

# encapsulate

## Welcome to 'encapsulate'

I wish to personally introduce this issue of **encapsulate** by discussing two major changes which will have an impact on private hospital pharmacy in the coming months.

Firstly, as you are no doubt aware, the **Government changes to the Pharmaceutical Benefits Scheme (PBS) are due to commence on 1<sup>st</sup> August 2008**. The reforms comprise a range of inter-connected measures:

- Price reductions on PBS listed medicines of up to 25%.
- Pharmacy and pharmaceutical wholesaler compensation arrangements.
- Streamlined authority approvals for some medicines.
- Establishment of an access to medicines working group.

As part of the reforms, the PBS is incentivising pharmacy to embrace the dispensing of premium-free medicines. Slade Pharmacy and Galen Health already encourage the use of generic medicines wherever possible and clinically appropriate. The use of a generic medicine over a brand results in lower pharmacy costs for the hospital and reduced patient costs, especially when these medications are supplied on discharge.

Going forward, generic substitution will be the greatest opportunity pharmacy has to ensure clinical services can be maintained. Given the critical role pharmacy plays in the provision of healthcare to our patients, it is important that the healthcare profession also supports generic medicines to ensure pharmacy services continue unaffected beyond the reforms.

**Further to these reforms, in the Budget on 13<sup>th</sup> May 2008, changes to funding of chemotherapy drugs were announced.**

Currently the PBS reimburses pharmacists by the number of vials opened to prepare a chemotherapy infusion. Under the new arrangements, the PBS will reimburse according to the quantity of the drug used - a per mg basis.

An additional reconstitution fee of \$40 per infusion will be paid to the pharmacy preparing the infusion. Community and Private Hospital pharmacies will also be able to claim a pharmacy mark-up based on the ex-manufacturer price of the drug.

These changes have taken the pharmacy industry by surprise. The Government did not consult the Pharmacy Guild or any other industry representatives prior to the announcement. As a result these changes have been greeted with some concern.

It is important to note that the changes are not scheduled to take effect until 1<sup>st</sup> July 2009. As an industry, we are now awaiting further details on this proposed change, and we anticipate there will be significant discussion between pharmacists and the Government to measure and understand the impact of the change in funding.

I will continue to keep you up to date on the status of both these issues.

Returning to **encapsulate**, we have chosen to focus this issue on side effects and the importance of reporting adverse drug reactions. Many medications have serious and potentially dangerous side effects, often identified from reports to the Adverse Drug Reaction Advisory Committee. With this in mind, we look at reports of concerning side effects from Pioglitazone and Zolpidem. We also cover recommendations to ensure medications are administered to patients via the correct route.

You can obtain further copies of **encapsulate** via our website - [www.slade.net.au](http://www.slade.net.au) . Please forward any comments or suggested topics for our next issue to [marketing@slade.net.au](mailto:marketing@slade.net.au) .

Regards,



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Managing Director

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## Adverse Drug Reactions

The World Health Organisation defines an adverse drug reaction as *"a response to a drug which is noxious and unintended, and which occurs at doses normally used or tested in man for the prophylaxis, diagnosis, or therapy of disease, or for the modification of physiological function"*.

An adverse drug reaction (ADR) is considered serious when it is suspected of causing death, danger to life, admission to hospital, prolongation of hospitalisation, absence from productive activity, increased investigational or treatment costs, or birth defects.

In Australia, clinical trials are used to assess the safety and efficacy of a drug prior to its registration for use. Within the clinical trial period, common ADRs may be detected. However, not all ADRs will be detected in this time. Ongoing monitoring and reporting of ADRs to the Adverse Drug Reaction Advisory Committee (ADRAC) is necessary to further develop the safety profile of medicines. ADR reporting is also an ACHS clinical indicator.

**Nurses, doctors and pharmacists play a vital role in the prevention, detection, assessment, management and reporting of ADRs.**

We must report all suspected reactions to new medicines and ADRAC Drugs of Current Interest (<http://www.tga.gov.au/adr/adrac.htm>), all suspected drug interactions, and all unexpected reactions (i.e. not consistent with product information or labelling).

If a patient has a suspected or confirmed reaction to a drug:

1. Complete all relevant documentation including the ADR report form.
2. Affix an ADR alert sticker to the medication chart and the patient record.
3. Submit the ADR report form to the relevant hospital authority.
4. Submit the ADR report form to ADRAC.

Pharmacists can assist by completing the above steps, where applicable.

**Be a life saver! Report ADRs!**

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## Medication Safety Alert: Zolpidem

Since the introduction of zolpidem to the Australian market in 1996, over 1000 adverse drug reactions have been reported to the Australian Adverse Drug Reaction Advisory Committee (ADRAC). The majority of reports have involved neurological or psychiatric reactions. Of particular interest have been reports of sleep walking, which describe inappropriate or strange automatic behaviour "while asleep", including binge eating, house painting and driving.

Side effects related to zolpidem can occur at therapeutic doses, without concomitant intake of alcohol, however alcohol heightens the risk.

Healthcare professionals must assess the risks and benefits of using zolpidem. If the benefits outweigh the risks and zolpidem is prescribed for the patient, caution should be exercised.

Patients must be counselled regarding appropriate use, side effects and strategies for getting to sleep without medicines.

