



NOTIFICATION OF APPLICATION

Receipt of licence application (DIR 126) from PaxVax Australia Pty Ltd for a clinical trial of a GM cholera vaccine

Application

The Office of the Gene Technology Regulator (OGTR) has received a licence application from PaxVax Australia Pty Ltd (PaxVax) for the intentional release of a genetically modified (GM) bacterial vaccine into the environment (DIR 126), which qualifies as a limited and controlled release under section 50A of the *Gene Technology Act 2000* (the Act).

PaxVax is seeking approval to conduct a clinical trial of a GM live bacterial vaccine against cholera. Once underway the trial is expected to be completed within one year, with trial sites selected from local government areas (LGAs) in Queensland, South Australia, Victoria and Western Australia. The trial will involve the inoculation of approximately 1000 children and adults. The applicant has proposed a number of control measures to restrict the spread and persistence of the GM vaccine and its introduced genetic material.

PaxVax has indicated that a Clinical Trial Notification will be submitted to the Therapeutic Goods Administration, and that they will be applying to Department of Agriculture for a permit to import the vaccines.

Purpose of this notification

This notification provides early information about the above application and the assessment process, including a forthcoming opportunity to comment. At this stage, comment is **not** sought from members of the public. Later, the public will be asked to comment on a comprehensive Risk Assessment and Risk Management Plan (RARMP) for the application. This is expected to be released for public comment and advice from a broad range of experts, agencies and authorities in **late January 2014**. A period of at least 30 days will be allowed for submission of comments, as required by the Act.

In the interim, you can obtain a copy of the application by contacting my Office (contact details below; please quote application DIR 126). As the application is quite lengthy, you may prefer to view a summary of the application, which is posted on our website along with this document (under '[What's New](#)').

If you have any questions or would like to receive a hard copy of the application summary, please contact the OGTR.

**The Office of the Gene Technology Regulator,
MDP 54, GPO Box 9848, Canberra, ACT, 2601**
Telephone: 1800 181 030 Facsimile: 02 6271 4202 E-mail: ogtr@health.gov.au
Website <http://www.ogtr.gov.au>

Dr Joe Smith
Gene Technology Regulator
11 November 2013