re:ACTION No.33

March 2006

An occasional bulletin from the West Midlands Centre for Adverse Drug Reaction Reporting

If you would like to receive this bulletin by email contact: help@csmwm.org

Influenza: be vigilant

(European Medicines Agency recommends no changes for Tamiflu safety information. http://www.emea.eu.int/pdfs/human/press/pr/42008705en.pdf - accessed 10th January 2005)

Current concern over an epidemic of influenza, or worse still, of some mutant avian influenza, has rekindled interest in neuraminadase inhibitors. Oseltamivir (Tamiflu) is licensed for use in both adults children over the age of 1 year for the treatment of influenza. If given in the first 48 hours after onset of symptoms, it may reduce the severity and duration of influenza.

The UK's Department of Health has ordered 14.6 million doses of oseltamivir to be used as the "first line of defence" for the treatment of flu if there is a pandemic. The Number-Needed-to-Treat (NNT) to avert one death from influenza may be 1800-3200 and the NNT to avert one hospitalisation 97 (all-cause mortality). (BMJ electronic response http://bmj.bmjjournals.com/cgi/eletters/331/7526/1203-b#123247 accessed 10th January 2006)

The most frequently reported undesirable effects of oseltamivir are nausea, vomiting and abdominal pain. These effects generally occur in the first two days of treatment and resolve spontaneously.

A recent review of new safety data, by the European Medicines Agency, related to psychiatric disorders has recommended no changes in oseltamivir's safety information, although they have advised that close monitoring of psychiatric disorders (started in February 2003) should be continued.

Oseltamivir is a Black Triangle ▼ medicine. Any suspected adverse reaction, no matter how trivial, should be reported. Rare adverse effects are difficult to detect in clinical trials. Wider prescribing of the drug, as in a mass prophylaxis campaign, may reveal rare effects not previously described.

Forgetful statins

(*Canadian Adverse Reaction Newsletter* 2005; 15(4): 361-4)

Patients may forget to take their medication; it seems statins may make patients forget themselves.

Health Canada describes a series of case reports of amnesia. The 19 reports include suspected cases related to atorvastatin, cerivastatin, lovastatin, rosuvastatin and simvastatin. Amnesia began between a month and a year after starting a statin. In 11 cases the amnesia resolved or improved when the statin was discontinued or given at a reduced dose.

A hypothetical mechanism for this effect is interference with the cholesterol formation essential for myelin, leading to demyelination of nerve fibres in the central nervous system.

Memory loss is a recognised effect of atorvastatin, and the issue of a possible class effect, and changes in product information, is being reviewed by European regulatory authorities.

Health Canada advises that changes in cognitive function in those taking statin therapy should be monitored. The West Midlands Centre for Adverse Drug Reaction Reporting has received one case of confusion and memory loss associated with a statin, which resolved on cessation of therapy. Amnesia is a serious reaction; don't forget to report it.

Out of Africa

(*http://www.mhra.gov.uk accessed 9th of February 2005*)

Herbal medicines continue to grown in popularity. While seen as natural, and therefore safe, herbs can be potent medicines, and they can have toxic effects. The MHRA has recently reported on the sale of African herbal products in the UK, M2 Formula and Energy 2000.

These products are thought to contain *Aristolochia* species, which can cause kidney failure or cancer, and *Strophanthus* species, which have a powerful

action on the heart and could result in serious heart problems including abnormal heart rate and heart failure. The MHRA has ordered that these products should immediately be withdrawn from sale.

The West Midlands Centre for Adverse Drug Reaction Reporting continues to receive reports of reactions to herbal medications. Vigilance in this understudied area is continued, and we are grateful for reports of suspicions of adverse reactions to herbs or interactions with concomitant medication.

Help, kelp!

(*Archives of Internal Medicine* 2005;165:2536)

Another example of the potential dangers of herbal medicines was reported in the *Archives of Internal Medicine*. A 35-year-old male athlete experienced hypokalaemic periodic paralysis and thyroid disorders after ingesting 5-10 kelp tablets daily. They contained 50µg of iodine. The daily requirement in euthyroid patients is 100 to 300 micrograms. After discontinuation of the kelp, the weakness resolved and he became euthyroid.

Kelp is advocated by some as a weight loss treatment. Care should be taken by those who may have a propensity for thyroid conditions. Please report on a Yellow Card any reaction that you suspect is due to a herbal medicine.

A Big Thank You

Our unit would like to wish all of our reporters all the best in 2006. We rely heavily on the goodwill of reporters to the Yellow Card Scheme to ensure drug safety from the moment a product becomes available for use until its use finally ceases

The efforts of the doctors, nurses, pharmacists, and other reporters in the West Midlands has made 2005 another bumper year for reports, and we are sure will continue to ensure the West Midlands Region performs well.

Each card adds a little more to our knowledge of drug safety. If you have never reported an adverse drug reaction before, visit our website for top tips on reporting and remember our motto:

"If in doubt, write one out."

Also, if you would like someone from our unit to come and talk to your organisation about adverse drug reactions or give training on the Yellow Card scheme – then contact us at:

help@csmwm.org

REPORTING TO: The West Midlands Centre for Adverse Drug Reaction Reporting

We welcome Yellow Card reports on all suspected adverse reactions to new (▼) drugs including vaccines and unlicensed herbal remedies and *all suspected reactions to all drugs used in children*, and on all serious or unusual reactions to well-established drugs. You do not have to be certain that a drug caused a reaction in order to report.

Please send reports to: CSM West Midlands, Freepost SW2991, BIRMINGHAM, B18 7BR. No stamp is needed. If you would like a supply of pre-addressed and reply-paid yellow cards, please contact the above address.

SOME ADDITIONS TO THE LIST OF INTENSIVELY MONITORED DRUGS

Approved name	Trade name	Indication
omalizumab	▼ Xolair®	asthma
insulin glulisine	▼ Apidra®	diabetes
rasagiline	▼ Azilect®	Parkinson's disease

Please report **all** adverse reactions you suspect are due to intensively monitored drugs.
Please send any comments to:

Dr R E Ferner at West Midlands Centre for Adverse Drug Reaction Reporting, or email: r.e.ferner@bham.ac.uk