of Questions and Answers on this decision and a copy of the licence, can be obtained on-line from the DIR-132 page of the Office of the Gene Technology Regulator's website or requested via the contacts detailed below.

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