Prof Richard Day: Reining in reps

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SHOULD we lose sleep over the influence of pharmaceutical company representatives on prescribing?

It depends if you are interested in value for money — a lot of money.

New drugs listed on the Pharmaceutical Benefits Scheme (PBS) cost a lot more than old drugs and we all pay for them through taxes that support the PBS and public hospitals, and personally through out-of-pocket spending for the copayments.

A substantial slice of the cost of the new medicine is for the promotion and education that goes with a new PBS listing.

Each visit to a prescriber by a drug rep costs hundreds of dollars that needs to be recouped in sales. The pharma companies must consider this expenditure to be money well spent; otherwise they wouldn't do it. In fact, it is a highly effective strategy in increasing prescriptions.

But does that increase in prescribing lead to a better result for the patient and society? Do individuals and society end up paying additional costs for avoidable adverse reactions? Does "promotion and education" by pharma companies result in better-informed prescribers and healthier patients with respect to the benefits, risks and cost-effectiveness?

A recent large, well conducted study, has found, yet again, that despite different attempts at regulating this activity, there is still a substantial imbalance in communication by drug reps of the benefits of new medicines compared to "minimally adequate safety information" (mention of at least one indication, serious adverse event, common adverse event and contraindication, and no unqualified safety claims or unapproved indications).

The study examined the information provided by drug reps in France and the US, where drug promotion is directly regulated, and Canada, where promotion is self-regulated. It found that despite some medicines having a "black box" warning or even having been withdrawn in other countries (eg, rosiglitazone and cardiac failure) this did not guarantee that any harms would be mentioned by the drug reps in Canada and the US (57% of these medicines). France has the strictest product information standards.

Unlike print advertisements, it is difficult to regulate what is said when a drug rep talks with a prescriber.

Codes such as Medicines Australia Code of Conduct indicate the standards that are to be met but what assurances do we have that self-regulation is practised? What should we do as prescribers?

Only a few us, maybe around 20%, don't see representatives at all. Many of our teaching hospitals try to limit exposure of staff to representatives.

If a prescriber is going to invest time with drug reps on behalf of their patients and also with an eye to the value for society, then a proactive approach is recommended.

This means respectful probing to have the key questions answered; namely, the risks including contraindications, the benefit relative to what you are prescribing now, and the cost to the patient and the PBS.

And it's good to ask for the evidence behind statements and to test claims. The representative should get back to you if they cannot answer your question.

The NPS has a great service called RADAR that all prescribers can receive electronically. It provides key information about new medicines about to be listed on the PBS, in a digestible form.

One radical dream I have in moments of madness is that a pharma company will engage the NPS to promote to, and educate doctors on its new drug — in other words, to outsource the

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whole process. The positioning of the new drug, with alternative and older therapies, would be outlined, and its benefits and risks would be fairly put, along the lines we see already with the RADAR communications.

And if I was running the PBS, I'd pay that company more for their drug too. But I'm not holding my breath.

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Comment

Submitted by Dr Ken Harvey on Mon, 29/4/2013 - 14:37

Ironically, to my knowledge, Medicines Australia monitoring committee have never evaluated the quality of information provided by drug reps despite data (Cegedim) showing that detailing accounts for 73% of the GP promotional spend.

See: Roughead EE, Gilbert AL, Harvey KJ. Self-regulatory codes of conduct: are they effective in controlling pharmaceutical representatives' presentations to general medical practitioners? Int J Health Serv 1998; 28: 269-279. http://www.ncbi.nlm.nih.gov/pubmed/9595344

Abstract

Self-regulatory codes of conduct are used to control the promotional practices of the pharmaceutical industry, but the effectiveness of these codes in controlling pharmaceutical representatives' presentations has not been examined. This is a matter of concern because pharmaceutical representatives have more influence than any other promotional media on prescribing practices.

The authors developed a method for monitoring the oral presentations of pharmaceutical representatives when promoting products to medical practitioners. Sixteen audio-recordings, detailing 64 medicines, were obtained; 38 of the 64 products were prescription-only medicines.

Information on indications and on dosage and administration was commonly provided, but information on other areas of drug knowledge, particularly product risk, was minimal. Thirteen presentations contained at least one inaccuracy when compared with Australian Approved Product Information. Presentations did not always comply with current guidelines in the Code of Conduct.

The Code provides only limited standards for pharmaceutical representatives' presentations, and no active monitoring system is in place to ensure adherence to the code.

There is an urgent need for policy development on the role of pharmaceutical representatives, their standards of practice, and regulation of their activities to ensure they contribute to the appropriate use of medicines.