



The Manitoba Pharmaceutical Association

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TO: NOTICE TO PHARMACISTS Summary of Amendments to the Regulation of Pseudoephedrine and Ephedrine: A Strategy Against Methamphetamine

Across this country a comprehensive strategy is being enacted to address the growing crisis in our communities associated with methamphetamine production and use. This multifaceted strategy focuses on awareness, education, prevention, and treatment efforts. Tighter controls and enhanced enforcement regarding the distribution and sale of precursor drug products and chemicals used in the illicit production of methamphetamine are presently in place.

Recently, amendments to legislation governing the retail sale of certain precursor drug products has been enacted both provincially and federally.

- ❑ The Lieutenant Governor in Council, acting under the authority of Section 74 of *The Pharmaceutical Act*, passed a Regulation that amended the definition of a drug in *The Prescribed Drugs Regulation* to include all single entity pseudoephedrine products. The sale of drugs by retail in Manitoba can only occur from a pharmacy.
- ❑ The Council of the MPhA asked pharmacists in Manitoba to consider changes to the regulations listing single entity pseudoephedrine as a Schedule II substance and limiting its sale to a maximum of 3,600 mg at the time of purchase. At a Special General Meeting held on January 4th, 2006, pharmacists voted unanimously in support of these amendments.
- ❑ Following recommendations made by the National Drug Scheduling Advisory Committee (NDSAC) and a period for comment and review, the NAPRA Executive Committee has approved amendments to the National Drug Schedules to move single entity pseudoephedrine and ephedrine products to Schedule II and combination products containing pseudoephedrine and ephedrine to Schedule III effective April 10, 2006.

The following table summarizes the provincial and federal legislative amendments that have been made for pseudoephedrine and ephedrine products, the responsibilities of the pharmacist in the sale of these products and the dates these amendments become effective. The MPhA has previously informed pharmacists of these pending amendments and therefore many of these changes may already be taking place in Manitoba pharmacies.

Effective Date	Legislation	Amendment	Action
January 15, 2006	Regulation to amend <i>The Prescribed Drugs Regulation</i>	Amended the definition of a drug to include all single entity pseudoephedrine products.	Single entity pseudoephedrine products may only be sold from a licensed pharmacy in Manitoba.
January 15, 2006	Amendment to the <i>Manitoba Pharmaceutical Regulations</i> to the <i>Pharmaceutical Act</i>	Pseudoephedrine and its salts and preparations in single entity products listed as Schedule II and limit on the sale of pseudoephedrine to a maximum quantity of 3,600 mg at the time of purchase	A pharmacist may only sell single entity pseudoephedrine products as a Schedule II drug to a maximum quantity of 3,600 mg at the time of purchase i.e., from the licensed dispensary following discussion between the pharmacist and the patient regarding symptom management and/or the condition to be treated in accordance with the NAPRA Standards of Practice for Schedule II Drugs.

Effective Date	Legislation	Amendment	Action
<p>April 10, 2006</p>	<p>Amendments to the <i>National Drug Schedules</i> following recommendations made by the National Drug Scheduling Advisory Committee (NDSAC), a period of comment and review and approval by NAPRA Executive Committee</p>	<p>Pseudoephedrine and its salts and preparations in single entity products – Schedule II</p> <p>Ephedrine and its salts and preparations in single entity products (in preparations containing no more than 8 mg per unit dose, with a label recommending no more than 8 mg/dose or 32 mg/day and for use not more than 7 days, and indicated for nasal congestion.) – Schedule II</p> <p>Pseudoephedrine and its salts and preparations or ephedrine and its salts and preparations in combination products (in preparations containing no more than 8 mg of ephedrine per unit dose, with a label recommending no more than 8 mg/dose or 32 mg/day and for use not more than 7 days, and indicated for nasal congestion.) [<i>Note: Pharmacists are advised that in areas where there is evidence of abuse or particular concern about abuse, pseudoephedrine and ephedrine products should not be located in a self-selection area of the pharmacy</i>] – Schedule III</p> <p>[<i>Note: Ephedrine and its salts (in preparations containing more than 8 mg per unit dose, or with a label recommending more than 8 mg/dose or 32 mg/day, or labelled or implied for use exceeding 7 days, or if indicated for other than nasal congestion will remain as a Schedule I drug.)</i>]</p>	<p>Provincial legislation in this respect is already in effect for single entity pseudoephedrine products.</p> <p>Single entity ephedrine products (in preparations containing no more than 8 mg per unit dose, with a label recommending no more than 8 mg dose or 32 mg day and for use not more than 7 days, and indicated for nasal congestion.) may only be sold as a Schedule II drug.</p> <p>Combination products containing pseudoephedrine or ephedrine (in preparations containing no more than 8 mg of ephedrine per unit dose, with a label recommending no more than 8 mg/dose or 32 mg/day and for use not more than 7 days, and indicated for nasal congestion.) may only be sold as Schedule III drugs i.e. from an area adjacent to the dispensary under the direct supervision of the pharmacist. [<i>Note: Pharmacists are advised that in areas where there is evidence of abuse or particular concern about abuse, pseudoephedrine and ephedrine products should not be located in a self-selection area of the pharmacy</i>]</p> <p>Pharmacist intervention shall be in accordance with the NAPRA Standards of Practice for Schedule II and III Drugs</p>

The MPhA is working with the Government of Manitoba and the Manitoba Society of Pharmacists to develop educational workshops and tools for pharmacists to facilitate taking an active role in education, prevention and treatment efforts against methamphetamine use and production. Resources may be also be found at your local office of the Addictions Foundation of Manitoba (AFM), through the AFM library (www.afm.mb.ca) or through the Meth Watch Program (www.methwatch.ca).

Should you have further questions regarding this issue, please contact the MPhA Office.

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