The European Agency for the Evaluation of Medicinal Products
Post-authorisation evaluation of medicines for human use

London, 28 April 2003
EMEA/8519/03

EMEA PUBLIC STATEMENT

EMEA reviews hexavalent vaccines: Hexavac and Infanrix Hexa

The EMEA within its Scientific Committee (Committee for Proprietary Medicinal Products, CPMP), reviewed the safety of the centrally authorised hexavalent vaccines, Hexavac and Infanrix Hexa[1]. The CPMP, during their 23-25 April 2003 meeting, concluded that there was no change in the benefit/risk profile of these products and therefore did not recommend any changes to the present conditions of use.

The Committee conducted a detailed review of in particular 5 reports of unexplained deaths in children occurring within 24 hours of vaccination with a hexavalent vaccine. These reports were received as part of routine post-marketing safety monitoring (pharmacovigilance) over a period of two and a half years. During this time an estimated 8.7 million doses of the vaccines have been used worldwide corresponding to the vaccination of some 3 million children.

Hexavac and Infanrix Hexa are the only vaccines authorised in the European Union with the potential to protect against six serious life-threatening infectious diseases (diphtheria, tetanus, poliomyelitis, whooping cough, hepatitis B and *Haemophilus influenzae b* invasive disease).

Panels of experts and CPMP members, led by the chairman of the CPMP, Dr Daniel Brasseur, met at the EMEA on 26 March and 8-9 April 2003, to investigate whether there might be a link between the vaccines and the reported cases. Participants at the meetings included the pathologists who had conducted the autopsies, paediatricians with experience in vaccines and Sudden Infant Death Syndrome (SIDS) and epidemiologists.

On the basis of the available information, the CPMP concluded that:

- Vaccination offers benefits to the individual child and to the general population. The CPMP considers that the benefits of vaccination far outweigh possible risks of existing vaccines, including hexavalent vaccines, and that vaccination should be continued according to national vaccination schedules.

- The causes of death remain unexplained and on the basis of available data, it is not possible to establish a cause and effect association with the hexavalent vaccines. In several cases SIDS, viral infection, metabolic disorders, allergic reactions or airway obstruction were plausible, however these could not be definitely proven to be the cause of death. The Committee also considered possible risk factors, including a family history of epilepsy or convulsions at an early age which was reported in three out of five cases. However, the CPMP concluded that the clinical description of these individual cases did not provide sufficient evidence to identify a family history of epilepsy as a possible risk factor.

[1] Both these medicinal products were authorised by the European Commission on 23 October 2000. The authorisations apply to all 15 EU Member States. Hexavac (MAH - Aventis-Pasteur MSD) is marketed as suspension for intramuscular injection in Austria, France, Germany, Greece, Italy, Spain and Sweden. Worldwide it is authorised in a further 15 countries, including Norway and Iceland. Infanrix Hexa (MAH - GlaxoSmithKline) is marketed as powder and suspension for injection in Belgium, France, Germany, Greece, Italy, Luxembourg and Spain. Worldwide it is authorised in a further 33 countries, including Norway and Iceland.

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- The CPMP does not recommend any changes to the present conditions of use for these products which should be followed closely by health care professionals (please refer to the European Public Assessment Reports and latest product information for Hexavac and Infanrix Hexa, which are available on the EMEA website at http://www.emea.eu.int/htms/human/epar/g-lepar.htm).

- The CPMP will continue to monitor these products closely in the light of any new information to be generated.

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