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INFECTIOLOGY
New medicinal product
July 2015

BRIEF SUMMARY OF THE TRANSPARENCY COMMITTEE OPINION

HEXYON, hexavalent vaccine against diphtheria, tetanus, poliomyelitis, pertussis, *Haemophilus influenzae* type b infections, hepatitis B

No clinical benefit demonstrated when compared with INFARIX HEXA for the primary and booster vaccination in infants

Main points

- HEXYON is a hexavalent vaccine which has Marketing Authorisation for the primary and booster vaccination against diphtheria, tetanus, poliomyelitis, pertussis, *Haemophilus influenzae* type b infections and hepatitis B, in infants from 6 weeks to 24 months of age.
- There is another vaccine authorised in France for the primary and booster vaccination in infants: INFANRIX HEXA. The immunogenicity of HEXYON is not inferior to that of INFANRIX HEXA and its safety profile is comparable despite a higher frequency of local reactions.

Therapeutic use

- In infants, vaccination against pertussis, diphtheria, tetanus and poliomyelitis is advised with two injections of combined vaccine containing the acellular pertussis component and the tetanus and diphtheria components at normal concentration (DTCaPolio) at 2 and 4 months of age, followed by a booster at 11 months of age.
- Vaccination against invasive infections with *Haemophilus influenzae* type b is recommended according to the same methods with a pentavalent vaccine combining the DTCaPolio and *Haemophilus influenzae* components.
- Vaccination against hepatitis B is also recommended in every infant according to a regimen of 3 doses, respecting an interval of at least 5 months between the 2nd and 3rd dose.
- The use of a hexavalent vaccine combining the DTCaPolio, Hib and hepatitis B components enables these diseases to be immunised against in a single injection at the ages of 2, 4 and 11 months according to the recommended vaccination regimen (vaccination schedule 2015).

Role of the medicinal product in the therapeutic strategy

HEXYON can be used for the primary vaccination and the booster vaccination in infants according to the regimens figured in the vaccination schedule in force.

Clinical data

- The immunogenicity data reveal a satisfactory vaccine response (above the predefined protective thresholds) as well as the non-inferiority of HEXYON compared with INFANRIX HEXA for all the vaccine components.
- No immunogenicity data are available in immunocompromised or premature infants or on the interchangeability of the HEXYON and INFANRIX HEXA vaccines for primary vaccination. For the booster dose, HEXYON can be used in people who have been previously vaccinated with another hexavalent vaccine or a pentavalent DTPCa/Hib vaccine combined with a monovalent hepatitis B vaccine.
- The safety profile of the HEXYON vaccine can be considered as satisfactory and close to that of the INFANRIX HEXA vaccine despite the higher frequency of local reactions.

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Benefit of the medicinal product

- The actual benefit* of HEXYON is substantial.
- HEXYON does not provide clinical added value** (CAV V) by comparison with INFANRIX HEXA.
- Recommends inclusion on the list of reimbursable products for supply by pharmacists and for hospital use.

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This document was created on the basis of the Transparency Committee Opinion of 22 July 2015 (CT-14330) and is available at **www.has-sante.fr**

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[i] * The actual benefit (AB) of a proprietary medicinal product describes its benefit primarily in terms of its clinical efficacy and the seriousness of the condition being treated. The HAS Transparency Committee assesses the AB, which can be substantial, moderate, low or insufficient for reimbursement for hospital use.

** The clinical added value (CAV) describes the improvement in treatment provided by a medicinal product compared with existing treatments. The HAS Transparency Committee assesses the degree of CAV on a scale from I (major) to IV (minor). A level V CAV means "no clinical added value".

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