

Despite these developments, the TGA remained publicly silent and the defamation action against Dr Harvey continued. In August 2011 the case was dismissed in the Supreme Court of New South Wales. Although costs were awarded they are unlikely to be recovered from a company in liquidation. However, this was not the end of Dr Harvey's ordeal as the company's director launched a new defamation action in the Supreme Court of Queensland. This time damages of over \$1 million were sought, but the case was eventually dismissed in February 2012.

The regulation of complementary medicines in Australia appears to be weak. The system should at least protect the public. Inaction in this case enabled false and misleading advertising to continue. The TGA may well have been working behind the scenes, but its strategy of silence and secrecy gave the appearance that it was doing nothing. The Complaints Resolution Panel had in fact recommended that the TGA consider cancelling the listing of SensaSlim on the Australian Register of Therapeutic Goods, but this did not occur until December 2011.

It is unacceptable that a health professional can face financial ruin for informing the government's medicines regulator that its rules are being broken.

There may be dangerous precedents here. Could reporting adverse effects be potentially defamatory?

Clearly there needs to be some protection for people who make genuine complaints about medicines. As the TGA prefers a 'light touch' when regulating complementary medicines, there needs to be a robust and timely complaints procedure with effective sanctions. If the medicines industry does not want more regulation, then it too should take an active role in identifying and reporting rogue operators to the TGA. Otherwise complementary medicines could be seen as fertile ground for pushing placebos to enrich entrepreneurs, charlatans and crooks. <

Conflict of interest: none declared

Could reporting adverse effects be potentially defamatory?

REFERENCES

1. Complaints Resolution Panel. Therapeutic Products Advertising Complaints. www.tgacrp.com.au/index.cfm [cited 2012 Mar 6]
2. Sweet M. Doctor who complained to regulator about weight loss product is sued for libel. *BMJ* 2011;342:d3728.
3. McIlwraith I, Medew J. Dodgy websites push diet spray. *The Age*. 2011 June 22. www.theage.com.au/national/dodgy-websites-push-diet-spray-20110621-1gdmu.html [cited 2012 Mar 6]
4. Australian Competition and Consumer Commission. ACCC takes court action against SensaSlim for alleged misleading claims. 2011. www.accc.gov.au/content/index.phtml?itemId=998494 [cited 2012 Mar 6]

Letters to the Editor

Medicines labelling

Editor, - I have major concerns about Ropivacaine Sandoz, which has appeared in several private hospitals.

This product is labelled ropivacaine 150 mg/20 mL. Nowhere on the packet or the ampoule does it say that this is equivalent to 0.75% ropivacaine, or 7.5 mg/mL. When ropivacaine was first marketed about ten years ago it was marketed as 2 mg/mL, 7.5 mg/mL or 10 mg/mL strengths. More recently this was changed to percent labelling (0.2%, 0.75% and 1%) to make it consistent with all the other available local anaesthetics.

My concern is that nowhere on the packaging does it say that this is 0.75% ropivacaine or 7.5 mg/mL. It only has the total amount of milligrams in the bottle.

This is a great potential source of confusion and particularly if ropivacaine is being used on the ward. Many nurses have expressed to me their confusion when looking for the requested local anaesthetic.

I think the labelling is inadequate and unsafe. It is clearly a potential source of medication error.

Paul Herreen
Specialist anaesthetist
Calvary Wakefield Hospital
Goodwood, SA

Editor, - There are two aspects of prescriptions that can cause problems to patients, pharmacy staff and doctors.

Firstly, repeat authorisation forms are confusing - all the information is there, but there are three boxes



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of information for the patient. Number of repeats remaining is sometimes not interpreted correctly, perhaps because the 'Number of supplies left' line is overshadowed by the bar code and the patient only reads the information in the two boxes above.

Patients ask for a repeat prescription when there is still one repeat outstanding, or are occasionally directed by pharmacy staff to ask for a repeat. If the form was altered so that it stated (1) the original prescription details – and put in the total number authorised (not just repeats), and (2) the number of supplies left – and leave the space for the bar code free, I think there would be no confusion.

