



Australian Government

Department of Health, Disability and Ageing

Office of the Gene Technology Regulator

Invitation to comment on a clinical trial of a genetically modified adenovirus for bladder cancer treatment (DIR-223)

The Gene Technology Regulator is assessing an application from Ferring Pharmaceuticals Pty Ltd (Ferring) to conduct a clinical trial, under limited and controlled conditions, of a genetically modified human adenovirus for treatment of bladder cancer. The trial is proposed to take place at clinical trial sites and hospitals in Australia. Up to 13 trial participants would be treated over a 5-year period.

The Regulator has prepared a Risk Assessment and Risk Management Plan (RARMP) for this application and welcomes written submissions relating to the protection of human health and safety and the environment prior to making a decision on whether to issue the licence. The consultation RARMP and related information can be obtained via the [consultation hub](#) (search for DIR 223), or from the contacts below. Submissions should reference DIR 223 and be submitted via the hub or email by **6 March 2026**.

Office of the Gene Technology Regulator
MDP 54 GPO Box 9848 CANBERRA ACT 2601
Telephone: 1800 181 030 [OGTR Website](#)
E-mail: ogtr@health.gov.au