# How to make the most of a visit from a pharmaceutical company representative

Richard Day, Professor of Clinical Pharmacology and Toxicology, St Vincent's Hospital and University of New South Wales, Sydney

### **SYNOPSIS**

Representatives of pharmaceutical companies visit health professionals principally to promote the prescription of their products. While the visit aims to change the prescriber's behaviour, it is also an opportunity for the health professional to obtain important information. Modern representatives are well trained and should be able to answer questions about a drug's efficacy, safety, utility and cost. However practitioners should be aware that the purpose of the visit is to alter their prescribing and there is the potential that the information they receive will be biased in favour of the product. Most representatives follow a code of conduct drawn up by the Australian Pharmaceutical Manufacturers Association. Complaints can be made to this association if the representative promotes a product inappropriately.

Index words: advertising, drug industry, prescribing.

(Aust Prescr 2000;23:97–9)

# Introduction

Whether we like it or not, visits from the representatives of pharmaceutical companies influence our prescribing practices. For many prescribers, drug company representatives are the main source of information about new drugs and an important factor in changing prescribing behaviour. Although most doctors when asked do not believe they are unduly influenced by pharmaceutical representatives, research shows that they are. I

Doctors can choose not to see drug company representatives. This has the advantages of saving time and money.<sup>2</sup> If we do decide to accept a visit from a pharmaceutical representative (and about 85% of general practitioners do) is it possible to gain more value from the visit?

# Who are the representatives?

Pharmaceutical representatives, or detailers, have been selected from applicants who may have degrees in nursing, pharmacy or science. Increasingly, they undertake the Australian Pharmaceutical Manufacturers Association (APMA) sponsored course for pharmaceutical representatives. This course is run by an Australian university and has been rated highly in independent annual reviews. It covers a range of important topics including a detailed study of the APMA's voluntary code of conduct on promotional practices.<sup>3</sup>

Each pharmaceutical representative receives intensive instruction about the product they will be promoting and how to market it. If there are competing products, obviously the characteristics favouring their own company's product will be focused upon and contrasts drawn with the competitors. Information about the diseases for which the drug is indicated will almost always be taught to the pharmaceutical representative. The depth and quality of the education and preparation of the pharmaceutical representative will vary with the pharmaceutical company, the importance of the product and the stage in the 'life-cycle' of the drug. Most effort will be expended when a new drug is being released. The representative may also be involved in briefing and familiarisation programs aimed at relevant specialists who are influential because of the letters they write and the opinions they give to general practitioners.

Detailing is just one part of a sophisticated marketing effort but it is very influential and a substantial investment for pharmaceutical companies. Each visit probably costs the company around \$200.

#### What to ask

Doctors need to know about the efficacy, safety and utility of new products. The fact that a drug has been registered for a particular indication means that the evidence for the efficacy and safety of the drug for that indication has been accepted by our regulatory authority, the Therapeutic Goods Administration (TGA). However, what about efficacy, safety and utility in our own patients? This is the question we should return to often.

# **Efficacy**

The question to ask is how does the new drug compare with the drug you usually use for that condition? If it does not seem much better, why would you prescribe the new drug? The pharmaceutical representative needs to know that you would like to be convinced by good evidence that the new drug is worth consideration. Remember that the product information (PI) for the drug is the equivalent of the Bible when it comes to key information about the drug. The PI has been reviewed, amended and finally approved by the TGA after much negotiation with the pharmaceutical company. Increasingly, the PI contains useful details about the 'pivotal' clinical trials of the new drug. These are the trials that are used to support the registration of the drug. The pivotal trials may compare the new drug with standard, accepted therapy.

Although a drug might be efficacious and registered for a particular indication it may be inappropriate to use it in all cases of that indication. For example, a new drug might have an indication for pneumonia approved by the TGA, but if it is a broad spectrum and expensive antibiotic it would be an inappropriate first choice for the average patient with pneumonia. Another useful question is to ask what a reputable and well-known guidelines publication, such as 'Antibiotic Guidelines', says about the place of this drug in the management of the condition. Often such guidelines do not recommend new drugs, certainly not as the first choice.

