Questions & Answers on licence application DIR 221 – Clinical trial of a genetically modified *Escherichia coli* for the treatment of ulcerative colitis

What is this application for?

Melius MicroBiomics Pty Ltd (Melius) is seeking approval for a clinical trial of a genetically modified (GM) *Escherichia coli* for the treatment of ulcerative colitis. Ulcerative colitis is a form of inflammatory bowel disease (IBD).

Probiotics containing parental (unmodified) *E. coli* Nissle strain 1917 (ECN) have been used for the treatment of ulcerative colitis. It is predicted that the GM *E. coli* would be able to persist longer in the gut of participants with ulcerative colitis and improve its therapeutic effect. The GM *E. coli* would be manufactured overseas and imported into Australia. It would be administered to up to 36 participants at clinical trial sites and hospitals in Brisbane.

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 *E. coli* treatment will also require approval from the Department of Agriculture, Water and the Environment.

How has the GM *E. coli* been modified?

The GM *E. coli* is based on the ECN probiotic strain, which has been used for over 100 years. The GM *E. coli* has been modified by the insertion of a gene that allows it to persist longer in inflammatory conditions, common in the gut of people with ulcerative colitis. The GM *E. coli* has also been modified to reduce its ability to persist outside the body in the broader environment and to reduce its ability to persist in healthy human gut.

What is the purpose of the trial?

The trial is to assess the safety and efficacy of the GM *E. coli* for the treatment of ulcerative colitis.

Has the GM treatment been previously tested or used?

This is the first human clinical trial of the GM treatment.

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 and where the trial can take place, limit the size of the trial, and restrict the spread and persistence of the GM treatment. For example, there are conditions relating to preparation and administration of the GM treatment, secure transport and storage of the GM treatment 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 221 are available on the OGTR website, the consultation hub or via the contacts listed below. You are invited to submit your written comments (via the consultation hub or by 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 **14 January 2026**.

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, will be 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

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