Australian Government
Department of Health
Office of the Gene Technology Regulator

10 April 2014

Issue of licence DIR 126 to PaxVax Australia Pty Ltd for a clinical trial of a genetically modified vaccine against cholera

On 24 January 2014, the Gene Technology Regulator invited submissions on the consultation version of the Risk Assessment and Risk Management Plan (RARMP) for licence application DIR 126 from PaxVax Australia Pty Ltd (PaxVax).

The Regulator has now made a decision to issue a licence in respect of application DIR 126, authorising the clinical trial of a genetically modified vaccine against cholera.

Licence DIR 126 permits a clinical trial which is authorised to take place in specified hospitals and health care facilities in Queensland, South Australia, Victoria and Western Australia, between April 2014 and 30 June 2015. The purpose of the trial is to verify the effectiveness of the vaccine in producing an immune response against cholera.

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.

As this would be a clinical trial involving the use of a therapeutic product, it must also meet Therapeutic Goods Administration (TGA) requirements and would require approval from, and oversight by, a human research ethics committee.

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. Public submissions on the consultation RARMP, the issues raised and their consideration are summarised in Appendix B of the RARMP.

The 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 the DIR 126 web page of the Office of the Gene Technology Regulator's website or requested via the contacts detailed below.