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Questions and answers

Questions and answers on the outcome of application to extend use of Menveo in children less than 2 years

On 25 April 2013, the Committee for Medicinal Products for Human Use (CHMP) finalised its assessment of an application to extend the use of Menveo to infants aged 2 to 23 months. The CHMP did not consider the results of the studies supporting the application to be sufficient to recommend use in children of this age group. However, the CHMP concluded that information on the new studies in children should be included in the product information for Menveo.

What is Menveo?

Menveo is a vaccine that contains parts of the bacterium *Neisseria meningitidis* (*N. meningitidis*). It is available as a powder (in a vial) and solution (in a vial or a pre-filled syringe) that are mixed together to make a solution for injection.

Menveo is used to protect adults and children from the age of two against invasive disease caused by four groups of the bacterium *N. meningitidis* (A, C, W135, and Y). The pre-filled syringe can only be used in adults and adolescents from the age of 11.

Menveo is used in people who are at risk of exposure to the bacterium. Invasive disease happens when the bacteria spread through the body causing serious infections such as meningitis (infection of the membranes that surround the brain and spine) and septicaemia (blood infection).

The vaccine should be given according to official recommendations.

What was Menveo expected to be used for?

Menveo was also expected to be used in infants aged 2 to 23 months for protection against invasive disease caused by the bacterium *N. meningitidis* groups A, C, W135, and Y.

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What did the company present to support its application?

The company presented data from 3 main studies involving over 6,700 infants aged 2 to 23 months. The first study looked at the ability of Menveo to trigger the production of antibodies (immunogenicity) when the vaccine was given in up to 4 doses (at 2, 4, 6 and 12 months of age). In the second study, Menveo was given in 2 doses (at 7 to 9 months and 12 months of age). The third study compared one dose of Menveo with one dose of a 'monovalent' vaccine (a vaccine only active against one group of the bacterium, in this case group C) given at 12 months of age.

In all of the studies, the main measure of effectiveness was the percentage of subjects who had an adequate immune response against the appropriate groups of *N. meningitidis*.

What was shown in the study?

In the first study, one month after receiving the last of the 4 doses of Menveo, the percentages of infants who achieved an adequate immune response against *N. meningitidis* groups A, C, W135, and Y were between 94% and 100%. In the second study, one month after receiving the 2 doses of Menveo, the percentage of infants who achieved an adequate immune response was between 88 and 100%. The third study showed that Menveo stimulated a weaker immune response than the monovalent vaccine: 83% of infants receiving Menveo achieved an adequate immune response against *N. meningitidis* group C compared with 92% of those receiving the monovalent vaccine.

What was the conclusion of the CHMP?

During the evaluation, the CHMP had 2 main concerns over the data provided by the company in children less than 2 years of age. Firstly, it had not been shown that Menveo was at least as effective as the monovalent vaccine against *N. meningitidis* group C in this age group. Secondly, data from the first study showed a fall in antibodies between the third and fourth dose which could result in children lacking protection between 6 months and 1 year of age.

The company was unable to address the concerns raised by the CHMP. Some of the data submitted had to be excluded from the analysis due to problems with the procedures that were followed in the third study. The CHMP concluded that the data provided were insufficient to extend the use of Menveo to infants aged 2 to 23 months. However, the Committee concluded that information on the results of the new studies in children should be included in the product information for Menveo, as they are important to healthcare professionals involved in vaccination programmes.

The full European Public Assessment Reports for Menveo can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European Public Assessment Reports