



## **Standards of Practice – Non-Prescription Drugs** **A Report to the National Association of Pharmacy Regulatory Authorities**

The following report and proposed standards by Barry E. Allen and Linda G. Suveges were endorsed in October 1995 by the National Association of Pharmacy Regulatory Authorities (NAPRA).

# **STANDARDS OF PRACTICE -**

# **NON-PRESCRIPTION DRUGS**

**A REPORT TO THE NATIONAL ASSOCIATION OF  
PHARMACY REGULATORY AUTHORITIES**

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***PREPARED BY:  
B.E. ALLEN  
L.G. SUVEGES***

## INTRODUCTION

On May 12, 1995, the National Association of Pharmacy Regulatory Authorities (NAPRA) adopted *Harmonized Drug Schedules in Canada: the Final Report of the Canadian Drug Advisory Committee (CDAC)*. This report included background information on the drug schedule harmonization process in Canada, a discussion of the cascading principle for drug scheduling, an outline of the scheduling factors and recommendations for three schedules of drugs. One of the recommendations made by the Committee was the need to establish standards of practice for the pharmacist when consulting about the use of medications in each drug schedule.

To ensure safe drug use, patients must be knowledgeable about the appropriate selection of a remedy depending on symptoms, compatibility with other drugs being used, efficacy, possible adverse drug reactions, expected outcomes and what to do if outcomes are not achieved. To ensure public safety, drugs are placed into a safe environment, dependent upon the amount of information required for safe use by the patient and the need for consultation with a health care professional.

The need for further development of the standards of practice required for the responsible provision of Schedule II and III drugs to the public has resulted in the development of the proposed standards outlined in this proposal.

## BACKGROUND

The CDAC model for making drug scheduling decisions embodies a cascading principle in which a drug is first assessed using the Factors for Schedule I. Should sufficient factors pertain, the drug remains in this schedule. If not, the drug is compared to the Factors for Schedule II and if appropriate, subsequently assessed against the Factors for Schedule III. Should the drug not meet the factors for any schedule, it becomes unscheduled or non-restricted and available for sale in any retail outlet. This process promotes the listing of drugs in schedules corresponding to the conditions of sale providing for proper drug use and patient safety.

Therefore, Schedule I Drugs require a regulated environment of selection and professional intervention including diagnosis by the physician. Schedule II Drugs, while less strictly regulated, do require consultation with the pharmacist and referral to the physician, when appropriate. Drugs listed in Schedule III are suitable for self-selection, but may pose risks for certain groups of people and should be sold where the pharmacist is available to provide advice when required. Unscheduled drugs can be sold without professional supervision. Adequate information is available for the patient to make a safe and effective choice and labelling is believed sufficient to ensure the appropriate use of the drug.

The CDAC Report states that the outcome of drug scheduling should serve the patient in a sensible, reasonable, and best possible manner in light of knowledge and practice. Scheduling factors were developed to reflect an assessment of risk to the public from drug use and the level

of professional control required for patients' safe and effective drug use. However, patients have the ultimate responsibility for their health and should have access to self-selected drugs for self-medication or access to the selection of nonprescription drugs, with the assistance of a pharmacist. Safety and effectiveness of nonprescription drugs depend on their appropriate use to treat minor ailments. Consultation, requiring professional knowledge and skills to provide needed information, must be appropriate in scope, content, and level to the needs of those seeking assistance.

Provincial pharmacy regulatory authorities are responsible for establishing, supporting and enforcing appropriate standards of practice for all professional activities undertaken by pharmacists. At present, standards of practice (also called principles of practice or guidelines for practice) exist for pharmacist consultation with patients about prescription drugs (Schedule I). Practice guidelines for pharmacist consultation with patients about self-medication with nonprescription drugs exist in six provinces. However, these guidelines tend to be very general in nature (e.g., “the pharmacist shall be accessible for consultation”) and do not provide significant insight into what is expected of the pharmacist to provide adequate control and consultation with patients about nonprescription drugs. Although seven provinces have developed “no public access” drug schedules (like Schedule II), only two of these have also developed practice guidelines for pharmacists regarding their role in the provision of such drugs.

Because drug scheduling using the cascading principle is based on the idea of the relative risk associated with taking medications with or without the advice of a health care professional, standards of practice must also reflect this concept. Therefore, standards of practice for Schedule II drugs should include activities that must be undertaken by the pharmacist interacting with a patient desiring to self-medicate with one of these products. Patients may self-select Schedule III drugs and therefore it is essential for pharmacists to be available for consultation. Patients should also be encouraged to seek consultation if they have any concerns about the safety and/or effectiveness of either Schedule II or Schedule III drugs. Although certain activities may vary for Schedule II and III drugs, the consultation process on all nonprescription drugs is very similar.

