SUMMARY

Cholera vaccine (recombinant, live, oral)

VAXCHORA,

effervescent powder and powder for oral suspension

First listing

Original French opinion adopted by the Transparency Committee on 29 May 2024

The legally binding text is the original French opinion version

Summary of opinion

Favourable opinion for reimbursement for active immunisation against disease caused by *Vibrio cholerae* serogroup O1 in adults and children aged 2 years and older in accordance with the current official recommendations of 15 April 2024 relative to cholera anticipation and management measures in Mayotte.

Transparency Committee's conclusions

Clinical Benefit

- Cholera is a rare disease in France (excluding French Guiana and Mayotte), with a potential risk of severe complications, spread to close contacts and chronic carriage.
- This is a preventive medicinal product.
- The efficacy/adverse effects ratio is high.
- VAXCHORA (cholera vaccine (recombinant, live, oral)) should be used in accordance with its MA and with current vaccine recommendations (HCSP 2024). It should be used for active immunisation against disease caused by *Vibrio cholerae* serogroup O1 in adults and children aged 2 years and older.

Public health benefit

Considering:

- the seriousness of the disease and its epidemic potential,
- the public health objective of reducing morbidity and mortality from this infection in endemic regions, in particular in Mayotte,
- the fact that vaccination is the most effective prevention tool against cholera, with an expected impact on morbidity and mortality,

- the medical need to expand the offer in order to be able to guarantee vaccination based on the evolution of the epidemiological situation,
- the expected impact of vaccination on the organisation of care in situations in which use of vaccination is envisaged,

VAXCHORA (cholera vaccine (recombinant, live, oral)) is likely to have an additional impact on public health.

Considering all these elements, the Committee deems that the clinical benefit of VAXCHORA (cholera vaccine (recombinant, live, oral)) is substantial in the active immunisation against disease caused by *Vibrio cholerae* serogroup O1 in adults and children aged 2 years and older in accordance with the current HCSP recommendations of 15 April 2024 relative to cholera anticipation and management measures in Mayotte.

The Committee issues a favourable opinion for inclusion of VAXCHORA (cholera vaccine (recombinant, live, oral)) in the list of covered drugs for inpatients approved for use in the active immunisation against disease caused by *Vibrio cholerae* serogroup O1 in adults and children aged 2 years and older in accordance with the current HCSP recommendations of 15 April 2024 relative to cholera anticipation and management measures in Mayotte, and at the MA dosages.

Clinical Added Value

Considering:

- **the need to reinforce the vaccine offer given the major requirement for access to cholera vaccines in Mayotte;**
- **the current HCSP recommendations of 15 April 2024 relative to cholera anticipation and management measures in Mayotte,**
- **available data suggesting an efficacy of around 90.3% at D11 and 79.5% at D91 in individuals aged 18 to 45 years in terms of reduction in the incidence of moderate to severe diarrhoea;**
- **immunogenicity data supporting these results in individuals aged 46 to 64 years and in individuals aged 2 to 18 years;**
- **the satisfactory safety profile, marked primarily by fatigue and headaches;**
- **the obvious advantage of using a vaccine with a one-dose regimen, particularly in an epidemic context;**

but:

- **the absence of clinical data having compared the efficacy of the DUKORAL vaccine (inactivated cholera vaccine, oral), which is an inactivated vaccine available in France;**
- **the contraindication in immunosuppressed individuals and their families due to a vaccine strain excretion duration that is still unknown;**
- **the impossibility of using it in the event of the post-exposure antibiotic prophylaxis necessary for individuals living in the same household as an identified case;**
- **the lack of data on the protection duration,**

the Transparency Committee deems that VAXCHORA (cholera vaccine (recombinant, live, oral)) provides no clinical added value (CAV V) in the preventive strategy including DUKORAL (inactivated cholera vaccine, oral), for active immunisation against disease caused by *Vibrio*

cholerae **serogroup O1 in adults and children aged 2 years and older in accordance with the current official recommendations of 15 April 2024 relative to cholera anticipation and management measures in Mayotte**