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

What is this application for?

Doherty Clinical Trials Ltd. has proposed to conduct clinical trials involving recombinant influenza viruses produced through gene technology. The goal of these studies is to investigate viral infections and the development of immunity. These trials also aim to evaluate methods for preventing and controlling influenza, including the effectiveness of new drugs or vaccines.

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. Before commencing, the trials would require ethics approval and must be conducted in accordance with the *Guidelines for Good Clinical Practice*. Import of the GM influenza viruses will also require approval from the Department of Agriculture, Fisheries and Forestry.

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.

Have similar clinical trials been conducted in Australia or in other countries?

This is the first time that clinical trials with GM influenza will be used in healthy participants in Australia; however, these types of trials have been conducted in several countries including the USA. The first GMO to be used in the clinical trial proposed under this licence has been used in a trial authorised by the FDA in the USA. No serious adverse events were reported.

What controls are proposed for this release?

The consultation Risk Assessment and Risk Management Plan (RARMP) prepared for this application concluded that the clinical trial poses negligible to moderate risks to people or the environment. A number of licence conditions have been drafted 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 draft licence conditions are available in the consultation RARMP.

How can I comment on this application?

The full consultation RARMP and a summary of the RARMP for application DIR 210 are available on the OGTR website or via the contacts listed below. You are invited to submit your written comments (including email) on the consultation version of the RARMP, related to any risks to the health and safety of people or to the environment from the proposed clinical trial. Please note that issues such as **patient safety, quality and efficacy of a therapeutic products, and marketability and trade implications** do **NOT** fall within the scope of the evaluations conducted under the *Gene Technology Act 2000* as these are the responsibility of other agencies and authorities. Comments must be received by the close of the consultation period on **7 February 2025**.

What are the next steps in the evaluation process?

The RARMP will be finalised, taking into account submissions related to the protection of people or the environment. A de-identified summary of all comments received and consideration of those comments is

included in the Appendices to the final RARMP. The finalised RARMP will inform the Regulator's decision on whether or not to issue a licence.

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