Malta, 20 September 2005

Circular No. P16/2005

Re: HEXAVAC® and concerns regarding decreased long-term protection against hepatitis B.

The Medicines Authority has been involved in discussions at the European Medicines Agency (EMEA) regarding HEXAVAC® (a vaccine for infants and children against diphtheria, tetanus, whooping cough (pertussis), hepatitis B virus, polio virus and Heamophilus influenzae type b). The local representatives of HEXAVAC®, have confirmed that to date HEXAVAC® has not been marketed in Malta.

Hexavac has been suspended as a precautionary measure due to concerns about the long-term protection against hepatitis B. This follows identification of decreased immunogenicity (body response to defend itself against a disease) of the hepatitis B component. This is 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.

This concern does not affect the protection against diphtheria, tetanus, whooping cough, polio and Haemophilus influenzae type b. Furthermore the decreased immunogenicity of the hepatitis B component relates only to HEXAVAC® and not to other hexavalent vaccines marketed locally.

There is no immediate concern for children already vaccinated with Hexavac, and children are protected against diphtheria, tetanus, whooping cough (pertussis), polio and Haemophilus influenzae type b. The concern relates only to hepatitis B, and in particular to the long-term protection (5-10 years), since appropriate levels of short-term protection against hepatitis B have been demonstrated. Taken together, the above suggest that there is no immediate need to revaccinate your child. However, Sanofi Pasteur MSD, the Marketing Authorisation Holder of Hexavac, has been asked by regulatory agencies to design a specific surveillance programme to investigate whether infants and children will need to be revaccinated at a later stage, for instance at adolescence, to ensure long-term protection against hepatitis B. The Medicines Authority is of the opinion that the advice provided in the attached **press release** and **Q & A document** issued by the EMEA is opportune and appropriate.

Medicines Authority
198, Rue D'Argens, Gzira, GZR 03 – Malta.
Tel. (+356) 23439000 Fax. (+356) 23439161 email: info.mru@gov.mt