

**17th Edition of Medicines Australia Code of Conduct: individual submission to the ACCC
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Section 8. Product Familiarisation Programs (PFPs)

According to MA's Code of Conduct, "PFPs have the aim of allowing the medical profession to evaluate and become familiar with a product". There are conducted in the first 12 months following first supply of a new approved medicine with no formal protocol and no individual data collected.

However, there is good evidence that information provided by the drug industry is often unbalanced and biased. For example, one extensive PFPs is currently run by Boeinger Ingelheim, the manufacturer of dabigatran (Pradaxa[®]), a new drug that is promoted as easier to use and safer than the widely used and cheap anticoagulant warfarin. Specialists and GPs in Australia have been proposed to enroll up to 10 patients each in this PFP. This PFP is misleading and dangerous as, according to the National Prescribing Service (see NPS submission at <http://www.pbs.gov.au/reviews/atrial-fibrillation-files/60-national-prescribing-service.pdf>) "safety and efficacy warnings were seriously understated by the manufacturer", "the majority of hospitals were unaware and ill equipped to manage patients presenting who were receiving this treatment", "most prescribing and dispensing systems carried inaccurate information".

PFPs can have disastrous consequences in terms of public health and increased numbers of severe and fatal adverse reactions. They can lead to a very rapid intake of new drugs whose safety are still very uncertain and aim to induce swapping from older drugs without medical need but with potential safety issues. In the latest report on serious adverse drug reactions reported to the Food and Drug Administration in 2011, Pradaxa[®] surpassed all other monitored drugs including overall number of reports (3,781), deaths (542), hemorrhage (2,367), acute renal failure (291), and stroke (644) (<http://www.ismp.org/QuarterWatch/pdfs/2011Q4.pdf>). Programs such as Boehringer Ingelheim's Pradaxa PFP encourages the rapid uptake of a specific drug, dabigatran, with an uncertain and worrying safety profile at the expense of older well-known drugs.

In Australia, health professionals can have access to a large range of industry-independent information resources and educational activities such as the NPS RADAR newsletter (http://www.nps.org.au/health_professionals/publications/nps_radar) for medicines that get listed on the PBS. There are also continuing medical education programmes provided by independent professional organisations and other independent information providers such as the Australian Medicines Handbook, Australian Prescriber or the Therapeutic Guidelines Ltd. In the absence of any demonstrated advantage of PFPs for patients and with evidence of harm, PFPs should be banned. If a drug company considers that an educational program could benefit health

professionals or patients, it should be carried on independently to prevent promotional biased guidance from occurring and ultimately harming patients. To my knowledge, PFPs are not allowed in other countries and there should be no exception in Australia.

Recommendation: Product familiarisation programs should be prohibited by Medicines Australia Code of Conduct.

Section 9. Relationship with healthcare professionals

Edition 17 now requires member companies to submit aggregate amounts of all payments made to healthcare professionals for advisory boards and consulting services, attendance and speaking at educational meetings.

However, the full disclosure of payments made to individual healthcare professionals has been required by many consumer and health professional groups and a number of Australian pharmaceutical companies and has become a regulatory requirement in a number of countries such as the United States with the Physicians Payment Sunshine Act adopted in 2010.

Recommendation: The ACCC should make full disclosure of individual payments to healthcare professionals an imposed "condition" for authorising the Code.

Section 13. Relationship with the general public

Direct-to-consumer advertising of prescription products is not allowed by the Commonwealth Therapeutic Goods Act. However, the current provisions of the Medicines Australia (MA) Code of Conduct do actually allow drug companies to circumvent the Act's advertising prohibition in different ways.

Educational information to the general public and disease and treatment awareness campaigns are allowed by the MA Code of Conduct as long as no brand name is mentioned (section 13.6)

However, these educational campaigns usually feature a condition treated by the manufacturer's product, and often encourage viewers or readers to ask their doctor about a newly available treatment. A recent example is the campaign run by Bayer. Bayer sells a range of testosterone products and ran an advertisement in the *Weekend Australian Magazine* in August 2009 claiming that "low testosterone can take the life out of you" and that "symptoms may include lack of vitality, reduced sex drive, mood swings, poor concentration and reduced strength". The advertisement encouraged readers to contact their doctors and ask about a testosterone test if they experienced these symptoms. It was also linked to a website that included a quiz that called on readers to test their testosterone levels if they exhibited only vague non-specific symptoms. After a complaint sent by a member of the organisation Healthy Skepticism, the MA Code of Conduct Committee found that the advertisement was in breach of section 9.5.1 ("the educational material must be current, accurate and balanced") as "it implied that low testosterone was the most prevalent cause of symptoms described" and "that there was a high incidence of low testosterone" whereas it was not an accurate reflection of the incidence across all ages. It was also found in breach of section 9.5.6 ("The tone of the message must not be presented in a way

that unnecessary causes alarm or misunderstanding in the community”) as the “tone and imagery were alarmist”¹. Bayer was fined \$10,000, less than half the cost of placing one advertisement in the *Weekend Australian Magazine*. However, the advertisement was not deemed to be promotional as it did not encourage patients to seek a prescription for a *specific* testosterone product.¹⁻³

Recommendation: Educational information to the general public by drug companies should NOT be allowed by the MA Code of Conduct because of inherent conflicts of interest. In particular unbranded product advertising, and the use of pseudo-branding or similar techniques, should be explicitly prohibited. This would bring the MA code of conduct into agreement with the intent of the Commonwealth legislation.

Section 18. Patient Support Programs

Health information is a fundamental and necessary part of healthcare. However, the development of industry-supported patient support programs has blurred the boundaries between drug promotion and health information. If patients are to be able to make informed choices about their health, there needs to be a clear distinction between information and promotion that is disguised as “information”. Most patient support programs aim to improve treatment compliance.

Treatment compliance, i.e. the notion that a patient follows a treatment prescribed by a doctor or recommended by a pharmacist, has its good and bad sides. A patient may have good reasons for stopping treatment, because of adverse effects, for example, or inefficacy. The decision to continue or to stop long-term treatment and should be discussed with a healthcare professional⁴.

The role of pharmaceutical companies in this area is inevitably compromised because of their inherent conflicts of interest. They want to promote loyalty to brand name drugs. How could anyone imagine that a pharmaceutical company would willingly explain to a patient that he or she had better stop taking one of its drugs, or switch to a competitor’s product?

Recommendations on compliance with treatment must be independent of companies that have a financial incentive to keep patients compliant. Independent medicine information should be provided to consumers by health professionals, doctors, pharmacists and organisations such as the National Prescribing service.

Recommendation: Patient Support Programs should be prohibited by Medicines Australia Code of Conduct.

Sanctions

Medicines Australia maximum fine for a severe breach of their Code is \$200,000. The average \$50,000 fines currently given are not an effective deterrent for drug companies that may gain millions of dollars from misleading advertising.

Recommendation. The ACCC should increase the maximum fine imposed to \$1.0 million as a "condition" for authorising the Code.

1 Medicines Australia Code of Conduct Committee. Code of Conduct Committee Meeting Monday 17 May 2010. Reasons for the decision - Testosterone 1045. Canberra 2010.

2 Medicines Australia Code of Conduct Appeals Committee. Minutes of the Appeals Committee Meeting held on Thursday 15 July 2010 at AMA House, 69 Christie Street St Leonards Canberra 2010.

3 Vitry AI, Mintzes B. Disease mongering and low testosterone in men: the tale of two regulatory failures. *Med J Aust.* 2012; **196**: 619-21.

4 Anonymous. Big Pharma's medication compliance programmes. *Prescrire International.* 2007; **16**: 32.