New drugs

Some of the views expressed in the following notes on newly approved products should be regarded as tentative, as there may have been little experience in Australia of their safety or efficacy. However, the Editorial Executive Committee believes that comments made in good faith at an early stage may still be of value. As a result of fuller experience, initial comments may need to be modified. The Committee is prepared to do this. Before new drugs are prescribed, the Committee believes it is important that full information is obtained either from the manufacturer’s approved product information, a drug information centre or some other appropriate source.

Adefovir dipivoxil
Hepsera (Gilead Sciences)
10 mg tablets
Approved indication: hepatitis B
Australian Medicines Handbook section 5.3
Although Australian children are now immunised against hepatitis B, infection still occurs in adults and is endemic in Aboriginal and Torres Strait Islander communities. Some people who are infected develop chronic hepatitis B which may lead to cirrhosis and liver failure. Patients with chronic hepatitis B can be treated with injections of interferon. Lamivudine, a nucleoside analogue, can be used as an oral treatment.
Adefovir is a nucleotide analogue of adenosine monophosphate. Cells convert adefovir to adefovir diphosphate which competes with the normal substrate of the viral DNA polymerase. The concentration of adefovir diphosphate needed to inhibit the enzyme in hepatitis B virus is lower than the concentration which inhibits human DNA polymerase. When adefovir diphosphate gets incorporated into viral DNA, it inhibits replication by preventing elongation of the nucleic acid chain.
As adefovir is not well absorbed it is given as a prodrug. Adefovir dipivoxil is taken once a day and is converted to adefovir (bioavailability 59%) by hydrolysis. Most of this adefovir is later excreted unchanged in the urine.
Patients who do not have detectable hepatitis B e antigen (HBeAg) may have an increased risk of progressive liver damage. A multicentre study randomised 123 of these patients to take adefovir dipivoxil and 61 to take a placebo for 48 weeks. Concentrations of viral DNA reduced significantly in 51% of the adefovir group but not in any of the patients given a placebo. Although 33% of the placebo group had improved liver histology, this was significantly less than the 64% who improved with adefovir dipivoxil.2

Book review

Health care and notions of risk. R.B. Clark.
72 pages. Price including GST $33; students $25.30; plus postage

Janette Donovan, Consumer Class Director, Board of the National Prescribing Service, Sydney

This book is a consumer view of medical adverse events, patient participation in healthcare decision-making, risk perception and patient safety in the Australian healthcare system. It is based on an analysis of the Australian Patient Safety survey which was a comprehensive study of Australians’ attitudes to participation in health care and perceptions of safety. The book explains the likelihood and types of medical adverse events, models of consumer involvement in healthcare decision-making and the views of consumers about the safety of health services.

Medicine-related adverse events are the main category of adverse events reported, but the lack of resources and the exposure to infection were the most important consumer issues in relation to safety. Chapter 5 discusses the factors which predict adverse events. It is interesting that consumers perceived nursing homes, residential aged care, hospitals and doctors’ surgeries as places where adverse events were likely to occur.
Younger people aged 18–34 years are significantly more likely to report an adverse event than the older age groups. According to the author, this may be due to younger people feeling more empowered in healthcare decision-making, but more data are needed to clarify why this is the case.

The final chapter of the book attempts to place the findings of the study within a policy context. A key finding is that the lack of resources and exposure to infection have contributed to a recent fall in confidence in relation to the safety of health care. Another finding with implications for health policy is consumers’ preference for a shared decision-making model. Sharing information reduces the risk of experiencing an adverse event.

The book concludes that the value of this Australian study is that future studies may be able to focus on vulnerable groups. These include people with poor health and those who have a number of hospital admissions.

I can recommend this book to all those interested in consumer perceptions of risk, safety and quality and participation in health care. It will also be valuable to those interested in greater consumer participation in the policy, planning, delivery and evaluation of health care.