The CRP has stated, 'Regulation 9 orders issued by TGA for advertising complaint determinations finalised by the Panel after 1 November 2010 will be publicised on the TGA's website'. In fact, since November 2010 at least 88 complaints have been referred to the TGA by the CRP because of non-compliance, of which only 14 have an 'outcome' recorded on the TGA website. In response to a query about this matter the TGA said, 'As part of the implementation of the Transparency Review, consideration is being given to publishing the outcome of all advertising complaint investigations in the future'.

Australian Public Assessment Reports for prescription medicines (AusPARs) summarise the evaluation process that led the TGA to approve or not approve a drug for use in Australia. They can be found using the search function. There has been some concern that since AusPARs were introduced the TGA has stopped publishing the resolutions of the Advisory Committee on Prescription Medicines. Another problem is that a drug can appear on the Australian market before the AusPAR is available.

In short, a good start has been made, and there are many more reforms to come. The implementation of some reforms will be protracted as regulatory impact statements and amendments to the *Therapeutic Goods Act 1989* or TGA regulations will be required.

Dr Harvey has represented consumer organisations on the TGA Transparency Review Panel, the TGA informal working group on the regulation of complementary medicines, and the Working Group on Promotion of Therapeutic Products, Department of Health and Ageing.

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Letters to the Editor

Safe and effective use of lithium

Editor, – Gin Malhi, Michelle Tanious, Danielle Bargh, Pritha Das and Michael Berk have provided an excellent article on the safe and effective use of lithium (Aust Prescr 2013;36:18–21). They make reference to a 'sustained slow-release formulation which may be better tolerated by some patients'. Only two of four lithium-containing compounds listed in MIMS are suitable for lithium treatment. These are lithium carbonate and are listed as Lithicarb and Quilonum SR. Lithicarb in a new gluten-free formulation is not sustained release. Quilonum SR is commonly believed to be a sustained-release preparation, but it is not. The manufacturer states 'While Quilonum SR tablets are designed to reduce fluctuations in plasma lithium concentrations, the formulation is not prolonged release in the usual sense'. Lithicarb is a 250 mg scored tablet readily permitting fine tuning of dose, but normally given twice a day. Quilonum SR tablets should be given every 12 hours as detailed in the product information. The 450 mg preparation may be suitable for many patients, but the larger dose means finetuning the dose may be difficult. At present we have no sustained-release lithium preparation in Australia.

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Melbourne

The Editorial Executive Committee welcomes letters, which should be less than 250 words. Before a decision to publish is made, letters which refer to a published article may be sent to the author for a response. Any letter may be sent to an expert for comment. Letters are usually published together with their responses or comments in the same issue. The Committee screens out discourteous, inaccurate or libellous statements and sub-edits letters before publication. Authors are required to declare any conflicts of interest.The Committee's decision on publication is final.

LETTERS

Gin Malhi, an author of the article, comments:

We are grateful to Professor Tiller for pointing out the lack of availability of a sustained-release lithium preparation in Australia. This underscores our primary concern that lithium is being 'forgotten' and that because of its declining use clinical experience is being lost. A key reason for this is its relatively modest promotion by pharmaceutical companies, possibly explaining the limited variety of formulations that are available.

Therefore coupled with exaggerated concerns regarding its safety profile, it is perhaps not surprising that lithium is prescribed less than other treatments. However, it is important to reiterate that lithium remains the gold standard among mood stabilisers for bipolar disorder and that in addition to its prophylactic effects with respect to mood, it is also antisuicidal and neuroprotective.

Prescription copayments and opioid substitution therapy

Editor, – One issue not mentioned by Michael Ortiz in his editorial on prescription copayments (Aust Prescr 2013;36:2-3) is the weekly fee paid by people on the Opioid Substitution Program for their methadone or buprenorphine. This program is intended for people who have an opioid addiction. The medicine itself is fully funded by government, but the pharmacy charges a dispensing fee of around $35 per week to compensate for the time and diligence required to dispense the medicine and monitor compliance.

This fee is not offset by the safety net and is about $1800 per year. No other sector of the community is required to pay this much for medicines. It is cheaper than a heroin habit, but the savings to government and the community are huge in terms of policing illegal drugs, crime reduction, court and imprisonment costs, and hepatitis C rates and treatment.

As a prescriber in the program, I see first-hand the benefits for all opioid addictions including the abuse of prescription opioids. These people can now lead reasonably normal lives and contribute to their community.

The case for generous government reimbursement of the pharmacist dispensing fee is compelling.

Tony Balint
GP
Blue Horizon Clinic
Yarra Junction, Vic.

FURTHER READING

McDonough M. Opioid treatment of opioid addiction. Aust Prescr 2013;36:83-7.

Urinary drug screening

Editor, – The article by Dimitri Gerostamoulos (Aust Prescr 2013;36:62-4) omits to mention the limitations of urinary drug screening.

Urinary drug screening does not identify the use of synthetic narcotics such as pethidine and fentanyl, a class of prescription drugs which are often abused. Most doctors do not know this.

These drugs can be detected and confirmed by hair analysis which is not mentioned in the article.

Sometimes incomplete coverage of the important issues related to an article can, by virtue of their omission, be problematic.

Mark Schulberg
GP
Mediscreen Clinic
Hawthorn East, Vic.

Dimitri Gerostamoulos, the author of the article, comments:

The comments from Dr Schulberg are valid in that some drugs will not be picked up by standard urine testing. However, as stated in the article 'Consultation with the laboratory is useful to find out which compounds can be tested as well as for interpretation of negative or positive findings'. A practitioner cannot just assume that all substances can be tested in urine.

Hair analysis has its own issues and cannot compare with the immediacy of urine testing for rapid detection of drugs. It is useful for retrospective drug analysis in cases where the normal avenues of blood, oral fluid and urine testing are not available.