

Carcinogen in AIDS drug?

Meds withdrawn but still available in Australia

Steve Wright and Rachel Cook

The US Food and Drug Administration have alerted the public to a "potential human carcinogen" found in the AIDS drug Viracept (otherwise known as Nelfinavir). The announcement has come months after Australian and European officials reported the same find.

Previously, Pfizer, makers of the US version of the drug, had maintained that levels of the carcinogen were "substantially lower" than in the European and Australian versions of the drug.

The drug was investigated after patients in the UK complained that their tablets possessed an unusual odour.

Drug manufacturer Roche previously supplied Viracept for use in Australia, but after consultation with the Therapeutic Goods Administration in early June, launched a sponsor-initiated recall after the drug was found to contain ethyl methanesulfonate (EMS), a chemical which has been shown to cause cancer in animals.

Spokesperson for Roche, Libby Day, told *MCV* that tests are currently being carried out to examine previous studies of Viracept.

"As the pre-clinical studies of Viracept with regards to it [containing a] potential human carcinogen were conducted in mice, we cannot say if it would have caused cancer in humans," Day said.

"What we do know however

is that the results of one of the pre-clinical studies looking at the threshold for toxicity of EMS and calculated for human exposure to EMS via Viracept was below the threshold thought to support toxicity."

Day went on to say that even though the Viracept license was not suspended in Australia, Roche notified health professionals that they should take their patients off the drug and switch them to another product once the company became aware of the elevated EMS levels.

"Roche would not knowingly expose patients to [the] risk of a potentially causing carcinogenic substance," she said.

Viracept has been one of the more common HIV/AIDS treatment drugs prescribed in

this country, and is subsidised under the Pharmaceutical Benefits Scheme.

While it is still available as a special arrangement item in Australia, PLWHA Victoria board member David Menadue recommends people stay off Viracept until such time that it is cleared by the manufacturers.

"The drug will be reinstated when they have changed the manufacturing process so that contamination won't happen again. Until then there are other options. Some people responded well to the drug but my feeling is that Viracept is not cutting edge anymore," Menadue said.

He also understands that some people may have been disappointed the product was taken off the market.

"You generally have to change the drugs you are on after awhile and readjusting to other drugs has its own complications and side effects, but I have no problem with Viracept being reinstated when they have eliminated the possibility of contamination. However it might take a year to see it again in Australia," explained Menadue.

Meanwhile the European Medicines Agency (EMA) has already recommended the market reintroduction of Viracept; however Roche isn't confident that sales would reach their previous levels given that patients had now switched to other drugs.

Viracept reached \$170 million in sales in 2006.

Discrimination dismissed Remembering Jamie

Rachel Cook

The Victorian Civil Administrative Commission (VCAT) has dismissed two claims of discrimination on the basis of sexuality against the Department of Sustainability and Environment (DSE).

Mansfield resident Ken Campagnolo claimed that the DSE refused to re-employ him as a Project Fire Fighter because of his sexual orientation, after his bisexuality became known.

Campagnolo said that he was the victim of ten years of homophobic harassment.

His case was heard last week, with the direction given by Judge Harbison that the proceeding be struck out.

Mr Campagnolo has retained the right to appeal the decision; however he told *MCV* he is not confident of the outcome:

"I have found the legal processes to have been a complete waste of time. There has been no me-

diation, not one question asked or answered and not one witness interviewed from over two hundred and fifty witnesses," he said.

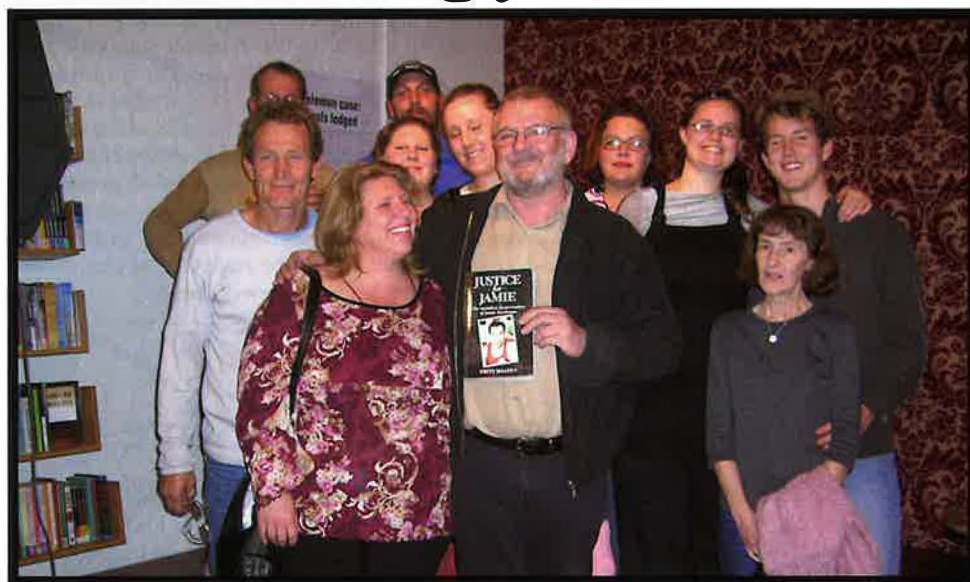
In April this year *MCV* reported that Campagnolo's troubles increased when he was stood down as a trainer with the Bonnedoon Football club, as a consequence of the media attention generated by his case against the DSE.

The football club claimed they were concerned about what the parents of their young players would think of a bisexual man working in the clubrooms.

Campagnolo says he has become systemically isolated in the Mansfield community.

Peter Farrell, a spokesperson for the DSE, stressed that Mr Campagnolo's failure to gain reemployment was because of work performance and nothing to do with his sexuality.

"We judge people on how they work and we don't discriminate on sexuality. We pride ourselves on that."



Friends and family members of Jamie Koeleman, a gay man imprisoned for a murder many believe he did not commit, gathered at Fitzroy's Hares & Hyenas Bookshop last Friday for the launch of a new book about the case.

Koeleman was sentenced to 19 years jail for the murder of 60 year-old gay man Francis Arnoldt, found stabbed to death in a Brunswick park in 1991.

Justice for Jamie, by Melbourne author Fritz Maaten (centre, holding a copy of the book) details numerous elements of the prosecution's case against Koeleman which Maaten considers erroneous.

Koeleman is due for release in 2012.

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