



**Safety concerns over COPD treatment**

CONCERNS have been raised over the safety profile of the COPD treatment tiotropium (Spiriva), after a review linked its use to a possible increased risk of stroke.

The US Food and Drug Administration (FDA) has asked the manufacturer, Boehringer Ingelheim, to supply more information.

The company recently informed the FDA that it had analysed safety data from 29 placebo controlled studies of products containing tiotropium bromide, used for maintenance treatment of bronchospasm and dyspnoea associated with COPD.

The analysis, involving 13,500 patients, showed that preliminary estimates of stroke risk were eight patients per 1000 treated for a year with tiotropium, compared to six patients per 1000 on a placebo.

A spokesman for Boehringer Ingelheim Australia said the company and partners Pfizer concurred with the FDA statement and were voluntarily providing information to the FDA and the TGA.

However, he emphasised that the FDA "has not reached a conclusion about whether this information warrants any regulatory action".

**GP cautioned over 'inadequate' records**

A VICTORIAN GP has been given a caution for failing to keep medical records for two of his patients for up to eight years.

Dr Peter Tisdall was ordered by the Medical Practitioners Board of Victoria to attend performance assessment, training and monitoring to ensure he kept adequate clinical notes in future, after it found his records were inadequate and, in some instances, contained only a date stamp relating to a consultation.

The board also investigated allegations that Dr Tisdall, a rural GP in Kyabram, caused or aggravated a dependency on pethidine in one female patient.

While the board was unable to conclude whether Dr Tisdall caused the dependency, prescribing the drug for such a long period was not good medical practice, it said. However, the board did acknowledge Dr Tisdall had little other option "in a rural setting".

# Oestrogen an aid in psychosis

**Rada Rouse**

PIONEERING Australian research suggests exogenous oestrogen may be a useful adjunct to treatment with antipsychotic medication in women with schizophrenia.

Researchers from the Alfred Psychiatry Research Centre, Melbourne, demonstrated faster and better resolution of symptoms in women using adjunctive 100 mcg transdermal oestradiol compared with women on antipsychotic medication alone.

The centre's director, Professor Jayashri Kulkarni, told the 3rd International

Congress on Women's Mental Health in Melbourne last week preliminary results from her study of 102 "floridly psychotic" women aged 27

*'It might help improve quality of life'*

to 48 years had found some dramatically improved in the treatment arm.

On entry to the trial the women scored an average 84 points in severity of hallucinatory and delusional symptoms, with the oestradiol group dropping an average 32

points compared to an average 14 points in the placebo group over four weeks (*Arch Gen Psychiatry* in press).

"This is statistically significant... and it makes the difference between [a woman] being an inpatient and being out of hospital," Professor Kulkarni said.

She added accumulating evidence showed many women were presenting with psychotic symptoms in the postpartum or perimenopausal periods.

"Women who have established psychosis often notice that they are worse in the premenstrual week," she added.

Clinical observations indicated that women who continued with adjunctive oestrogen following the completion of trials were able to reduce their antipsychotic medication.

While antipsychotics reduced hallucinatory and delusional symptoms, they often had the effect of "numbing" the emotions, but this did not occur with oestradiol, suggesting it might help improve quality of life, she said.

Professor Kulkarni's group was also testing raloxifene and tamoxifen in treating schizophrenia and bipolar disorder respectively.

# Govt backdown on pathology law

**Andrew Bracey**

IN a victory for the profession, the federal government has backflipped on laws regarding leasing agreements and pathology providers following concerns practices could go out of business.

The legislation, which came into effect on 1 March, stipulates practices charging above market value for co-located services face fines of up to \$600,000 and jail terms (MO, 15 February).

But in a letter to the AMA, the federal health department has backed down and agreed to clarify its definition of 'market value' to reflect

the highest offered bid by a service provider for practice space in an open tendering process.

According to the letter obtained by MO, pathology provider proximity to a "source of referrals" would also no longer need to be excluded as a factor in determining market value.

Practice management specialist David Dahm, who voiced industry concerns to the department, congratulated the government for listening.

Mr Dahm said the changes meant practices could now include practice infrastructure, equipment, fittings, staff and common areas in open



tendering evaluations.

"To some extent it reverses [the legislation] and creates more opportunity," he said.

Australian Association of Practice Managers vice-

president Brett McPherson said the changes should not interfere with existing lease agreements or create requirements for practices to gain new evaluations.



# Folate decreases sperm abnormalities

**Kirrilly Burton**

US researchers have linked increased folate intake to reducing human sperm aneuploidy, a condition that may account for over a third of spontaneous abortions.

In a study of 89 men, they found lower overall frequencies of aneuploid sperm in men with higher micronutrient intake.

Previous studies had shown there was a high paternal contribution to sex chromosome aneuploidies, the most frequent numerical chromosomal abnormalities in humans at birth.

The researchers argued that if their findings were replicated by other studies, "a possible public

health intervention would be to increase folate intake for men considering fatherhood".

Professor Robert McLachlan, director of Andrology Australia, agreed that if an interventional study demonstrated that folic acid did relate to sperm aneuploidy, and that supplementation decreased aneuploid sperm levels, it "could potentially have significant implications for public health fertility".

The men with high folate intakes - over 722 µg, 1.8 times the recommended daily amount - had 20% lower levels of sperm aneuploidy compared to men with low folate intakes (114-333

µg), the researchers said (*Human Reproduction*, in press).

However, Professor McLachlan said there were problems with the study, in particular its small sample size and the use of a questionnaire to analyse food intake. ANZAC Research Institute director Professor David Handelsman agreed, saying the study used a relatively small sample of volunteers, with normal sperm counts, who might not represent a typical population of men in the community.

"The significance of this observational study is uncertain, and it is not a reason to start any dietary interventions," he added.