30 January 2020
EMA/CHMP/33389/2020
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Vaxchora

Cholera vaccine (recombinant, live, oral)

On 30 January 2020, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Vaxchora, intended for prophylaxis against disease caused by *Vibrio cholerae* in adults and children. The applicant for this medicinal product is Emergent Netherlands B.V.

Vaxchora will be available as an effervescent powder and a powder for oral suspension. Vaxchora is a bacterial vaccine (ATC code: J07AE02) containing as active substance live attenuated cholera bacteria (*V. cholerae* O1 classical Inaba strain live attenuated CVD 103-HgR), which replicate in the gastrointestinal tract of the recipient and induce serum vibriocidal antibody and memory B cell responses.

The benefits with Vaxchora are its ability to protect immunologically naïve people against moderate to severe diarrhoea induced by cholera bacteria. The most common side effects are tiredness, headache, abdominal pain, nausea/vomiting, and lack of appetite.

The full indication is: "active immunisation against disease caused by *Vibrio cholerae* serogroup O1 in adults and children aged 6 years and older. This vaccine should be used in accordance with official recommendations."

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

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