28 May 2020
EMA/CHMP/138172/2020
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Zabdeno

Ebola vaccine (Ad26.ZEBOV-GP [recombinant])

On 28 May 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 Zabdeno, intended for prophylaxis against *Zaire ebolavirus* disease (EVD). Zabdeno was reviewed under EMA's accelerated assessment programme. The applicant for this medicinal product is Janssen-Cilag International N.V.

Zabdeno will be available as a suspension for injection. The active substance of Zabdeno consists of a monovalent, recombinant, replication-incompetent Ad26-vectored vaccine that encodes the full-length glycoprotein (GP) of the *Zaire ebolavirus*. Zabdeno is a viral vaccine (ATC code: J07BX02). It is given with the vaccine Mvabea as a 2-dose vaccination regime, and provides active immunisation for prevention of *Zaire ebolavirus* disease by inducing an immune response that protects against the disease.

The benefits with Zabdeno are its ability to contribute to the generation of a protective response against the virus that causes *Zaire ebolavirus* disease. The most common side effects in adults are injection-site reactions (pain, warmth and swelling), fatigue, headache, myalgia, arthralgia and chills. The most common side effects in children are injection-site pain, fatigue, decreased activity, decreased appetite and irritability.

The full indication is:

> Zabdeno, as part of the Zabdeno, Mvabea vaccine regimen, is indicated for active immunisation for prevention of disease caused by Ebola virus (*Zaire ebolavirus* species) in individuals ≥ 1 year of age. The use of the vaccine regimen should be 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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