Secondly it is frustrating, and potentially dangerous for patients that the highlighted name on dispensed medications and the repeat prescription is the trade name, with the generic name in smaller print.

We used to know the trade names, but now there are so many it is impossible to know them all. For prescribers, it is a time consuming process to try to work out what is being requested – and the worst situation by far is the Webster pack system. It is dangerous for patients. For example, recently a patient was taking the same medication twice because of different trade names.

It would be safer and so much more logical if the large print name was the generic name and the trade name was in smaller print.

John Jackson
General practitioner
Ipswich, Qld

Daniel Lalor, author of the article 'Medicines labelling' (Aust Prescr 2011;34:136-8), comments:



Drs Herreen and Jackson provide some excellent examples of how medicines labelling and packaging can be detrimental to the quality use of medicines.

Dr Herreen has demonstrated to us the difficulties that health professionals have when product strength is expressed in a non-standardised way. The use of ratios and percentages to express the strength of a medicine has long been known to cause confusion. Doctors make considerably more calculation errors when concentrations are expressed as ratios or percentages rather than as milligrams per millilitre (mg/mL).^{1,2}

Simulation studies have shown that expressing a dose as concentration (mg/mL), quantity (total mg in packaging) and volume (total volume in packaging) can improve safety.³ Standardising the way in which

strength is presented should be strongly considered as a mechanism to improve safety.

I firmly support Dr Jackson's call for an increased prominence of the active ingredient on all medicines labelling, as do many consumers and other healthcare professionals. Standardising the prominence and position of medicines names on manufacturers' labelling as well as pharmacy applied labels, would also assist consumers in identifying their medicines and prevent medication misadventure.

These issues, and others, must be considered as part of the current Therapeutic Goods Administration medicines labelling review process.

REFERENCES

1. Wheeler SJ, Wheeler DW. Dose calculation and medication error - why are we still weakened by strengths? *Eur J Anaesthesiol* 2004;21:929-31.
2. Simpson CM, Keijzers B, Lind JF. A survey of drug-dose calculation skills of Australian tertiary hospital doctors. *Med J Aust* 2009;190:117-20.
3. Garnerin P, Perneger T, Chopard P, Arès M, Baalbaki R, Bonnabry P, et al. Drug selection errors in relation to medication labels: a simulation study. *Anaesthesia* 2007;62:1090-4.

Lanthanum carbonate

Editor, – Shire Australia wishes to update the information about lanthanum carbonate that was published when the drug was new (New drugs, *Aust Prescr* 2006;29:54-5). Much has changed over the last six years and many more studies have been published, including long-term studies and a head-to-head comparison with sevelamer hydrochloride.

Given the current body of evidence, there appears no reason to suggest that lanthanum carbonate should not be used beyond two years. In fact, the Therapeutic Goods Administration considered the body of evidence in 2007 and made a decision to remove the two-year restriction. Treatment of patients for up to six years has not shown change in the harm-benefit profile.

Lanthanum carbonate is an effective binder of dietary phosphate for use in controlling the hyperphosphataemia of patients with chronic kidney disease on dialysis. Studies have shown that lanthanum carbonate can reliably be used to reduce serum phosphate concentrations and to effectively maintain control of serum phosphate during long-term use, up to six years.^{1,2} Maintenance of target phosphate concentrations has been shown to be similar between lanthanum, calcium phosphate binders¹ and sevelamer hydrochloride.³

To date, 6297 patients have been exposed to lanthanum carbonate in Shire-sponsored clinical studies. In addition 5020 patients have been exposed for up to five years in two observational studies. Cumulatively the estimated worldwide patient exposure to lanthanum is 225 224 person-years treatment. The most commonly reported adverse drug reactions are headache, hypocalcaemia and gastrointestinal reactions (for example abdominal pain, diarrhoea, nausea and vomiting). Gastrointestinal reactions can be minimised by taking the tablets with food.

Results from long-term studies demonstrated that bone lanthanum concentration had no apparent effect on bone health (assessment has considered bone biopsy) or treatment outcome for up to 4.5 years.¹ There are no clinical data examining the potential deposition of lanthanum in other tissues.

