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GUEST EDITORIAL

Drifting policies are wasting billions

The growing proportion of older people, their longer survival and their longer period of morbidity and disability, have seen health expenditure increase exponentially, which no government can afford. Pharmaceutical expenditure is an increasingly important part of overall healthcare costs and the growing costs of prescription medicines have become a major burden to health care systems worldwide. Medicines account for 20–60% of health spending in developing and transitional countries, in which some governments consistently pay prices above the international reference prices to procure a number of medicines (Suh, 2011). Owing to the different interests of stakeholders (the pharmaceutical companies, medical professionals, patients and family members) who play a major role in healthcare policy-making, international or national policies for cost-containment are drifting or sometimes take a back seat.

Origin and history of the debate on the use of antipsychotics for dementia (1999–2009)

What follows is an international case. Over three years (1999–2002), the marketing campaign for olanzapine promoted its use for the treatment of the behavioral and psychological symptoms of dementia. This contributed to the doubling of annual sales of olanzapine from $US 1.5 billion to $US 3 billion in the USA alone. However, olanzapine was only approved for schizophrenia and bipolar disorder. In 2003, this issue was raised in the Federal Court by a civil action, which revealed that from September 1999 through to at least November 2003, Eli Lilly promoted olanzapine for the treatment of the following off-label uses: agitation, aggression, hostility, dementia, Alzheimer's dementia, depression and sleep disorder. In 2004, the UK Committee on Safety of Medicines (CSM) advised of increased risk of mortality and stroke when using olanzapine or risperidone for people with dementia and recommended that these two atypical antipsychotics not be used. The warning refueled longstanding concerns about the inappropriate use of antipsychotics in older people with dementia. In 2005, the US Food and Drug Agency (FDA) instituted a black-box warning, which was later extended to all antipsychotics. This decision forced other national health agencies to warn that no antipsychotics should be used for people with dementia. Since 2004, more than 1000 papers have been published in scientific journals debating, discussing, and/or providing evidence for or against the decision to ban antipsychotics using their own study results obtained from research on people with dementia in the community or nursing homes. The topic has been given top priority at many international and national scientific meetings. Several large-scale naturalistic studies conducted in nursing homes failed to show a greater mortality rate in people with dementia using antipsychotics (Suh and Shah, 2005), while others suggest that the risk is greater with conventional than with novel antipsychotics. However, these scientific discussions have all been confined to the question of whether these drugs cause harm or not. Evidence showed an initial decline in antipsychotic prescriptions after the US FDA warnings, but ultimately the overall prescription rate did not reduce (Valiyeva *et al.*, 2008; Kales *et al.*, 2011). On 15 January 2009, the US Justice Department ordered Eli Lilly and Company to pay penalties totaling $US 1.415 billion, including a criminal fine of $US 515 million, the largest such fine ever paid out in a healthcare case, to resolve allegations that the company had promoted olanzapine for uses not approved by the FDA. Ironically, at the moment when the Justice Department ordered this criminal fine for promoting off-label use, the FDA contradictorily *permitted* such off-label promotion by pharmaceutical companies by formalizing the guidance rules on the promotion of off-label uses of drugs to physicians (US FDA, 2009). Earlier in 2008, risperidone had already been given a US license to treat behavioral disturbances in Alzheimer's disease for a limited period (up to 6 weeks).

Permitting the promotion of drugs for off-label uses may be appropriate in instances in which a drug can improve outcome at lower cost. Off-label use of an approved drug can help patients, but apparently desirable off-label promotion generally pertains to generic drugs for which there is no strong commercial interest.

Wasting trillions: a lesson of the 80% rule

What follows is a case study from South Korea. In South Korea, healthcare decision-making is often conducted through political processes. For example, on 12 August 2011 the Korean Ministry of Health and Welfare announced a cut in the prices of all off-patent drugs of about 20% and a change in the 80% rule for the pricing of drugs in the national drug formulary to save 2.1 trillion Korea Won annually. The 80% rule is a Korean national policy to set the price of off-patent original brand drugs and their generics. For example, if the price of patent-protected Drug A is $10, it will be $8 when the patent expires. Then, the price of the first five generics of Drug A will be set at 80% of that of the original accordingly. The prices of the next-listed generics are then lowered gradually.

