Australian Government

Department of Health and Aged Care

Office of the Gene Technology Regulator

Invitation to comment on the commercial supply of a genetically modified dengue vaccine, Qdenga

The Gene Technology Regulator is assessing an application from Takeda Pharmaceuticals Australia Pty Ltd for the commercial supply of a genetically modified (GM) dengue vaccine, Qdenga. The vaccine would be available under prescription for people travelling to dengue-affected areas. Before it can be used commercially, Qdenga must also be registered by the Therapeutic Goods Administration (TGA), which is responsible for assessing the quality, safety, and efficacy of human vaccines.

The Regulator has prepared a Risk Assessment and Risk Management Plan (RARMP) for this application and welcomes written submissions prior to making a decision on whether or not to issue the licence. The consultation RARMP and related information can be obtained via our website (search for DIR 196), or from the contacts below. Written submissions should reference DIR 196 and be received by **18 October 2023**.

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