Australian Government
Department of Health and Aged Care
Office of the Gene Technology Regulator

30 November 2023

Notification of decision on application DIR 196 from Takeda Pharmaceuticals Australia Pty Ltd for the commercial supply of a genetically modified (GM) dengue vaccine, Qdenga

The Regulator has issued licence DIR 196 to Takeda Pharmaceuticals Australia Pty Ltd. The licence allows for the import, transport, storage, and disposal of a genetically modified (GM) dengue vaccine, Qdenga, associated with its commercial supply in Australia.

Before it can be used commercially, Qdenga must also be approved by the Therapeutic Goods Administration (TGA), which is responsible for assessing the quality, safety, and efficacy of human vaccines. The import of the vaccine will also require a permit from the Department of Agriculture, Fisheries and Forestry (DAFF).

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 this commercial supply poses negligible risks to the health and safety of people and the environment and does not require specific risk treatment measures. However, general licence conditions have been imposed to ensure ongoing oversight of the release.

The finalised RARMP, a summary of the RARMP, the licence, and Questions and Answers about this decision can be obtained online from the DIR 196 page of the Office of the Gene Technology Regulator's (OGTR) website or requested via the contacts detailed below.

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