Questions & Answers on licence DIR 217 – Commercial supply of genetically modified therapeutic for bladder cancer treatment

What does this licence allow?

Ferring Pharmaceuticals Pty Ltd has received an approval under the *Gene Technology Act 2000* for the import, transport, storage, and disposal of a genetically modified (GM) therapeutic, nadofaragene firadenovec, as part of its commercial supply in Australia for bladder cancer treatment.

How has the GM therapeutic been modified

The GM therapeutic is a human adenovirus which has been genetically modified by removing DNA sequences to make it safe for patients and introducing a gene for a protein with anti-tumour effects. It can enter urothelial and tumour cells and produce the protein with anti-tumour effects within the infected cells.

What regulatory processes apply to this commercial supply?

The Gene Technology Regulator (the Regulator) has specific responsibility to protect the health and safety of people, and to protect the environment from any risks posed by gene technology. For this type of application, the activities assessed by the Regulator are the import, transport, storage, and disposal of the GM therapeutic.

The use of the GM therapeutic in people will also require approval by the Therapeutic Goods Administration (TGA). The TGA considers the safety and efficacy of the therapeutic in people being treated as part of their approval process, as well as determines conditions for the use of the therapeutic.

The import of the GM therapeutic will also require a permit from the Department of Agriculture, Fisheries and Forestry (DAFF).

Has nadofaragene firadenovec been used previously?

This GM therapeutic has not previously been approved for commercial use in Australia.

Internationally, it has been approved for commercial use by the Food and Drug Administration in the USA.

What controls have been imposed for this commercial supply?

The licence is for import, transport, storage, and disposal as part of ongoing commercial supply of the GM therapeutic. The Regulator has not imposed any specific measures to manage risk, as the risk assessment concluded that the supply of this GM therapeutic poses negligible risks to the health and safety of people or the environment. However, general conditions have been imposed to ensure that there is ongoing oversight of the commercial supply.

Want more information?

A number of documents relating to this decision are available on the DIR 217 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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