

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?

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The need for new drugs: a response

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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

argument we need more, not fewer, new drugs.

Perhaps this relative paucity reflects the limitations of our old methods for drug discovery. However, the relative paucity of solutions demands new solutions and new technologies, not a retreat.

During the last 20 years new indications have emerged for older drugs, for example ACE inhibitors in acute myocardial infarction and (with indapamide) in prevention of secondary stroke, aldosterone antagonists and beta blockers to reduce mortality in heart failure, and the use of antibiotics to treat peptic ulcer. When a drug is first developed its ultimate indications (and degree of innovation) may not be recognised. At the same time, we have seen, frighteningly rapidly, the emergence of antibacterial, antimalarial and antiviral drug resistance, making some old drugs progressively less effective.

The need for new drugs is obvious – for old and new infections, as well as for the chronic diseases mentioned by Burnet – and there is enormous potential for the development of new drugs. According to the WHO Report on Genomics and World Health:

It has been estimated that successful drug therapy currently is directed at fewer than 500 targets. Considering that the human genome contains some 30 000 genes, it is possible that its study could lead to at least 3000 to 5000 potential new targets for therapy. Currently, predominant candidates include G protein-coupled receptor families and other receptors and related molecules, a wide range of enzymes including proteases, kinases and phosphatases, hormones, growth factors, chemokines, soluble receptors and

related molecules, and many others. Exactly the same principles are being applied to the search for agents to interfere with key biochemical pathways in pathogens, based on information which is being obtained from the pathogen genome project.⁴

Just as discoveries in the old disciplines of chemistry and biochemistry in the early 20th century took many years to translate into new drugs, so it will take time to learn how to realise the potential of the new discipline of genomics. But learn we must.

If a potential drug discovery/innovation/invention is not patented, it will never find its way into practice. With new drugs said to cost around \$1 billion to bring to market, investment will only be made if patent protection is assured. If the degree of 'real innovation' must be predetermined, based on previous experience, valuable therapies may be lost. Whatever our differences of emphasis, the ultimate goal is the same: effective, accessible, affordable medicines for all.

References

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Letters

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Quality use of medicines – prescribing for manufacturers or patients?

Editor, – I refer to the editorial 'Quality use of generic medicines' (*Aust Prescr* 2004;27:80–1).

Confusion resulting from the availability of multi-sourced brands of medications is predictable within our rapidly changing prescribing and dispensing environments.

For decades, prescribing by manufacturers' brand names was manageable when most medications were available as a single brand. It should also be noted that brand names are required for all products as part of Therapeutic Goods Administration (TGA) regulatory requirements.

Australia has a growing generics segment. This is synonymous with growing numbers of brands of the same medications and it is time for current prescribing practices to be reviewed to determine better ways to manage multi-sourced brands.

An Australian Pharmaceutical Advisory Council (APAC) subcommittee has concluded that Australia should move towards increased use of active ingredient names. In the UK, this has served to educate the public and health professionals to identify medications, primarily, by their international (approved) active ingredient names and not by local, brand names.