Australian Government
Department of Health
Office of the Gene Technology Regulator

1 August 2016

Issue of licence DIR 144 to Clinical Network Services (CNS) Pty Ltd for a clinical trial of GM influenza vaccines

On 18 May 2016, the Gene Technology Regulator invited submissions on the consultation version of the Risk Assessment and Risk Management Plan (RARMP) for licence application DIR 144 from Clinical Network Services (CNS) Pty Ltd.

The Regulator has now issued a licence in response to application DIR 144, authorising clinical trials of genetically modified (GM) influenza vaccines.

The purpose of the clinical trials is to assess the safety and tolerability of a new type of influenza vaccine, known as SAVE flu vaccines. The new vaccines will be compared to another type of GM influenza vaccine, FluMist.

The GM flu vaccines would be nasally administered by qualified health professionals to up to 500 healthy adult male volunteers, over a 5 year period. For the initial trial, administration is proposed to take place in clinical facilities in Brisbane, while later trials may also take place in clinical facilities in Melbourne, Perth and Adelaide.

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 trials involve 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. One submission was received from the public, summarised in Appendix B.

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 144 page of the Office of the Gene Technology Regulator's website or requested via the contact details below.

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