Questions & Answers on licence DIR 182 – Commercial supply of a COVID-19 vaccine from Janssen-Cilag

What does this licence allow?
Janssen-Cilag Pty Ltd has received an approval under the *Gene Technology Act 2000* for the import, transport, storage and disposal of a COVID-19 vaccine, as part of its commercial supply as a vaccine in Australia.

What is COVID-19?
Coronavirus disease 2019 (COVID-19) is caused by a virus called severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). People with COVID-19 exhibit a wide range of symptoms which varies from mild to severe illness and in some cases death.

How has the COVID-19 vaccine been made and how does it work?
The vaccine contains an adenovirus vector that has been modified so that it cannot multiply, spread or cause disease. It is produced by deleting or modifying the adenovirus genes required for multiplication and inserting a gene to make the SARS-CoV-2 spike protein. After injection, the adenoviral vector enters human cells and instructs them to make the spike protein. Vaccinated people then produce antibodies against the spike protein and this helps to protect against COVID-19.

Who approves the use of the vaccine?
The Therapeutic Goods Administration (TGA) has responsibility for assessing the quality, safety and efficacy of any vaccine intended for use in people in Australia. Once approved for use in Australia, they are registered by the TGA and can be widely distributed.

What is the role of OGTR in approving the vaccine?
The Office of the Gene Technology Regulator (OGTR) has a specific responsibility to protect the health and safety of people, and to protect the environment by identifying any risks posed by or as a result of gene technology, and by managing those risks through regulating dealings with genetically modified organisms. The Gene Technology Regulator must also issue an approval before the vaccine can be distributed.

More information about COVID-19 Vaccines

- Department of Health website
- Therapeutic Goods Administration website

What controls have been imposed for this COVID-19 vaccine?
The licence is for an ongoing commercial supply of a COVID-19 vaccine from Janssen-Cilag. The Regulator has not imposed any specific measures to manage risk, as the risk assessment concluded that this release of the COVID-19 vaccine poses negligible risks to the health and safety of people or the environment. However, general conditions have been imposed to ensure that there is ongoing oversight of the release. The TGA may impose conditions on use of the COVID-19 vaccine.

Want more information?
A number of documents relating to this decision are available on the DIR 182 page of the OGTR website or via Freecall 1800 181 030. These documents include the finalised Risk Assessment and Risk Management Plan (RARMP), a summary of the RARMP and the licence.

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