#### Safety

Pharmaceutical representatives are less likely to dwell on adverse effects or interactions. This is not surprising, but it means that you may need to ask. The PI is helpful as it lists contraindications and the reported frequencies of adverse effects. It is often helpful to run through these parts of the PI with the pharmaceutical representative. Apart from the known adverse drug reactions, you would also want to hear about critical drug interactions, for example with warfarin.

Increasingly, it is important to know about the metabolism of a new drug and the potential drug interactions which can result. For example, drugs that are metabolised by or block the hepatic cytochrome P450 enzyme system are subject to a large number of potential interactions. As these details are often used in comparing one drug with another, having access (perhaps via the pharmaceutical representative) to a good, recent review or article in a reputable journal is useful.

### Utility

Usually the combination of a drug's efficacy and safety features determines its value in our patients. Its efficacy may be similar to older drug therapies, but an advantage that might induce us to prescribe the drug for some of our patients could be a better safety profile. Claims of greater utility, that is the efficacy to safety ratio combined with factors such as convenience due to a better dosing schedule, or a cost advantage for the individual or the taxpayer, may be the argument for prescribing a new drug. You will also want to know other practical details, such as dosing with food, and whether you need to adjust the dose in the elderly or those with impairment of kidney or hepatic function.

Some of the claims made by the pharmaceutical representative will be supported with evidence beyond that found in the PI. This is where you might ask for a copy of the evidence to peruse later, for example original papers. Pharmaceutical representatives are generally very pleased to provide you with scientific papers or to seek additional information from their medical information departments to support their position. They should also be able to provide you with a copy of the consumer medicine information.

# **Precautions**

Most of us with experience of interacting with pharmaceutical representatives recognise some of the sales methods they commonly use. These include appealing to your pride, for example 'Of course you know the latest treatment for this condition', or telling you that your colleagues are switching to the detailed product. The representative may also tell you that well-known leaders in the relevant specialties are switching their prescribing to the drug. Offering samples is a familiar ploy to induce some feeling of commitment from you to try the drug out on a few of your patients. This feeling is perhaps assisted with the giving of some practice-relevant gifts or brand reminders, such as pens and notepads.

## **Complaints**

There may be situations where you feel that the pharmaceutical representative has displayed inappropriate bias or given you misleading information. If this is the case then complain to the pharmaceutical company (usually the medical department is best) or, if this proves unsatisfactory, the APMA.\* Every month the APMA has a meeting to discuss such complaints.<sup>3</sup> More complaints about the practices of pharmaceutical representatives will be extremely effective in improving the quality of pharmaceutical representatives' visits, and their value to prescribers.

#### Conclusion

By now time is almost up. About 5–15 minutes is all you might allocate to a pharmaceutical representative. Essentially the pharmaceutical representative's visit can be used to boost your knowledge concerning efficacy, safety and utility of drugs. Remember that pharmaceutical representatives are well-trained individuals, generally with good communication skills and knowledge, who are keen to assist you in understanding the advantages of their product. Respectful communication combined with an enquiring and critical attitude will allow you to obtain the maximum benefit possible from the time you invest in the meeting. Indeed, you might reasonably be aggrieved if the visit is not helpful, at least in part, because you have forgone the income from a consultation while talking to the representative. Increasingly, undergraduate medical courses provide training including role-play to help future prescribers understand and perhaps profit more from seeing representatives. Given the significance of detailing to prescriber education, perhaps more attention needs to be paid to equipping current prescribers to deal more effectively with detailers.

#### REFERENCES

- Avorn J, Chen M, Hartley R. Scientific versus commercial sources of influence on the prescribing behavior of physicians. Am J Med 1982;73:4-8.
- 2. Griffith D. Reasons for not seeing drug representatives [editorial]. Br Med J 1999:319:69-70.
- Roughead EE. The Australian Pharmaceutical Manufacturers Association Code of Conduct: guiding the promotion of prescription medicines. Aust Prescr 1999;22:78-80.
- Writing Group for Therapeutic Guidelines: Antibiotic. Therapeutic Guidelines: Antibiotic. 10th ed. Melbourne: Therapeutic Guidelines Limited; 1998. http://www.tg.com.au
- \* Australian Pharmaceutical Manufacturers Association Telephone 02 9922 2699; fax 02 9959 4860

#### FURTHER READING

Australian Pharmaceutical Manufacturers Association. Code of Conduct of the Australian Pharmaceutical Manufacturers Association. 13th ed. Sydney: Australian Pharmaceutical Manufacturers Association Inc; 2000.

