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Have we reached the limit of effectiveness of self-regulation and codes of ethics?

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Over the past decade, both the health-care professions and the pharmaceutical industry have revised the codes governing their interaction. These adjustments were responses to changing public standards and to data demonstrating the adverse impact of such interactions on prescribing behaviour and on health spending.

Now the relationships between health professions and industry are more tightly regulated than ever before. They're characterised by a commitment to transparency and to processes that avoid conflicts of interest – more than at any time in the past.

Perhaps the two most significant sets of guidelines governing interaction between doctors and the pharmaceutical industry - the Royal Australasian College of Physician's "[Guidelines for relationships between physicians and industry](#)" and the "[Code of Conduct](#)" of [Medicines Australia](#) (the peak industry group for the pharmaceutical industry) – are currently under review.

It's clear that each body will likely introduce incremental changes to the way relationships are managed in the health sector. Sadly, incremental variations achieve little and what we need is fundamental change to the ways in which medicine and medical professionals interact with industry.

And despite the progress to date, promotional activities continue, often under the guise of education. Marketing data remain generally aggregated, obscuring the identities of the beneficiaries of industry support.

Drug samples, including starter packs, continue to be available on the shelves of general practices throughout Australia, while medicinal drugs continue to be inappropriately promoted to physicians and (indirectly) to consumers and advertising of herbal preparations is barely regulated at all. Product familiarisation programs, disease education programs and patient support programs are increasingly a feature of our hospitals, media and community services.

Even where companies breach accepted standards of behaviour, the [Therapeutic Goods Association \(TGA\)](#) appears unwilling to invoke the criminal penalties open to it under legislation. And the fines that may be imposed under the Medicines Australia [Code of Conduct](#) are, at least in Australia, of little financial consequence and completely out of step with fines imposed in other parts of the world.

While codes of ethics or conduct and self-regulation perform important functions – providing some clarity around what may or may not be acceptable practice, promoting considered self-reflection and encouraging public and professional debate - there are times when they are insufficient.

Such regulations are by their nature open to different interpretations. There's a risk that self-regulation is self-serving and resistant to transparent processes for monitoring and applying sanctions, and they depend crucially on recognition by the individuals to whom they apply of key values relating to public trust and the importance of moral oversight.

These features are both strengths and weaknesses: where moral agency is to be fostered, voluntary codes are preferred. And where enforcement of certain behaviours is required, stronger direction may be needed.

As is well recognised, there's a place for both voluntary ethical codes and enforceable regulations. In the case of relationships between doctors and industry, on occasions harmless and malign influences cannot be easily distinguished and undue influences may not be completely avoidable through disclosure and transparency alone.

On these occasions, stronger “rules of engagement” set by institutions or professional associations that prescribe interactions that are unnecessary or actually harmful to their underlying values and interests are needed.

Under such rules, relationships necessary for research might be acceptable while industry-funded education may not. For the latter, alternative sources of support and means of delivery would have to be found for [continuing medical education](#) and for [scientific meetings](#), perhaps entailing better utilisation of social media and the internet.

If this means that doctors and their employers have to pay more for education, at least in the short term, then that's a price we may need to accept.

Changes in this area have never been easy. Medicine is so permeated by a culture of expectation that affordable top-class conference venues, lavish catering, free access to opinion-leaders and travel sponsorship is the rule rather than the exception.

Studies conducted in the United States and Scotland suggest that doctors will resist paying higher fees for [continuing medical education](#) in order to reduce commercial support.

But change will come, either with the support of the health professions and industry or without it. Pressure is building for industry to adopt voluntarily sufficiently stringent standards of disclosure of sponsorship of physicians, pharmacists and non-government bodies (with some companies, notably GlaxoSmithKline, already moving in this direction).

Failing that, we need to introduce mandatory rules requiring public disclosure of financial contacts (along the lines of the US Physicians Sunshine Act 2010).

Evidence of the extent of interaction between health professionals and industry revealed under Sunshine legislation (such as the [massive gratuities](#) paid to leading US orthopaedic surgeons and “opinion leaders” (in excess of US\$4,000,000 each) by bioprosthetic companies) will only increase public and political scrutiny of industry and the medical profession, and on the adequacy of existing regulation.