For further information please refer to the recent Medication Safety Alert – Zolpidem.

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## Pioglitazone and Type 2 diabetes mellitus

Pioglitazone is a thiazolidinedione antidiabetic drug that is used as a second or third line agent in the treatment of type 2 diabetes mellitus. Pioglitazone should not be used in the treatment of type 1 diabetes mellitus.

The decision to use pioglitazone instead of insulin should be made after careful consideration of the risks and benefits of using the drug.

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Considerations include:

- Pioglitazone is contraindicated in patients who have moderate to severe heart failure.
- Pioglitazone may cause peripheral or pulmonary oedema and increase the risk of developing or exacerbating heart failure.
- A diabetic patient is already at a higher risk of developing cardiac disease or heart failure because of their condition.
- Insulin is known to reduce the risk of diabetic complications whereas the effect of pioglitazone is still unclear.
- Pioglitazone and insulin produce similar improvements in blood glucose levels
- Pioglitazone may cause worsening macular oedema, increased risk of peripheral fractures amongst women, and liver toxicity
- The long term safety profile of insulin is clearer

Pioglitazone should be commenced at a dose of 15mg per day for 6 to 8 weeks and then slowly titrated until the desired treatment effect is achieved. It is imperative that healthcare professionals are alert to the symptoms of developing heart failure and counsel patients accordingly.

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## Medication Safety Alert: Wrong Route of Administration

Critical and fatal incidents have occurred throughout Australia and overseas when oral liquid medicines have been administered via both the intravenous (IV) and subcutaneous (SC) routes. In response to this, Slade Pharmacy and Galen Health released a Medication Safety Alert in May 2008.

In the alert, Slade Pharmacy and Galen Health endorse the recommendations released by the Victorian Medicines Advisory Committee (VMAC) to reduce future incidents.

The recommendations include:

- Prescribers clearly specifying the route of administration on the order.

- Pharmacists clearly labelling dispensed medication with the route of administration. i.e. 'by mouth'.
- Using 'oral 'dispensers' (not parenteral 'syringes') for measuring oral liquid medicines for administration.
- Transporting medicines to be administered via different routes separately.
- Preparing medications for administration one at a time.
- Double checking (by two nurses), at the bedside, for all oral liquid medicines when patients also have a parenteral access line.

For further information please refer to the recent Medication Safety Alert – Wrong Route of Administration.

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*This publication is intended to provide a general outline and is not intended to be and is not a complete or definitive statement of the information on the subject matter. Further professional advice should be sought before any action is taken in relation to the matters described in this publication. To obtain further copies of all documents referred to in this publication please see your pharmacist.*

# Medication Safety Alert

## Zolpidem

### Safe Practice Recommendation No. 07

Since the introduction of zolpidem to the Australian market in 1996, over 1000 adverse drug reactions have been reported to the Australian Adverse Drug Reaction Advisory Committee (ADRAC). The majority of reports involve neurological or psychiatric reactions such as visual hallucinations, confusion, depression and amnesia. Of particular interest have been reports of sleep walking, which describe inappropriate or strange automatic behaviour "while asleep", including binge eating, house painting and driving. This pattern of adverse drug reporting is not evident with other hypnotics.

Side effects related to zolpidem can occur at therapeutic doses, without concomitant intake of alcohol, however alcohol heightens the risk. These side effects are not limited to initial doses and can manifest for the first time after periods of apparently uneventful use.

In January 2008, the Therapeutic Goods Association (TGA) imposed the requirement for a boxed warning in all product information documents for zolpidem. The warning must read:

***“Zolpidem may be associated with potentially dangerous complex sleep-related behaviours which may include sleep walking, sleep driving and other bizarre behaviours. Zolpidem is not to be taken with alcohol. Caution is needed with other CNS depressant drugs. Limit use to four weeks maximum under close medical supervision.”***

Furthermore, Slade Pharmacy recommends the following action to reduce the risk of adverse events associated with zolpidem. They are based on recommendations by the TGA, the National Prescribing Service and Sanofi Aventis:

- 1. Healthcare professionals must assess the risks and benefits of using zolpidem. If the benefits outweigh the risks and zolpidem is prescribed for the patient, caution should be exercised.**
- 2. No packs greater than 14 tablets should be prescribed by doctors or dispensed by pharmacists**
  - Where greater quantities are prescribed, pharmacists must contact the doctor to clarify requirements.
- 3. Zolpidem must be supplied in its original pack to ensure all updated warnings and batch numbers are readily available**
- 4. All dispensed packs must feature a prominent ‘no alcohol warning’ and include a current patient Consumer Medication Information (CMI) leaflet**
- 5. Health Professionals are to advise patients to take the medication strictly in accordance with the approved Product Information and Consumer Medication Information. Counselling should include:**
  - A warning that the medication causes drowsiness, particularly when used in combination with other central nervous system depressants.
  - An explanation of the adverse interaction between alcohol and zolpidem
  - Never take doses higher than recommended by the doctor
  - Take the smallest dose required, for the shortest period of time and for no longer than four weeks
  - Patients should be advised to take zolpidem once they are in bed and not on the way to bed as it can work within minutes
  - Strategies for getting to sleep without medicines

