Prescription drug expenditures rising — too fast?

Western societies spend a lot of money on prescription drugs. According to the Canadian Institute for Health Information (CIHI), prescription drug costs reached $18 billion in Canada last year. (Physician costs were $17 billion, and total hospital costs $40 billion).[1] Canadians pay $562 per capita per year for prescription drugs, and this sum does not include drugs provided in hospital, which account for an additional $1.3 billion or more. Prescription drug costs are increasing at 9% annually, far above the rate of inflation (see page 1279).[2] Canada is surpassed in total per-capita drug expenditures only by the United States and France. Assuming equivalent drug prices, Canadian physicians prescribe almost twice as many drugs per person as their colleagues in Denmark and the Netherlands.[1]

In this issue, Steve Morgan puts this latest surge in drug spending into historical perspective (see page 1323).[3] The authors of the report attribute some of the increase in spending to the substitution of newer, more expensive drugs for older off-patent and cheaper drugs, and some to increased utilization. But behind these proximate causes are other, more complex, reasons that derive from our system of funding drug research. In brief, in Canada along with other Western nations, responsibility for pharmaceutical research rests almost entirely with the private sector, which invests literally billions in new drug development and, once a new drug has been approved, aggressively markets it to physicians. The purchase of those drugs by patients either directly or indirectly through health care systems or drug plans returns that investment to industry along with an acceptable profit to shareholders.

Given the profit motive that underlies drug development and research, we should find nothing surprising in the fact that new patent-protected pharmaceuticals are "preferred" to older generic ones and that drug utilization is increasing at a rate that, unfortunately, sometimes outpaces the benefits of increased uptake. Nor should we expect — or wish for — a slowdown in pharmaceutical research. We all stand to benefit from new pharmaceutical breakthroughs. But, while the "genomification" of human health sciences is poised to propel even more new chemical entities toward clinical trials and subsequent marketing and sales, much of the impetus will still be commercial self-interest, which brings with it dangerous tendencies toward biased research and a "big sell."

As we and many others have commented, clinical trials designed to obtain regulatory approval are required only to demonstrate efficacy compared with placebo (not with existing generic drugs), and to a large extent the detection of harms is left to virtually nonexistent postmarket research and to a haphazard and intrinsically unreliable reporting system for adverse drug reactions.[4]

That a system of drug development and approval founded on commercial interests is bound to be this way is, again, not astonishing. But the implications of the CIHI report might be read as follows: patients are being made to bear the burden of the costs of drug development by consuming drugs that are at least some of the time of less-than-advertised benefit and for which, in many cases, a cheaper and equally effective generic alternative exists — one that has the added advantage of longer market use and clinical experience and is thus less likely to have unknown serious adverse effects.

Clear recent examples — and there are many — are the exuberant marketing of COX-2 inhibitors and the subsequent discovery that they have life-threatening adverse effects and the accumulating clinical trial evidence that heavily marketed drugs for Alzheimer's disease — donepezil, rivastigmine, galantamine and memantine — are of questionable efficacy,[5] leading to poor reviews of their cost-effectiveness.[6]

The alternatives? As a society that has chosen to pursue pharmaceutical research in the private sector, our only fallback is to more tightly control the marketing of the products that emerge. When a truly novel compound emerges with the potential to reverse or greatly improve a serious illness (some of the HIV drugs are good examples), then it should move rapidly through the approvals process, receive a temporary time-limited approval and be required to undergo further clinical evaluations of efficacy and safety in real-life situations. Comparisons at this stage should be made with existing alternative drugs, not with placebos. The second wave of me-too drugs (chemical derivatives of the original discovery) should not be approved until they have been extensively tested in clinical trials that compare them with existing drugs. Not only is there no need to hurry after these me-too compounds, but to do so is terribly expensive. — *CMAJ*

References

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