Questions & Answers on licence application DIR 210 – Clinical trials of controlled infection with seasonal influenza viruses

What does this licence allow?

This licence will allow Doherty Clinical Trials Ltd. to conduct clinical trials involving recombinant influenza viruses produced through gene technology. These studies aim to investigate viral infections and the development of immunity. These trials also seek to evaluate methods for preventing and controlling influenza, including the effectiveness of new drugs or vaccines. Up to 150 volunteers are permitted to be treated with the recombinant influenza viruses at DCT clinical trial sites over 5 years.

Where will this organism be grown?

The recombinant influenza viruses will be grown in a facility in the USA and imported to Australia.

How has the GM influenza viruses been produced?

GMOs are produced from seasonal influenza viruses using a method called reverse genetics. The GMOs produced are similar to seasonal influenza viruses and are not more pathogenic than influenza viruses already present in the environment.

What is the purpose of the trial?

Influenza is an acute respiratory viral infection caused by influenza A or B viruses, with up to 650,000 deaths worldwide annually. For most healthy adults, seasonal influenza is a self-limited illness from which complete recovery is expected. These trials aim to better understand how the human immune system fights off influenza infections. Understanding the physiological and immunological responses of humans to these viruses is critical to develop vaccines and antivirals drugs for the control of influenza.

What other regulatory processes apply to this trial?

Clinical trials must be conducted in accordance with requirements of the Therapeutic Goods Administration (TGA), which address the safety of trial participants. In addition, the trials would require ethics approval from Human Research Ethics Committee (HREC) and must be conducted in accordance with the Guidelines for Good Clinical Practice. Import of the GM (vaccine/treatment) will also require approval from the Department of Agriculture, Fisheries and Forestry.

What controls are imposed for this release?

The consultation Risk Assessment and Risk Management Plan (RARMP) prepared for this application concluded that the clinical trials pose negligible to moderate risks to people or the environment based on the pathogenicity of circulating influenza. A number of licence conditions have imposed to restrict the spread and persistence of the GMO. For example, there are conditions relating to preparation and administration of the GM influenza virus, use of personal protective equipment, and appropriate waste disposal. Full details of the licence are available in the DIR 210 page of the OGTR.

Want more information?

A number of documents relating to this decision are available on the DIR 210 page of the OGTR website or via Freecall 1800 181 030. These documents include the finalised Risk Assessment and Risk Management Plan (RARMP), a summary of the RARMP and the licence.

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