



21 October 2025

Notification of decision on application DIR 217 from Ferring Pharmaceuticals Pty Ltd for the commercial supply of genetically modified therapeutic for bladder cancer treatment

The Regulator has issued licence DIR 217 to Ferring Pharmaceuticals Pty Ltd. The licence authorises the import, transport, storage, and disposal of a genetically modified (GM) human adenovirus, nadofaragene firadenovec, as part of its commercial supply in Australia.

Before it can be used commercially, the GM therapeutic must also be approved by the Therapeutic Goods Administration (TGA), which is responsible for assessing the quality, safety, and efficacy of therapeutic products. The import of the GM therapeutic will also require a permit from the Department of Agriculture, Fisheries and Forestry (DAFF).

The Risk Assessment and Risk Management Plan (RARMP) and the licence were finalised taking into account input received during consultation with the public, State and Territory governments, Australian Government agencies, the Minister for the Environment, the Gene Technology Technical Advisory Committee and local councils. The Regulator thanks submitters for their contributions.

Submissions are summarised in Appendix B and Appendix C of the RARMP, together with information about how the issues raised relating to risks to human health and safety or the environment were considered in preparing and finalising the RARMP.

The finalised RARMP concludes that this commercial supply poses negligible risks to the health and safety of people and the environment and does not require specific risk treatment measures. However, general licence conditions have been imposed to ensure ongoing oversight of the release.

The finalised RARMP, a summary of the RARMP, the licence and Questions and Answers about this decision can be obtained online from the [DIR 217](#) page of the Office of the Gene Technology Regulator's (OGTR) website or requested via the contacts detailed below.

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