companies need to advise and fully inform doctors and patients about the process of changing treatment to try and avoid inappropriate actions. Medicolegal issues relating to duty of care and responsibility are clearly relevant and no doubt will surface in time, potentially affecting the companies, individual doctors, pharmacists, specialist colleges and government bodies.

Currently, when a company decides to discontinue a drug, there is no formal process in place to prevent these problems. Nor is it usual for a company to secure the ongoing supply of an essential drug, by arranging for another company to continue its production or distribution, before announcing the decision to withdraw the product. Often the notice given is much too short for all patients to be satisfactorily transferred to an alternative drug before supplies run out, a situation compounded by the inevitable stockpiling which follows the announcement. In some instances the drug supply can continue by finding a generic supplier or through further price negotiations, but this is a lengthy process during which the drug may become temporarily unavailable.

Clearly it is in the best interest of all parties, particularly patients, to develop a co-ordinated and systematic approach to the discontinuation of important drugs. The pharmaceutical industry needs to develop guidelines to follow whenever a drug is being considered for withdrawal, including the early notification of health professionals, their colleges, and other relevant organisations. This would provide the opportunity for the profession to make a case for the retention of essential drugs. Ideally, companies should then join in the process, with government, of securing an alternative supplier. The colleges and other professional organisations need to ensure that they can respond quickly and have an established process for participating with the companies and government in trying to retain the drug. If unsuccessful, the colleges and the company need to work together to ensure that individual patients can be transferred to alternative drugs safely and effectively before supplies run out. This requires a system of rapid communication with clinicians to disseminate information and advice about potentially complex management problems. With sufficient goodwill between the parties involved and with a common focus on patient welfare, significant improvement in the management of drug discontinuations should be achievable.

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Letters

Letters, which may not necessarily be published in full, should be restricted to not more than 250 words. When relevant, comment on the letter is sought from the author. Due to production schedules, it is normally not possible to publish letters received in response to material appearing in a particular issue earlier than the second or third subsequent issue.

Global drug prices

Editor, – According to Professor Ron Penny, there is an unbelievable array of effective medicines that have reduced the number of HIV/AIDS related deaths in Australia from 2790 in 1992 to 97 in 2001.

The World Health Organization (WHO) has categorically stated that access to innovative medicines and vaccines has been substantially the most important factor in achieving the dramatic decline in mortality rates throughout the twentieth century.[1]

These statements contrast starkly with the opinion of Dr Moran who hypothesised in her recent editorial ('Why are global drug prices so high… and other questions' Aust Prescr 2003;26:26–7) that the interests of the prescription medicines industry lie in 'maximising profits and growth, not in identifying and filling health needs'.

There are many industry driven programs that treat disease and alleviate suffering in resource poor countries. One of the most successful partnerships is the Accelerating Access Initiative program that includes UNAIDS (Joint United Nations Programme on HIV/AIDS), WHO, the World Bank and pharmaceutical companies. This currently has 27 000 people on antiretroviral therapy throughout the world.[2]

Dr Moran suggested that the medicines industry targets 'money-spinner drugs and diseases'. This ignores the critical fact that in Australia these diseases are precisely the diseases that are the focus of the seven National Health Priorities (asthma, cancer, cardiovascular health, diabetes, injury prevention, mental health and arthritis) established not by the medicines industry but by Australian Health Ministers.

Innovative cures to treat disease only come from the research-based medicines industry because governments and even venture capitalists are not prepared to invest in such a high-risk venture. Latest research estimates that it costs about $1.1 billion[3] to bring a new medicine from discovery to patient – along a 12–15 year journey.

This vitally important commitment of the medicines industry is ignored by Dr Moran.

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REFERENCES

1. The World Health Report 1999. Geneva: World Health Organization; 1999. p. xxi.
2. Accelerating Access Initiative Progress Report June 2002. Geneva: World Health Organization; 2002.
3. DiMasi JA, Hansen RW, Grabowski HG. The price of innovation: new estimates of drug development costs. J Health Econ 2003;22: 151-85.

Dr M. Moran, author of the article, comments:

I absolutely agree that the pharmaceutical industry develops useful, new drugs. My point is that they only do so when these new drugs are also likely to deliver substantial profits, thereby effectively restricting new drug development to common diseases of Western consumers.