## **SCHEDULE II DRUGS**

Schedule II Drugs do not require a prescription but are available only from the pharmacist, and must be retained within an area of the pharmacy to which public access is restricted and there is no opportunity for patient self-selection. Schedule II drugs require consultation between the pharmacist and the patient, with attention given to communication about the symptoms or condition to be treated, other disease states, possible side effects or drug interactions and the selection of an appropriate drug or therapy. To fulfil this role, the pharmacist must present an opportunity to the patient and should be responsive to the patient's request for assistance in selecting the appropriate therapy for self-medication.

## **SCHEDULE III DRUGS**

Schedule III Drugs may present risks for the patient in self-selection. Although available without a prescription, these drugs are to be sold from the self-selection area of the pharmacy, which is operated under the direct supervision of the pharmacist. They are subject to increased degrees of control at the discretion of provincial regulatory authorities when problems with self-selection have been identified. The self-selection area for Schedule III drugs should be accessible to the patient, clearly identified as a professional services area of the pharmacy and one which is under the sight, hearing and direct supervision of the pharmacist. The pharmacist should be available, accessible and approachable to assist the patient in making an appropriate self-medication selection. There needs to be sufficient professional staff to meet the information needs of those patients who require professional advice.

# STANDARDS OF PRACTICE

The cascading principle for drug scheduling implies that varying degrees of risk are associated with the use of nonprescription drugs. Standards of practice and associated operational guidelines describe the role of the pharmacist in helping patients manage the risks and benefits of nonprescription drug use.

The following document outlines **standards** which represent those services and activities that are expected of the pharmacist who is providing nonprescription drugs to patients. The **operational guidelines** provide interpretations of the policies outlined in the standards. It is understood that individual provincial regulatory authorities may need to modify the wording of these standards and guidelines to conform to their individual needs, providing the intent of each standard is maintained.

**Standard 1:**     **The pharmacist shall locate nonprescription drugs in the area of the pharmacy consistent with the appropriate drug schedule classification which reflects the level of risk of the drug.**

**Operational Guideline 1.1**

Schedule II drugs must be located in the prescription services department (dispensary) or in a secure area adjacent to the prescription services department, ensuring the area is readily accessible for the pharmacist but provides no opportunity for self-selection by the patient.

Schedule III drugs should be located in an area of the pharmacy immediately adjacent to the prescription services area (dispensary) which is within sight, hearing and supervision of a pharmacist who is working in the dispensary. This area should allow self-selection of Schedule III drugs by a patient, but also provide opportunities for pharmacist-patient consultation. Schedule III drugs may also be located within the dispensary.

Unscheduled nonprescription drugs should also be located in an area of the pharmacy immediately adjacent to the prescription services area (dispensary) which is within sight, hearing and supervision of a pharmacist who is working in the dispensary. This area should allow self-selection of unscheduled nonprescription drugs by a patient, but also provide opportunities for pharmacist-patient consultation. Unscheduled nonprescription drugs may also be located in the dispensary.

**Standard 2:**     **The pharmacist shall be available, accessible and approachable to consult with the patient who is seeking to self-medicate with a nonprescription drug.**

**Operational Guideline 2.1**

The pharmacist should be available within the pharmacy to consult with patients about Schedule II, III and unscheduled nonprescription drugs.

**Operational Guideline 2.2**

To ensure accessibility for consultation with patients, the pharmacist should be located in or near the prescription services area and the area where Schedule III and unscheduled nonprescription drugs are located. The pharmacist should also be readily identifiable.

**Operational Guideline 2.3**

The pharmacist should take reasonable steps to enter into a dialogue with the patient or patient's agent. The pharmacist should offer service, assistance or advice, if the patient:

- requests help in selecting a Schedule II, III or unscheduled nonprescription drug;
- engages in self-selection of certain Schedule III or unscheduled nonprescription drug;
- exhibits behaviour traits suggesting assistance is desired or required due to the duration of time spent self-selecting a Schedule III or unscheduled nonprescription drug;
- makes frequent repeat purchases of a Schedule II, III or unscheduled nonprescription drug;
- is perceived to purchase or observed to purchase inappropriate quantities of a Schedule II, III or unscheduled nonprescription drug; or
- is recognized as a member of a specific patient population for whom self-selection and use of a Schedule III or unscheduled nonprescription drug may pose a risk (such as, pregnant or nursing women; the elderly; infants or young children; and those with known medical conditions, or those currently on other drug therapy).