Roughead EE, Harvey KJ, Gilbert AL. Commercial detailing techniques used by pharmaceutical representatives to influence prescribing. Aust N Z J Med 1998;28:306-10.

Sandhu GS, Day RO. Factors affecting prescribing in general practice – a role play. Med J Aust 1992;157:621-2.

Day R. Pharmaceutical company promotion: striking a balance [editorial]. Aust N Z J Med 1998;28:291-3.

E-mail: R.Day@unsw.edu.au

# **Self-test questions**

The following statements are either true or false (answers on page 111)

- 3. Pharmaceutical promotion has no effect on prescribing patterns.
- 4. The Code of Conduct of the Australian Pharmaceutical Manufacturers Association covers the interaction between health professionals and drug company representatives.

# Your questions to the PBAC

I note the list of generic brands in the 'New drugs' section of each edition. I wonder how many will have the same bioavailability as their competitors?

The matter of bioavailability is of concern to my patients who frequently speak of coercion to accept a strange brand currently stocked in the pharmacy. The reported variability of effect experienced by patients, for example in swapping brands of frusemide, cannot be lightly dismissed as anecdotal.

I am very doubtful that equal weights of drugs translate to bioequivalence, but would be pleased to be reassured that this is so. If generic drugs are not bioequivalent, then the parties concerned should be aware of the differences.

Perhaps *Australian Prescriber* could provide a service to its readers by documenting the bioavailability studies done on each generic registered for inclusion on the Pharmaceutical Benefits Scheme? The name of the testing laboratory, its ownership, the techniques used, the quality control standards employed and the number of samples taken, should all be on the public record and available to all.

John Mackellar General Practitioner Mooroopna, Vic.

Dr Leonie Hunt, Drug Safety and Evaluation Branch, Therapeutic Goods Administration, comments:

The Therapeutic Goods Administration (TGA) is the body responsible for the registration of medicines in Australia, including generic equivalents of prescription medicinal products. Applications for generic products, which are claimed to be essentially similar to an innovator product, must include bioavailability data which demonstrate that the proposed product is bioequivalent to a leading brand of the medicine available in Australia. Guidance in relation to how a bioequivalence study should be conducted is available to sponsors of medicinal products in the document issued by the Commission of the European Communities entitled 'Investigation of Bioavailability and Bioequivalence'. Further information is available from the TGA web site (www.tga.health.gov.au/) and the Committee for Proprietary Medicinal Products web site (www.eudra.org/humandocs/ humans/qwp.htm).

In general, a comparison of the time course of the blood concentrations of the drug resulting from administration of the two brands to a group of volunteers is required. Comparison of the rate and extent of absorption of the drug from the two products is conducted by a statistical analysis using internationally recognised methods. A decision whether to register the generic product is then made taking these results into account. Modified-release products, such as delayed-release tablets and slow-release tablets, may require studies to be conducted under a variety of conditions to confirm equivalence. Where there is any doubt as to the bioequivalence of the two products, the TGA is able to seek advice from the independent expert committee, the Australian Drug Evaluation Committee.

The actual data sets, on which decisions to register individual products are made, may contain commercially confidential information. They are not usually available to the public.

Associate Professor R. Moulds of the Executive Editorial Board, comments:

Dr Mackellar's concern is a common one. The regulatory processes outlined by Dr Hunt are good at ensuring the plasma concentrations of a generic drug are similar to those obtained with the 'innovator' brand of the drug, usually the market leader. The limits allow for differences of no more than 20% in the overall plasma concentration versus time curves of the two drugs.

It is a more difficult question whether or not such allowable differences might be noticed by a patient. The intraindividual variation in plasma levels of a drug when it is taken on different occasions is usually greater than 20%. So a patient will probably only genuinely notice a difference between various brands of a drug if they also notice a difference when they take the same brand on different occasions.

A patient is also only likely to notice a difference between brands if the drug has a steep concentration-effect curve, so that a 20% change in concentration results in a significant change of effect. Few drugs have such a steep curve.

There are very few clear examples where differences between brands of a drug are clinically important. One very important exception, however, is that of warfarin, and patients should not shift from one brand of warfarin to another.