Questions & Answers on licence application DIR 187
Clinical trial of a genetically modified alphavirus for treatment of cancer

What is this application for?

VRT Pharmaceutics Pty Ltd is seeking approval for a clinical trial of genetically modified (GM) *Getah virus* as a cancer treatment. The GM virus has been designed to preferentially multiply in and kill cancer cells, and the trial would evaluate its safety and tolerability. GM *Getah virus* would be manufactured overseas and imported into Australia. Up to 20 adults with cancer that is locally advanced or has spread throughout the body would receive a series of seven treatments, delivered intravenously in a hospital setting. The trial would take place at a clinical trial site in Adelaide, South Australia and at other locations in Australia if needed.

What other regulatory processes apply to this trial?

Clinical trials must be conducted in accordance with requirements of the Therapeutic Goods Administration, which address the safety of trial participants. Before commencing, the trial would require ethics approval, and must be conducted in accordance with the *Guidelines for Good Clinical Practice*. Import of the GM virus would also require approval from the Department of Agriculture, Water and the Environment.

How has the GM treatment been created?

The GM virus is based on the mosquito-borne *Getah virus* which is found mainly in Asia. The M1 strain of *Getah virus* has been shown to preferentially target cancer cells and is itself is being studied as a cancer treatment. For this clinical trial, the M1 strain has been genetically modified by making two small changes to the genetic code to increase its preference for cancer cells.

Has the GM treatment been previously tested or used?

This is a first-in-human clinical trial. However, preclinical studies using animal models have been completed and fourteen cancer patients have received treatment overseas under compassionate use access. No serious adverse events were reported.

What controls are proposed for this release?

The consultation 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 drafted 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 virus. 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 the draft licence conditions are available in the consultation RARMP.

How can I comment on this application?

The full consultation RARMP and a summary of the RARMP for application DIR 187 are available on the OGTR website or via the contacts listed below. You are invited to submit your written comments (including by email) on the consultation version of the RARMP, related to any risks to the health and safety of people or to the environment from the proposed clinical trial. Please note that issues such as **patient safety, quality and efficacy of a therapeutic products, and marketability and trade implications** do **NOT** fall within the scope of the evaluations conducted under the *Gene Technology Act 2000* as these are the responsibility of other agencies and authorities. Comments must be received by the close of the consultation period on **7 January 2022**.

What are the next steps in the evaluation process?

The RARMP will be finalised, taking into account submissions related to the protection of people or the environment. A de-identified summary of all comments received and consideration of those comments is included in the Appendices to the final RARMP. The finalised RARMP will inform the Regulator's decision on whether or not to issue a licence.

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