

Letters

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Over-the-counter misnomers

Editor, – I am appalled to find that there are now two 'over-the-counter' S3 medications bearing the Sudafed label which do not contain pseudoephedrine. The first is Sudafed PE tablets, the second Sudafed nasal spray.

The new products contain phenylephrine, which is an active vasoconstrictor and decongestant when administered intravenously or intranasally, but its efficacy in a per-oral tablet formulation is questionable, as most pharmacological data suggest its first-pass metabolism is almost complete.

My family's experience in using these tablets confirms this. Indeed, I was so appalled that I returned the Sudafed PE tablets to the pharmacy where purchased, pointing out that they were not as labelled.

Sudafed has been a registered, recognised name for pseudoephedrine for more than 40 years, so to have it used for a completely different compound is confusing and misleading. How can the Therapeutic Goods Administration justify allowing the misuse of this name? What data were submitted to justify using the Sudafed label on products which do not contain Sudafed?

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Dr Peter Bird, Head, Office of Non-prescription Medicines, Therapeutic Goods Administration, comments:

In recent years, concerns about the diversion of pseudoephedrine to the illicit drug trade led to more stringent limitations being placed on the supply of medications containing this ingredient. These restrictions resulted in some companies formulating new products that replaced pseudoephedrine with phenylephrine hydrochloride.

In common with general retail practice, over-the-counter (OTC) medicine companies use brand extensions (umbrella/family branding) to market their products. The Therapeutic Goods Administration (TGA) has specific guidelines to determine the acceptability of proposed brand extensions for OTC medicines (see http://tga.gov.au/docs/pdf/argom_5.pdf).

While the safety and efficacy of phenylephrine has been documented in standard reference texts, it is recognised that there may be differences in effectiveness compared to pseudoephedrine. For this reason, where there are medicines containing either pseudoephedrine or phenylephrine

with similar presentations, the TGA requires that the letters 'PE', together with other distinguishing features, are included prominently on the label of the product containing phenylephrine. This is consistent with practices in a number of other countries in which these medicines are marketed. Similarly, nasal sprays containing decongestant ingredients are required to include distinguishing features on their labels.

Prescription pricing demystified

In a recent article Dr Tatchell gives a comprehensive review of the pricing of prescription medicines (Aust Prescr 2009;32:6–8). While he addresses issues in the community setting, he fails to include the complexity of prescription pricing in public hospitals.

Access to Pharmaceutical Benefits Scheme (PBS) dispensing was introduced into public hospitals in 2002. While this was intended to parallel the structure in community dispensing, some pricing anomalies exist. Brand price premiums, therapeutic group premiums and special patient contributions do not generally apply. Safety net contributions also differ. Any patient co-payment is added to the patient's safety net, whether for PBS or non-PBS subsidised items. In some hospitals, patient co-payments for non-PBS items are capped at the patient co-payment contribution rate. For example, concession patients pay no more than \$5.30 per item, and safety net exemption cardholders may find they are not charged for non-PBS items or even over-the-counter items.

The availability of chemotherapy under the Chemotherapy Pharmaceuticals Access Program¹ adds another layer of complexity. Patients can access PBS-subsidised chemotherapy under this program. While they do not pay a co-payment, the actual dollar value of the co-payment (for example, \$5.30 per concession patient) is still added to their safety net.

In this era of continuum of care, patients need to be aware that pricing structures differ between the hospital and community setting. Physicians who work in both the public and private sectors must also have an understanding of this pricing anomaly.

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Reference

1. www.health.vic.gov.au/pbsreform/clinic.htm [cited 2009 May 8]