# Questions & Answers on licence DIR 197 – Clinical trial of genetically modified *Lactobacillus brevis*

**What does this licence allow?**

Novotech (Australia) Pty Ltd is conducting a clinical trial of genetically modified (GM) bacteria designed to treat inflammatory bowel disease.

The GMO will be imported into Australia. Up to 28 trial participants will be treated with the GMO. The treatment will be taken at medical facilities or at the trial participants' homes, in Melbourne, Victoria.

**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 clinical trial is a first stage in developing the GM treatment, and will test the safety of the GM treatment in healthy adults. Later development stages, involving trials of the GMO in people with inflammatory bowel disease, would need additional approval from the Gene Technology 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. Trials require ethics approval before commencing, and must be conducted in accordance with the *Guidelines for Good Clinical Practice*. Import of the GMO will also require an import permit from the Department of Agriculture, Forestry and Fisheries.

**What conditions are imposed for this release?**

The Risk Assessment and Risk Management Plan (RARMP) for this application concludes that the clinical trial poses negligible to moderate risks to people or the environment. Strict licence conditions have been imposed to manage these risks. These conditions limit the number of trial participants, limit the location of the clinical trial, limit the duration of the trial, and specify a range of controls to minimise the potential for the GMO to spread in the environment. For example, there are conditions relating to secure transport and storage of the GMO, hygiene measures for trial participants, and appropriate waste disposal. Full details of these risk treatment measures are in the licence.

**Want more information?**

A number of documents relating to this decision are available on the DIR 197 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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