



Oral trial of a cholera vaccine in Australia



In 2014 the Gene Technology Regulator (the Regulator) approved a trial of an oral live genetically modified cholera vaccine. Up to 1000 people were given a dose of the vaccine in a drink.

Cholera causes tens of thousands of deaths per year. The vaccine is for travellers to parts of the World where cholera is endemic, as well as for use in developing countries in response to cholera outbreaks.

The OGTR legislation uses the term 'environmental release' to describe applications where the GMO will not be confined to a laboratory. This has led to speculation on some websites that the vaccine would be distributed by aerial spraying. This speculation is false. There was never any proposal to deliver the vaccine by spray. The vaccine is intended for delivery to individuals in a drink as part of a clinical trial and only with their consent.

Background

PaxVax Australia Pty Ltd (PaxVax) received approval from the Regulator (Licence DIR126) in 2014 to conduct a clinical trial with a GM cholera vaccine. The trial took place in clinical facilities in Queensland, South Australia, Victoria and Western Australia. The trial was concluded in 2015.

This trial was approved by the Regulator and the Therapeutic Goods Administration (TGA) under oversight by human research ethics committees at each site.

The purpose of the trial was to verify the effectiveness of a single-dose oral vaccine against cholera infection. The bacterium that causes cholera (*Vibrio cholerae*) was genetically modified to remove its ability to cause disease.

Up to 1000 healthy volunteers, covering different age groups, participated in the clinical trial. All volunteers were given extensive information about the GM vaccine prior to consenting to participate in the trial.

The vaccine was administered as a drink, and was administered by qualified health professionals in clinical facilities. The vaccine was not injected into participants. There was never any proposal to spray the vaccine into the air. Because this was a clinical trial involving the use of a GM therapeutic product it was required to meet the requirements of both the Regulator and the TGA.

Following conclusion of the trial in 2015, the vaccine was approved by the US Food and Drug Administration in June 2016.

Prior use of the vaccine

This GM cholera vaccine strain was previously approved and marketed in several different countries, including Australia, under the brand name Orochol (or Mutacol). Orochol was registered in Australia as a prescription medicine by the TGA, after undergoing extensive evaluation of its safety, quality and efficacy, and it was licensed by the Gene Technology Regulator in 2003 (licence number DIR 033/2002). However, since the manufacturer of Orochol ceased production of this vaccine for business reasons, they voluntarily surrendered the licence in 2010.

PaxVax was developing this GM vaccine as a new commercial product. Clinical trials are required to confirm the safety and efficacy of the newly manufactured product because it is manufactured in different facilities to Orochol.

Why was the trial conducted in Australia?

The Australian clinical trial was part of a larger international study including trials in the USA and Canada. The purpose of the larger trial is to test the safety and efficacy of the vaccine. In order to produce clearer efficacy data, it is preferred that the study is conducted in locations where cholera is not endemic or is present only at low levels (such as USA, Canada and Australia). Conducting the clinical trial in these locations is likely to produce clearer efficacy data than a clinical trial in a location with endemic cholera.

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