



Australian Government

Department of Health

Office of the Gene Technology Regulator

19 April 2021

Notification of decision on application DIR 182 from Janssen-Cilag Pty Ltd for the commercial supply of a COVID-19 vaccine

The Office of the Gene Technology Regulator (OGTR) has issued licence DIR 182 to Janssen-Cilag Pty Ltd. This licence allows for the importation, transport, storage and disposal of a COVID-19 vaccine.

Approval from the Therapeutic Goods Administration (TGA) is also required for the commercial supply and administration of the vaccine.

The licence decision was informed by a Risk Assessment and Risk Management Plan (RARMP) undertaken by the OGTR with input from stakeholders nationwide. This included consultation with the public, state and territory governments, Australian Government agencies, the Minister for the Environment, and the Gene Technology Technical Advisory Committee.

Submissions are summarised in Appendix B and C of the RARMP, together with information about how the issues raised relating to health, safety and the environment were considered.

The RARMP concludes that import, transport, storage and disposal of the Janssen-Cilag COVID-19 vaccine poses negligible risks to people and the environment.

General licence conditions have been imposed to ensure ongoing oversight of the supply and distribution of the 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 182](#) page of the Office of the Gene Technology Regulator's (OGTR) website or requested via the contacts detailed below.

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