

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

### **What is this application for?**

Western Sydney Local Health District is seeking approval to use genetically modified (GM) bacteriophages in the treatment of bacterial infections that are unable to be treated with antibiotics. The trial would be conducted over five years in hospitals or under the Hospital in the Home program.

### **What are bacteriophages?**

Bacteriophages are viruses that only infect bacteria, and have previously been used to treat bacterial infections in humans. They are not known to infect people or cause harm to people or the environment.

### **How has the GM bacteriophages been modified?**

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

### **What is the purpose of the trial?**

The study will evaluate the efficacy of GM bacteriophage therapies for the treatment of various types of bacterial infections, administered by various methods including endobronchial lavage, nebuliser, intravenous injection, instillation, or topical application.

### **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 risks to people or the environment. However, as this is a clinical trial under limited and controlled conditions, a number of licence conditions have been drafted to restrict when the trial can take place and to restrict the spread and persistence of the GM bacteriophages. For example, there are conditions relating to the sites and personnel involved in preparation and administration, secure transport and storage, 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-206 are available on the [OGTR website, DIR 206](#), 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 application. Comments must be received by the close of the consultation period on **9 December 2024**.

### **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.

**The Office of the Gene Technology Regulator**

**OGTR Website**

**Tel: 1800 181 030**

**E-mail: [ogtr@health.gov.au](mailto:ogtr@health.gov.au)**