Questions & Answers on licence application DIR 192 – Clinical trial of a genetically modified (GM) chimeric orthopoxvirus as a cancer treatment

What does this licence allow?

Medpace Australia Pty Ltd is conducting a clinical trial, under limited and controlled conditions, of a genetically modified (GM) chimeric orthopoxvirus as a cancer treatment. The GM virus, known as CF33-hNIS, has been designed to preferentially multiply in and kill cancer cells, and the trial would evaluate its safety and efficacy. The GM virus would be manufactured overseas and imported into Australia. It would be administered to up to 18 patients with solid cancerous tumours locally advanced or spreading throughout the body. The trial would take place at clinical trial sites and hospitals in Australia.

How has the GM virus has been produced?

The GM treatment is based on a chimeric orthopoxvirus, which is genetically similar to the vaccinia virus used as a vaccine during the global smallpox eradication campaign. It has been modified to preferentially multiply in and kill cancer cells. Additionally, a gene derived from humans has been introduced to facilitate the visualisation of the GMO after administration to patients by medical imaging.

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

Has the GM treatment been previously tested or used?

The GM treatment is currently in a Phase 1 clinical trial in the United States.

What controls are proposed for this release?

The Risk Assessment and Risk Management Plan (RARMP) prepared for this application concluded that the clinical trial poses negligible risks to people or the environment. However, as this is a clinical trial under limited and controlled conditions, a number of licence conditions have been imposed to restrict when and where the trial can take place, limit the size of the trial, and restrict the spread and persistence of the GM treatment in the environment. For example, there are conditions relating to preparation and administration of the treatment, secure transport and storage of the treatment and appropriate waste disposal. Full details of these control measures are included in the licence.

Want more information?

A number of documents relating to this decision are available on the DIR 192 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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