From: Geoff Kirwood [redacted]
Sent: Monday, 21 July 2014 4:00 PM
To: Adjudication
Subject: TRIM: A91436-A91440 - Medicines Australia Limited - submission

Categories: Submission
HP TRIM Record Number: D14/97087

A second memo has now gone unanswered by the [redacted]. PBAC has rejected pregabalin for neuropathic pain and AusPAR rejected duloxetine for somatic pain. Yet posing the question on a fibromyalgia patient community forum as to whether the [redacted] were "encouraging Lyrica or Cymbalta despite expressly stated wish to avoid such?" resulted in affirmations including this statement:

If you speak up and say I don't want to use these drugs, they get quite cross. Your (sic) *wasting their time.*

Concerns over academic and institutional governance have been raised after the sacking by [redacted] for her allegations of misconduct, subsequently shown to have substance. A cloak of secrecy also applies to questions of unethical commerce in research, due to the absence of any equivalent to the US Office of Research Integrity. And undue influence indeed appears to be applied to rheumatologists – [redacted] in the last reporting year of Education Events. Pfizer's declared spend was over the million dollars when 1-day pain management seminars are included.

I fear that approving Edition 18 for five years will enhance financial wellbeing only.

Yours sincerely,

Geoff Kirwood

From: Geoff Kirwood [mailto:[redacted]
Sent: Thursday, July 17, 2014 9:50 AM
To: [redacted]
Subject: RE: Conflicts of interest and MA TWG

Dear [redacted]

No reply has been received to a memo of Feb 14[h] titled 'Impartiality' where I extend my concerns about duloxetine, citing the FDA advisory on Cymbalta Withdrawal Syndrome. Failure of Medicine Australia's Transparency Working Group to achieve consensus on proposals which still fall short of the US standards – "…. *categorisation of payments and transfers of value, recognising that the US Physician Payments Sunshine Rule categories might not be applicable to the Australian environment*" raise questions of institutional governance in pharma's funding of research. These are also publicly raised on www.fnmyalgia.com/2014/01/12 with detail regarding Pfizer's pregabalin product Lyrica. In particular, section 5.3 of the defunct TWG discussion paper suggestion "The transparency model suggests that payments associated with clinical research would not be required to be reported" is implicitly carried into the latest voluntary Code of Conduct submission to the ACCC, by its omission.

What transparency guarantee can [redacted] offer for public disclosure of institutional payments by industry sponsors?

Yours sincerely,

Geoff Kirwood

From: [redacted]
Sent: Thursday, February 06, 2014 8:46 AM
To: Geoff Kirwood
Subject: RE: Conflicts of interest

Best wishes,

[redacted]

From: Geoff Kirwood [mailto:[redacted]
Sent: Thursday, 6 February 2014 7:27 AM
To: [redacted]
Subject: FW: Conflicts of interest

Dear [redacted]

The furore over the potential for a commercial interest with Swisse to override academic integrity is also close to your home. [redacted] with a Lilly employee, and also declares in [redacted] *have received consultancy fees from Pfizer and Lilly, and they and their institution have been involved in clinical trials of pregabalin and duloxetine*."

Yet declines to acknowledge any treatment other than an anti-depressant for a syndrome which exhibits characteristics of an immunological disorder. Having published [redacted] (?), his allegiance was unquestionable.

Yours sincerely,

Geoff Kirwood

PS, the success of gauifenesin was explained in regression – patients weren't following the maverick protocol but were using it as an adjunct to medications in order to relieve symptoms of sicca and snot!

---------- Forwarded message ----------
From: **Geoffrey Alan Kirwood** [redacted]
Date: 25 November 2013 08:13
Subject: Fibromyalgia medication effectiveness study
To: [redacted]

Dear [redacted],

I'm keen to know the scope of treatments being considered in proposed research. I note that the Eli-Lilly/Chappell study into duloxetine was considered ineligible for Cochrane review, and have a concern that pharmaceutical influence is limiting patient options.

I query a 20,000 strong diagnosed FM patient database for pain, sleep & fatigue scores and rank medications accoring to the odds of an outcome in the best quintile. Cymbalta was below the TCAs & SSRIs, and these palliatives were in turn below the interventions - DMARD & corticoid. But way ahead were fish oil/Omega3 and guaifenesin, although like [redacted] the latter result disturbs my scientific mind!

regards,

Geoff Kirwood