



Australian Government

Department of Health and Aged Care

Office of the Gene Technology Regulator

26 September 2022

Notification of decision on application DIR 192 from Medpace Australia Pty Ltd – Clinical trial of a genetically modified (GM) chimeric orthopoxvirus as a cancer treatment

The Regulator has issued licence DIR 192 to Medpace Australia Pty Ltd, authorising the clinical trial of a genetically modified (GM) chimeric orthopoxvirus (CF33-hNIS) as a 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 and Water, 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 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 192](#) page of the Office of the Gene Technology Regulator's (OGTR) website or requested via the contacts detailed below.

Office of the Gene Technology Regulator

MDP 54 GPO Box 9848 CANBERRA ACT 2601 Tel: 1800 181 030 E-mail: ogtr@health.gov.au

[OGTR website](#)