

From The Chief Medical Officer:
Dr Henrietta Campbell

Castle Buildings
Upper Newtownards Road
Belfast BT4 3SJ

Telephone: 028 90 520563
Fax: 028 90 520574

E-Mail: henrietta.campbell@dhsspsni.gov.uk

URGENT COMMUNICATION

HSS(MD)33/2002

14th November 2002

To:

All General Practitioners, including locums (for onward distribution to practice staff including practice nurses)
Directors of Public Health, Health & Social Services Boards (for onward distribution to all general practitioners, out-of-hours co-operatives and consultants in public health medicine)

CCDCs, Health & Social Services Boards

Directors of Nursing, Health & Social Services Boards

Medical Directors of Health & Social Services Trusts (for onward distribution to all consultant paediatricians, obstetricians, infection control teams)

Nursing Directors of Health & Social Services Trusts (for onward distribution to all paediatric nursing staff, hospital midwives, health visitors, community midwives)

All Community Pharmacists

Directors of Pharmacy, Health & Social Services Boards

Directors of Pharmacy, Health & Social Services Trusts

Dear Colleague

PAVIVAC, UNLICENSED MUMPS VACCINE **SEVAPHARMA, CZECH REPUBLIC**

CEM/CMO/2002/15

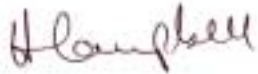
1. The purpose of this urgent communication is to alert you to a press release regarding unlicensed mumps vaccine being issued from the Committee on Safety of Medicines (CSM) today. Between mid-May and the end of September this year an unlicensed single mumps vaccine (Pavivac) has been imported for use in private clinics in the UK. The CSM has a number of major questions and concerns about the manufacture, testing and storage of the unlicensed vaccine Pavivac, which are not answered by the information currently available.
2. **CSM have recommended that no further Pavivac vaccine should be imported and used and have asked the Medicines Control Agency (MCA) to seek further information urgently.**
3. A Press Release to this effect is being issued today (copy attached). A Question and Answer briefing is attached to provide you with a response should you receive any enquiries from concerned parents.
4. The DHSSPS continues to recommend MMR as the safest and most effective way to protect children against measles, mumps and rubella. There is absolutely no evidence to support the use of single vaccines against measles, mumps and rubella and, as this communication confirms, legitimate concerns exist over the safety and efficacy of these single vaccines.

For specific enquiries regarding this issue contact: Andrew McKendrick, Rm 18-110, Medicines Control Agency, 1 Nine Elms Lane, London SW8 5NQ

On general vaccine policy issues contact:

Dr Lorraine Doherty
Tel: 02890 520717
E-mail: lorraine.doherty@dhsspsni.gov.uk

Yours sincerely



Dr Henrietta Campbell
Chief Medical Officer

cc: Dr Vanessa Chambers
Dr Norman Morrow
Mrs Judith Hill
Mr Jim Hamilton
Mr Gerry Dorrian
Regional Epidemiologist, CDSC(NI)

This letter is available on the DHSSPS Extranet which can be accessed directly at <http://extranet.dhsspsni.gov.uk> or by going through the HPSS Web at <http://www.n-i.nhs.uk> and clicking on DHSSPS

1. Can you assure me that the single vaccine I gave my child was safe?

A. Unfortunately we cannot give you any assurances about the safety and effectiveness of Pavivac. Sufficient details are not available to assure us that this vaccine is safe enough to be used in the UK. Nor is there sufficient information to judge whether the vaccines are effective.

2. What else should I know?

A. Pavivac has highly unusual storage requirements – it must be stored at between -20°C and -10°C . If it has not been stored properly, the vaccine has to be considered ineffective. We do not have any information either on the test results of these vaccines since they were not tested by the routine UK laboratory, or any other EU laboratory.

3. Would it matter if my child has had Pavivac [or Movivac] that was not stored properly?

A. Yes. Storage of the vaccines outside of the conditions recommended by the manufacturer may render them seriously sub-potent and they may not protect your child. If these vaccines have been stored at the incorrect conditions they must be considered to be sub-potent and should have been discarded. All parents of children who have received single mumps vaccine need to contact the clinic that provided them to determine whether or not vaccine was stored properly. They should ask if their child was given Pavivac, and ask for information on the storage conditions. Unless they are told that the vaccine was stored at minus 20°C to minus 10°C , apart from up to 72 hours in transit, they must assume that the vaccine was ineffective and the child will need to be re-immunised. Current information suggests that the vaccines have been stored correctly; the MCA is urgently seeking further confirmation that this is correct.

4. How would I know if the vaccine has been stored correctly?

A. You must discuss this with the clinic. The DHSSPS has advised MMR all along, and even if your child has had some single vaccines, it is not too late to have MMR.

5. Concerns have been raised about TSE in relation to other vaccines; do the same concerns exist with this vaccine?

A. The MCA is urgently seeking additional information on this issue.

6. Are Pavivac and Movivac licensed in the UK?

A. No – they are not licensed in the UK. They are only available through importation by a licensed wholesaler. Unlicensed vaccines have not been assessed for safety, quality and effectiveness, as is the case for medicines licensed in the UK.

