

EDITORIAL

The secrecy of drug regulatory information

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(*Aust Prescr* 2002;25:78–9)

Recent Australian legislation has reinforced the community's desire to preserve the privacy of personal information, as far as this is compatible with the public good. Yet the community has a desire for more 'open' government and demands increased public access to information held by government. However, some of this information may have been supplied to the government in confidence. Can a satisfactory balance be found between these sometimes competing desires?

Government decisions on the marketing and subsidy of drugs depend on the assessment of data provided by the pharmaceutical industry. These data are largely 'commercial-in-confidence'. Clinical trials and other data are evaluated within the Therapeutic Goods Administration (TGA), or externally, before a new drug can be approved in Australia. The evaluations, and the TGA's recommendation based on them, are assessed by the Australian Drug Evaluation Committee (ADEC) which then recommends to the Minister for Health which drug should be approved. Unlike the situation which applies for regulatory bodies in certain overseas

countries*, virtually none of the information held by the TGA is currently made available publicly. Much of it will also never appear in the medical literature. The cost-effectiveness data considered by the Pharmaceutical Benefits Advisory Committee (PBAC), when recommending that a drug be listed on the Pharmaceutical Benefits Scheme (PBS), are also secret.¹

Would there be advantages for the community if the drug regulatory information held by government was more widely available? The evaluations, the TGA's recommendation, and the ADEC and PBAC assessments would provide an extensive and balanced source of information about a new drug. Their availability should ultimately result in better therapeutic practice, and the Australian drug regulatory process would be more transparent. Scientifically valid information concerning trials with unfavourable outcomes would be available. These negative studies currently rarely reach the public domain. Toxicological data about drugs which have been rejected for marketing would provide a valuable additional resource for predicting, on the basis of analogy, potential problems with similar drugs. Additionally, there is an ethical consideration. Should information be allowed to remain secret, when its wider availability could prevent the unnecessary repetition of studies that are likely to have negative or otherwise unfavourable outcomes? Resources would be saved and animals and human participants would be spared pointless and perhaps hazardous procedures.

Would there be disadvantages for those who currently expect that the information will remain secret? Some disadvantages for the pharmaceutical industry are obvious. The knowledge would put competitors in a stronger position, and at an earlier stage. Some item of knowledge, missed or ignored by the original owners of the information, might spark an idea which is ultimately of great commercial advantage to someone else. The original investigators who produced the pharmaceutical industry's data may find that the information was in the public domain before they had published it in the scientific literature. This might deter the better investigators from working in drug development. Evaluators of drug regulatory data, if identified, could be exposed to various external pressures. The staff of the TGA and members of ADEC and PBAC might also face increased public criticism of their recommendations.

* New drug information is available from the web sites of the US Food and Drug Administration (www.fda.gov) and the European Medicines Evaluation Agency (www.emea.eu.int).

In this issue...

There has been recent debate about increasing the transparency of the Pharmaceutical Benefits Advisory Committee. *Australian Prescriber* has previously discussed the need to know what lies behind the decision to subsidise a drug, but Mervyn Eadie reminds us that the evidence to support the marketing of a drug in Australia is also kept secret. Much of the evidence about the new drugs on page 94 is not in the public domain.

Some old drugs, such as warfarin, may have had difficulty in meeting modern drug regulatory standards. Warfarin has serious adverse effects and Lye Lin Ho and Timothy Brighton warn us about the risks of prescribing it with an antiplatelet drug.

Cats feature in two articles. Pet hair is a common cause of perennial respiratory symptoms and Richard O'Brien tells us which test to use if a clinical suspicion of allergy needs to be confirmed. Cats are the definitive host for *Toxoplasma gondii* and Peter McCluskey suggests what treatment to use when the parasite invades the eye.

Can some reconciliation be achieved between the potential public benefit available from the release of currently confidential drug regulatory information, and the understandable commercial and possibly individual wish for continued secrecy of this information? The names of the ADEC members are already public knowledge and the identity of evaluators could be concealed when their evaluations were released. It would be no bad thing if investigators, and the pharmaceutical industry, expedited the publication of original data in the scientific literature.

From the commercial-in-confidence standpoint, the timing of the public availability of governmental-held information would be critical. The pharmaceutical industry might have relatively little problem with information becoming publicly available 20 to 30 years after it was lodged with government, yet its immediate public availability appears to be unacceptable to the industry in Australia. Some mutually agreed intermediate

position might be achieved. Perhaps pharmacological and clinical data could be released after PBS listing (a drug in Australia is unlikely to be widely used without such listing), or a certain time after ADEC has recommended its approval. The release of formulation data could be deferred until expiry of the drug's patent, or later, so that generic manufacturers were not advantaged. In all such matters, Australia would need to act in co-ordination with other nations.

Surely there is a case that the potential community benefit, and also ethical considerations, require that better use should be made of the treasure trove of drug information that government and industry in Australia currently keep secret?

REFERENCE

1. Marley J. Cost-effectiveness: the need to know. *Aust Prescr* 1996;19:58-9.
Professor Eadie was chairman of ADEC from 1985 to 1993.

Letters

Letters, which may not necessarily be published in full, should be restricted to not more than 250 words. When relevant, comment on the letter is sought from the author. Due to production schedules, it is normally not possible to publish letters received in response to material appearing in a particular issue earlier than the second or third subsequent issue.

Search engines

Editor, – I read with interest *Australian Prescriber* Vol 25 No 1, 2002. In particular the letters section caught my attention. The comment on the search for information on immunisation stated that information retrieval was limited by the indexing of the databases and by databases being overburdened by too much content.

In fact the problem may simply rest with the manner in which the web page was set up. Keywords and key phrases are important factors in being found by a search engine. A search engine (e.g. Google, Lycos, Excite) is like a librarian that selects certain web pages in response to a search request according to the search engine's own criteria. Search engines rank web pages according to keywords or phrases:

- in the title
- in headings
- in the body text
- in the metatags provided for every web page as the source code or document code. You can access this code by going into 'View' on the menu bar of the browser (e.g. Netscape, Windows Explorer). This code gives instructions to browsers and search engines. It is written in HTML (Hypertext Markup Language).
- in the hyperlinks (links the reader can click on to go to other pages)
- in the URL and other tags.

How you place your keywords is integral to how easily your web site is found.

It is possible that the Webmaster of the Department of Health and Ageing did not consider 'vaccination' and 'guidelines' to be significant keywords and did not place them in a

prominent position in the necessary sections. Perhaps the computing expert simply needs to have further consultation with the content expert about essential keywords or phrases in order to remove any barriers to accessing the very important database about immunisation.

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Does pethidine still have a place in therapy?

Editor, – We read with interest the article 'Does pethidine still have a place in therapy?' (*Aust Prescr* 2002;25:12-3). The author concluded that pethidine 'can be used to treat acute pain for a short time' and suggests that it results in smaller increases in common bile duct pressures as well as less urinary retention and constipation when compared with morphine.

Our Drug Committee has debated whether or not there was a place for pethidine in acute pain management. We were not convinced that there was any good evidence to suggest that repeated doses (required if analgesia is to be maintained) resulted in clinically significant reductions in bile duct pressures compared with morphine. There was also no good evidence comparing effects on urinary retention and constipation. However, it is known that signs consistent with norpethidine toxicity can be seen within 24 hours of starting treatment with pethidine if higher doses are required.

A review of the use of opioids in pain management also expressed concerns about pethidine's continuing use.¹ It states 'Since use of pethidine is not associated with any