European Medicines Agency
Press office

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PRESS RELEASE
European Medicines Agency finds no signal for decreased effectiveness of HBVAXPRO and Procomvax

The European Medicines Agency concluded a review of HBVAXPRO and Procomvax, two centrally authorised vaccines (Marketing Authorisation Holder is Sanofi Pasteur MSD), saying that these vaccines continue to offer effective protection against hepatitis B.

The review conducted by the Committee for Medicinal Products for Human Use (CHMP) was started in February 2006 at the request of the European Commission in order to assess the benefit of HBVAXPRO and Procomvax. The two products share the same recombinant hepatitis B component as Hexavac. The marketing authorisation for Hexavac is currently suspended due to concerns about the long-term protection against hepatitis B.

The Committee requested the marketing authorisation holder to conduct a range of studies in different age and risk groups to further ensure that the vaccines provide a sufficient level of long-term protection against hepatitis B.

While awaiting more data on long-term protection, the review did not find any evidence of decreased effectiveness. However, the Committee requested changes to the product information for doctors, in order to ensure the optimal use of the two vaccines. These changes are as follows:

- The recommended schedule for HBVAXPRO in infants and adolescents is defined as 0, 1 and 6 months or 0, 1, 2 and 12 months. Depending on national vaccination schedules, where infants receive the compressed administration schedule at 0, 1 and 2 months a booster dose at 12 months is needed.
- Reinforcing recommendations to carry out blood tests and, if needed, to administer additional doses in high-risk populations, such as children born to hepatitis B positive mothers and dialysis patients.
- In renal dialysis patients in whom insufficient antibody titre is achieved after boosting, the use of alternative hepatitis B vaccines should be considered.
- Informing that the concomitant administration of pneumococcal conjugate vaccine (Prevenar) is not recommended since this has not been sufficiently studied for HBVAXPRO.

It is important to stress that these changes are not related to the safety profile of the vaccines. Furthermore, there is currently no evidence of decreased effectiveness and consequently there is no need to revaccinate individuals who have received the appropriate dosing in the past.

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NOTES:
1. HBVAXPRO is marketed in the following EU and EEA Member States: Austria, Belgium, Germany, Spain, Finland, France, United Kingdom, Greece, Hungary, Ireland, Italy, Luxembourg, The Netherlands, Poland and Sweden.
2. Procomvax is marketed in the following EU and EEA Member States: Greece, Italy and Poland.
3. The review procedure for both vaccines was initiated by the European Commission under Article 20 of Regulation (EC) No 726/2004. This type of procedure is initiated in cases where there are public health concerns with a centrally authorised medicine.

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4. The product information (summary of product characteristics – SPCs) revised during the Article 20 Procedures is available for HBVAXPRO and PROCOMVAX
5. A Questions and Answers document on the review of HBVAXPRO and Procomvax can be found here.
6. The European public assessment report (EPAR) for HBVAXPRO (recombinant hepatitis B virus small surface antigen (HbsAG)) can be found here (last update: 18 August 2005). The EPAR for Procomvax (haemophilus influenzae b conjugate and hepatitis B (recombinant) vaccine can be found here (last update: 24 June 2005).
7. A Press Release on the suspension of the marketing authorisation of Hexavac can be found here.
8. This press release, together with other information about the work of the EMEA, can be found on the EMEA website: http://www.emea.eu.int.

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