#### **Operational Guideline 2.4**

The pharmacist should ensure that all pharmacy personnel are made aware of the availability and location of Schedule II, III or unscheduled nonprescription drugs in the pharmacy. Education of personnel should also include an understanding of the reasons for the location of Schedule II, III and unscheduled nonprescription drugs and the need for patients to consult with the pharmacist about the selection of Schedule II drugs. Personnel should also be trained to refer patients asking questions about any nonprescription drug to the pharmacist for consultation.

#### **Operational Guideline 2.5**

The pharmacist should make programs available to enhance patient awareness of the benefits, limitations, appropriate use and risks associated with Schedule II, III or unscheduled nonprescription drugs. Where supplementary information is available for Schedule II, III or unscheduled nonprescription drugs, the pharmacist should make such information available to patients seeking to self-medicate with a nonprescription drug.

#### **Operational Guideline 2.6**

The pharmacist should make the patient aware of the location and availability of Schedule II, III and unscheduled nonprescription drugs by one or more of the following:

- signage in the pharmacy which is visible and in a prominent location;
- shelf talkers; or,
- general advertising encouraging the patient to consult with the pharmacist about Schedule II, III or unscheduled nonprescription drugs and about the availability of information programs such as the Drug Caution Code.

**Standard 3:     The pharmacist shall interact with the patient to receive and provide information needed when that patient is seeking to self-medicate with a nonprescription drug.**

**Operational Guideline 3.1**

While ensuring the patient's right to confidentiality is respected, the pharmacist should interview the patient or the patient's agent (when appropriate) to determine and assess (as appropriate to the request):

- the condition or symptoms to be treated and the patient's self-diagnosis or physician's diagnosis of the situation;
- the background and history of the patient's complaint, disease state and urgency of the situation;
- the history of current disease states (as they relate to the condition being treated); known patient risk factors for adverse drug reactions, drug allergies or sensitivities; known contraindications to nonprescription drug use; and, dietary restrictions,
- other medications or treatments that the patient may have previously tried for this condition and subsequent efficacy or problems;
- other medications or treatments the patient is currently taking that may contribute to this condition or interact with suggested therapy; and,
- the seriousness of the symptoms which may indicate the need for referral to another health care professional or an emergency treatment centre.

**Operational Guideline 3.2**

As part of the patient/pharmacist dialogue, the pharmacist should consult, review and update the patient medication profile, if appropriate.

**Operational Guideline 3.3**

As part of the patient/pharmacist dialogue, the pharmacist should determine with the patient the need for referral to another health professional, the appropriateness of drug therapy, or the advisability of non-drug therapies.

The following situations should prompt the referral of a patient to another appropriate health care professional or emergency treatment centre for further evaluation:

- information from the patient indicating a potentially severe or worsening condition;
- patient uncertainty about the symptoms or condition;
- doubt about the accuracy of the patient's self-diagnosis; and/or
- failure of an appropriate treatment to remedy a condition within a predetermined period of time.

### **Operational Guideline 3.4**

For a patient seeking to self-medicate with a Schedule III or unscheduled nonprescription drug, the pharmacist should discuss with the patient, the drugs available and/or the appropriateness of the self-selected product to either:

- reassure the patient and concur with the self-selection.
- indicate the self-selected product is inappropriate; and/or,
- assist in the selection of a more suitable product.

### **Operational Guideline 3.5**

The pharmacist should recommend appropriate therapy with a Schedule II, III or unscheduled nonprescription drug if a need has been identified during the patient interview. The pharmacist should use information from the patient assessment to assist in the selection of a product or recommendation for treatment (including non-drug measures) which best meets the patient's needs.

The pharmacist should discuss with the patient the recommended drug therapy, and provide any available written information, as appropriate, on:

- directions for the proper use;
- how to monitor the response to therapy and expected outcomes within defined time periods;
- common adverse effects;
- precautions;
- correct storage; and,
- when to seek the attention of another health care professional.

Assessment and information provision may be accomplished by telephone when deemed appropriate by the pharmacist and/or requested by the patient.

**Standard 4:**     **The pharmacist shall respect the patient’s right to confidentiality by endeavouring to ensure that pharmacist/patient communication takes place in an area where the discussion cannot be overheard by others.**

**Operational Guideline 4.1**

The pharmacist and/or the pharmacy manager(s) should establish an appropriate area which will ensure patient confidentiality to use for consultation with patients, including one of the following, but not limited to:

- an acoustically private consulting room;
- a secluded area of the pharmacy; or,
- a semi-private area with suitable traffic and/or noise barriers.

