Australian Government
Department of Health
Office of the Gene Technology Regulator

13 December 2021

Notification of decision on application DIR 185 from Novotech (Australia) Pty Ltd for a clinical trial with genetically modified *Bordetella pertussis* for the prevention of whooping cough

The Regulator has issued licence DIR 185 to Novotech (Australia) Pty Ltd, authorising a clinical trial with genetically modified Bordetella pertussis for the prevention of whooping cough.

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 number of trial participants, limit the location of the clinical trial to hospitals and clinical trial sites, limit the duration of the trial, and specify a range of controls to minimise the potential for the GMO to spread 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 185 page of the Office of the Gene Technology Regulator's (OGTR) website or requested via the contacts detailed below.

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