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

NOTIFICATION OF APPLICATION

Receipt of licence application from Takeda Pharmaceuticals Australia Pty Ltd for the commercial supply of a genetically modified dengue vaccine, Qdenga

The Office of the Gene Technology Regulator (OGTR) has received a licence application (DIR 196) from Takeda Pharmaceuticals Australia Pty Ltd (Takeda) for the import, transport, storage, and disposal of a genetically modified (GM) dengue vaccine, Qdenga. A summary of the application and a Questions and Answers document is posted on our website (search for 'DIR 196').

Takeda propose to supply the vaccine Australia-wide, where it would be available under prescription for travellers to areas where dengue is endemic. The use of the GM vaccine will also require approval by the Therapeutic Goods Administration (TGA), which considers the safety and efficacy of the vaccine in people being vaccinated as part of their approval process.

The OGTR is preparing a Risk Assessment and Risk Management Plan (RARMP) for the application. The RARMP will be prepared taking into account advice received from a broad range of experts, agencies and authorities, and relevant local councils, as specified in the *Gene Technology Act 2000*. This is expected to be released for public comment and advice from experts, agencies and authorities in **August 2023.** There will be at least 30 days for submission of comments.

If you have any questions or would like to receive a copy of the full application or the summary, please contact the OGTR and quote the reference number DIR 196.

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