



From The Chief Pharmaceutical Officer  
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**For Action:** Directors of Pharmaceutical Services of the Boards & CSA  
Directors of Pharmaceutical Services of HSC Trusts  
Regional Quality Improvement Authority

Our reference: PHC/7/09  
Date: 26 February 2009

## **DRUG ALERT MEDICINES RECALL**

**Novartis Vaccines and Diagnostics S.r.l.  
Menjugate Kit  
Meningococcal group C conjugate vaccine  
PL 13767/0023-13767/0024**

<b>Batch Number</b>	<b>Expiry Date</b>	<b>Pack Size</b>	<b>First Distributed</b>
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.

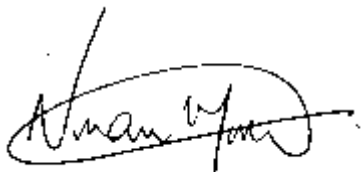
There has been significant national press coverage of this matter. **However, I can confirm that none of the product from these batches has been issued in Northern Ireland as part of the childhood vaccination programme.**

I have enclosed for your information the Q&A brief issued by MHRA.

Area Boards/RQIA should bring this information to the attention of private hospitals/clinics registered with them, Out of Hours Centres and any other relevant care facilities.

The Central Services Agency is asked to bring this information to the attention of Community Pharmacists and General Medical Practitioners directly.

Yours sincerely

A handwritten signature in black ink, appearing to read 'Norman Morrow', enclosed within a large, loopy oval flourish.

**DR NORMAN MORROW**  
Chief Pharmaceutical Officer

For information:

CMO  
CNO  
CDO  
CISSI  
SMO  
Director, Health Estates  
Public Health Branch  
DHSSPS, Library  
Extended nurse prescribers

Regional Medicines and Poisons Information Service

Regional Director of Supplies  
RPLS  
Pharmaceutical Society of NI  
Senior Prison Pharmacist  
Prison Service, Dundonald House  
Nursing Officer, Health Estates  
Medical Officer, Castle Buildings  
Regional Procurement Pharmacist  
NICPPET

## **Questions and answers**

### **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.