Expensive new drugs—do we really need them?

R. F. W. Moulds, Professor of Medicine, Fiji School of Medicine, Suva, Fiji

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It is an article of faith in modern medicine that we need new drugs to treat most disorders. This belief has important implications. It underpins the patent system, which assumes that investment in the development of new drugs is so important that the principles of the free market should be abrogated to reward pharmaceutical companies with a legally enforced period of protection from competition. The Australian Pharmaceutical Benefits Scheme (PBS) is also based on the belief that all Australians should have access to new drugs.

No one would deny the impact that drugs introduced over 20 years ago had when they were new. Penicillin (and other antibiotics), beta blockers, H_2 antagonists, and non-steroidal anti-inflammatory drugs are examples of drugs that markedly altered clinical practice and are still widely used. However, it is harder to think of drugs introduced over the last 20 years that have had a similar impact[1] – antiretroviral drugs are perhaps one example – so has the time come to question our faith in new drugs?

In this issue…

In April 2000 *Australian Prescriber* published an editorial expressing concern about the risk of thrombosis with COX-2 inhibitors. Ric Day and Garry Graham explain why the vascular effects of COX-2 inhibitors ultimately led to the sudden worldwide withdrawal of rofecoxib in October 2004.

This recall will not greatly affect developing countries where access to new drugs is limited. Rob Moulds says his experience in Fiji shows that most patients can be managed without expensive new drugs, while Judith Whitworth argues that there is an obvious need to continue drug development.

The controversy about old and new drugs rages in psychiatry. Nick Keks and Vaughan Carr debate whether the atypical antipsychotics are significantly better than the older typical drugs.

There are new analgesics, but Stephan Schug and Philip Dodd tell us that new approaches to perioperative analgesia have improved pain relief for surgical patients.

One way of looking at the question is to ask what the practice of medicine would be like if the drugs developed over the last two decades had never been introduced. The experience of treating patients in a developing country (in my case, Fiji), where most new drugs are not freely available, can bring a special perspective to the question.

Fiji has a health budget that, per capita, is less than 10% of the Australian health budget, so it cannot possibly afford a system like the PBS. Instead, Fiji has adapted the World Health Organization's model list of essential medicines[2] for local circumstances. Drugs on Fiji's essential drugs list are available free from government health centres and hospitals. Drugs not on the list must be obtained from a private pharmacy and the patient must pay the full price. The essential drugs list contains one or two representatives from most drug groups: for instance, two beta blockers (atenolol and propranolol), one ACE inhibitor (enalapril), one H_2 antagonist (ranitidine), and most of the old (and cheap) antibiotics, for example penicillin, amoxycillin and gentamicin.

Almost all the drugs on the list were introduced over 20 years ago and their patents have expired. This enables the central government pharmacy to purchase supplies at the lowest price available – often from generic manufacturers in India or Malaysia.

The diseases we treat are remarkably similar to those seen in Australia. Diabetes, hypertension, asthma and smoking-induced respiratory disorders are common. Infections are also common, but are usually caused by pathogens such as *Streptococcus pneumoniae* and *Staphylococcus aureus* rather than exotic tropical organisms.

So, do we find ourselves seriously handicapped in Fiji by lack of access to new drugs? The short answer is no. We can treat most conditions perfectly adequately with the older drugs available on the essential drugs list. We perhaps have to be more adept than doctors in developed countries at using the drugs we do have rather than simply switching the patient to a new drug. For instance, we may have to explore a wider range of doses than are commonly used in Australia. However, we are seldom seriously concerned by not being able to prescribe COX-2 inhibitors, angiotensin receptor antagonists, long-acting $beta_2$ agonists or new antiplatelet agents.

There are definite exceptions to this generalisation. Lack of a 'statin', for instance, penalises patients with cardiovascular

disease, and most patients with AIDS do not yet have access to antiretroviral drugs. Some patients whose 'gastric' conditions are not controlled with ranitidine can suffer from lack of access to a proton pump inhibitor. Perhaps our patients with diabetes might have better control with new oral hypoglycaemic drugs, although our woefully poor control of diabetes is mainly caused by socio-economic factors rather than lack of access to new drugs.

My experience in Fiji suggests that, over the last 20 years, the article of faith that we need new drugs has largely not been fulfilled. So much so that I suggest we should seriously question our belief that these new drugs are essential rather than blindly continue to support it. If we reject this faith it follows that patent protection, and subsidisation by the taxpayer, should be much harder to obtain.

Patent protection assumes that innovation requires reward to ensure continuing investment. However, the faith that we must ensure that new drugs continue to be developed has meant that patent protection is given for even trivial developments. If we reject the faith, then patent protection should only be given to real innovation.

The PBS came into being when most new drugs, such as penicillin, were truly life-saving, but unaffordable to most people. However, even when many new drugs were not life-saving, listing on the PBS continued because of the faith that we need new drugs. Listing now requires a new drug to be cost-effective in comparison to other drugs subsidised by the PBS, but many of the drugs currently available have themselves never been proven to be cost-effective. So if we reject the faith, then cost-effectiveness in comparison to current drugs should not be sufficient to justify public subsidy. Perhaps we should go back to the original criterion that a drug should be truly life-saving to justify subsidisation.

Restricting patent protection to real innovation, and restricting subsidies to truly life-saving drugs is almost certainly too powerful a pill for any government (or the medical profession) to swallow. However, is it not better to admit the true situation rather than adhere blindly to an outmoded article of faith?

References

1. Lexchin J. Are new drugs as good as they claim to be? Aust Prescr 2004;27:2-3.
2. WHO model list of essential medicines. http://www.who.int/medicines/organization/par/edl/eml.shtml [cited 2004 Nov 8]

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The need for new drugs: a response

Judith A. Whitworth, Director, John Curtin School of Medical Research, Australian National University, Canberra

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In 1899 Charles Duell, Commissioner for the US Patent Office, urged President McKinley to abolish his office, because 'Everything that can be invented has been invented'. At that time life expectancy was over 20 years less than it is now and infant mortality was about 15-fold higher than today. It is hard to imagine that these gains would have been made without invention.

Sir Macfarlane Burnet, one of Australia's greatest ever scientific minds, wrote in his 'atypical autobiography' in 1968, 'No one can deny that medical research has provided, by any criterion, immeasurably important benefits during 'my' fifty years … But at the risk of being proved wrong in an embarrassingly short space of years, I do not think there will be practically applicable laboratory discoveries about cancer, autoimmune disease or the degenerative conditions associated with ageing and natural death, nor in regard to schizophrenia, the other acute psychoses, and the degenerative mental changes of old age. … from the point of view of health and medical care, all that 99 per cent of the world's people would ask for, if they were articulate, is for the full implementation for their benefit of what medical science had provided by 1955.'[1]

There is a resonance here with the views expressed by Professor Moulds.[2] The World Health Organization's (WHO) model list of essential medicines has indeed contributed significantly to global medical care. In a recent article on emerging drugs in management of hypertension I wrote, 'Hypertension is a major global health problem … it is likely that, in the short term, emerging drugs will play second fiddle to more targeted use of existing drugs and that the emphasis in emerging drugs will be on modification of existing classes, proven to be of benefit in outcome studies.'[3]

Our views are less congruent in other areas. Even if one excludes 'statins' and antiretroviral drugs, it is difficult to argue we have not seen important advances in the last couple of decades. Examples include protease inhibitors, hepatitis vaccines, erythropoietin, ondansetron and kinase inhibitors. It is true the list is not as long as one would wish, but given the global and national burdens of disease, this is a strong