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Press release

European Medicines Agency recommends approval of first vaccine for meningitis B

Vaccine to provide broad coverage against meningococcal group B infections

The European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has recommended the granting of a marketing authorisation for Bexsero, a new vaccine intended for the immunisation of individuals over two months of age against invasive meningococcal disease caused by *Neisseria meningitidis* group B.

There is currently no authorised vaccine available in the European Union (EU) for bacterial meningitis caused by *Neisseria meningitidis* group B.

Meningitis B: an unmet public-health challenge in Europe

Each year, approximately 1.2 million cases of invasive meningococcal disease are recorded worldwide, of which 7,000 occur in Europe. Over 90% of cases of meningococcal meningitis and septicaemia are caused by five of the 13 meningococcal serogroups, specifically groups A, B, C, W135 and Y. In Europe, group B is the most prevalent meningococcal serogroup, with 3,406-4,819 cases reported annually between 2003 and 2007, according to a surveillance report published by the European Centre for Disease Prevention and Control.

Whereas there are authorised vaccines to protect against meningococcal disease caused by groups A, C, W135 and Y, there is currently no authorised vaccine available that provides broad coverage against group B meningococcal disease.

The disease mainly affects infants and young children, but could occur also in older children and young adults. Despite the availability of medical treatment and effective antibiotics, 8% of European patients die and some 11-19% of survivors suffer life-long consequences, including permanent brain damage, learning disabilities and hearing loss. There are currently some geographical regions within the EU with higher incidence rates, mainly in Belgium, Ireland, Spain and the United Kingdom.

The impact of invasive disease in different age groups as well as the variability of antigen epidemiology for group B strains in different geographical areas should be considered when vaccinating. Vaccination with Bexsero should be in accordance with official recommendations applicable in the Member States.

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The CHMP's opinion on Bexsero will now be sent to the European Commission for the granting of a marketing authorisation.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. The applicant for Bexsero is Novartis.
3. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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