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# Legal Insights

## What are pharmacists' obligations when supplying pseudoephedrine?

Pseudoephedrine ('PSE') is indicated for the relief of congestion associated with conditions such as rhinitis, sinusitis and the common cold.[1] However in recent decades, it has been targeted for non-therapeutic purposes, such as for the manufacture of illicit drugs.

Meridian Lawyers has recently assisted pharmacists to respond to notifications that were referred to the Australian Health Practitioner Regulation Agency ('AHPRA'). In those cases, a public health unit audit of the pharmacy found that the of sales of PSE products were abnormally high for a community pharmacy environment. As a result, the practice of each pharmacist that worked in the pharmacy was scrutinised, and this ultimately resulted in disciplinary action against them. This should serve as a timely reminder of pharmacists' obligations when a patient requests medications that contain PSE.

Before supplying an S3 PSE, a pharmacist must satisfy themselves that the purchaser has a genuine therapeutic need for it and if the identity of the purchaser is unknown, an acceptable form of identification must be provided. Therapeutic need is to be established by careful questioning. This principle is reproduced in some Australian jurisdictions[2] and is endorsed by the Pharmacy Board of Australia.[3]

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[1] 'Code of Practice – Pseudoephedrine' (2006) *Pharmaceutical Society of Australia* <https://www.psa.org.au/download/codes/pseudoephedrine-code-2006.pdf>.

[2] *Health (Drugs & Poisons) Regulation* (Qld) 1996 reg. 277; *Drugs, Poisons and Controlled Substances Regulation* 2017 (VIC) reg. 141; *Poisons and Therapeutic Goods Regulation* 2008 (NSW) reg. 23; *Medicines, Poisons and Therapeutic Goods Regulation* 2008 (ACT) reg. 171 and *Medicines, Poisons and Therapeutic Goods Act* 2008 (ACT) s 7; Note: South Australia, Western Australia and the Northern Territory requirements only relate to the record of sale.

[3] 'Guidelines on Practice-Specific Issues', Pharmacy Board of Australia.

Regulations in all States and Territories[4] except Victoria[5] also require that pharmacists must make a record of the following at the time of sale of S3 PSE:

(a) date;

(b) brand name and quantity of PSE sold;

(c) purchaser's name and address; and

(d) details of the identification presented by the purchaser.

In most jurisdictions, the failure to make an appropriate record may be considered an offence punishable by payment of a monetary penalty.[6] Where available, pharmacists should review Project STOP for prior sales of PSE to the purchaser and also enter the above details into the data-base. Project STOP may assist the pharmacist to make a more informed decision on the appropriateness of the proposed sale by helping them to avoid value judgements based on superficial qualities like physical appearance and answers to questions. Because Project STOP records PSE sales in real time, it will alert the pharmacist to prior sales during a threshold period.

In one of the cases Meridian Lawyers was involved in, the pharmacist, to their credit, demonstrated an in-depth understanding of these requirements. They vowed consistent compliance with legislative requirements each time PSE was sold. Despite this, the Board was not satisfied that there had been a sufficient assessment of purchasers' therapeutic needs, because if there had been, certain instances of supply should not have occurred. The pharmacist was ultimately cautioned for his failure to make an appropriate record of sale and also had conditions imposed on their registration requiring the completion of education on the safe and appropriate sale of PSE (at their own cost).

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[4] *Controlled Substances Act* 1984 (SA) s 17B; *Poisons and Therapeutic Goods Regulation* 2008 (NSW) reg. 24(1A); *Health (Drugs and Poisons) Regulation* 1996 (Qld) reg. 285A; *Medicines, Poisons and Therapeutic Goods Regulations* 2017 (NT) reg. 66; *Medicines, Poisons and Therapeutic Goods Regulation* 2008 (ACT) reg. 171-173; *Medicines and Poisons Regulations* 2016 (WA) reg. 142.

[5] Victoria does not have any mandatory recording requirement for the supply of S3 PSE, however, where there is reason to believe it might be misused, abused or used excessively a supplier should make a record so that reference can be made to it if further supplies are sought.

[6] *Controlled Substances Act* 1984 (SA) s 17B; *Poisons and Therapeutic Goods Regulation* 2008 (NSW) reg. 24(1A); *Health (Drugs and Poisons) Regulation* 1996 (Qld) reg. 285A; *Medicines, Poisons and Therapeutic Goods Regulations* 2017 (NT) reg. 66; *Drugs, Poisons and Controlled Substances Regulation* 2017 (VIC) reg. 107-108 (S4 drugs only); Western Australia and the Australian Capital Territory are excluded.

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There are reported decisions from various State and Territory Tribunals that concern the supply of PSE where there was inadequate or no assessment of therapeutic need by pharmacists. In some cases, the supply occurred when the amount requested was high and well in excess of any indication. In such cases, pharmacists may be reprimanded, fined and/or in extreme cases, their registration may be suspended or even cancelled (depending on the gravity of the conduct). In addition, in some jurisdictions, pharmacists can be ordered to pay the legal costs of the statutory authority that referred them to the Tribunal. Such orders can, in some instances, amount to tens of thousands of dollars.

These cases should serve as a reminder to pharmacists to be conscious of their professional obligations and exercise their own independent judgment as to the appropriateness of supply of PSE because any shortcomings may have serious consequences.

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