Questions & Answers on licence DIR 213 – Clinical trial of a genetically modified human adenovirus for treatment of melanoma

What does this licence allow?

Novotech (Australia) Pty Ltd (Novotech) has been issued a licence to conduct a clinical trial, under limited and controlled conditions, of a genetically modified (GM) human adenovirus for treatment of melanoma.

The GM human adenovirus has been designed to preferentially multiply in and kill cancer cells. It is intended to significantly increase survival rates of patients that have been unresponsive to other treatments. The GM human adenovirus would be manufactured overseas and imported into Australia. Up to 30 patients with melanoma are permitted to be treated with the GM adenovirus at clinical trial sites and hospitals in Australia, over a period of 3 years.

How has the GM human adenovirus been modified?

The GM treatment is based on human adenovirus, which can cause respiratory illness in some people. It has been modified by deleting parts of several genes, so that it multiplies in and then kills cancerous tumour cells with limited effects on healthy cells. One gene has also been introduced into the GM treatment that stimulates the body's immune system to recognise and kill tumour cells.

What is the purpose of the trial?

The aim of the clinical trial is to gather data to assess the safety and effectiveness of the GM treatment in patients with melanoma.

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 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-213 page of the OGTR website or via Freecall 1800 181 030. These documents include the finalised RARMP, a summary of the RARMP and the licence.

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