



Australian Government

Department of Health

Office of the Gene Technology Regulator

**Invitation to comment on the assessment
of the Janssen-Cilag COVID-19 vaccine**

The Office of the Gene Technology Regulator (OGTR) is assessing an application from Janssen-Cilag Pty Ltd for a COVID-19 vaccine.

Janssen-Cilag's vaccine contains a modified virus, which requires the pharmaceutical company to seek review from both the OGTR and the Therapeutic Goods Administration (TGA) before it is able to be legally approved for use in Australia.

The Regulator is investigating if there are any risks to human health and the environment posed by the import, transport, storage and disposal of this vaccine and is seeking comment on the assessment.

Submissions on the assessment are welcomed by the OGTR, and should be received by close of business on 30 March 2021.

The assessment and further information can be obtained from the contacts below with reference number DIR-182.

Office of the Gene Technology Regulator
MDP 54 GPO Box 9848 CANBERRA ACT 2601
Telephone: 1800 181 030 Website: www.ogtr.gov.au
E-mail: ogtr@health.gov.au