ATAGI recommendation for using CVD 103–HgR (Vaxchora) cholera vaccine compared to placebo in children and adults aged ≥2 years who have a high risk of exposure to cholera

Recommendation

CVD 103–HgR (Vaxchora) cholera vaccine is recommended as an alternative to WC–rBS (Dukoral) cholera vaccine in immunocompetent children and adults aged ≥2 years who have a high risk of exposure to cholera.

Additional considerations

CVD 103–HgR (Vaxchora) is a live, attenuated vaccine. Advice and precautions regarding the administration of live vaccines should be followed, and for certain people the oral inactivated cholera vaccine (Dukoral) should be used instead.

Justification

There is evidence for the efficacy of CVD 103–HgR (Vaxchora) against different severities of cholera diarrhoea up to 90 days after vaccination. There is also evidence for antibody persistence for up to 180 days (6 months) after vaccination with CVD 103–HgR (Vaxchora), based on clinical trial immunogenicity data.

Given the moderate certainty of evidence overall, ATAGI considers that there is sufficient evidence to demonstrate CVD 103–HgR (Vaxchora) is more protective against different severities of cholera diarrhoea compared with placebo.

Compared with placebo, some studies show rates of systemic adverse events are slightly higher for CVD 103–HgR (Vaxchora), but there is variability in these results and CVD 103–HgR (Vaxchora) likely results in little to no difference in undesirable effects compared with placebo. There were no vaccine-related serious adverse events reported in the included studies.

The body of evidence suggests that the overall balance of desirable and undesirable effects of CVD 103–HgR (Vaxchora) are favourable compared to placebo.

However, the safety and effectiveness of current formulation CVD 103–HgR (Vaxchora) vaccine in immunocompromised persons have not been established. The safety and efficacy of current formulation CVD 103–HgR (Vaxchora) vaccine in children aged less than 2 years and adults 65 years and older have also not been established. No data are currently available for these age groups.

The effectiveness of CVD 103–HgR (Vaxchora) vaccine in persons who have pre-existing immunity due to previous exposure to *V. cholerae* or receipt of a cholera vaccine has not been established. The real-world effectiveness of CVD 103–HgR (Vaxchora) vaccine in cholera-endemic areas has not been studied.