Editorial

Time for transparency at the TGA

Agnes Vitry, Senior Research Fellow, Quality Use of Medicines and Pharmacy Research Centre, University of South Australia, Adelaide

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Full transparency in pharmaceutical regulation is crucial. There are several reasons why we need access to drug regulatory information about prescription medicines.

First, access to clinical and pharmaceutical data allows health professionals, independent researchers and information providers to review the data to make sure that published findings do not misrepresent the efficacy and safety of medicines. The withdrawal of rofecoxib has shown the importance of scrutinising registration data in order to identify safety problems early. Another example is the recent review of antidepressant trials registered with the US Food and Drug Administration. It showed that antidepressant trials with negative results were much less likely to be published than trials with positive results.[1]

Second, regulatory decisions involve value judgements in balancing multiple data about the benefits and harms of medicines.[2] These value judgements should be disclosed with the reasons for regulatory decisions. This would help people to make their own choices about whether the medicines are suitable for them.

Third, as with many medicines agencies, the Therapeutic Goods Administration (TGA) is now totally financed from fees paid by pharmaceutical companies. Its decisions will be increasingly subject to public scrutiny because of the worry about conflicts of interest. Transparency in pharmaceutical policy making is required to maintain public trust in the TGA.

In this issue …

The Therapeutic Goods Administration (TGA) is a highly regarded organisation. Although it produces detailed evaluations of new drugs, it is prevented from releasing this information. The TGA is currently considering how it could share more of its knowledge. This is a welcome move and Agnes Vitry explains why transparency is important.

Aravind Ravi Kumar talks about transparency of a different kind in his review of positron emission tomography. Specialist imaging is not needed to diagnose attention deficit hyperactivity disorders, but Alasdair Vance says our understanding of the aetiology is increasing.

Three years ago, the Editorial Executive Committee of *Australian Prescriber* published a call for increased transparency in the regulation of prescription medicines.[3] What has happened since then? A recent study compared the provision of information on the websites of national drug regulatory agencies.[4] It found that the TGA ranked among the most 'secret' of the agencies. Assessment reports for new medicines, lists of refused or cancelled marketing authorisations, minutes of advisory meetings, and reports submitted by drug companies are not available publicly in Australia.

Although 'To be as transparent as possible in our processes and decisions' was a key priority announced in the TGA's 2006–2008 strategic plan, a 2006 report commissioned by the TGA made minimalist recommendations in this regard.[5] The main recommendation for increasing the level of transparency involved publishing a short summary of the advice of the Australian Drug Evaluation Committee (ADEC) on the approval of new drugs. The option of publishing full minutes of the ADEC meetings was not supported by the pharmaceutical industry. The option of providing edited evaluation reports on new drugs was also rejected as it was 'inappropriate' and 'would result in increased confusion and anxiety amongst consumers'. However, in 2008 the TGA is considering some regulatory reforms which will include increased transparency.[6]

As regards the provision of product information and consumer medicine information (CMI), the task has been entirely left to other groups with no assurance that this information is comprehensive or regularly updated. Putting the approved product information and CMI on the TGA website (the option that was most favoured by all stakeholders during an extensive public consultation) was initially rejected by the TGA because it was said to be the most expensive option and there was a perceived risk of litigation. However, the recent reforms propose publishing the information on the TGA website.

In the meantime, other international agencies have moved towards greater transparency. In 2004, a European directive required that national regulatory authorities make meeting records, assessment reports of marketing authorisations as well as the underlying reasons for decisions publicly accessible.[7] In the USA, which already has by far the most open regulatory agency, a new law (the Food and Drug Administration Amendments Act) requires that the results of all clinical trials, except phase I drug trials, be posted in a registry from September 2008.

This is not to say that the situation in other countries is optimal; a lot remains to be done. There are also valid exceptions to transparency such as manufacturing information that needs to be protected. However, the current Australian situation, in which the data used to make decisions and the reasons behind these decisions remain secret, is no longer tenable. Full transparency is required at all steps in the marketing of medicines, from publication of the trial protocols to assessment of the data by the TGA. It includes public disclosure of the potential conflicts of interest of all external experts involved in the TGA advisory committees. It concerns not only positive decisions, but also negative decisions, for example when a marketing application for a drug has been refused.

Transparency requires political will and leadership. This is an active process that needs to be adequately resourced. While drug companies spend millions of dollars on promotion of medicines each year, it seems paradoxical that limited funding and cost recovery could prevent the TGA from appropriately informing the Australian public. The TGA urgently needs to take steps to improve its transparency if it wants to retain its credibility not only with the Australian public and health professionals but also on the international scene.

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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.

Varenicline and quitting

Editor, – While Mark Ragg (Aust Prescr 2008;31:60–2) is technically correct in saying that most people quit by themselves[1], he overlooks the more important point that the unaided quit rate is around 5–7%.[2] It is not surprising that quitting is so difficult. Nicotine addiction is a chronic relapsing condition with a relapse curve that resembles that for heroin addiction.[3] Popularity of strategy should not be confused with likelihood of success.

Most smokers find it very difficult to quit and are reluctant to seek help.[4] It is difficult to capture the true natural history of smoking cessation in a study.[1] Studies that have done so show that less than 2% of smokers quit per year.[5] On average, smokers make between five and eight attempts before they are successful despite expressing strong interest in quitting.[6]

In a survey, 92% of smokers used only one strategy to quit.[1] The majority of published evidence recommends the use of a combination of strategies that include some form of pharmacotherapy if nicotine dependent, referral to a proactive callback program like the Quitline, enlisting support, and addressing motivation and confidence.[7,8,9,10] This is reflected in a reduction in the numbers needed to treat as selected strategies are combined. For example, eight smokers need to be treated with varenicline and supportive counselling to get one long-term quitter. Smokers shouldn't have to 'go it alone'. Health professionals should help them to increase their chance of success.

John Litt
Department of General Practice
Flinders University
Adelaide

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