**Standard 5: Where continuity of care is an important factor in achieving an optimal therapeutic outcome, the pharmacist shall document the service provided.**

**Operational Guideline 5.1**

The pharmacist should maintain an appropriate record management system (electronic or written) for all documentation about nonprescription consultation services. Such documentation should preferably be linked with the patient medication profile. Possible documentation methods may include, but are not limited to, patient medication profiles, consultation sheets or requisition forms.

**Operational Guideline 5.2**

When documenting the service provided for Schedule II drugs, the pharmacist should note, as a minimum, the following information:

- patient's name, address, and phone number;
- drug name, strength and quantity;
- date of the consultation;
- description of the indication, and the recommendation(s) and information given;
- details of a monitoring and evaluation plan, if appropriate, to monitor the patient's response to therapy;
- notation containing the reason counselling did not take place, if applicable; and,
- pharmacist's identity.

When deemed necessary by the pharmacist and/or requested by the patient, this information should also be documented for consultations between the patient and pharmacist about Schedule III or unscheduled nonprescription drugs.

Further documentation of consultations about Schedule II, III or unscheduled nonprescription drugs may also include:

- specific information to identify the patient;
- history of disease, allergy and previous conditions, including drug usage;
- monitoring of drug therapy and key aspects of patient counselling;
- follow-up to decide and document, where possible, the patient's outcomes;
- reporting of adverse drug reactions; and,

- other information, consultation or intervention provided with or instead of the drug therapy recommendation.

The patient should be informed that documentation has occurred and that confidentiality is assured.

**Standard 6:**     **The pharmacist, and/or the pharmacy manager(s), shall assemble the human, material and financial resources needed to promote the rational use of nonprescription drugs.**

**Operational Guideline 6.1**

The pharmacist and/or the pharmacy manager(s) should ensure that staffing is reasonable to facilitate patient/pharmacist dialogue about Schedule II, III or unscheduled nonprescription drugs in a convenient and responsive fashion.

Only a licensed pharmacist, or a registered student, intern or an apprentice supervised by a licensed pharmacist, should advise a patient about the use of a Schedule II Drug.

The pharmacist should supervise the selection of all Schedule III drugs, ensuring that no person other than a licenced pharmacist, or a registered student, apprentice or intern under the direct supervision of a licenced pharmacist, gives advice to a patient on the selection and use of Schedule III or unscheduled nonprescription drugs.

The pharmacist should ensure that all personnel are trained to refer patients' questions for advice on Schedule II, III or unscheduled nonprescription drugs directly to the pharmacist.

**Operational Guideline 6.2**

The pharmacist should maintain current, required references and patient information materials for use by the pharmacist in consultation with the patient seeking to self-medicate with a Schedule II, III or unscheduled nonprescription drug. The pharmacist should also provide access to pertinent information materials on Schedule II, III or unscheduled nonprescription drugs (and the ailments they can be used to treat) for patients to self-select within the professional services area of the pharmacy.

# APPENDIX A

## RECOMMENDATIONS

In addition to adopting the harmonized drug schedules and proposed standards of practice for nonprescription drugs, it is recommended that NAPRA, in collaboration with other national and provincial pharmacy organizations:

1. develop and evaluate patient information strategies regarding nonprescription drugs, and strategies which inform the patient about the value of consulting with a pharmacist about these drugs.
2. develop and/or enhance educational programs for pharmacists on nonprescription drugs, in particular on the skills necessary to assess and meet the needs of patients seeking to self-medicate with nonprescription drugs.
3. encourage provincial adoption of the concept of the professional services area where an area of the pharmacy is designated as such. This area should include, as a minimum, the prescription services area (dispensary) and the adjacent area where Schedule III or unscheduled nonprescription drugs are located. Where pharmacy size permits, it should be segregated from the front shop.
4. work closely with pharmacy associations and computer vendors to develop documentation tools, templates and programs for documentation of nonprescription drug consultations, with emphasis on how these can be incorporated into existing patient medication profiles.
5. develop a format (template) for the standard documentation or recording of pertinent information from each patient assessment and recommendation provided during nonprescription drug consultations.
6. request provincial review of current guidelines controlling the advertising of nonprescription drugs. Such guidelines may need to be amended to establish standards for the advertising and/or labelling of nonprescription drugs.
7. develop evaluation mechanisms to examine the need and effectiveness of the schedules and standards of practice.
8. develop guidelines for the provision of consultation areas to ensure patient confidentiality within the professional services area.

9. encourage provincial regulatory authorities to standardize signage and/or postings to advise the patient to consult with the pharmacist and to indicate the availability of Schedule II Drugs, supplementary information and/or private and confidential consultation.
10. suggest appropriate training for pharmacy personnel about the role of pharmacists in the provision of nonprescription drugs.
11. establish reasonable time schedules to facilitate the appropriate implementation of the standards of practice.