## Book reviews AMH Children's Dosing Companion

#### **Yashwant Sinha**

Clinical research fellow Centre for Kidney Research The Children's Hospital at Westmead Sydney Australian Medicines Handbook; 2013. Electronic version (also available in print)

This Australian Medicines Handbook dosing companion is Australia's new national paediatric formulary, representing more than 10 years planning and development facilitated by the Australian Health Ministers' Advisory Council and the Paediatric Medicines Advisory Group. It aims to provide clear guidance for practitioners prescribing for children and to reduce variability in prescribing practices.

It provides dosing information for the most commonly used medicines in children in community and hospital practice, and includes neonates born at term up to children aged 18 years. It does not include dosing



guidelines for premature infants or some medicines used in hospitals such as anaesthetics, normal human

immunoglobulins and intravenous fluids.

This resource is for use on desktop computers, tablets and smartphones. It is arranged as an alphabetical list of drug monographs which may be searched using generic or brand names. Dosing guidelines are provided 'per indication' and 'per dose' with a maximum dose provided where possible. Sections outlining off-label use and practice points are included. There is a link to the Pharmaceutical Benefits Scheme (PBS), although all monographs include the statement 'PBS restrictions may not pertain to children'. This is a little confusing as many PBS-listed medicines are not restricted by age.

General guidelines include principles of prescribing for children, common paediatric prescribing errors, off-label prescribing and prescribing in special situations. The appendices include the Australian Immunisation Handbook vaccination schedule and some useful algorithms for body surface area, resuscitation, topical corticosteroids and intraosseous injection technique. Lists of contact details for pharmaceutical companies and drug information centres in each state are provided.

Overall, the companion provides accurate, useful information to assist practitioners prescribing for children. It is of greatest practical value for children in the community, however the need for a paid subscription may limit uptake by prescribers. Use within tertiary paediatric settings would require a more complete list of medicines.

## Ethics and law for the health professions. 4th ed.

Kerridge I, Lowe M, Stewart C.

#### **Paul A Komesaroff**

Professor of Medicine Monash Centre for Ethics in Medicine and Society Monash University Melbourne

### Sydney: The Federation Press; 2013. 1232 pages

This book is an extraordinary undertaking that, against the odds, succeeds in providing a comprehensive, entertaining and readable introduction to the key issues in contemporary bioethical theory and law. It offers health professionals an impressive and valuable resource of almost breathtaking ambition and scope.

The first challenge the authors had to address in writing this work was how to define bioethics. This is a controversial issue because what constitutes the boundaries of the discipline is disputed, the possible list of topics and philosophical perspectives from which to consider them is very extensive and there are deep disagreements about the relationship between bioethics and law. In response to this uncertainty they have chosen the broadest possible approach, covering all the major extant philosophical theories, key concepts, areas of clinical practice and subjects raising ethical issues in research and public policy.

Familiar topics such as end-of-life issues, consent, competency, truth telling and confidentiality and privacy are well treated. Specific topics arising in relation to nursing, students, indigenous issues, children, the elderly and mental illness are usefully addressed, and there are extensive sections on ethical issues associated with new technologies, genetics and public and global health.

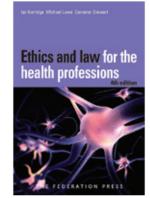
An especially welcome feature is the extension of the discussion to include contemporary debates about non-human animals and the environment. In all cases, the ethical and legal issues are discussed in a complementary manner, with clarity, precision and at times even humour. Indeed, the jargon-free style of presentation is one of the book's most striking attributes.

This is not to say that the book is without problems or limitations. The sheer size of the project makes it inevitable that many issues and philosophical theories are treated in a rudimentary, sometimes superficial, manner. This makes the discussion at times uneven, with some topics – such as consent and competency – being treated in authoritative detail in relation both to legal and ethical theory. Other topics – such as the presentation of some contemporary philosophical works – remain excessively brief and schematic.

It is possible that this may confuse and even frustrate some readers. However, it is always open to those who object to brief summaries of large and complex areas of thought to overcome the problem the hard way – by going back to the primary literature itself. Even here it can be argued that the mere provision of a summary and reading list will help facilitate access to unfamiliar, specialist areas of ethical and legal theory for many readers in the healthcare professions who would not otherwise come into contact with them.

Health workers new to bioethics will find this book a convenient and readable introduction, and those already familiar with the field will find it a useful, up-to-date guide to the rapidly expanding contemporary literature.

Paul Komesaroff is Chair of the Editorial Board of the Journal of Bioethical Inquiry



# New drugs: transparency

Access to the information collected during clinical trials is important for preparing the new drug comments in *Australian Prescriber*. A lot of this information is unpublished, but is used by the Therapeutic Goods Administration (TGA) when it evaluates new drugs. *Australian Prescriber* routinely asks pharmaceutical companies to provide a copy of the clinical evaluation data which support the safety and efficacy of their products. Few companies provide this level of transparency.

Almost 10 years ago *Australian Prescriber* started to publish a rating of the companies' cooperation. This was called the T-score (see box). While some companies are willing to provide data, others do not even respond to the request for information (see Table online at www.australianprescriber.com/ magazine/37/1/artid/1488).

In the last few years the TGA has started to publish information about what was considered when it evaluated a new drug for the Australian market. These Australian Public Assessment Reports (AusPARs) include information from the TGA's clinical evaluation. This then resulted in some companies, responding to requests for data, referring *Australian Prescriber* to the AusPAR rather than providing the data. As the AusPAR is a public document and does not contain the full clinical evaluation, the Editorial Executive Committee decided that companies which only provided an AusPAR would be given the minimum T-score. To be advised to read the AusPAR is particularly unhelpful if the AusPAR has not been published before the drug is launched onto the Australian market. The TGA is working to reduce this delay in publishing AusPARs. In addition, the TGA has been providing extracts of its evaluations, as attachments to the AusPARs, since July 2013.

The transparency of drug regulation is gradually improving, but *Australian Prescriber* will continue to monitor the willingness of the pharmaceutical industry to provide information about clinical trials of new drugs.

## **T-scores**

X

X

- T T manufacturer provided the clinical evaluation
  T T manufacturer provided additional useful information
  T manufacturer provided the AusPAR and/or the product information
  - manufacturer declined to supply data

manufacturer did not respond to request for data