Primary and Community Care Directorate
Pharmacy Division

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26 February 2009

The Scottish Government

IMMEDIATE MESSAGE TO:

1. Directors of Pharmacy
2. Chief Pharmacists, NHS Boards
3. Hospital Pharmacy Managers
4. Medical Directors NHS Boards
5. Chief Executives NHS Boards

Dear Healthcare Professional,

DRUG ALERT NO 6 – CLASS 2

Please find attached drug safety information from the Medicines and Healthcare Products Regulatory Agency (MHRA) for onward transmission (see list below).

1. Please could Directors of Pharmacy forward this alert to:-

   - Hospital pharmacists
   - Chief Pharmacists to forward on to Medicines Information Pharmacists
   - Community pharmacists

2. Please could Medical Directors forward the message on to :-

   - General Practitoners
   - Dispensing Doctors
   - Chief Executives NHS Boards

Thank you for your co-operation.

Yours sincerely

IRENE FAZAKERLEY
Pharmacy Division

* NB: Drug alerts have the following classifications:
1. Action now (including out-of-hours); 2. Action within 48 hours; 3. Action within 5 days; 4 Caution in use

Safeguarding public health
Defective Medicines Report Centre
Market Towers
1 Nine Elms Lane
London
SW8 5NQ
Telephone: +44 (0)20 7084 2574 **Fax: +44 (0)20 7084 2676**

DRUG ALERT

CLASS 2 MEDICINES RECALL

Action Within 48 Hours
PHARMACY OR EQUIVALENT LEVEL RECALL

Date: 25 February 2009 EL (09)/A06 Our Ref: MDR 44-02/09

Dear Healthcare Professional,

Novartis Vaccines and Diagnostics S.r.l.

Menjugate Kit PL 13767/0023-13767/0024

Meningococcal group C conjugate vaccine

Batch Number	Expiry Date	Pack Size	First Distributed
235012A	July 2011	Single Dose	22 January 2009
236011	July 2011	Single Dose	20 February 2009

Novartis Vaccines and Diagnostics S.r.l. are recalling the above batches of Menjugate Kit as a precaution following an initial failure of a sterility test carried out as part of a shipping validation study of the batch of aluminium hydroxide solvent used in them, batch number 088902. This batch passed its sterility test at the time of release.

Recipients are asked to quarantine any stock and notify Movianto UK Ltd on 01234 248789 that you have product to be collected. Alternatively please email Rosina.Clark@movianto.com with details of the product to be collected.

In the UK, Novartis Vaccines' co-promotion partner is Sanofi Pasteur MSD Ltd. However for information regarding this action please contact Novartis Vaccines and Diagnostics Limited on 08457 451500.

Primary Care Trusts are asked to bring this information to the attention of relevant clinics, General Practitioners and Community Pharmacists by copy of this letter.

Yours faithfully

Alison Bunce

Pharmaceutical Assessor, DMRC

MHRA Distribution:
Regional Contacts for NHS Trusts and Provider Units
Chief Pharmacists: England, Scotland, Wales, Northern Ireland
Prison Health Policy Unit (DH)
Chief Pharmacists: Jersey, Guernsey, Alderney, Sark, Isle of Man, Gibraltar
Special Hospitals
Healthcare Commission for distribution to Independent Health Care Establishments
Primary Care Trusts (England)

Q and A

Q Why are these lots of Menjugate Kit being recalled?

A The tested samples were of one batch of solvent used in two batches (235012A and 236011) of Menjugate Kit, and were identified positive for the bacteria Staphylococcus aureus during the sterility test, they were not distributed to the UK market. However, as a precaution, these two batches of Menjugate Kit which were distributed in the UK are being recalled. There is at present no evidence that these two batches of Menjugate Kit are affected.

The batches concerned were tested prior to release and complied with all tests, including the sterility test. Product supplied to the UK was shipped using routine validated transport. The tested samples that failed the sterility test were part of a non-routine study undertaken by the company and were not part of the UK market product.

Q If there are no problems why have these batches of vaccine been withdrawn?

A This is an entirely precautionary action. There is no reason to believe the UK batches are at risk of the problems of the material that was tested. These batches of vaccine have been withdrawn to ensure that there are no grounds for anyone to be concerned. The MHRA have no reports of adverse reactions associated with these batches.

Q. Are UK children at risk?

A. There is no reason for UK children to be at any risk from this product. All vaccine supplied to the UK had passed the tests required for its use.

Q. What action should be taken if a child has recently had a MenC vaccine?

A. Other meningitis vaccines, and other batches of Menjugate, are not affected by this recall. If a parent has any concerns about the MenC vaccine administered to their child they should discuss this with their doctor.

Q Are there any manufacturing issues with this Solvent

A Novartis are investigating the root cause for the non-conforming sterility result. We have no evidence that any other lots of Aluminum-hydroxide solvent would be impacted.