19 September 2024
EMA/424272/2024
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Penbraya

meningococcal groups A, C, W, Y conjugate and group B vaccine (recombinant, adsorbed)

On 19 September 2024, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Penbraya, intended for protection against invasive meningococcal disease caused by meningococcal bacteria of the serogroups A, B, C, W and Y.

The applicant for this medicinal product is Pfizer Europe MA EEIG.

Penbraya will be available as a powder and suspension for reconstitution prior to injection. Penbraya is a meningococcal vaccine (ATC code: J07AH11). It contains the active substances *Neisseria meningitidis* serogroups A, C, W and Y polysaccharides and serogroup B factor H binding protein (fHbp) subfamilies A and B. Immunisation with Penbraya stimulates the production of antibodies that recognise polysaccharides or fHbp expressed by the respective meningococci.

The benefits of Penbraya are its ability to induce protective serum bactericidal antibody responses against meningococci of the serogroups A, B, C, W and Y, which have the potential to cause invasive meningococcal disease. The most common side effects with Penbraya are pain at injection site, fatigue, headache, muscle pain, and swelling and redness at the injection site.

The full indication is:

> Penbraya is indicated for active immunisation of individuals 10 years of age and older to prevent invasive disease caused by *Neisseria meningitidis* groups A, B, C, W, and Y.
>
> 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 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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