

How we write about new drugs

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The 'New drugs' section of *Australian Prescriber* has been a consistent feature of the journal since 1975. Health professionals value its brief, unbiased comments about recently marketed products. These comments will continue to be published, but following the acquisition of *Australian Prescriber* by the National Prescribing Service^{1,2} there have been some changes in the way the 'New drugs' section is prepared.

When the journal was published by the Department of Health, the editors had access to the drug evaluations prepared by the Therapeutic Goods Administration. As the editors were usually senior medical advisers to the Drug Evaluation Branch they were able to see all the (published and unpublished) research evidence submitted by pharmaceutical companies applying to have their drugs approved for use in Australia.

As the National Prescribing Service operates independently of the Department of Health and Ageing, it does not have access to the research evidence held by the Therapeutic Goods Administration. This is because the applications containing the evidence are considered to be 'commercial-in-confidence'.³

To overcome this barrier *Australian Prescriber* is increasingly using information published by the European Medicines Evaluation Agency and the US Food and Drug Administration. Although it would be better to have access to Australian assessments of new drugs, these overseas regulatory authorities currently have less restriction on making information available.

The 'New drugs' comments in *Australian Prescriber* continue to draw information from the medical literature and databases such as the Cochrane Collaboration. Although only a few key references are published in the 'New drugs' section many more are considered when preparing the comments. When

dealing with published clinical trials there is, however, a risk that only the trials with positive results have been published.⁴

Sometimes the results of an unpublished trial can appear in the product information for the drug. The product information also contains helpful information about a drug's pharmacology and adverse effects.

The Editor prepares draft 'New drugs' comments using the available sources of information. These drafts are then considered by the Editorial Executive Committee. This peer-review process helps to ensure the comments are correct and relevant to clinicians. The 'New drugs' comments are not intended to be a comprehensive review of a product, but should help health professionals decide if they need to find out more information for their own practices.

Now that new drugs are often reported by the general media before health professionals are informed about them, *Australian Prescriber* is speeding up the dissemination of its 'New drugs' comments. Instead of waiting for the next issue to review a new product, a 'New drug' comment will be published on the *Australian Prescriber* web site as soon as the drug is marketed. This will help to ensure *Australian Prescriber* remains a helpful and trusted source of drug information.

REFERENCES

1. The Executive Editorial Board. Changes at *Australian Prescriber*. *Aust Prescr* 2002;25:2.
2. Phillips S. The National Prescribing Service and *Australian Prescriber*. *Aust Prescr* 2002;25:26-7.
3. Eadie MJ. The secrecy of drug regulatory information. *Aust Prescr* 2002;25:78-9.
4. Hall RC. Published information on drugs – the tip of the iceberg? *Aust Prescr* 1991;14:22-3.

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 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.

Amisulpride

Solian (Sanofi-Synthelabo)

100 mg, 200 mg and 400 mg film-coated tablets

Approved indication: schizophrenia

Australian Medicines Handbook section 18.2

Amisulpride is a benzamide antipsychotic which antagonises dopamine receptors. It binds to the D₂ and D₃ dopamine receptors, but has little affinity for muscarinic or serotonin receptors. This pattern of activity differs from that seen with atypical antipsychotics.

The oral formulation has a bioavailability of 48%, but is not extensively metabolised. Most of the drug is excreted unchanged, with an elimination half-life of 12 hours. Clearance is reduced in patients with renal impairment.

A meta-analysis of trials which compared amisulpride with conventional antipsychotic drugs found that it had greater efficacy in patients with acute schizophrenia.¹ Amisulpride has been compared with haloperidol in patients with chronic schizophrenia. After one year, a study of 60 inpatients found no significant difference in overall efficacy, but there was a trend suggesting amisulpride may be more beneficial for