

From the Chief Medical Officer
Dr Henrietta Campbell CB

URGENT COMMUNICATION

SENT BY ELECTRONIC VERSION ONLY

HSS(MD) 35/2004

To: Medical Directors of HSS Trusts for cascade to
All Consultants
Directors of Public Health in HSS Boards
Directors of Nursing in HSS Boards
Directors of Nursing in HSS Trusts
GP Advisers in HSS Boards
Regional Medicines and Poisons Information Service

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Your Ref:
Our Ref: HSS(MD) 35/2004
Date: 1 October 2004

Dear Colleague

REFECOXIB (Vioxx/VioxxAcute –WITHDRAWAL DUE TO INCREASED RISK OF THROMBOTIC EVENTS

Merck Sharpe & Dohme have ceased to distribute all strength and formulations of Vioxx/VioxxAcute to wholesalers on a worldwide basis with immediate effect. This is as a result of new safety concerns raised following long-term use.

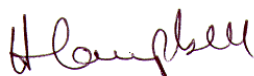
This electronic communication is to make you aware of the attached Drug Alert Medicines Recall sent by the Chief Pharmaceutical Officer to Director of Pharmaceutical Services of HSS Boards and Trusts and General Practitioners.

For further information please see the attached message from Professor Gordon Duff, the Chairman of the Committee on Safety of Medicines.

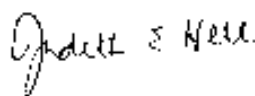
The CSM advice to patients is “patients taking Vioxx should contact their doctor by phone or at the next convenient appointment to arrange an alternative prescription.

Further information is available from the Medicines and Healthcare Products Regulatory Authority website at <http://www.mhra.gov.uk> or by telephoning 020 7084 2000

Yours sincerely



**Dr Henrietta Campbell
Chief Medical Officer**



**Miss Judith Hill
Chief Nursing Officer**

Encs

From The Chief Pharmaceutical Officer
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For Action: Directors of Pharmaceutical Services of the Boards & CSA
Directors of Pharmaceutical Services of H&SS Trusts

Our reference: PhC/9/04
Date: 30 September 2004

DRUG ALERT

MEDICINES RECALL

Dear Sir/Madam

MERCK SHARP & DOHME

Vioxx and VioxxAcute
All formulations and Lot Numbers
(Refecoxib)

PL 00025/0383, 0348, 0385,
0386, 0408, 0409

Merck Sharp and Dohme have ceased to distribute all strengths and formulations of Vioxx and VioxxAcute to wholesalers on a worldwide basis with immediate effect. This is as a result of new safety concerns raised following long-term use.

For further information please see the attached message from the Chairman of the Committee on Safety of Medicines.

This Class 2 alert requires recall from wholesaler level. Individual customers of wholesalers should contact their wholesaler directly to arrange return. Limited stocks of product for compassionate use remain available in the short term by direct contact with the company.

Parallel importers should cease distribution to wholesalers and contact their suppliers for instructions.

All medical enquiries should be directed to Ms Helen Wright, External Affairs Advisor, on 01992 467272. Enquiries related to stock return should be directed to Mr Alex McKenzie on 01992 452111.

MHRA/CSM advice to patients is "Patients taking Vioxx should contact their doctor by phone or at the next convenient appointment to arrange an alternative prescription".

The Central Services Agency is asked to bring this information to the attention of Community Pharmacists and all General Practitioners within 48 hours.

Yours sincerely

DR NORMAN MORROW
Chief Pharmacist

For information:
CMO
CNO
CDO
CISSI
SMO
Director, Health Estates
Public Health Branch
DHSSPS, Library
Pharmaceutical Wholesalers

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

IMMEDIATE WITHDRAWAL OF ROFECOXIB (VIOXX/VIOXXACUTE)

Dear Colleague

The Committee on Safety of Medicines has today been informed of the immediate voluntary worldwide withdrawal of the 'COX-2 selective NSAID' rofecoxib (Vioxx/VioxxAcute) by the manufacturer. This follows new clinical trial results showing an increased risk of confirmed serious thrombotic events (including myocardial infarction and stroke) compared to placebo, following long-term use.

Patients taking Vioxx/VioxxAcute should contact their doctor by telephone or at the next convenient appointment to arrange an alternative prescription.

The new data and advice is specific to rofecoxib.

Background

Rofecoxib is a cyclo-oxygenase-2 (COX-2 selective) non-steroidal anti-inflammatory medicine (NSAID) first used in the UK in 1999. It is indicated for osteoarthritis, rheumatoid arthritis (Vioxx) and higher dose-strength are indicated for short-term relief of acute pain (VioxxAcute).

The cardiovascular safety of rofecoxib and other COX-2 inhibitors has been reviewed by the Committee on Safety of Medicines on a number of occasions since 2000, as evidence of a possible increase in risk of cardiovascular events has emerged.

COX-2 inhibitors do not affect platelet function and are therefore not thought to offer anti-thrombotic cardiovascular protection afforded by some non-selective NSAIDs (e.g. naproxen). The possibility of an additional thrombotic risk has, up until now, not been established although this possibility has resulted in changes to the Summary of Product Characteristics and Patient Information Leaflets highlighting the need for caution in high risk patients.

New Data

The APPROVe study was a multi-centre, randomised, placebo-controlled, double-blind study to determine the effect of 3 years treatment with Vioxx on the recurrence of neoplastic polyps of the large bowel in patients with a history of colorectal adenoma. The trial, which started in 2000, enrolled 2,600 patients and compared Vioxx 25mg to placebo. In this study 25 patients taking placebo versus 45 patients taking Vioxx experienced a confirmed serious thrombotic event. The absolute event rates were approximately 3 per 400 patient years for placebo and 6 per 400 patient years for Vioxx, i.e. an absolute increase in risk of approximately 3 thrombotic events per 400 patient years of treatment. The difference in event rates was only apparent after 18 months of treatment.

On the basis of these data the Marketing Authorisation holder for rofecoxib (Merck Sharp and Dohme) has today announced that it is withdrawing the product worldwide, with immediate effect, and is stopping all clinical trials. The new data relate specifically to rofecoxib and is not generalised to other selective COX-2 inhibitors.

What action should patients take?

Patients taking Vuioxx/VioxxAcute should contact their doctor by telephone or at the next convenient appointment to arrange an alternative prescription.

It is important that serious suspected adverse drug reactions (ADRs) are reported to the Committee on Safety of Medicines using the Yellow Card Scheme. Please report all suspected ADRs for black triangle medicines.

If you have any enquiries, please contact the MHRA (medicines on 202 7084 2000 or e-mail info@mhra.gsi.gov.uk)

Yours sincerely

Prof. Gordon Duff
Chairman
Committee on Safety of Medicines