Code of Practice – Pseudoephedrine

This Code of Practice is issued in relation to a specific therapeutic substance that is a potential source of harm to consumers or other members of the community if misused or abused. The Code is not legally binding but may be considered in any legal action. It has been revised to reflect the recent changes to the schedule of products containing pseudoephedrine. Pharmacists are expected to comply with relevant Pharmacy Board/Council and legislative requirements at all times.

Background

Pseudoephedrine is a sympathomimetic decongestant which acts through the alpha adrenoreceptors on vascular smooth muscle in the respiratory tract. It is used for the relief of congestion associated with conditions such as acute and chronic rhinitis, sinusitis, otitis media and the common cold.1,2

For some time now, pseudoephedrine has been targeted for non-therapeutic purposes. All forms (single ingredient and compound solid dose forms, liquid preparations and raw powder) are being used in the manufacture of amphetamines in clandestine laboratories for the illicit drug market. Recent reports confirm that most of the methamphetamine now available on Australia’s illicit drug market is produced from pseudoephedrine-containing medicines diverted from community pharmacy.3,4

Commonwealth, state and territory governments, police services and other law enforcement agencies are working cooperatively to monitor patterns of illicit drug use and emerging trends in an effort to minimise the harm associated with illicit drug activity.3,5 Recognising the important role played by pharmacy and other sectors, a National Working Group on the Prevention of the Diversion of Precursor Chemicals into Illicit Drug Manufacture was established in 2002.6 One outcome of this forum was to make a submission for consideration by the National Drugs and Poisons Schedule Committee which resulted in the rescheduling of all pseudoephedrine-containing products to Pharmacist Only Medicine (Schedule 3; effective 1 January 2006) or Prescription Only Medicine (Schedule 4; effective 1 April 2006).7

The recent rescheduling as well as the reformulation of many products to replace pseudoephedrine with phenylephrine is likely to decrease the availability of pseudoephedrine generally. However, the potential for diversion of pseudoephedrine-containing products from community pharmacy remains and therefore justifies higher levels of vigilance and professional supervision. This Code is intended to ensure pharmacists can continue to provide the most appropriate medicines and therapeutic advice to consumers without inadvertently contributing to the continuing diversion problem. This is also consistent with the pivotal role pharmacists play under the National Medicines Policy9 of promoting quality use of medicines.

Pharmacists will note there are state-specific storage requirements for Pharmacist Only Medicines. Other recommendations contained in this Code are similar to those already required or recommended in most jurisdictions.9-15

This document reinforces PSA’s Code of Professional Conduct16 that requires pharmacists to adhere to legislative requirements and to uphold the reputation of their profession. The obligations of this Code extend those professional practice obligations presented in the Code of Professional Conduct and may also impose a higher level of professional responsibility on pharmacists than is required by the quality standard relating to the supply of Pharmacist Only Medicines.17

Various community pharmacy initiatives18-20 are assisting to raise awareness within pharmacy and the community of the importance of monitoring usage patterns and minimising diversion, whilst still ensuring that consumers with genuine therapeutic needs are managed appropriately.

Endorsed by National Council November 2006
(Supersedes v.1 September 2002)
Pharmacists' obligations

1. Pharmacist Only Medicines containing pseudoephedrine should be stored in the professional area of the pharmacy and be genuinely not accessible by the public.9,15 Any additional state-specific storage requirements must also be met. Storing these medicines in the dispensary out of sight and out of reach of the public is desirable and is consistent with the view that these medicines require a higher degree of monitoring.

2. Where stock is visible to the public, products should be arranged in a way that minimises the facings.10,15 This avoids the creation of a visual ‘promotion’ of the products and also minimises the likelihood of the quantity on hand attracting undue attention in relation to possible non-therapeutic uses. Wherever possible, backup stock should be stored in a separate storeroom.

3. Stock holdings should be minimised to a level that can be justified by turnover and supported by appropriate ordering arrangements.15,21

4. Pharmacists must be appropriately involved in the supply of Pharmacist Only Medicines according to professional standards.17 Policies and procedures should be in place to ensure that pharmacy personnel refer requests for these products to them.17

5. Pharmacists must be satisfied that a genuine therapeutic need exists. This means that prior to supply the pharmacist should satisfy themselves that a clinical condition exists which would benefit from treatment with a pseudoephedrine-containing product.

6. The quantity supplied should be consistent with the level of therapeutic use that might reasonably be expected for that condition.10,15 It is unlikely that supply of multiple packs on any single occasion would be necessary or justified given the self-limiting nature of the conditions for which pseudoephedrine is generally used.

7. Pharmacists should act professionally when:
   a. more than one pack is requested;10,15
   b. frequent requests are received from or on behalf of an individual; or
   c. the ‘bona fides’ of the request is in doubt.9,14

     Behaviours such as refusal to purchase an alternative recommended product or evasive or aggressive behaviour when therapeutic need is discussed have been noted as alerts to possible product misuse.22

8. Pharmacists must remain vigilant to further assist the control of illicit diversion. As with any prescription, pharmacists must satisfy themselves of the legitimacy of prescriptions for pseudoephedrine-containing medicines. With the supply of Pharmacist Only Medicines containing pseudoephedrine, pharmacists must be familiar with details of state-specific requirements. Where legislation does not specifically require pharmacists to request photographic or other identification from purchasers who are not known to the pharmacist and to maintain a record of details of the supply, PSA strongly recommends that these steps be taken by pharmacists for each supply.

These obligations are not intended to compromise supply of pseudoephedrine-containing products to individuals with a genuine clinical need. A study in 2002 confirmed earlier findings that there is no particular ‘type’ of person more likely than others to misuse over-the-counter medicines. Therefore, in observing these obligations, pharmacists will need to exercise sensitivity and professional judgment to ensure fair, equitable and non-judgemental service is provided that meets the health care needs of consumers.

References

13. Pharmacy Board of South Australia. Newsletter, issue no. 18. 2006 Mar.