European Medicines Agency

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QUESTIONS AND ANSWERS ON HBVAXPRO AND PROCOMVAX

Following a request from the European Commission, the Committee for Medicinal Products for Human Use (CHMP) has reviewed the benefit of HBVAXPRO and Procomvax. They concluded saying that these products continue to offer effective protection against Hepatitis B, but recommended some changes to the prescribing information.

What are HBVAXPRO and Procomvax?
HBVAXPRO is a vaccine against hepatitis B to be used in children (from birth), adolescents and adults.
Procomvax is a vaccine against hepatitis B to be used in infants 6 weeks to 15 months of age. It also protects against invasive disease caused by *Haemophilus influenzae* type b (infection of brain and spinal cord tissues, infection of the blood, etc.)

Why did the CHMP review these medicines?
The two products share the same component as Hexavac for preventing hepatitis B. The marketing authorisation for Hexavac is currently suspended due to concerns about the long-term protection against Hepatitis B. This was supposed to be due to variability in the production process for the vaccine's hepatitis B component that could lead to a decreased long-term protection against hepatitis B. Therefore, the CHMP has reviewed if these concerns also apply to HBVAXPRO and Procomvax.

What data has the CHMP reviewed?
The Committee has reviewed all the technical and clinical data available for HBVAXPRO and Procomvax. This included data from quality, preclinical and clinical studies, epidemiological studies (studies of causes of diseases in the population) and information published in scientific journals.

What are the conclusions of the CHMP?
The CHMP concluded that there is no evidence of decreased effectiveness. However, the Committee requested the Marketing Authorisation Holder (Sanofi Pasteur MSD) 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.
The CHMP also recommended changes in the information that is made available to doctors in order to ensure the optimal use of the two vaccines.

What are the recommendations for patients?
HBVAXPRO and Procomvax offer effective protection against Hepatitis B. Vaccination should be continued according to national recommendations and vaccination schedules. Parents are advised to discuss any concerns with their child's healthcare professional.

What are the recommendations for prescribers?
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.
When prescribing HBVAXPRO and Procomvax, doctors should be aware that:

- Depending on national vaccination schedules, infants receiving HBVAXPRO compressed regimen (0, 1, 2 months dosing schedule) must receive the 12 month booster to ensure long-term protection.
- They should carry out blood tests for antibody testing and, if needed, they should administer additional doses in high-risk populations, such as children born to Hepatitis B positive mothers and dialysis patients.
- They should consider the use of alternative hepatitis B vaccines in dialysis patients in whom no sufficient antibody titre is achieved after boosting.
- For HBVAXPRO, the concomitant administration of pneumococcal conjugate vaccine is not recommended since this has not been sufficiently studied.

It should be noted that these changes are not related to the safety profile of the vaccines.

7 Westferry Circus, Canary Wharf, London E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 86 68
E-mail: mail@emea.eu.int http://www.emea.eu.int