

QUESTIONS & ANSWERS ON LICENCE APPLICATION DIR 097 FOR THE LIMITED AND CONTROLLED RELEASE OF A GENETICALLY MODIFIED VACCINE FOR PREVENTION OF SELECTED CHILDHOOD RESPIRATORY DISEASES

What is this application for?

Pharmaceutical Product Development Australia Pty Ltd (PPD) has received approval under the *Gene Technology Act 2000* to conduct a clinical trial of an imported genetically modified (GM) vaccine for prevention of childhood respiratory disease caused by two common viral pathogens, *Human parainfluenza virus type 3 (hPIV3)* and *Human respiratory syncytial virus (RSV)*.

What are hPIV3 and RSV?

Human parainfluenza virus type 3 and *Human respiratory syncytial virus* are two related viruses that occur worldwide in annual outbreaks and may cause respiratory disease requiring hospital treatment in infants less than two years of age. Although they cause similar symptoms, these viruses are not related to seasonal or pandemic influenza.

What is the vaccine?

The GM vaccine is based on a related virus, *Bovine parainfluenza virus type 3 (bPIV3)*, which commonly infects cattle in Australia. The bPIV3 has been modified to contain genes from hPIV3 and RSV. When a person is inoculated with the vaccine, it is expected they will develop a protective immune response against hPIV3 and RSV, which will help to prevent respiratory disease.

Has the vaccine previously been trialled in Australia?

No. The GM vaccine has undergone preliminary safety testing, and is the subject of clinical trials currently approved in the USA and the United Kingdom. Clinical trial applications are undergoing regulatory scrutiny in other countries including Spain, Finland, Germany, South Africa, Brazil and Canada.

What does the trial involve?

The trial will take place in six specified hospitals in ACT, NSW, Qld, SA, Vic and WA and involves the inoculation of a maximum of 70 children aged 2 – 24 months. The trial will occur between January 2010 and March 2012.

What controls have been imposed for this release?

The Risk Assessment and Risk Management Plan (RARMP) for this application concludes that the approved release poses negligible risks to people and the environment. However, a range of licence conditions have been imposed to restrict the release to the size, locations and duration requested by the applicant as these were important considerations in the assessment process. As well as limits on the scale of the release, control measures have been imposed to restrict exposure to the GMO and the introduced genetic material. These include exclusion criteria to restrict exposure of at-risk individuals; that transport and storage of the GM vaccine is in accordance with OGTR guidelines; and that waste is disposed of according to standard clinical practices. Full details of the imposed licence conditions are set out in the RARMP, which is available on the OGTR website.

What other regulatory approvals are needed for this trial?

The Therapeutic Goods Administration (TGA) is responsible for human safety assessment of the participants in clinical trials. The clinical trial of the vaccine has been approved by TGA under the Clinical Trial Exemption (CTX) scheme. The OGTR liaised with TGA during the assessment of this licence application.

Want more information?

A number of documents relating to this decision are available on the OGTR website (<<http://www.ogtr.gov.au>> under “What’s New”) or via Freecall 1800 181 030. These documents include the finalised RARMP, an Executive Summary, a Technical Summary and a copy of the full licence.