Questions & Answers on licence DIR 171 – Clinical trial of genetically modified (GM) influenza vaccine

What does this licence allow?

Clinical Network Services (CNS) Pty Ltd is conducting a clinical trial, under limited and controlled conditions, of a live genetically modified (GM) vaccine for the protection of people against *Influenza virus* infection. The clinical trial will be assessing the safety and effectiveness of the GM vaccine in children.

Influenza viruses are highly infectious pathogens which are found in Australia. Symptoms include runny nose, cough, fever and tiredness. Healthy people normally recover within two weeks, but the elderly, young children, pregnant women and people with low immunity can suffer more severe symptoms.

Where will the GM vaccine be trialled?

The clinical trial will be conducted in up to four medical facilities, which would be located in Adelaide, Brisbane, Melbourne, Perth or Sydney. Up to 240 trial participants are permitted to be vaccinated in the trial, over a period of three years.

How has the GM vaccine been created?

The GM vaccine is based on a version of *Influenza virus*, which has been modified so that it cannot reproduce or spread. In addition, two genes to make proteins lying on the exterior surface of the virus have been introduced from a naturally occurring *Influenza virus* strain into the GM vaccine. These proteins are expected to cause an immune response that will protect a vaccinated person against the *Influenza virus*.

What is the purpose of the clinical trial?

The aim of the clinical trial is to gather data to assess the safety and effectiveness of the GM vaccine in children. It is hoped that this GM vaccine may provide better protection from *Influenza virus* than currently available vaccines. If this trial is successful, the GM vaccine may be tested in further trials, which would need additional approval from the Regulator.

Does this GM vaccine require any other approvals in Australia?

The Therapeutic Goods Administration (TGA) requires all clinical trials to have an appropriate authorisation, including being assessed and approved by a Human Research Ethics Committee (HREC) before trials begin. The HREC assessment includes looking at the safety of trial participants and ethical acceptability of the trial. HRECs are responsible for continuous monitoring of trial participant safety and are able to stop clinical trials by withdrawing approval if safety concerns arise. Import of the GM vaccine will require approval from the Department of Agriculture, Water and the Environment. CNS have indicated that they will obtain all appropriate approvals before conducting the clinical trial.

What controls are imposed for this release?

The Risk Assessment and Risk Management Plan (RARMP) for this application concludes that the trial poses negligible risks to people or the environment. However, as this is a trial, Clinical Network Services Pty Ltd must comply with a range of licence conditions that limit the size, location and duration of the trial, and restrict spread and persistence of the GM vaccine. For example, there are conditions relating to administration of the GM vaccine, secure transport and storage of the vaccine and appropriate waste disposal. Full details of these control measures are in the licence.

Want more information?

A number of documents relating to this decision are available on the DIR 171 page of the OGTR website or via Freecall 1800 181 030. These documents include the finalised RARMP, a summary of the RARMP and the licence.

The Office of the Gene Technology Regulator

Tel: 1800 181 030 E-mail: ogtr@health.gov.au

OGTR Website