Questions & Answers on licence application DIR 206 – Clinical trial for the treatment of mycobacterial infections using bacteriophages

What does this licence allow?

The licence holder, Western Sydney Local Health District (WSLHD) is conducting a clinical trial of genetically modified (GM) bacteriophages for the treatment of mycobacterial infections that are unable to be treated with antibiotics. The trial would be conducted over five years in hospitals or under Hospital in the Home programs.

Where will this bacteriophage be grown?

Bacteriophage may be grown in the clinical trial sites within hospitals.

How have the GM bacteriophages been modified?

Once bacteriophages infect a bacterial cell, they typically either live inside the bacterial cell, or reproduce and kill the cell. The GM bacteriophages have been modified to remove the ability to live in bacteria, so they can only reproduce in the bacteria and destroy the infection.

What is the purpose of the trial?

The study will look at how well the GM bacteriophage therapies work for the treatment of various types of bacterial infections, administered by various methods including endobronchial lavage, nebuliser, intravenous injection, instillation, or topical application. The aim of the clinical trial is to gather data to assess the effectiveness of the GM bacteriophage treatment both in hospitals and under Hospital-in-the-Home programs. It is hoped that this GM bacteriophage treatment offers an option to patients with multi-drug resistant mycobacterial infections, where standard measures either do not exist or are no longer effective. If this trial is successful, the GM bacteriophage treatment may be tested in further trials, which would need additional approval from the Regulator.

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 bacteriophages will also require approval from the Department of Agriculture, Fisheries and Forestry.

What controls are imposed for this release?

The Risk Assessment and Risk Management Plan (RARMP) for this application concludes that the clinical trial poses negligible risks to people or the environment. However, as this is a clinical trial, Western Sydney Local Health District must comply with a range of licence conditions that restrict when and where the trial can take place, limit the size of the trial and stop GM bacteriophages from spreading outside the trial. These conditions limit the locations of the clinical trial, limit the duration of the trial, and specify a range of controls to minimise the potential for the GM bacteriophages to spread in the environment. For example, there are conditions relating to administration of the GM bacteriophages, secure transport and storage of the GM bacteriophages 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 206 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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