MacLeod, Heather

From: Ken Harvey [k.harvey@medreach.com.au]
Sent: Tuesday, 24 January 2006 8:56 AM
To: Adjudication
Cc: Davis, Bronwyn; David Graham; Joan Corbett; Tony Abbott MP; Julia Gillard MP
Subject: Application A90994-6 by Medicines Australia re revised Code of Conduct [15th Ed]

The Director
Adjudication Branch
Australian Competition & Consumer Commission PO Box 1199 DICKSON ACT 2602

Re: Application A90994-6 by Medicines Australia re revised Code of Conduct [15th Ed]

Dear Mr. Gregson,

I am following up my initial E-mail on this topic dated Wed, 14 Dec 2005. Because I have just come back from holidays your staff kindly granted me a few days extension to your Jan 20, 2006 deadline so that I could expand my original brief submission.

First, let me state that I agree with the main thrust of many of the submissions [1] you have received - the 15th Ed. of Medicines Australia Code of Conduct does represent an incremental improvement over the 14th Ed.

The key issue however is whether the small improvements to the Code contained in the 15th Ed. represent an adequate response to the concerns raised. A related and equally important issue is whether industry self-regulation, by itself, will ever be capable of adequately responding to public health concerns about the role of promotion in encouraging inappropriate drug use (tobacco, alcohol, pharmaceuticals).

My original submission noted concerns published in the Medical Journal of Australia [2-3] about the recent infiltration of pharmaceutical promotion onto GP's computer screens.

The first concern was that advertisements for prescription pharmaceuticals are now visible to patients in direct contradiction to the prohibition by the Therapeutic Goods Act of advertising such products to consumers. Over 90% of GPs use computerized prescribing software and most doctors position the screen so that it can be viewed by both themselves and their patients. The alternative is to have the screen interposed between doctor and patient to the detriment of communication. In addition, many doctors believe that sharing the computer screen with the patient positively facilitates communication as the patient can see and discuss the data being entered into their electronic medical record (clinical problems, blood pressure, weight, drugs prescribed, etc). Pharmaceutical advertising in prescribing software was opposed by both the authors of the MJA article and the accompanying editorial because it breaches the Therapeutic Goods Act, it is intrusive, it interferes with the doctor-patient relationship and, by constantly promoting newer, expensive drugs (as distinct from non-drug, or more cost-effective generic drug solutions) it biases doctor - patient decision-making.

Medicines Australia's response to these concerns in the 15th Ed. of their Code is merely to prohibit the inclusion of advertisements, "in any clinical tool or patient educational material which may be used by a prescriber for consultation or discussion with a patient". However, as the MJA article [3] pointed out [Box 1], drug advertisements occur in many other places where they are visible to patients apart from those functions now prohibited by the 15th Ed. of the Code. Does Medicines Australia really expect that GPs will turn their computer screens away from the patient for most of the consultation (while drug ads are flashing) and merely turn them back when accessing a specific clinical tool such as a cardiovascular risk calculator? I predict that this cosmetic prohibition (and Medical Director's elimination of advertisements that occur while the 'script was printing) will do little or nothing to reduce the volume of prescription drug advertisements visible to patients.

I note that the Australian Medical Association, in their submission to the ACCC were also, "opposed to advertising and promotion in prescribing software because of its potential to interfere with the doctor-patient relationship". To which Medicines Australia, in their Counsel's Jan 9,

2006 submission to the ACCC responded that, "electronic prescribing software, which is a tool for use exclusively by doctors, is a legitimate medium for advertising prescription medicines to health care professionals". This view conveniently ignores the reality that most GPs share their computer screens with patients! It also ignores the view that pharmaceutical promotion should not intrude into the doctor-patient decision-making space.

A second concern was illegible generic names. Clearly, the main goal of "banner" advertisements in computer software is not to provide education about the drug's generic name, indications, contra-indications and side-effects but rather is to promote originator drug brand name reinforcement. The marketing goal is to produce, "patents in perpetuity", to ensure that GPs continue to write the originator brand name on all prescriptions despite patent expiry and the subsequent introduction of more cost-effective (and thus rarely promoted) generic drugs. The 2005 Pharmaceutical Benefits Pricing Authority Annual Report shows how effective this saturation marketing is - currently 44% of 'scripts are written for heavily promoted brand names which cost consumers, on average, an extra $2.65 "brand premium", an additional cost that does not contribute to consumer's PBS safety-nets.
Furthermore, Australia has a very low use of cost-effective generic drugs compared to other countries [5].

Medicines Australia Counsel's Jan 9, 2006 submission to the ACCC, noted that their monitoring committee had also found illegible generic names in a later version of Medical Director software than that analyzed in the MJA article. Medicines Australia response was to merely to reiterate the need for companies to comply with the Code rather than sanctioning offenders and mandating a clear standard that would ensure legibility (insisting that generic names precede and have the same size, font, color and background as the brand name).

