17 September 2020
EMA/CHMP/452678/2020
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

MenQuadfi

meningococcal group A, C, W and Y conjugate vaccine

On 17 September 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 MenQuadfi, intended for prophylaxis against invasive meningococcal disease caused by *Neisseria meningitidis* serogroups A, C, W and Y. The applicant for this medicinal product is Sanofi Pasteur.

MenQuadfi will be available as a solution for injection. The active substance of MenQuadfi is a conjugate of meningococcal group A, C, W and Y capsular polysaccharides with tetanus toxoid as carrier protein, forming a meningococcal vaccine (ATC code: J07AH08) that stimulates the production of antibodies specific to those capsular polysaccharides. The anti-capsular antibodies protect against meningococcal disease via complement-mediated bactericidal activity.

The benefits with MenQuadfi are its ability to prevent invasive disease caused by *Neisseria meningitidis* groups A, C, W and Y in individuals aged 12 months and older. The most common side effects are injection site reactions such as erythema, swelling and pain.

The full indication is:

> MenQuadfi is indicated for active immunisation of individuals from the age of 12 months and older against invasive meningococcal disease caused by *Neisseria meningitidis* serogroups A, 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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