

Doctors, drugs, information and ethics: a never-ending story

Combining commercial interests and public good is a broad social, political and ethical challenge

Health care, the practice of medicine, provision of medicines and medical information management are big business. There are deep, inherent tensions and potential for conflict between the needs and vulnerabilities of the sick, and the conduct of a large proportion of health care as a commercial activity. Every doctor in private practice spans this ethical tension each working day. Commercial organisations which provide essential health care and health goods, such as pharmaceutical companies, also tread this fine line. Industry is the largest funder of medical research and provides needed medicines and vaccines. The timelines, costs and risks of product development are substantial — around 80% of pharmaceutical and vaccine candidates which enter human clinical trials do not make it to registration, and the road to registration is formidable. An average of around a decade's preclinical research, up to 9 years' clinical development, and a highly variable but average cost of around US\$500–800 million are involved in bringing on-stream a new product that is a new entity rather than a “me-too” product.^{1–3} Coupling these realities with the benefits of global reach to access the best knowledge, candidates and processes means that innovative drug and vaccine development needs big, responsive organisations with diverse skills.

But marrying the private, commercial sector with equitable and sustainable development and provision of public goods is a much broader social, political and ethical challenge. The promotional dollars the pharmaceutical industry spends can have clear benefits, such as appropriate use of established and new therapies, encouraging best practice and contributing to policy development. However, the many billions of dollars spent each year in promotion dwarfs, by a factor of 2–3, its research and development expenditures⁴ — an issue not only for the industry but for all of us in terms of distorted priorities and large opportunity costs.

Research in this issue of the Journal suggests that there are serious issues regarding the complex relationship between commercial health care organisations and the healing professions, and regulation of this relationship. Harvey and colleagues (*page 75*) demonstrate potential breaches of compliance with the Medicines Australia Code of Conduct in many pharmaceutical advertisements placed within the most widely used general practice prescribing software.⁵ This Code is the benchmark for the pharmaceutical industry's marketing and promotional activities in Australia, including its interactions with health professionals, and adherence to it is solely the responsibility of pharmaceutical companies. Some of the criteria used in the study were subjective (eg, legibility, inadequate time for comprehension) or quite conservative (eg, reference to the Product Information considered present only if contained within the body of an advertisement, not adjacent to it), and analysis was not comprehensive (eg, accuracy of promotional claims was not systematically assessed). Although the proportion of all advertisements noncompliant by at least one criterion is not specified, this was a majority. The pharmaceutical industry's Code of Conduct was

first developed in 1960 and is currently in its 14th edition; newness or lack of familiarity should not apply.

The Code contains a section (3.10) on “Advertising in electronic prescribing software packages”.⁶ However, compliance with the Code is the responsibility of the pharmaceutical companies, not the software developer. Software companies have the Medical Software Industry Association Code of Practice,⁷ which refers only to the Media Council of Australia Advertising Code of Ethics. The Media Council has been replaced by the Therapeutic Goods Advertising Code Council.⁸

The thematic analysis by Harvey et al of email postings by a self-selected group of general practitioners indicates that some GPs may be perturbed by pharmaceutical advertising appearing in their clinical software. Nevertheless, the software package referred to by Harvey et al as “the only Australian prescribing software containing pharmaceutical advertisements” continues its market dominance among GPs,⁹ although other prescribing software packages are available.¹⁰ It follows that many GPs, irrespective of their opinion on the promotional material it contains, continue to use the package and tolerate pharmaceutical advertising for a complex variety of reasons. These are likely to include ease of use, cost, lack of knowledge of competitive products, reluctance to change and lack of flexibility in learning new systems, absence of standards for electronic health records, and time limitation. Ultimately, the question posed by Harvey et al as to “whether pharmaceutical advertisements in clinical software should be banned” does not revolve solely around the opinions and behaviour of GPs, already subject to a range of forces. It also turns on the ethical principles and professional standards that guide the relationship between health care professionals and their patients, the genuine willingness of powerful health care organisations to affirm and facilitate the application of these principles, along with legal and other enforcement mechanisms.

A number of recommendations flow from the findings of Harvey et al:

- All codes of conduct and other professional standards require regular review and updating, as well as implementation. As expressed by the Australian Competition and Consumer Commission in its November 2003 authorisation of the 14th edition, concern remains about the enforcement of the Code.¹¹ Sanctions for breaches are generally modest, especially in comparison with the sales revenue of many widely prescribed pharmaceuticals. During 2003–04, 41 complaints were finalised by the Code of Conduct Committee. Fines totalling \$205 000 were imposed in 12 cases (an average of \$17 083).¹¹ Corrective letters or advertisements were required in only seven cases. Sanctions could appropriately be increased, and perhaps linked to sales revenue for the product in question.
- Capping advertising expenditures across the industry, as occurs in the United Kingdom, deserves serious consideration.¹² The closer to the doctor–patient interface, the less appropriate is the presence of advertising. The doctor–patient relationship should be free of intrusion or interference. Advertising at the doctor–patient interface is at a minimum intrusive, and may

cause distraction and delay in the consultation. At worst, it may inappropriately influence prescribing and, as noted by Harvey et al, when visible on the doctor's desk during a consultation, could function as prohibited direct-to-consumer advertising of prescription products. In our view, Harvey and colleagues' recommendation that pharmaceutical promotion be eliminated from prescribing software is justified.