Beata Niechoda
 Medical Director
 Shire Australia
 Sydney

REFERENCES

1. Fosrenol Product Information. Shire Australia Pty Ltd. 2011. www.shireaustralia.com.au/images/Fosrenol%20PI%206Apr2011%20finalised.pdf [cited 2012 Mar 6]
2. Hutchison AJ, Barnett ME, Krause R, Kwan JTC, Siami GA. Long-term efficacy and safety profile of lanthanum carbonate: results for up to 6 years of treatment. *Nephron Clin Pract* 2008;110:c15-23.
3. Sprague SM, Ross EA, Nath SD, Zhang P, Pratt RD, Krause R. Lanthanum carbonate vs. sevelamer hydrochloride for the reduction of serum phosphorus in hemodialysis patients: a crossover study. *Clin Nephrol* 2009;72:252-8.


New drugs for osteoporosis

Editor, – Professor Ebeling’s article (*Aust Prescr* 2011;34:176-81) provided a succinct summary of the current available pharmacological interventions for osteoporosis.

However, with regard to Pharmaceutical Benefits Scheme-listed indications for osteoporosis drugs (Table of the article), alendronate is now indicated for patients (aged 70 or older) with a T-score of -2.5 or less (www.pbs.gov.au/medicine/item/8511Y).

Kevin Kwan
 Registrar, Geriatric medicine
 Nedlands, WA

Professor Peter Ebeling, author of the article, comments:

 I thank Dr Kwan for the additional information. This was not available when the article was finalised for publication.

Thromboprophylaxis and elective surgery


Editor, – Thank you for the informative and detailed article on antiplatelets, anticoagulants and elective surgery (*Aust Prescr* 2011;34:139-43).

The authors noted that patients requiring a biopsy during an elective endoscopy should follow the recommendations for those having general surgery. However, patients who do not require a biopsy during an endoscopy should follow the recommendations for dental, dermatological and ophthalmological procedures. In practice, it is usually not known before a colonoscopy whether or not a polypectomy will be required, and some gastroenterologists perform biopsies on most or all patients having elective endoscopies. I therefore presume the take-home message is to treat most patients according to the recommendations applying to general surgery.

I was also interested to read that warfarin could be resumed on the evening of the procedure, but at the usual maintenance dose with no loading dose. Why is a loading dose not advised? Having a patient at a sub-therapeutic INR level for a relatively prolonged period after a procedure can complicate the logistics of their care, particularly if they are unable or unwilling to self-administer low molecular weight heparin, and live in a rural area.

Kylie Fardell
 General practitioner
 Cooma, NSW

Dr Merriman and Dr Tran, authors of the article, comment:

 Thank you for your comment on our article. You are correct – if it is likely that a biopsy is to be taken or a polyp removed during an endoscopic procedure, then we would advise following the recommendations for general surgery. When resuming warfarin after such procedures, for atrial fibrillation one would usually commence this at the usual maintenance dose as these patients are not generally loaded with higher doses even when first started on warfarin. For patients at higher risk, such as atrial fibrillation with prior thrombosis, mechanical heart valves or previous deep vein thrombosis or pulmonary embolism, one could start with a higher loading dose using a warfarin nomogram and bridge with low molecular weight heparin as per our guideline.

Atrial fibrillation

Editor, – We read with interest the article ‘Current management of atrial fibrillation’ (Aust Prescr 2011;34:100-4). We commend the authors for their comprehensive overview of the topic and for presenting some pertinent issues relating to atrial fibrillation and stroke medicine.

From a stroke perspective, atrial fibrillation is not only a major risk factor for future stroke – it is an independent predictive factor for severe stroke and early death in patients with acute ischaemic infarction.¹ Data from a large Japanese stroke registry demonstrated that acute ischaemic stroke severity was significantly higher in patients with atrial fibrillation compared to those without atrial fibrillation (median National Institutes of Health Stroke Scale score 12 vs 5, $p < 0.0001$). Mortality rate within 28 days from admission was also higher in patients with atrial fibrillation than for those without atrial fibrillation (11.3% vs 3.4%, $p < 0.0001$).

