# in that case

A pharmaceutical company that makes generic versions of commonly used drugs has produced a generic of a proprietary drug widely prescribed in a particular service. Pharmac (The Pharmaceutical Management Agency in New Zealand set up to manage government expenditure on drugs) currently pays $100 (per tablet) to buy the proprietary version of this drug. The newly produced generic version costs $33. However, Pharmac is unlikely to buy the generic as its equivalence is not clearly established.

During a routine visit to a hospital unit, a drug rep from the company offers a special deal. If the unit buys the generic version of the drug then the company will give the difference in price directly to the unit. Given the high use of the proprietary drug, the financial benefits to the unit would be considerable.

The staff are very excited about this possibility, given the inadequate level of funding in their speciality, but are wary about getting involved. The extra income could make a genuine difference in the provision of the service in question in the region, and improve staff conditions.

## response

**John Adams**
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As usual such dilemmas in modern practice generate a number of competing ethical issues. There are facts:

(a) the medication is less expensive
(b) its effectiveness is unclear
(c) if the unit takes the deal some patients will benefit.

In our modern health system where resources are scarce, professionals must take some responsibility for the fair distribution of resources to benefit most people. If there is a cheaper and equally effective way of doing something – we must use it.

However, that is predicated on the alternatives being at least equivalent, or at a minimum that the cheaper treatment is certainly not harmful. Primum non nocere. The NZMA Code of Ethics, for instance, has as its first principle that the health and wellbeing of the patient must be the first priority.

As a society, through the government, we have delegated Pharmac to do the job of assessing and purchasing medications on our behalf. Though we might not always like Pharmac's decisions, and sometimes raise our voices in dispute, we also have to have some trust that the advice to Pharmac and the subsequent decisions are robust. If Pharmac has doubts about a drug's equivalence and will not buy it, we must assume that this is because they believe that patients might be harmed or at least compromised. After all, most of our concerns about Pharmac's functioning have been that they may be too ready to buy cheaper drugs that don't work as well to save money.

Therefore, while some patients might benefit from this deal

through increased services, some patients could be harmed.

The company would not be offering this deal unless it stood in some way to make money. That is part of their perfectly logical and acceptable reason for existence. Perhaps they hope that if the unit takes this deal, and patients start using their drug, it will put pressure on Pharmac to change its mind. We would hope that Pharmac would be stronger than this.

It is not wrong for a company or anyone else to make money from treatment. Doctors and nurses do it all the time, directly from the patient or for a salary. What must not happen is for any patient to be harmed for the sake of a company making money. This is certainly the possibility in this case.

In addition, no patient can be exploited, even if it is in the service of benefiting another. Incentives to provide a particular treatment, however laudable the cause may seem, are capable of creating distortions in clinical judgement. Using the cheaper drug would also give direct benefits from improved conditions to staff. These pressures are around us all the time, often in ways that we do not recognise. This is one potential incentive to use a treatment of questionable effectiveness, that is clear and should be avoided.

If the unit were to go ahead with the deal and provide some patients the cheaper medication to assist some patients, a further issue of consent arises. Patients receiving the dodgy drug would need to be given the choice of doing so in order to assist the unit in providing more services, or being prescribed the reputable drug. In situations where such a dilemma arises, it must be explained to patients.

As a final comment, there is also a professional duty here for the doctors involved. If it is that in order to provide necessary services a unit is forced into an ethical dilemma and the possible use of a sub-standard drug, people must speak out, and the issues be open to public scrutiny.

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## response

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The case raises a number of issues. The issues are not simply to do with the difference in price of the drug. They extend beyond the seeming obviousness of being able to improve the provision of service and condition of staff, to include faith in the system of testing drugs, faith in the rhetoric of drug companies, and the politics of cost-centre managerialism.

Much of the case turns on the weight given to the 'generic' drug not having its equivalence with the proprietary drug established, and in the deciders' faith in the system that would establish (or otherwise) that equivalence.

Here we are dealing with a range of beliefs about the process of establishing equivalence, whether it is understood as simply a bureaucratic exercise (as will likely be the line of argument touted by the drug rep), or whether it is understood as one of the fundamental institutions of responsible health policy.

If we simply choose to take up the offer on the basis of the espoused equivalence of the 'generic' drug, we are, in effect, arguing that drug testing is unnecessary. And that we believe the claims of the drug companies.

