



**Australian Government**  
**Department of Health and Ageing**  
**Office of the Gene Technology Regulator**

15 January 2010

## **NOTIFICATION OF DECISION**

### **ISSUE OF LICENCE DIR 097 TO PPD FOR A LIMITED AND CONTROLLED RELEASE OF GM PARAINFLUENZA VIRUS**

The Gene Technology Regulator has made a decision to issue a licence in respect of application DIR 097 from Pharmaceutical Product Development Australia Limited (PPD). The applicant has received approval for the limited and controlled release of a genetically modified vaccine for prevention of selected childhood respiratory diseases. The trial is authorised to take place in six specified hospitals in ACT, NSW, Qld, SA, Vic and WA and will involve a maximum of 70 children aged 2 – 24 months. The trial is expected to occur between January 2010 and March 2012.

The decision to issue the licence was made after extensive consultation on the Risk Assessment and Risk Management Plan (RARMP) with the public, State and Territory governments, Australian Government agencies, the Minister for the Environment, Heritage and the Arts, the Gene Technology Technical Advisory Committee and relevant local councils, as required by the *Gene Technology Act 2000* and corresponding State and Territory laws. The clinical trial of the vaccine has been authorised by the Therapeutic Goods Administration (TGA) under the Clinical Trial Exemption (CTX) scheme, and the OGTR has been liaising with the TGA during evaluation of this application.

Issues relating to the health and safety of people and the protection of the environment raised during the consultation process on this application were considered in finalising the RARMP and in making the decision to issue the licence.

The Executive Summary, Technical Summary and complete finalised RARMP, together with a set of Questions and Answers on this decision and a copy of the licence, can be obtained on-line from the Office of the Gene Technology Regulator's website or requested via the contacts detailed below.

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