

From The Chief Pharmaceutical Officer  
**Dr Norman Morrow**

Castle Buildings  
Upper Newtownards Road  
Belfast BT4 3SJ

Telephone: 028 90 523219  
Facsimile: 028 90 522335

E-Mail: norman.morrow@dhsspsni.gov.uk  
Our reference: PhC/ 10 /07  
Date: 7 June 2007

**For Action:** Directors of Pharmaceutical Services of the Boards & CSA  
Directors of Pharmaceutical Services of H&SS Trusts  
Regional Quality Improvement Authority

## **DRUG ALERT**

### **MEDICINES RECALL**

Dear Sir/Madam

#### **CONTAMINATED ORIGINATOR AND PARALLEL DISTRIBUTED PRODUCT**

**VIRACEPT (ALL PRESENTATIONS)**  
**(nelfinavir mesilate)**

**EU/1/97/054/001**  
**EU/1/97/054/003**  
**EU/1/97/054/004**  
**EU/1/97/054/005**

The MHRA in conjunction with the EMEA, with assistance from Roche Registration Ltd, are recalling all batches of Viracept products irrespective of whether they have been supplied directed from Roche or as parallel distributed stock.

#### Action Required

An attempt should be made to recover product from patients.

Recipients are requested to quarantine stock, including part packs and return to your original supplier.

For medical information please call Roche Registration on 0800 328 1629.

Additional information is available in the Q&As sheet attached.

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 Practitioners immediately.

Yours sincerely

**DR NORMAN MORROW**

Chief Pharmacist

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

## Q&As

### **Why has a Class 1 Drug Alert been issued in this case?**

We have been informed that a toxic contaminant may be present in this product and we are aware that this product may be used HIV patients including women and children.

### **What advice should I give to patients who have taken any Viracept products?**

Patients should be advised to contact their clinic immediately to arrange for provision of an appropriate alternative to Viracept to include in their HIV treatment regimen.

### **What are the implications of the toxic contaminant?**

Toxic contaminants are highly undesirable in any population but we have special concerns as this drug may be used in children and pregnant women who are high risk. In addition HIV patients are a vulnerable population.

### **Why are you recalling all presentations and batch numbers?**

We are informed that the contamination affected the active ingredient which was later used in all the presentations.

Early tests indicate that the level of contamination may vary between products and batches but we believe patient safety is best addressed by recalling all remaining stock.

### **Who is the Marketing Authorisation Holder for this product?**

The Marketing Authorisation is held by Roche Registration Ltd, Shire Park, Welwyn Garden City AL7 1TW.

The authorisation is issued by the EMEA.

### **What is the difference between parallel distribution and parallel imports?**

Parallel traded products are often sold at lower prices in the EU and are allowed to be imported and relabelled for sale in the UK. Parallel distributed products have a marketing authorisation issued by the EMEA.

The repacking and relabelling of parallel distributed products is inspected by the MHRA but the importation and/or distribution takes place outside the original manufacturer's supply chain.