- Appropriate professional interactions with industry and standards for these should be part of undergraduate and post-graduate medical training programs, and Continuing Medical Education.

- All clinicians should have ready access to authoritative, independent, regularly updated, best-practice prescribing guidelines, such as *Therapeutic guidelines*,¹³ the *Australian medicines handbook*,¹⁴ *Central Australian Rural Practitioners Association standard treatment manual*¹⁵ and *Australian adverse drug reactions bulletin*.¹⁶ Such resources should be user-friendly and could appropriately be included in prescribing software.

- Doctors working in the pharmaceutical industry play a crucial role as ethical and scientific guardians and gatekeepers. They should be trained and supported in this role from inside and outside the companies, with companies unequivocally committed to developing and sustaining organisational cultures that have ethical and scientifically-based conduct and compliance with the Code at their core. All staff — especially sales and marketing staff — involved in the development, review and approval of promotional material should have compliance with the Code as individual objectives subject to performance appraisal, and should face personal sanction, such as forfeiture of bonus, for breaches of the Code for which they bear responsibility. Pharmaceutical companies should make scientific and ethical competence, and demonstrated familiarity with the Code, a condition of selecting agencies and individuals involved in developing promotional materials. Many of these recommendations are also relevant to medical software companies.

- Deficiencies described in medical software relate not only to advertising, but also to technical content, for example, in relation to quality of travel medicine information¹⁷ — more effective implementation of scientific and ethical standards, and regulation, are required. A step towards addressing these deficiencies is the evaluation and accreditation of GP clinical software packages. The work program of the General Practice Computing Group relating to the Review of Software Systems and the feasibility of a Software Supplier Accreditation Scheme¹⁸ is timely; the latter should incorporate the ethical standards, codes of practice and legal requirements for the industry.

Tilman A Ruff

Associate Professor, Nossal Institute for Global Health, Faculty of Medicine, Dentistry and Health Sciences, University of Melbourne, VIC
tar@unimelb.edu.au

Hadia Haikal-Mukhtar

General Practitioner, and Medical Educator and Lecturer, Joint Universities Centre for Education and Training in General Practice Department of General Practice, Faculty of Medicine, Dentistry and Health Sciences, University of Melbourne, VIC

Competing interests: TAR is a part-time consultant for GlaxoSmithKline Australia and GSK Biologicals. He was formerly Medical Director, Clinical R&D and Medical Affairs, GlaxoSmithKline Biologicals, Australia/New Zealand/Oceania. He has never owned any pharmaceutical industry shares. HH-M owns shares in Biotech Int.

- 1 Douglas RG. The vaccine industry. In: Plotkin SA, Orenstein WA, eds. *Vaccines*. 4th edition. Philadelphia: Saunders, 2005: 47-51.
- 2 Henry D, Lexchin J. The pharmaceutical industry as a medicines provider. *Lancet* 2002; 360: 1590-1595.
- 3 Di Masi JA, Hansen RW, Grabowski HG. The price of innovation: new estimates of drug development costs. *J Health Econ* 2003; 22: 151-185.
- 4 Angell M. Excess in the pharmaceutical industry. *CMAJ* 2004; 171: 1451-1453.
- 5 Harvey KJ, Vitry AI, Roughead E, et al. Pharmaceutical advertisements in prescribing software: an analysis. *Med J Aust* 2005; 183: 75-79.
- 6 Medicines Australia. Code of Conduct. Edition 14. Canberra: Medicines Australia Inc, 2003. Available at: http://www.medicinesaustralia.com.au/html/coc_full.asp (accessed Jun 2005).
- 7 Medical Software Industry Association. Code of Practice. Available at <http://www.msia.com.au/100137.php> (accessed Jun 2005).
- 8 Therapeutic Goods Advertising Code Council. A brief history of the TGACC. Available at: <http://www.tgacc.com.au/history.cfm> (accessed Jun 2005).
- 9 Health Communications Network. Medical Director - product details. Available at: <http://www.hcn.com.au/products/md/md.asp> (accessed Jun 2005).
- 10 The Drs Reference Site. Medical software and computing. Available at: <http://www.drsref.com.au/medsoftware.html> (accessed Jun 2005).
- 11 Medicines Australia. 2004 Code of Conduct Annual Report. Canberra: Medicines Australia Inc, 2004. Available at: http://www.medicinesaustralia.com.au/html/coc_full.asp (accessed Jun 2005).
- 12 Collier J, Iheanacho I. The pharmaceutical industry as an informant. *Lancet* 2002; 360: 1405-1409.
- 13 Therapeutic guidelines. Melbourne: Therapeutic Guidelines Ltd, 2005.
- 14 Australian medicines handbook. Adelaide: Australian Medicines Handbook Pty Ltd, 2005.
- 15 Central Australian Rural Practitioners Association. CARPA standard treatment manual. 4th ed. Alice Springs: CARPA, 2003.
- 16 Adverse Drug Reactions Advisory Committee. Australian adverse drug reactions bulletin. Canberra: Therapeutic Goods Administration, 2005. Available at: <http://www.tga.gov.au/adr/aadrb.htm> (accessed Jun 2005).
- 17 Yung A, Ruff T, Torresi J, et al. Manual of travel medicine. 2nd ed. Melbourne: IP Communications, 2005: 305.
- 18 General Practice Computing Group. GP IM/IT Work Program Phase One. Available at: <http://www.gpcg.org/projects/Current-Projects.html> (accessed Jun 2005). □