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

What is this application for?

AstraZeneca Pty Ltd is seeking approval 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

Has this vaccine been approved in any other country/region?

As of 6 January 2021, this COVID-19 vaccine from AstraZeneca has been approved for emergency use in the United Kingdom, Argentina, El Salvador, India, Dominican Republic and Mexico.

How can I comment on this application?

You are invited to submit your written comments on the consultation version of the Risk Assessment and Risk Management Plan (RARMP) that has been prepared for application DIR 180. The full consultation RARMP and a summary are available on the What's New page of the OGTR website. Advice is sought in the context of the risks to the health and safety of people as a consequence of import, transport, storage and disposal of the vaccine and risks from persistence of the GMOs in the environment. Please note that the consultation period closes on **18 January 2021** and written submissions are required by that date.

What are the next steps in the evaluation process?

The RARMP will be finalised, taking into account submissions related to the protection of people or the environment. A de-identified summary of all comments received and consideration of those comments is included in the Appendices to the final RARMP. The Regulator will then make a decision on whether or not to issue a licence.

The Office of the Gene Technology Regulator

OGTR Website

Tel: 1800 181 030 E-mail: ogtr@health.gov.au