A clear trend in South Korea during the first decade of the twenty-first century has been the rapid increase in pharmaceutical expenditure, which reached about 30% of the total national health insurance budget, equivalent to 11.7 trillion Korea Won in 2009. This is much higher than the average of 17.6% among other OECD countries. However, the Korean government had already predicted the increase in pharmaceutical expenditure and steadily implemented several different policies to control pharmaceutical expenditure growth. As a first measure, in 2000, a national health reform separating the drug prescribing and dispensing functions of physicians was implemented. Unfortunately, this reform brought about a rapid rise in pharmaceutical expenditure, contrary to the initial expectation that the separation would greatly *reduce* pharmaceutical expenditure. Policy-makers might have thought that the rapid increase was caused by the intense lobbying by multinational pharmaceutical companies to allow marketing of high-cost novel drugs. The rule for deciding the price of a novel drug was to set the price using the average price in the G7 countries. Some politicians blamed the government for playing into the hands of the multinational pharmaceutical industry. In 2007, the government implemented a new policy requiring health and economic evaluation of novel drugs for listing in the national drug formulary. Since then, reimbursement decision-making has been made according to cost-effectiveness and budget-impact data of candidate novel drugs. In addition to lower drug prices, a series of measures have been implemented including the "positive list system", which offers health insurance benefits only when cost-effective; the "price reduction system", which lowers the prices of drugs from companies that are found to have offered rebates; the "renewal of drug lists" covered by national health insurance which removes less effective drugs from the national drug formulary; and the latest "market-based actual transaction price system", which guarantees financial incentives for medical institutions that purchase formulary-listed drugs at the cheaper price compared to that in the national health insurance scheme. Further, in 2010, the government began stepping up its efforts to eliminate rebate practices by revising the medical law which stipulates punishment of physicians as well as pharmaceutical companies involved, and clearly defines such rebates as criminal. However, all these policy alternatives have failed to reduce pharmaceutical expenditure in Korea. Recently, the Ministry of Health and Welfare declared a blunt cut of drug prices to get a direct cost-saving effect. By this action, it becomes obvious that the most critical reason for the failure to reduce pharmaceutical expenditure is the consistent policy to keep the 80% rule to set the prices of off-patent original drugs and their generics very high.

The obvious question then is: "Why has the 80% rule not yet been changed?" Policy-makers may argue against this idea from different viewpoints, but they should have lowered the rate in 2000 along with the first measure to reduce pharmaceutical expenditure. What would have happened if policy-makers had changed the 80% rule earlier towards the level of the USA (16%) or average European countries (30–50%)? By consistently keeping the 80% rule, Korea has wasted trillions annually – and thanks to the 80% rule to set drug prices higher, pharmaceutical companies have made huge profits. Yet few local pharmaceutical companies have invested money for the research and development needed to develop novel drugs. Instead, most pharmaceutical companies have devoted almost all their energies to marketing. They have provided money as rebates to prescribing physicians and hospitals, a practice which recently was re-defined as criminal by the revised medical law. Too many countries, including some in Europe and America, are likely to have experienced similar problems to those of Korea, leading to the wastage of billions of dollars worldwide. Every policy-maker should be advised not to make the same mistake. A valuable lesson should be learned!

Conclusion

We are like blind men who are touching an elephant to learn what it is like. In our collective darkness, we cannot imagine an elephant as a whole. However, when we put together individual instances related to a certain event, we may be able intuitively to find relationships between individual instances and the

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event as a whole. We need to think about who will be the winners and who the losers. In these two cases, we can easily find motives of pharmaceutical companies to make higher profits even though they are not always successful. The companies' fiduciary duty to their shareholders is in direct conflict with physicians' fiduciary duty to do what is best for patients. One verse of the ancient Hippocratic Oath – "I will prescribe regimens for the good of my patients according to my ability and my judgment and never do harm to anyone" – is a golden saying for all prescribing physicians today.

Conflict of interest

None.

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