Questions & Answers on licence application DIR 174 – Commercial supply of a genetically modified (GM) cholera vaccine, Vaxchora®

What is this application for?

Biocelect Pty Ltd is seeking approval for the import, transport, storage and disposal of a genetically modified (GM) cholera vaccine, Vaxchora®, as part of its commercial supply as a vaccine in Australia.

What is cholera?

Cholera is an acute diarrhoeal disease caused by eating food or drinking water contaminated with the bacterium *Vibrio cholerae*. Cholera affects people of all ages who can experience symptoms from mild stomach ache to excessive watery diarrhoea which can result in death.

How has the cholera vaccine been made?

The vaccine contains living bacteria, *Vibrio cholerae*, that have been genetically modified so that they cannot cause disease. Disease caused by *Vibrio cholerae* is due to the production of a cholera toxin and a protein (haemolysin) which can break open red blood cells. The vaccine has been produced by deleting a part of the cholera toxin gene and inserting a marker into the haemolysin gene. As a result of these genetic modifications, the vaccine cannot produce the cholera toxin or the protein which breaks open red blood cells and will not cause disease.

Why do we need a vaccine against cholera in Australia?

Vaxchora® is a vaccine developed to prevent cholera disease in people who travel overseas to areas where cholera is present. This vaccine will be available for adults and children aged 2 years or older who would be travelling to places where they could be infected with cholera.

Who approves the use of Vaxchora®?

The Therapeutic Goods Administration (TGA) has responsibility for assessing the quality, safety and efficacy of vaccines intended for use in humans in Australia. Before it can be used commercially, Vaxchora® must be registered by the TGA. It is proposed that the vaccine would be made available under prescription for oral administration at home or in medical facilities.

Has this GM vaccine been tested or used in any other country?

Vaxchora® was approved by the Food and Drug Administration (FDA) in the USA in 2016 and has been recently approved by the European Medicine Agency for use in the European Union for people traveling to cholera-affected areas. Clinical trials for this vaccine were conducted in Australia between 2014 and 2015, authorised by the Gene Technology Regulator.

How is this vaccine different from the previous GM cholera vaccine?

A GM vaccine named Orochol® was previously approved by the Gene Technology Regulator and TGA. This vaccine is no longer available for purchase. Vaxchora® is the same modified bacterium, but it is being manufactured in different facilities so a new approval is required. Clinical trials have confirmed that the newly manufactured product Vaxchora® is as safe and is as effective against cholera as Orochol®.

How can I comment on this application?

You are invited to submit your comments on the consultation version of the Risk Assessment and Risk Management Plan (RARMP) that has been prepared for application DIR 174. The full consultation RARMP and a summary are available on the What's New page of the OGTR website or via the Free call number below. Your advice would be appreciated on any risks to the health and safety of people or to the environment that may be posed by the proposed release. Please note that the consultation period closes on **17 November 2020** 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 finalised RARMP will inform the Regulator's decision on whether or not to issue a licence.

The Office of the Gene Technology Regulator

OGTR Website

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