4 July 2024

Summary of Licence Application DIR-206

The Western Sydney Local Health District (WSLHD) has made an application under the *Gene Technology Act 2000* (the Act) to conduct a limited and controlled administration of a therapy using genetically modified organisms (GMOs).

Project Title	*Clinical trial for the treatment of mycobacterial infections using bacteriophages*[1]
Parent organism	Bacteriophages (mycobacteriophages)
Genetic modifications	
Introduced genes	Deletion of genes including the repressor gene, rendering the bacteriophages lytic in order to destroy host bacteria.
Genetic modification method	Homologous recombination
Principal purpose	The proposed dealings are to administer genetically modified bacteriophages to treat Australian patients with mycobacterial infections.
Previous licences	DNIR-620 for the Sydney Children's Hospital Network authorised the *Therapeutic treatment of paediatric patients with cystic fibrosis and Mycobacterium abscessus disease.* DNIR-655 for the Alfred Hospital authorised *Bacteriophage therapy for severe lung disease due to Mycobacterium abscessus infection*.
Proposed limits and controls	
Proposed duration	5 years
Proposed location/s	Clinical sites; potential administration at home by qualified persons.
Proposed controls	• Administration will be in hospital or by qualified persons at home. • Administration will only be to patients under Special Access Scheme categories A and B. • Administration will be limited to the treatment of those with mycobacterial infections. • A 5-year limit on licence.

The application

The applicant proposes to administer the GM bacteriophage to patients with mycobacterial infections. These GM bacteriophages have been designed to kill mycobacteria responsible for these patient's recurrent infections.

The proposed clinical trial must meet Therapeutic Goods Administration (TGA) requirements and would need approval from a registered Human Research Ethics Committee prior to commencement.

The application is for limited and controlled trial under section 50A of the Act, as the Regulator was satisfied that its principal purpose is to enable the applicant to conduct the trial, and the proposed limits and controls are such that consultation with prescribed experts, agencies and jurisdictions is not required at this stage.

[1] Original title: *Bacteriophages for treatment of mycobacterial infections under the STAMP protocol*

Next steps

The Gene Technology legislation sets out what the Regulator must do, as well as what the Regulator can or must consider, before deciding whether or not to issue a licence for this application.

The Regulator's staff will prepare a consultation version of the Risk Assessment and Risk Management Plan (RARMP) considering aspects of the application including the proposed limits and controls in accordance with the legislation.

The Regulator will seek comment on the consultation RARMP from the public, as well as a wide range of experts, agencies and authorities. The public and experts will be invited to provide submissions on the risks to human health and safety, and on risks to the environment from the proposed clinical trial.

At this stage, the consultation RARMP is expected to be released for comment in **August 2024**.

After consultation, the Regulator's staff will finalise the RARMP, taking into account advice on relevant matters. The finalised RARMP will form the basis of the Regulator's decision whether or not to issue a licence. The consultation and final versions of the RARMP and associated documents will be available on the OGTR website when they are released.

Other information available from the OGTR website:

- information on Australia's national scheme for regulation of gene technology and
- information on the DIR application process.

Please use the contact details below, if you

- would like a copy of the application. Please include the identifier DIR-206.
- have any questions about the application or the legislated evaluation process or
- wish to register on the mailing list.

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