Australian Government
Department of Health and Ageing
Office of the Gene Technology Regulator

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Issue of licence DIR 116 to PPD Australia Pty Ltd for a limited and controlled release of GM live viral vaccines

On 23 July 2012, the Regulator invited submissions on the consultation version of the Risk Assessment and Risk Management Plan (RARMP) for licence application DIR 116 from PPD Australia Pty Ltd (PPD).

The Gene Technology Regulator has now made a decision to issue a licence in respect of application DIR 116, authorising the limited and controlled release (clinical trial) of two types of genetically modified live viral vaccines against prostate cancer.

The release is authorised to take place in specified hospitals and health care facilities in ACT, NSW, QLD, SA, VIC and WA, between October 2012 and December 2017. The purpose of the trial is to evaluate the efficacy of the GM vaccines against prostate cancer, their safety and tolerability. The trial will form part of an international clinical trial involving 1200 patients in approximately 22 countries.

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 relevant local councils, as required by the *Gene Technology Act 2000* and corresponding State and Territory laws.

The Therapeutic Goods Administration (TGA) is responsible for human safety assessment of participants in clinical trials. The OGTR has liaised with the TGA during the assessment of this licence application. The clinical trial will be authorised under the TGA's Clinical Trial Notification scheme.

Issues relating to the health and safety of people and the protection of the environment raised during the consultation process were weighed against the body of current scientific information in reaching the conclusions set out in the finalised RARMP and in making the decision to issue the licence.

The finalised RARMP concludes that this limited and controlled release poses negligible risks to people and the environment. Licence conditions have been imposed to restrict spread and persistence of the GMOs and their genetic material in the environment and to limit the trial in size, location and duration, as these were important considerations in the evaluation process.

Appendix A of the RARMP summarises the submissions that were received from prescribed experts, agencies and authorities, and indicates 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 consultation RARMP, and the issues raised and their consideration are summarised in Appendix B of the RARMP.

The Executive Summary, Technical Summary and complete finalised RARMP, together with a set of Questions and Answers on this decision and a copy of the licence, can be obtained on-line from DIR 116 web page of the Office of the Gene Technology Regulator’s website or requested via the contacts detailed below.