If, on the other hand, we have faith in the medical system that demands scientific testing of products to ascertain equivalence (and safety), we will be concerned that this equivalence is in fact not established. By putting faith in the anecdotal or corporate rhetoric of equivalence, we might say that we are calling into question the scientific method not only as it is applied to the testing of drugs, but that is one of the foundations of the medical profession.

Should we think that the testing regime is inadequate in some way, we could well turn our attention towards lobbying to have this issue addressed. Unfortunately, such efforts are

unlikely in the context of managerialist cost centres where the focus is upon each department doing best for themselves, irrespective of broader cost, efficiency, or political effects.

In some sense this entire scenario can be seen to have emerged out of the logic of managerialism that uses cost centres as a way of disciplining individual departments and of companies that use the weakness of this system as an integral element of their marketing strategy. While mobilising competition between departments may well facilitate a heightened attention to the particulars of costings, it also allows drug companies, and other suppliers, to take advantage of the lack of centralisation. As drug companies seek to play one department, or product, off against another, the broader service or societal effects of the system are reduced to localised questions of staff self interest and the benefits of 'obvious' cost savings.

There are many additional issues that deciders might want to consider: the proprietary product may be just about to come out of its patent period, at time which time the cost saving may actually be minimal if anything at all; the inducements to change supplier may form part of a marketing strategy to undermine a local supplier who may well provide any number of other products and services otherwise unaccounted for in the current decision, and whose imminent collapse would soon see the price quickly raised; this decision may form a dangerous precedent that forms part of building a culture of undermining control and safety mechanisms that extends far beyond that of testing the safety of drugs.

In summary, there are many reasons to look beyond the seeming obviousness of the benefits of cost saving. If the cost differential is looking like it is going to be ongoing, there are many reasons to do something other than simply taking the money and running. Not the least because who you are taking the money from is not unproblematically the drug company, and where you are running to is not simply the promised land.

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## response

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**Patients' Interests Are Paramount**

This case raises a number of interesting clinical-ethical issues. To clarify the purchasing issue, PHARMAC's role is, as first stated in the case, to manage government pharmaceutical expenditure, not to 'buy' the generic or other drugs as indicated later in the same paragraph. Indeed, the case as posed rather depends on the clinical service having control over its expenditure, to the extent that savings in drug spending could be legally allocated to other, needed, priorities. Interpretation of the case also assumes that the drug rep, and her company, have the legal authority to offer such a deal.

PHARMAC's commitment to get the best value for money for New Zealanders relies on a set of principles and criteria for deciding which pharmaceuticals to subsidise centrally, and to which volumes (PHARMAC, 1999). Such decisions are often controversial, as even Cochrane-quality evidence can be interpreted in different ways and most stakeholders, from prescribers and other clinical staff, through managers to service users, have particular and understandable priorities (Menkes, 2002). For these reasons, a national agency like PHARMAC is unlikely to be popular, but needs to be systematic and unbiased to do its job and maximise health gains within existing resources. In the present case, if the generic alternative were shown to be comparably effective, its use and the resulting cost savings would in all likelihood be earnestly

sought by PHARMAC. Alternatively, the cost of the proprietary version might be driven down, in competition with the generic, and it is PHARMAC's job to cut the best deal with available suppliers. Local 'deals', such as proposed here, are discouraged in part because they can weaken PHARMAC's negotiating hand and, somewhat ironically, jeopardise getting the best national 'deal'.

Another ethical problem with a local 'deal' arises from equity considerations. Introduction of a local incentive available to augment services for patients in one catchment area creates inequity; patients in other areas who do not have access to the cheaper drug and linked subsidy of services are unlikely to receive the same standard of care. This is unethical in a socialised health system where equal access to resources forms the cornerstone of healthcare philosophy. Untoward effects could also arise in a competitive system, in which patients are consumers and have a choice of service providers; in this scenario unequal access to a cheap treatment could advantage one provider; by drawing patients away, this could impair service delivery to remaining patients in adjacent areas.

A third ethical problem with the proposed 'deal' stems from potential conflicts of interest for staff. As described, the 'deal' could unduly influence prescribing behaviour, since increased prescription volumes would be of direct financial benefit to the service. One would hope that existing prescription of the drug in question is made solely on clinical criteria. The proposed scheme can be seen as an example of pharmaceutical industry promotion, motivated primarily by profit not patient care, and which evidence indicates can impair both clinical judgement and prescribing quality.[1] Furthermore, since benefits are likely to accrue for staff 'working conditions', the nature of these might bear scrutiny as to their potential impact on prescribing behaviour not directly linked to clinical outcomes.