The third issue was concern that management of Code breaches by Medicines Australia has failed to deter unethical behavior by the pharmaceutical industry as evidenced by the fact that many pharmaceutical companies repeatedly breach the Code. Medicines Australia Counsel's Jan 9, 2006 submission to the ACCC, said that no evidence had been provided for this assertion despite the fact that the MJA article referred to [3] referenced Code of Conduct annual reports.

Medicines Australia counsel also noted that many companies have never been found in breach while those that have had repeated breaches were usually larger companies with a wider range of products. While the former is commendable, I fail to see why the latter is an excuse for repeated Code breaches. In addition, despite Medicines Australia Monitoring Committee agreeing that illegible generic names and missing information was also present in advertisements found in a more recent version of Medical Director to that analyzed in the MJA, no sanctions were applied to offending companies. I reiterate that failure to apply sanctions for multiple proven breaches of the Code can only encourage repeat offenses.

I reiterate that the end result is a Code which encourages inappropriate demand and prescribing of heavily promoted drugs that is often not in accord with cost-effective best-practice. This is one reason why the cost of the Pharmaceutical Benefits Scheme has increased exponentially over the last decade (at about 11% per annum, twice the increase of medical or hospital services). In response, the government has recently introduced large increases in co-payments and safety-nets (transferring more of the costs of the PBS from government to consumers) which have inevitably resulted in consumer detriment; poorer consumers are now forgoing necessary medicines to the detriment of their health.

The final issue is whether industry self-regulation will ever be capable of adequately responding to public health concerns about the inappropriate use of drugs (tobacco, alcohol, pharmaceuticals), a proportion of which is clearly driven by promotion. Clearly there is a gradation between risk and benefits with tobacco, alcohol and pharmaceuticals. But the similarity is that highly profitable industries which spends a large proportion of their earnings on sophisticated promotion all encourage overconsumption and unhealthy habits. And in each case, self-interest inevitably blinds self-regulation. A recent WHO international study on pharmaceutical promotion concluded that government regulation (particularly the power given to the US FDA) was more effective than industry self-regulation [6].

In conclusion, while I support industry self-regulation (acting in the first instance), I also believe in co-regulation (with government instrumentalities intervening when self-regulation fails). While I commend a number of incremental improvements in the 15th Edition of Medicines Australia Code I argue that their self-

regulatory process has clearly failed in connection with the matters detailed above. I am also saddened that the Therapeutic Goods Administration has failed to take up their co-regulatory responsibilities in this regard (possibly because they are now 100% funded by the pharmaceutical industry).

Accordingly, I ask the ACCC to take over this co-regulatory role (in accord with their responsibilities for consumer protection) and only authorize Medicines Australia Code subject to amendments that will:

1. Eliminate all pharmaceutical promotion from prescribing software;

2. Mandate that generic names must precede and have the same size, font, color and background as the brand name in all pharmaceutical promotional (and educational) material;

3. Provide fines, publicity and corrective advertising for ALL proven breaches of the Code, including illegible generic names and missing information required by the Code;

4. Double the fine each time a company has an additional Code breach within the Code authorization period (all companies have fines set to base levels when a new Code is authorized);

5. Restrict ACCC authorization of Medicines Australia Code to 3 years only.

Yours sincerely,

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REFERENCES

1. Australian Competition and Consumer Commission. Medicines Australia Inc - Revocation & Substitution of A90779-A90780 - A90994-A90996 - Submissions received. http://www.accc.gov.au/content/index.phtml/itemId/716327

2. Ruff TA, Haikal-Mukhtar H. Doctors, drugs, information and ethics: a never-ending story. MJA 2005; 183: 73-7. http://www.mja.com.au/public/issues/183_02_180705/ruf10450_fm.html

3. Harvey KJ, Vitry AI, Roughead E, et al. Pharmaceutical advertising in prescribing software: an analysis. MJA 2005; 183: 75-79. http://www.mja.com.au/public/issues/183_02_180705/har10263_fm.html

4. Pharmaceutical Benefits Pricing Authority Annual Report for the year ended 30 June 2005. http://www.health.gov.au/internet/wcms/publishing.nsf/Content/health-pbs-general-pricing-pbpartp.htm

5. Lofgren H. Generic Drugs: International Trends and Policy Developments in Australia. Working Paper No. 10, 2002, Centre for Strategic Economic Studies, Victoria University of Technology http://www.cfses.com/documents/pharma/10-Role_of_generics.PDF

6. Norris P, Herxheimer A, Lexchin J & Mansfield P. Drug promotion: What we know and what we have yet to learn. WHO (Department of Essential Drugs), Health Action International, 2006 http://www.who.int/medicines/areas/rational_use/drugPromodhai.pdf

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