Questions & Answers on licence DIR 180 – Commercial supply of a COVID-19 vaccine from AstraZeneca

What does this licence allow?
AstraZeneca 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 vary from mild to severe illness, or death in some cases.

How has the AstraZeneca COVID-19 vaccine been made and how does it work?
The vaccine contains an adenovirus vector that has been modified to contain a gene to make the SARS-CoV-2 spike protein. Once vaccinated, people produce antibodies against the spike protein and this helps to protect against COVID-19. The adenovirus vector cannot multiply, spread or cause disease, as genes required for multiplication have been deleted or modified.

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, products are registered by the TGA and can then be 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. In addition to the TGA, the Gene Technology Regulator must also issue an approval before the vaccine can be distributed.

More information about COVID-19 Vaccines

- https://www.health.gov.au/covid19-vaccines
- https://www.tga.gov.au/covid-19-vaccine-news-and-updates

Has this vaccine been approved in any other country/region?
This vaccine has been authorised for commercial use in the European Union. As of 31st January 2021, this COVID-19 vaccine from AstraZeneca has also been approved for emergency use in the United Kingdom, Argentina, Bahrain, Bangladesh, Brazil, Dominican Republic, Ecuador, El Salvador, India, Iraq, Mexico, Myanmar, Morocco, Nepal, Pakistan, Philippines, Saudi Arabia, Sri Lanka, Thailand and Vietnam.

What controls have been imposed for this COVID-19 vaccine?
The licence is for the ongoing import, transport, storage and disposal activities associated with the commercial supply of a COVID-19 vaccine from AstraZeneca. The Regulator has not imposed any specific measures to manage risk because there is negligible risk to the health and safety of people or the environment as supply of vaccine will follow *the Australian code of good wholesaling practice for medicines in schedules 2, 3, 4 & 8* (2011)*, the WHO's Good Distribution Practices for pharmaceutical products (*WHO 2010), the *National Vaccine Storage Guidelines: Strive for 5* (2019) and the *Standard for the Uniform Scheduling of Medicines and Poisons* (2020) which all provide appropriate controls and informed the risk assessment. Any unused vaccine or waste material will be disposed of in accordance with local requirements for clinical waste. General conditions have been imposed

however to ensure that there is ongoing oversight of these activities as a part of supply of the COVID-19 vaccine. The TGA may also 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 180 page of the OGTR website or via Free call 1800 181 030. These documents include the finalised Risk Assessment and Risk Management Plan (RARMP), a summary of the RARMP and the licence.

The Office of the Gene Technology Regulator
Tel: 1800 181 030 E-mail: ogtr@health.gov.au
OGTR Website