Australian Government
Department of Health
Office of the Gene Technology Regulator

01 February 2021

Notification of decision on application DIR 177 from Novotech (Australia) Pty Limited for a clinical trial of GM human adenovirus for bladder cancer treatment

The Regulator has issued licence DIR 177 to Novotech (Australia) Pty Limited, authorising a clinical trial of human adenovirus genetically modified (GM) for bladder cancer treatment.

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 A and Appendix B 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 clinical trial poses negligible risks to the health and safety of people and the environment, thus it does not require specific risk treatment measures. However, licence conditions have been imposed to limit the size, location and duration of the trial and to restrict spread and persistence of the GMOs and their genetic material in the environment, as these were important considerations for the RARMP.

The finalised RARMP, a summary of the RARMP, the licence, and Questions and Answers about this decision can be obtained online from the DIR 177 page of the Office of the Gene Technology Regulator's (OGTR) website or requested via the contacts detailed below.

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