It is important to emphasise that transient ischaemic attacks contribute two points to CHADS₂ scoring, and so even in the absence of any other CHADS₂ risk factors, a transient ischaemic attack is a compelling reason to commence anticoagulation in a patient with atrial fibrillation.

It is significant to note that a history of falls is not a component of the HASBLED score. Clinicians commonly elect not to commence warfarin if the patient has a history of falls. The evidence supporting this clinical decision is lacking. In patients with atrial fibrillation and at risk of falls, the data suggest that stroke risk reduction with anticoagulation outweighs haemorrhage risk.²

The new oral inhibitors of thrombin and factor Xa have other limitations, including adherence and the lack of a test of anticoagulant activity.³ It remains to be seen how these drugs will affect thrombolysis decisions. An absolute contraindication to thrombolysis may have to apply to any patient thought to be taking dabigatran, due to the inability to quantify its anticoagulant effects and the unknown risk associated with thrombolysis in patients on dabigatran therapy.

Doron Hickey
Intern

Benjamin Tsang
Registrar/advanced trainee in neurology
Stroke Unit, Austin Hospital
Heidelberg, Vic.

REFERENCES

1. Kimura K, Minematsu K, Yamaguchi T; Japan Multicenter Stroke Investigators' Collaboration (J-MUSIC). Atrial fibrillation as a predictive factor for severe stroke and early death in 15,831 patients with acute ischaemic stroke. *J Neurol Neurosurg Psychiatry* 2005;76:679-83.
2. Sellers MB, Newby LK. Atrial fibrillation, anticoagulation, fall risk, and outcomes in elderly patients. *Am Heart J* 2011;161:241-6.
3. Hankey GJ, Eikelboom JW. Dabigatran etexilate: a new oral thrombin inhibitor. *Circulation* 2011;123:1436-50.

Dr Himabindu Samardhi, Dr Maria Santos, Dr Russell Denman, Dr Darren Walters and Dr Nick Bett, authors of the article, comment:



We thank Doron Hickey and Benjamin Tsang for their comments and agree that there is no simple overall protocol for managing patients with atrial fibrillation and a history of falls. Their individual risks have to be assessed¹ and weighed against the risk of stroke.

We are also concerned because of the lack of tests of anticoagulant activity and adherence² for patients taking factor Xa and direct thrombin inhibitors, and because drugs to reverse their effects are not routinely available.^{3,4} There is insufficient information about the risks of administering thrombolysis, unfractionated heparin, enoxaparin or glycoprotein IIb/IIIa inhibitors such as abciximab to patients on these drugs.

Since our article appeared, trials of factor Xa inhibitors for atrial fibrillation have been published.^{5,6} Further studies will be required to compare the efficacy and safety of these drugs and direct thrombin inhibitors, especially in those with renal impairment.

REFERENCES

1. Sellers MB, Newby LK. Atrial fibrillation, anticoagulation, fall risk, and outcomes in elderly patients. *Am Heart J* 2011;161:241-6.
2. Hankey GJ, Eikelboom JW. Dabigatran etexilate: a new oral thrombin inhibitor. *Circulation* 2011;123:1436-50.
3. Mega JL. A new era for anticoagulation in atrial fibrillation. *N Engl J Med* 2011;365:1052-4.
4. del Zoppo GJ, Eliasziw M. New options in anticoagulation for atrial fibrillation. *N Engl J Med* 2011;365:952-3.
5. Granger CB, Alexander JH, McMurray JJ, Lopez RD, Hylek EM, Hanna M, et al. Apixaban versus warfarin in patients with atrial fibrillation. *N Engl J Med* 2011;365:981-92.
6. Patel MR, Mahaffey KW, Garg J, Pan G, Singer DE, Hacke W, et al. Rivaroxaban versus warfarin in nonvalvular atrial fibrillation. *N Engl J Med* 2011;365:883-91.