EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

13 November 2025
EMA/CHMP/354843/2025
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

VacPertagen

Pertussis vaccine (recombinant, acellular, component, adsorbed)

On 13 November 2025, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product VacPertagen, a vaccine intended for prophylaxis against pertussis.

The applicant for this medicinal product is BioNet Europe.

VacPertagen will be available as a suspension for injection in pre-filled syringes. The active substances in VacPertagen are two purified pertussis antigens: recombinant pertussis toxin (PT_{gen}) and filamentous haemagglutinin (FHA). Following intramuscular administration of a single dose, VacPertagen induces a boost in PT-specific and FHA-specific antibody responses. Maternal antibodies are transferred to infants born to women vaccinated during the second or third trimester of pregnancy.

The benefits of VacPertagen were shown in 3 clinical studies, which found that VacPertagen triggered the production of antibodies at 28 days after vaccination in adults and adolescents, with antibodies persisting for up to 3 years in adults and 5 years in adolescents. It also induced an immune response in pregnant women 28 days after vaccination during the second or third trimester of pregnancy. In addition, the pertussis antibodies were transferred from mothers to infants at birth and persisted for up to 2 months of age. The most common side effects with VacPertagen include pain at the injection site, headache, fatigue, myalgia, arthralgia, malaise and nausea.

The full indication is:

> VacPertagen is indicated for:
>
> - booster immunisation against pertussis of individuals 12 years of age and older,
> - passive protection against pertussis in early infancy following maternal immunisation during pregnancy (see sections 4.4, 4.6 and 5.1).
>
> The use of this vaccine should be in accordance with official recommendations.

Detailed recommendations for the use of this product will be described in the summary of product

[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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characteristics (SmPC), which will be published on the EMA website in all official European Union languages after the marketing authorisation has been granted by the European Commission.