Questions & Answers on licence DIR 222 – Clinical trial of a genetically modified adenovirus for the treatment of locally advanced rectal cancer

What does this licence allow?

Novotech (Australia) Pty Ltd (Novotech) is conducting a clinical trial, under limited and controlled conditions, of a genetically modified (GM) adenovirus for the treatment of locally advanced rectal cancer.

The GM virus would be manufactured overseas and imported into Australia. It is permitted to be administered to up to 40 patients with locally advanced rectal cancer at clinical trial sites and hospitals in Australia, over a period of 4 years.

How has the GM adenovirus been modified?

The GM treatment is based on a non-GM adenovirus which lacks several genes, making it preferentially infect and multiply in cancer cells rather than healthy cells. The non-GM adenovirus has been used in clinical trials to treat different cancers in people. The GMO has been produced by modifying the non-GM adenovirus by inserting two genes encoding for one protein that stimulates the body's immune system to recognise and kill tumour cells.

What is the purpose of the trial?

The aim of the trial is to assess the safety, tolerability and efficacy of the GM adenovirus for treating locally advanced rectal cancer.

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 treatment will also require approval from the Department of Agriculture, Forestry and Fisheries (DAFF).

What controls are imposed for this release?

The Risk Assessment and Risk Management Plan (RARMP) for this application concludes that the clinical trial poses negligible risks to people or the environment. However, as this is a clinical trial, Novotech must comply with a range of licence conditions. These conditions limit the number of trial participants, limit the location of the clinical trial to hospitals and clinical trial sites, limit the duration of the trial, and specify a range of controls to minimise the potential for the GM treatment to spread in the environment. For example, there are conditions relating to the preparation and administration of the GM treatment, secure transport and storage of the GM treatment and appropriate waste disposal. Full details of these control measures are in the licence.

Want more information?

A number of documents relating to this decision are available on the DIR 222 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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