Australian Government
Department of Health, Disability and Ageing
Office of the Gene Technology Regulator

Invitation to comment on commercial supply of genetically modified therapeutic for bladder cancer treatment (DIR 217)

The Gene Technology Regulator (Regulator) has received an application from Ferring Pharmaceuticals Pty Ltd (Ferring) for the commercial supply of a genetically modified human adenovirus for treatment of bladder cancer.

The GM therapeutic contains a modified virus, which requires Ferring to seek review from both the Regulator and the Therapeutic Goods Administration before it is able to be used in Australia.

The Regulator has prepared a Risk Assessment and Risk Management Plan (RARMP) for this application and welcomes written submissions on any risks to human health and the environment posed by the import, transport, storage and disposal of this GM therapeutic and is seeking comment on the RARMP prior to making a decision on whether or not to issue the licence.

The consultation RARMP and related information can be obtained via the consultation hub or from the contacts below. Submissions should reference DIR 217 and be received by **18 September 2025**.

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