Questions & Answers on licence application DIR 116 for limited & controlled release of genetically modified (GM) vaccines

What does this licence allow?

PPD Australia Pty Ltd has received approval to trial, under limited and controlled conditions, two genetically modified (GM) live viral vaccines against prostate cancer. The clinical trial may take place in specified hospitals and health care facilities in ACT, NSW, QLD, SA, VIC and WA, between October 2012 and December 2017.

What is the purpose of the trial?

The purpose of the trial is to evaluate the efficacy of the GM vaccines against prostate cancer, and their safety and tolerability. The trial will form part of an international clinical trial involving 1200 patients in approximately 22 countries.

How have the GM live viral vaccines been modified?

The two GM vaccines are based on a *Vaccinia virus* and a *Fowlpox virus* that have been modified to contain the same four human genes. Expression of these genes is expected to induce immune responses against the prostate-specific antigen (PSA). This is intended to stimulate the immune system to attack and destroy prostate cancer cells expressing PSA.

What controls have been imposed for this release?

The Risk Assessment and Risk Management Plan (RARMP) for this application concluded that the proposed release poses negligible risks to people or the environment. However, a range of licence conditions have been imposed to limit the trial to the size, locations and duration proposed in the application, 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 the dissemination of the GMOs in the environment. These include conditions which provide for secure transport and storage of the GM live viral vaccines, exclusion of potential trial participants who may come into contact with individuals at risk of disease, administration of the vaccines only by trained clinical staff, and secure disposal of trial waste.

What other regulatory approvals are required?

The Therapeutic Goods Administration (TGA) is responsible for human safety assessment of participants in clinical trials. The OGTR has liaised with the TGA during the assessment of this licence application. The clinical trial will be authorised under the TGA's Clinical Trial Notification scheme.

Want more information?

A number of documents relating to this decision are available on the DIR 116 web page of the OGTR website 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.