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GOVERNMENT NOTICES

Australian Government

Department of Health

Office of the Gene Technology Regulator

22 September 2020

Invitation to comment on the commercial supply of a genetically modified cholera vaccine, Vaxchora®

Australia's gene technology regulatory system is designed to protect the health and safety of people and the environment by identifying risks posed by, or as a result of, gene technology and managing those risks.

The Gene Technology Regulator is assessing licence application DIR 174 from Biocelect Pty Ltd (Biocelect) for commercial supply of a genetically modified (GM) cholera vaccine, Vaxchora®. This vaccine will be available for adults and children aged 2 years or older who would be travelling overseas to places where they could be infected with cholera.

Before it can be used commercially, Vaxchora® must also be registered by the Therapeutic Goods Administration (TGA), which has regulatory responsibility for assessing quality, safety and efficacy of therapeutic goods. If approved by both the Regulator and the TGA, Vaxchora® would be available under prescription, for oral administration at medical facilities or at home.

A consultation Risk Assessment and Risk Management Plan (RARMP) has been prepared, which concludes that the proposed release would pose negligible risk to human health and safety or to the environment. Draft licence conditions are proposed to ensure ongoing oversight of the release.

The Regulator welcomes written submissions in order to finalise the RARMP, which will then inform the decision on whether or not to issue the licence. The consultation RARMP and related documents can be obtained from the OGTR website under What's New or by contacting the Office. Please quote application DIR 174 in any correspondence.

Submissions should be received by close of business on **17 November 2020**.

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