I am not criticising industry for seeking profitable research investments nor suggesting that they stop doing so – this is unrealistic. What I am saying is that profit-seeking firms should not be in charge of setting global drug research agendas, since the vast bulk of the world lies outside their sphere of economic interest. An alternative model is needed: for instance, an international research and development convention to define research needs and establish mechanisms to fund these.

I disagree that 'innovative cures only come from the research-based medicines industry because governments are not prepared to invest in such a high risk venture'. This is not true. Half of the US$70 billion invested in drug research each year comes from the public sector, chiefly as funding for basic research, which is the **highest** risk part of the drug development pipeline.[1] Ten AIDS drugs were fully developed or supported by publicly funded research[2], and the US Government supported the clinical research for 34 of the 37 new cancer drugs marketed in the USA since 1955.[3]

The time for pointing the finger or seeking public relations wins is over. We must accept that our current system is not delivering the drugs the world needs and start working together to solve this problem.

REFERENCES

1. The 10/90 Report on Health Research 2001-2002. Global Forum for Health Research; Chap. 6, p.107. http://www.globalforumhealth.org (go to Publications)
2. Consumer Project on Technology. Additional notes on government role in the development of HIV/AIDS drugs. February 23, 2000. http://www.cptech.org/ip/health/aids/gov-role.html
3. Nader R, Love J. Federally funded pharmaceutical inventions. Testimony before the Special Committee on the Aging, of the United States Senate. February 24, 1993. http://www.cptech.org/pharm/pryor.html

The gift of the gabapentin

Editor, – Your fascinating article outlines the decision by one pharmaceutical company to employ unethical strategies to promote off-label uses for gabapentin (Aust Prescr 2003;26:3–4), a decision which could be described as corporate risk. However, the prescriber and the patient also share the risks associated with off-label prescribing. While the final paragraph highlights an 'imperative to carefully weigh the potential benefits and harms' of off-label prescribing, I believe the article stopped prematurely in developing this notion of who bears the risks.

Off-label prescribing includes using the drug for an unapproved indication, or at an unapproved dose or by an unapproved route, or disregarding the contraindications or precautions of the product information. In the gabapentin example, a belief by prescribers that off-label use was supported by clinical evidence was probably unfounded. The decision as to whether this use was appropriate will come down to standards of reasonable care. The pharmaceutical company will consider that its drug has been used in an unauthorised manner and so cannot officially sanction such prescribing.

It has been noted that 'prescribing outside the licence [approved product information] alters, and probably increases, the doctor's professional responsibility'.[1] When considering prescribing a drug, it is important to be aware of what is on the label to minimise the chances of being left 'hung out to dry'.

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REFERENCE

1. Prescribing unlicensed drugs or using drugs for unlicensed indications. Drug Ther Bull 1992;30:97–9.

Editor, – Further to the articles in *Australian Prescriber* on prescribing of gabapentin (Aust Prescr 2003;26:3–4), in addition to the issues discussed, there are legal issues for the prescriber and the manufacturer/sponsor of the product to consider.

My first observation is that prescribers who use gabapentin for a condition which is outside the marketing approval in Australia could be subjected to a compensation claim should a patient suffer a serious adverse event due to the drug. If such an event occurred it could also involve the promoter of the drug if off-label promotion was involved.

The second observation concerns prescribing gabapentin as a pharmaceutical benefit. The National Health Act provides penalties for prescribing 'restricted' and 'authority required' drugs for other than the allowable conditions determined for that drug. In instances of off-label prescribing, the prescriber has breached the legislation. The articles allude to off-label promotion of gabapentin overseas. If this occurred in Australia it follows that the manufacturer promoting the drug for an off-label condition may also be party to an offence under the National Health Act.

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(Until 1996 I was Manager of the Pharmaceutical Benefits Branch of the Health Insurance Commission in Victoria. I joined the Pharmaceutical Branch of the Commonwealth Department of Health in 1969 and retired from the Health Insurance Commission in 1996.)

Sulfadiazine

Editor, – In the article 'Treatment of ocular toxoplasmosis' (Aust Prescr 2002;25:88–90) sulfadiazine is described as a *sulfur* analogue. It is, however, a *sulfa* analogue as sulfur is the element and sulfa, or sulfonamide, is the class of antimicrobial having the chemical group $-SO_2NHR$ in its structure.

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