Australian Government
Department of Health
Office of the Gene Technology Regulator

10 March 2016

Issue of licence DIR 140 to Clinical Network Services (CNS) Pty Ltd for a clinical trial of GM vaccinia virus

On 16 December 2015, the Gene Technology Regulator invited submissions on the consultation version of the Risk Assessment and Risk Management Plan (RARMP) for licence application DIR 140 from Clinical Network Services (CNS) Pty Ltd.

The Regulator has now issued a licence in response to application DIR 140, authorising the limited and controlled release (clinical trial) of vaccinia virus genetically modified (GM) for use as a cancer therapeutic.

The clinical trial and any follow-up studies are authorised to take place at hospitals in major cities throughout Australia, between March 2016 and March 2021. The purpose of the trial is to assess the effectiveness and safety of the GMO as a treatment for advanced Hepatocellular Carcinoma.

The Regulator's decision to issue the licence was made after 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 corresponding State and Territory legislation.

As the clinical trial involves the use of a therapeutic product, it must also meet Therapeutic Goods Administration (TGA) requirements and will 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 considered in the context 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 clinical trial poses negligible to low risks to people and the environment. To manage these risks, strict licence conditions have been imposed to restrict spread and persistence of the GMO and its genetic material in the environment. Conditions have also been imposed to limit the size, location and duration of the trial, as these were important considerations in the evaluation process.

Appendix A of the RARMP summarises the advice 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. No submissions were received from the public.

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 online from the DIR 140 page of the Office of the Gene Technology Regulator's website or requested via the contact details below.

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