EDITORIAL

Why are global drug prices so high... and other questions

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(Aust Prescr 2003;26:26–7)

Why are drug prices so high in much of the world? Why isn't there an AIDS vaccine? Why don't we have effective antimalarials anymore? Why was there a shortage of noradrenaline in the UK last year?

The answers to these questions are pretty simple. We do not have the drugs we need, at the prices we want, because we have very little control over what drug companies do or do not do. Over the last 30 years we have largely relinquished control of drug development, supply and pricing decisions to the private sector, whose interests lie in maximising profits and growth, not in identifying and filling health needs. In most Western countries, the impact of this change has been ameliorated by health insurance systems, government subsidies or expensive carrots (like the Orphan Drug Act in the USA). However, this is not the case in developing countries, where governments are often too poor to shield patients from the brunt of industry production and pricing strategies.

Pharmaceutical industry strategies make commercial sense, but, particularly in developing countries, they can also conflict with what is best for public health. In response to shareholder

In this issue...

New drugs, including some of the arthritis treatments mentioned by Anita Lee and Kevin Pile, can be expensive. While developing a new drug can cost a lot of money, Mary Moran asks if profits are sometimes put ahead of people.

Many medicines are developed to treat disorders of lifestyle in wealthy countries. While there are drugs for the treatment of obesity, Louise Baur says they currently have no role in children.

There is always a risk when treating a patient with drugs. Paul Komesaroff discusses some of the ethical issues involved, in the conclusion to our series on perceptions of risk.

Having an intravenous catheter involves a risk of infection. Catheters should therefore not be inserted if they are not needed, but if infection does occur Robert Horvath and Peter Collignon tell us how to treat it.

pressure, drug companies have increasingly narrowed their research to focus on money-spinner drugs and diseases. The 10 best-selling drugs worldwide are for depression (4), cholesterol (2), hypertension (2), heartburn/ulcers (1) and hayfever (1). The chief executive officer of the UK pharmaceutical company Amersham put the case bluntly: 'When I took on the biological business, two-thirds of our research was on tropical disease. I couldn't see how, virtuous as it was, that was going to deliver the revenue flows for the company. I was quite rigorous about cutting back on this research.' The result of this trend is that in developing countries patients with malaria or sleeping sickness have little prospect of seeing new drugs developed for them unless there is government intervention.

Maximising profits also means getting rid of non-competitive products, irrespective of the health needs they may address. Companies faced with the need to improve the bottom line will, and have, simply stopped production of low-profit drugs like noradrenaline or isoprenaline, oily chloramphenicol for epidemics of bacterial meningitis, or eflornithine for sleeping sickness.

The real key to drug industry profit, however, is the ability to maintain high prices over long periods of time. Hence the enormous resources expended by the industry on lobbying governments to support measures that protect prices, reduce competition (which exerts downward pressure on prices) and extend patent monopolies.

The drug industry's greatest coup was the passage of new international trade laws in 1995, which stipulated that all countries—even the poorest—were compelled in most instances to purchase brand versions of all new drugs for a minimum of 20 years after they were patented, rather than relying on cheaper generic copies which had long been the mainstay of their health systems. Unfortunately, this success for the industry, effectively handicapping future generic competition, had life-threatening consequences for patients. Patients with AIDS, in particular, found themselves forced to forgo treatment with cheap generic antiretrovirals (then available for as little as \$350 per patient per year) despite being unable to afford the equivalent brand name drugs which cost more than \$10 000 per patient per year. A public outcry subsequently led to these laws being re-examined.

Of course prices and profits must be sufficiently high to foster a thriving drug industry and to fund research and development of new cures. However, drug company tax returns show that the bulk of their revenues are not allocated to research. The lion's share goes to marketing and administration, followed closely by returns to shareholders. The US pharmaceutical industry is consistently ranked by Fortune 500 as the most profitable industry in the US, with a staggering 33% return on shareholders' equity (other Top 10 performers deliver returns of between 14% and 26%); and with profits representing a generous 18% of revenues (other Top 10 performers range from 6% to 13%).3 Compared to these figures, research and development spending comes a poor third. This is not because industry is uninterested in research, indeed, they are anxious to find the next 'blockbuster' drug. The problem is that breakthrough drugs are increasingly rare. The US Food and Drug Administration estimates that only one third of new drugs submitted to it are truly innovative, the remainder being little or no improvement on existing therapies. In the absence of a real breakthrough, the next best thing is to **make** your drug seem like a breakthrough. This explains the huge marketing budgets, the teams of drug representatives visiting general practice surgeries with glossy folders, and the pressure for direct-to-consumer advertising of new drugs (which assumes that consumers are more easily swayed than physicians).

Drug companies, desperate to maintain growth rates and profits, are increasingly turning to standard business remedies. They are cutting out 'deadwood' (low-profit drugs and research

targets), focusing on proven winners (blockbuster drugs and key US, Japanese and European markets) and ensuring that governments legislate in their favour, be this regulatory agencies or trade authorities.

Understanding these corporate practices helps us understand what has gone wrong and what needs to change. We are allowing a private sector industry that has other interests at heart to set the agenda on public health. While industry clearly has a central and important role to play, it is up to health professionals and governments to ensure that issues relating to health, not just wealth, are on the table when decisions affecting drug access are made.

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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.

Splitting tablets

Editor, – The recent article (Aust Prescr 2002;25:133–5) 'Splitting tablets' is very useful, but one point needs clarification.

I refer to the statement: 'Tablets that are scored are usually considered by the manufacturer to be suitable for division...' and to the reference to azathioprine (Imuran) in Table 1.

It is correct that film-coated tablets should not usually be split, but the more important reason not to split Imuran tablets is that it is a cytotoxic drug. Splitting would be likely to release small particles into the air. Strangely though, Imuran tablets are scored. Apparently, the reason for this is that the tablets which are made in just one location are marketed in many countries, and at least one of them (Germany, I think) requires ALL tablets to be scored.

Jeff Lerner

Pharmacist

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Editor, – The article 'Splitting tablets' (Aust Prescr 2002;25:133–5) outlines practical issues on the splitting of tablets. However, it does contain one deficiency. It fails to mention the potential problem associated with the splitting of tablets containing antineoplastic drugs.

Antineoplastic drugs are potentially toxic medicines and it is

essential that patients and other healthcare workers adequately understand their correct use. Many antineoplastic drugs have been found to be mutagenic, teratogenic and carcinogenic on the basis of cell DNA and chromosomal studies, animal models and, to a lesser degree, experience in treated patients. The risk associated with occupational low-level exposure has not been determined. Therefore, without evidence to the contrary, risk is assumed to be present.

Tablets and capsules of antineoplastic drugs must be handled in a manner which minimises exposure to healthy individuals. This includes avoiding skin contact and liberation of powdered drug into the air. Based on this premise, antineoplastic drugs in tablet form should not be split or crushed, and capsules should not be opened. Where required, antineoplastic mixtures should be prepared according to accepted standards.

With the increasing number of oral cytotoxic drugs available on the market, prescribers and consumers must be made aware of the potential dangers, albeit small, in splitting these tablets.

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