Questions & Answers on licence DIR 208 – Clinical trial of a GM vaccinia virus for the treatment of solid tumours

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) vaccinia virus for treatment of solid tumours.

The GM treatment has been designed to have enriched replication in cancer cells. It is predicted to significantly increase survival rates of patients that have been unresponsive to other treatments. The GM treatment will be manufactured overseas and imported into Australia. Up to 40 patients with refractory tumours are permitted to be treated with the GM treatment at clinical trial sites and hospitals in Australia, over a period of 5 years.

How has the GM treatment been created?

The GM treatment is based on *Vaccinia virus*, which was used as a vaccine during the global smallpox eradication campaign. The *Vaccinia virus* has been modified by deletion of several genes so that it multiplies in and then kills cancerous tumour cells with limited effects on healthy cells. Three genes have also been introduced into the *Vaccinia virus* that stimulate 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 advanced solid tumours. If this trial is successful, the GM treatment may be tested in further trials, which would need additional approval from the 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. 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.

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 208 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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