



Summary of Licence Application DIR 217

FERRING Pharmaceuticals Pty Ltd has made an application under the *Gene Technology Act 2000* (the Act) for Dealings involving the Intentional Release (DIR) of genetically modified organisms (GMOs) into the Australian environment.

Project Title	Commercial supply of nadofaragene firadenovec for bladder cancer treatment ¹
Parent organism	Human adenovirus type 5 (Ad5)
Genetic modifications	Modified human adenovirus: <ul style="list-style-type: none">• deletion of gene sequences² to improve safety and• insertion of the human interferon alfa-2b gene to produce the protein with anticancer activities
Principal purpose	Commercial supply of a GM adenovirus for the treatment of Australian patients with bladder tumours that are unresponsive to standard treatment
Previous releases and clinical trials	<ul style="list-style-type: none">• Clinical trials (Phases 1-3) were undertaken in the United States (US).• In December 2022, the US Federal Drug Administration approved a request for permission to introduce this GMO into interstate commerce for the treatment of certain bladder cancers.
Proposed period of release	Ongoing from issue of licence

The application

The applicant proposes to supply the GM therapeutic to Urology and Oncology departments of hospitals for administration to patients with certain types of treatment-unresponsive bladder cancer. The proposed commercial supply must meet Therapeutic Goods Administration requirements, and the proposed import would need approval from the Department of Agriculture, Fisheries and Forestry (Biosecurity) prior to commencement.

Next steps

The Gene Technology legislation sets out what the Regulator must do, as well as what the Regulator can or must consider, before deciding whether or not to issue a licence for this application.

After seeking advice from prescribed experts, agencies and authorities, the Regulator's staff will prepare a consultation version of the Risk Assessment and Risk Management Plan (RARMP) considering aspects of the application in accordance with the legislation.

The Regulator will seek comment on the consultation RARMP from the public, as well as a wide range of experts, agencies and authorities. The public and experts will be invited to provide submissions on the risks to human health and safety, and on risks to the environment from the proposed commercial supply.

At this stage, the consultation RARMP is expected to be released for comment in **July 2025**.

¹ The original title supplied by the applicant is: *Gene therapy for bladder cancer*

² Confidential Commercial Information: Some details about the deleted DNA sequences are the subject of an application for declaration as Confidential Commercial Information under section 185 of the Act.

After consultation, the Regulator's staff will finalise the RARMP, taking into account advice on relevant matters. The finalised RARMP will form the basis of the Regulator's decision whether or not to issue a licence. The consultation and final versions of the RARMP and associated documents will be available on the [OGTR website](#) when they are released.

Other information available from the [OGTR website](#):

- 'Questions and Answers' document for this application
- information on Australia's national scheme for regulation of gene technology and
- information on the DIR application process.

Please use the contact details below if you:

- would like a copy of the application. Please include the identifier DIR 217.
- have any questions about the application or the legislated evaluation process or
- wish to register on the mailing list.

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