Questions & Answers on licence DIR 177 – clinical trial of genetically modified (GM) human adenovirus

What does this licence allow?
Novotech (Australia) Pty Limited is conducting a clinical trial of genetically modified human adenovirus for bladder cancer treatment. Transitional cell carcinoma (TCC) is the most common type of bladder cancer. Each year almost 2,700 new cases and approximately 1100 deaths of TCC are recorded in Australia. Current treatment includes surgery to remove the bladder tumour, chemotherapy or immunotherapy. The combination of the above gives best results but cancer reoccurrence rates are still high.

Where will the GM treatment be trialled?

It would be administered into the bladder to a maximum of 60 patients at multiple hospitals located in New South Wales (NSW) and Victoria (VIC), over a period of up to 5 years.

How has the GM treatment been constructed?
The vaccine is based on a modified human adenovirus. The GM treatment has been modified so that it reproduces preferentially in cancer cells. Two genes have been introduced into the GM vaccine that inhibit viral replication in normal cells and stimulate immune response in tumours. The GM human adenovirus would be manufactured overseas and imported into Australia.

What is the purpose of the clinical trial?

The aim of the clinical trial is to gather data to assess the efficacy of the GM treatment. The proposed GM human adenovirus treatment is predicted to significantly increase survival rates and limit the reoccurrence in patients that have been unresponsive to other treatments.

Has the GM treatment been previously tested or used?

The GM treatment has been tested in the United States and in Canada. These studies have shown that people receiving the GM treatment have mild to moderate urinary-tract effects (sudden and frequent need of urination, bladder discomfort, presence of blood in urine and painful urination) and occasionally mild-flu symptoms. There have been no severe reactions to the GM treatment.

What other regulatory processes apply to this trial?

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 human adenovirus treatment will also require approval from the Department of Agriculture, Water and the Environment. The Therapeutic Goods Administration (TGA) are notified of any clinical trials being conducted.

What controls are imposed for this release?
The Risk Assessment and Risk Management Plan (RARMP) for this application concludes that the trial poses negligible risks to people or the environment. However, as this is a trial under limited and controlled conditions, Novotech (Australia) Pty Ltd must comply with a range of licence conditions that limit the location and duration of the trial, the size of the trial, and restrict the spread and persistence of the GM treatment. 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 in the licence.

Want more information?

A number of documents relating to this decision are available on the DIR 177 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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