

STATEMENT FROM THE MEDICINES CONTROL AGENCY

MEDICINES CONTROL AGENCY TO OBJECT TO IMPORTATION OF UNLICENSED SINGLE URABE STRAIN MUMPS VACCINE

The Committee on Safety of Medicines (CSM) has advised that Urabe mumps vaccine is associated with an unacceptable risk of aseptic meningitis and that the Medicines Control Agency (MCA) should object to importation of unlicensed mumps vaccine containing the Urabe strain of mumps virus. On the basis of that advice, the MCA has today contacted importers notifying them that the vaccine should not be imported.

This is not a new safety issue but has been considered at this point due to notifications received by MCA to import these vaccines. The risk of Urabe mumps vaccine meningitis has been recognised for over 10 years. Indeed, MMR vaccines containing the Urabe mumps strain has not been used in the UK since 1992 due to this risk. Since then, the only MMR vaccines used in the UK have contained Jeryl Lynn mumps strain.

At its meeting on 25 July 2002, the independent scientific advisory body reviewed the most up to date data in relation to the risk of Urabe mumps vaccine meningitis and the risk associated with the Jeryl Lynn strain of mumps vaccine contained in the two MMR vaccines currently used in the UK.

In reaching its decision the CSM considered data from UK studies which have shown the risk of Urabe mumps meningitis to be in the region of 1 case per 3,800 doses distributed but acknowledged that this risk could be higher. Viral meningitis is a potentially serious and distressing condition and Urabe mumps vaccine-associated meningitis has led to seizures, hospitalisation and invasive clinical tests including lumbar puncture. After many years of worldwide experience, Jeryl Lynn mumps vaccine has not been shown to be associated with meningitis.

Professor Alasdair Breckenridge, Chairman of the Committee on Safety of Medicines, said:

"There is sound evidence that mumps vaccine containing the Urabe strain of virus is associated with a risk of meningitis and no proven additional benefits. This risk to children of a potentially serious neurological complication makes its use unacceptable and we are advising MCA not to allow importation of vaccines containing this strain. The currently available MMR vaccines, which contain the Jeryl Lynn strain of mumps virus, are very effective, are not associated with meningitis and are the safest way of preventing measles, mumps and rubella, themselves serious and occasionally fatal diseases."

Note to Editors

1. The Committee on Safety of Medicines (CSM) is an independent expert scientific committee which advises the Government on medicines. The CSM has a responsibility to monitor the safety of medicines, including vaccines, used in UK practice. It achieves this through assessment of data on suspected adverse drug reactions, received predominantly via the Yellow Card Scheme, and data from scientific studies published in medical literature.
2. The Medicines Control Agency (MCA) is an Executive Agency of the Department of Health. The MCA, with expert advice from the CSM, is responsible for safeguarding public health by ensuring that all medicines on the UK market meet appropriate standards of safety, quality and efficacy.
3. MMR is a combined vaccine usually given to children between 12-15 months of age and again at around 4 years, as protection against measles, mumps and rubella. MMR was introduced into the UK immunisation programme in 1988 and has substantially reduced the incidence of death and disability due to these three infections.
4. MMR vaccines containing the Urabe strain of mumps vaccine were withdrawn from use in the UK in 1992 following confirmation of the risk of aseptic meningitis. Since then, only MMR vaccines containing the Jeryl Lynn strain of mumps vaccine virus have been used in the UK.
5. Two MMR products are currently used in the UK, MMRII and Priorix. These products are not associated with aseptic meningitis.
6. In accordance with medicines legislation, unlicensed medicines may be imported into the UK by licensed importers following notification to MCA. Such unlicensed medicines may only be imported to meet the special needs of individual patients which an equivalent licensed product cannot meet. As such unlicensed single Jeryl Lynn mumps vaccines have been imported by licensed importers following notification to MCA.
7. For media enquires only, please contact David Daley in the Department of Health Media Centre on 020 7210 5656.

[ENDS]