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GOVERNMENT NOTICES

Australian Government

Department of Health

Office of the Gene Technology Regulator

25 May 2016

Invitation to comment on draft assessment for clinical trial of live attenuated genetically modified influenza vaccines

Australia's gene technology regulatory system is designed to protect the health and safety of people and the environment by identifying risks posed by, or as a result of, gene technology and managing those risks.

The Gene Technology Regulator is assessing licence application DIR 144 from Clinical Network Services (CNS) Pty Ltd to conduct clinical trials of live attenuated genetically modified (GM) influenza vaccines. The GM vaccines would be administered by qualified health professionals to up to 500 healthy adult male volunteers, over a 5 year period. For the initial trial, the applicants propose to administer the GM flu vaccines in clinical facilities in Brisbane, while later trials may also take place in clinical facilities in Melbourne, Perth and Adelaide.

A consultation Risk Assessment and Risk Management Plan (RARMP) has been prepared, which concludes that the proposed clinical trials would pose negligible to low risk to human health and safety or to the environment. Licence conditions are proposed to manage the risk and to limit the scale and scope of the clinical trial and restrict the spread and persistence of the GMO's.

The Regulator welcomes written submissions on the RARMP to inform the decision on whether or not to issue a licence. The consultation RARMP and related documents can be obtained from the OGTR website under 'What's New' or by contacting the Office. Please quote application DIR 144 in any correspondence.

Submissions should be received by close of business on **27 June 2016**.

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