Australian Government
Department of Health
Office of the Gene Technology Regulator

17 February 2021

Notification of decision on application DIR 174 from Biocelect Pty Ltd for the commercial supply of a GM cholera vaccine, Vaxchora®

The Regulator has issued licence DIR 174 to Biocelect Pty Ltd, authorising import, transport, storage and disposal associated with commercial supply of a genetically modified (GM) cholera vaccine, Vaxchora®. Vaxchora® is a vaccine developed to prevent cholera disease in people who travel overseas to areas where cholera is present. These activities associated with GM vaccine supply are authorised to take place throughout Australia. This vaccine also requires approval from other agencies including the Therapeutic Goods Administration.

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 the import, transport, storage and disposal associated with commercial supply of the GM vaccine poses negligible risks to people and the environment and does not require specific risk treatment measures. However, general licence conditions have been imposed to ensure ongoing oversight of these activities associated with supply of the GM vaccine.

The finalised RARMP, a summary of the RARMP, the licence and Questions and Answers about this decision can be obtained online from the DIR 174 page of the Office of the Gene Technology Regulator's (OGTR) website or requested via the contacts detailed below.

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