Questions & Answers on licence application DIR 197 – clinical trial of genetically modified *Lactobacillus brevis* bacteria

What is this application for?

Novotech (Australia) Pty Ltd is seeking approval for a clinical trial of genetically modified (GM) *Lactobacillus brevis* for treatment of inflammatory bowel disease.

The proposed treatment uses GM bacteria which have been designed to reduce gut inflammation. Up to 60 trial participants would be treated across Australia. The treatment would be taken at medical facilities or at the trial participants' homes.

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. Trials require ethics approval before commencing, and must be conducted in accordance with the *Guidelines for Good Clinical Practice*. Import of the GM bacteria will also require an import permit from the Department of Agriculture, Forestry and Fisheries.

How was the GM treatment created?

The GM treatment is based on *Lactobacillus brevis* bacteria, which are sometimes used in probiotics. The GMO has been modified by introduction of a gene encoding a human peptide that signals the immune system to reduce inflammation.

What is the purpose of the trial?

The first part of the trial will test the safety of the GMO in healthy adults. The second part of the trial will test the safety and efficacy of the GMO in patients with ulcerative colitis, which is a form of inflammatory bowel disease.

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 low risks to people or the environment. Risk treatment measures have been proposed to manage these risks. 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 197 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 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 **25 August 2023**.

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

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