

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

### What does this licence allow?

Bioclect Pty Ltd has received an approval under the *Gene Technology Act 2000* 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 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/region?

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.

### What controls have been imposed for this GM cholera vaccine, Vaxchora®?

The licence is for an ongoing commercial supply of a GM cholera vaccine, Vaxchora®. The Regulator has not imposed any specific measures to manage risk, as the risk assessment concluded that this release of the GM 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 GM vaccine.

### Want more information?

A number of documents relating to this decision are available on the [DIR 174](#) 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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