7. How long have these vaccines been available for use in the UK?

A. From May this year until late September.

8. How many doses of Pavivac and Movivac have been administered?

A. Only the clinics providing separate vaccines know how many doses have been used. What we know is that the maximum number of doses of Pavivac that have been supplied is 5,720. We believe that no Movivac has been used in the UK – the supplies that were imported were re-exported to Ireland. The authorities in Ireland have been alerted.

9. Why have the problems with this vaccine only just come to light?

A. This is because the MCA only became aware of potential concerns over the manufacturing of this vaccine in late September 2002. The information provided by the importer did not fully reflect the facts about these vaccines.

10. How can unlicensed medicines (including vaccines) be used in this country?

A. Where a doctor feels that their patient has a special clinical need, which is not met by a licensed medicine, they may use an unlicensed medicine. Where unlicensed medicines are imported, it must be via a licensed wholesaler. A doctor prescribes unlicensed medicines on their own personal responsibility. These vaccines are manufactured and licensed in the Czech Republic.

11. Shouldn't the MCA have blocked Pavivac [and Movivac] at the outset, particularly given its country of origin?

A. The process of approving imports of unlicensed pharmaceuticals works on a process where the MCA does not object where there are no known safety concerns. The use of an unlicensed medicine is on the direct personal responsibility of the prescriber. The MCA will object to importation of an unlicensed medicine where there are known safety concerns.

12. Is there a safety issue for children who are hypersensitive to dog antigens?

A. Yes. The datasheet for this product warns specifically of the possibility of allergic reactions in individuals who are hypersensitive to dog protein (dog hair).

13. How come I wasn't advised about the presence of dog protein in Pavivac [or Movivac]?

A. The doctor giving the vaccine is responsible for talking you through these issues. If you have any concerns please contact the doctor/clinic who administered the vaccine.

14. Should my child have an antibody test to see if the vaccine has worked?

A. The DHSSPS does not recommend testing for antibodies. Unless mumps antibodies are tested in a specialist laboratory, you cannot be sure that the results do confirm that your child is protected.

15. But what can I do to protect my child?

A. The best thing you can do for your child is to have MMR. This vaccine has passed rigorous safety, effectiveness and quality testing. There remains no evidence that there are valid safety concerns over MMR. The present experience suggests that there can indeed be safety concerns over the use of certain single vaccines.

16. Isn't all this the Department's fault by blocking single vaccines and forcing clinics to use vaccines they cannot guarantee being safe?

A. No. The MCA has not blocked importation of any single vaccines that match the safety and effectiveness requirements of the vaccines that the NHS routinely provides. The MCA has only blocked importation of single vaccines where there are concerns about safety or level of protection. The MCA has blocked imports of Urabe mumps vaccine that has a known risk of causing aseptic meningitis, import of Leningrad-Zagreb Mumps vaccine for the same reason and Rubini Mumps vaccine because of concerns about level of protection.

17. But why doesn't the Department give licenses to single vaccines, then there wouldn't be the problem?

A. Single mumps and single measles vaccines are licensed in the UK. However, the pharmaceutical companies that hold the product licences do not manufacture the vaccines for, or market them in this country.

STATEMENT FROM THE COMMITTEE ON SAFETY OF MEDICINES
ADVICE THAT UNLICENSED PAVIVAC SINGLE MUMPS VACCINE SHOULD NOT
BE IMPORTED OR USED

As a precautionary measure, the Committee on the Safety of Medicines (CSM) has advised that the use of an unlicensed single mumps vaccine, Pavivac, should be suspended, pending further investigations by the Medicines Controls Agency (MCA). The MCA should also continue to oppose further imports of this product.

The CSM met following concerns raised over the manufacture, testing and storage of the vaccine. At its meeting yesterday (13 November 2002), the independent scientific advisory body reviewed the most up to date data available on Pavivac. The CSM said that it had insufficient information to be able to offer any assurances on its safety, quality or efficacy.

The Committee has asked the MCA to seek further information from the Czech manufacturer and the Czech Regulatory Authority. In the meantime the CSM also asked the MCA to contact clinics that have imported this vaccine and instruct them that any remaining stocks must not be used.

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

"There are a number of major questions about the manufacture, testing and storage of the unlicensed vaccine Pavivac which are not answered by the information currently available. Because of this lack of information we are advising that its importation and use should be halted as a precautionary measure. Further information and clarification has been urgently requested."

Notes to Editors

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 the medical literature.

The Medicines Control Agency 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.

Pavivac is a single mumps vaccine manufactured by Sevapharma in the Czech Republic. It is licensed by the Czech Regulatory Authority but it is not licensed in the UK. Sevapharma also manufactures a single measles vaccine, Movivac. Information is also being sought on Movivac although there have been no imports of this unlicensed product for use in the UK.

The CSM will be reconsidering this issue at its meeting on December 11.

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.

For media enquiries only, please contact David Daley on 020 7210 5656.