The staff of the hypothetical unit is right to be wary of the drug rep's proposal, for the above reasons and because of the uncertain quality of the generic alternative. It would obviously be useful to establish whether additional evidence of clinical equivalence of the two preparations was available, or soon to become available. Both the company and the Pharmacology and Therapeutics Advisory Committee (PTAC), which provides specialist advice to PHARMAC, could be consulted in this regard. If adequate research has not been conducted, it might be appropriate for the service to advocate for this, even participate in a trial, within local ethical guidelines. This could perhaps offer a more appropriate way for the local service to gain benefit from industry, while at the same time advancing knowledge and potentially benefiting other services as well.

**Note**

1. See articles at www.healthyskepticism.org/risk.htm, accessed 9 October 2003, and at www.drugpromo.info, accessed 12 October 2003.

**References**

Menkes, D.B. (2002). PHARMACopsychiatry: problematic but promising. *New Zealand Medical Journal* 115, pp.62-3.

PHARMAC, (1999). A prescription for pharmacoeconomic analysis. Version 1 (24 September 1999) @ http://www.pharmac.co.nz/pdf/pfpa.pdf

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## response

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In this case it appears that the generic version of the drug has been registered by Medsafe for use in New Zealand. If the drug has not been registered for use it is illegal and unethical for the company to promote it (by any method), and for the hospital doctors to use it, except under section 29 of the Medicines Act (1981) relating to the supply of unregistered medicines.

It could be the case that this generic medicine, whilst registered, has been judged not to be interchangeable with the original. This could be because of concerns over bioequivalence or, more likely, because the range of plasma levels associated with therapeutic or toxic effects is narrow. If so, it would not be recommended for patients to switch from the original to the generic, or vice versa, having once been stabilised on therapy with one or the other. Any move by the company or the medical staff to switch patients between

the treatments for whatever reason would therefore be bad practice and unethical. There would not on the face of it appear to be any medical or ethical reason however, to prevent patients receiving a complete course of treatment with the generic drug.

If Pharmac has concerns over the generic medicine despite it being registered and substantially cheaper (I struggle to think of a reason for this as Pharmac is usually very willing to fund list cheap generics) and if the hospital agrees with this and does not want to fund it, then we come to some interesting points. As the medicine is registered, the company has every right to promote it for its registered indications whether Pharmac fund it or not, and the doctors have every medical and legal right to use it. If the doctors use a drug that is not favoured by the hospital this may have contractual implications between hospital and employee, but is not in my view unethical as such.

We come now to the question of the funding arrangements proposed by the representative. The representative proposes to remit to the hospital department $67 for each pill used, despite the fact that the pill normally sells for $33. This is clearly economic madness unless some other arrangement also applies. If the company plans to bill HBL/Pharmac or the hospital the price of the patented drug ($100 per tablet) and then remit $67-00 back to the hospital as a payment to the department in question then there are issues with misleading the funder over which drug they are actually purchasing (which may carry legal as well as ethical implications), and with what amounts to a redistribution of departmental funding within the hospital (which has contractual implications but may not be unethical as such). In both instances the department staff would be culpable along with the company involved.

If the company proposes to bill the hospital $33-00 and remit $67-00 to the department then this might be economically sustainable for a short period of time as an inducement by the company to change the prescribing patterns of the department on a long term basis. As the remit is larger than the billed price, this would not amount to a rebate, but to payment for prescriptions. Payment for prescriptions, or the giving of gifts on the understanding that prescription habits will alter are both in contravention of the Researched Medicines Industry (RMI) Code of Practice and are therefore unethical and could result in penalties (up to $80,000 in fines for example) being imposed on the company by the RMI. The implications for the department staff who have accepted the gift or payment would be ethically similar in my view.

It is of some interest that a tight code of conduct currently exists in New Zealand for prescription medicines, but not for medical devices. If the distributor of, say, a hip prosthesis were to provide generous gifts or remits to doctors or departments in return for use of the particular prosthesis in orthopaedic surgery, there are no mechanisms for action to be taken despite the ethical similarities between the two situations.