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Questions and answers on the use of Trumenba in children between 1 and 9 years of age

The European Medicines Agency has finalised its assessment of an application to extend the use of Trumenba to children between 1 and 9 years of age for the prevention of invasive meningococcal disease caused by *Neisseria meningitidis* group B.

Although EMA's human medicines committee (CHMP) did not recommend this extension, it agreed that relevant data from the study submitted with the application be included in the medicine's product information.

What is Trumenba and what is it used for?

Trumenba is a vaccine used to protect individuals from 10 years of age against invasive meningococcal disease caused by a group of bacteria called *Neisseria meningitidis* group B.

Invasive disease occurs when these bacteria spread through the body causing serious infections such as meningitis (infection of the membranes that surround the brain and spinal cord) and septicaemia (blood infection).

Trumenba is available in a pre-filled syringe and is given by injection into a muscle, preferably in the shoulder. Treatment consists of 2 or 3 doses at intervals of several months. An additional booster dose may be given to people at greater risk of invasive meningococcal disease.

Trumenba has been authorised in the EU since May 2017. Further information on Trumenba's current uses can be found on the Agency's website: ema.europa.eu/en/medicines/human/EPAR/trumenba

What change had the company applied for?

The company applied to extend the use of Trumenba to children between 1 and 9 years of age.

How does Trumenba work?

Vaccines work by preparing the immune system (the body's natural defences) to defend itself against a disease. When a person is given the vaccine, the immune system recognises the parts of the bacterium contained in the vaccine as 'foreign' and makes antibodies against them. When the person is then

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exposed to the bacterium, these antibodies together with other components of the immune system will be able to kill the bacteria and help protect against the disease.

Trumenba contains two proteins that are found in the outer coats of *N. meningitidis* group B bacteria. These proteins are fixed onto a compound containing aluminium (adsorbed), which helps to stabilise them, allowing the immune system to respond to them.

What did the company present to support its application?

The company presented the results of two studies. The first study involved 396 children between 1 and 2 years of age, and the second involved 371 children between 2 and 9 years of age. All children were given 3 doses of the vaccine and production of protective antibodies against *N. meningitidis* group B was measured one month after the last injection.

What were EMA's conclusions?

Based on the review of the information and the company's response to the Agency's questions, the Agency had some concerns and was of the opinion that Trumenba could not be authorised for use in children between 1 and 9 years of age.

The Agency was concerned that the proposed vaccination schedule was inadequate to ensure sufficient protection against *N. meningitidis* group B in children of this age group as the level of antibodies declined shortly after vaccination. An additional dose seemed to be required to ensure lasting protection, and more data were needed to support such use.

Although Trumenba will therefore not be authorised in this age group, the prescribing information for Trumenba will be updated to include information from these studies and about a decline in antibodies after 3 doses of the vaccine in children between 1 and 9 years of age.

Does this outcome affect patients in clinical trials?

The company informed the Agency that there are no consequences for patients in clinical trials using Trumenba.