



Australian Government

Department of Health and Aged Care
Office of the Gene Technology Regulator

NOTIFICATION OF APPLICATION

Receipt of licence application from FERRING Pharmaceuticals Pty Ltd for the commercial supply of nadofaragene firadenovec for bladder cancer treatment

The Office of the Gene Technology Regulator (OGTR) has received a licence application (DIR 217) from FERRING Pharmaceuticals Pty Ltd (Ferring) for the import, transport, storage, and disposal of a genetically modified (GM) therapeutic for bladder cancer treatment in Australia. A summary of the application is posted on our [website](#) (search for DIR 217).

The applicant proposes to supply the GM therapeutic to Urology and Oncology departments of hospitals for administration to patients with certain types of 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.

The OGTR is preparing a Risk Assessment and Risk Management Plan for the application. The RARMP will be prepared taking into account advice received from a broad range of experts, agencies and authorities, and relevant local councils, as specified in the *Gene Technology Act 2000*. This is expected to be released for public comment and advice from experts, agencies and authorities in **July 2025**. There will be at least 30 days for submission of comments.

If you have any questions or would like to receive a copy of the application or the summary, please contact the OGTR and quote the reference number DIR 217.

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4 April 2025