



Australian Government

Department of Health

Office of the Gene Technology Regulator

24 January 2014

Invitation to comment on genetically modified cholera vaccine clinical trial

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 126 from PaxVax Australia Pty Ltd for a clinical trial of a genetically modified vaccine against cholera.

The primary purpose of the clinical trial is to verify the effectiveness of the vaccine in producing an immune response against cholera. The trial is proposed to take place in clinical facilities in Queensland, South Australia, Victoria and Western Australia. The trial would involve a maximum of 1000 volunteer adults and children receiving an oral dose of the GM vaccine. If approved, the trial is expected to be completed within one year.

A consultation Risk Assessment and Risk Management Plan (RARMP) has been prepared, which concludes that the proposed clinical trial would pose negligible risk to human health and safety or to the environment. A range of draft licence conditions would limit the scale and scope of the clinical trial and restrict the spread and persistence of the GMOs and the introduced genetic material.

The Regulator welcomes written submissions, which will be considered in finalising the RARMP. The finalised RARMP 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 126 in any correspondence.

Submissions should be received by close of business on **6 March 2014**.

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