Australian Government
Department of Health
Office of the Gene Technology Regulator

12 April 2018

Invitation to comment on clinical trials of a genetically modified (GM) vaccine against respiratory syncytial virus

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 currently assessing licence application DIR 161 from Clinical Network Services (CNS) Pty Ltd. The application is for conducting clinical trials of a GM vaccine against *respiratory syncytial virus* (RSV). RSV causes a range of respiratory diseases in people, including pneumonia and bronchiolitis. The purpose of the trials is to assess the safety, tolerability and efficacy of the newly developed GM vaccine. There are currently no available vaccines against RSV.

The GM vaccine would be administered to up to 350 healthy adult volunteers over a five year period. The vaccine will be administered by intranasal spray at specialised clinical trial facilities in Melbourne, Sydney, Brisbane, Adelaide and/or Perth. The applicant proposes a number of control measures to restrict the spread and persistence of the GMOs and their genetic material.

Clinical trials must also be conducted in accordance with requirements of the *Therapeutic Goods Act 1989*, which is administered by the Therapeutic Goods Administration (TGA). Before commencing, each trial must be approved by a Human Research Ethics Committee, and notified to the TGA under the Clinical Trial Notification scheme.

A consultation Risk Assessment and Risk Management Plan (RARMP) has been prepared, which concludes that the proposed clinical trials would pose negligible risk to human health and safety or to the environment. A range of draft licence conditions would limit the scale, location and duration of the release, as well as restrict the spread and persistence of the GMO and its genetic material.

The Regulator welcomes written submissions in order to finalise the RARMP, which will then inform the decision on whether or not to issue the 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 161 in any correspondence.

Submissions should be received by close of business on **25 May 2018**.

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