

## Over the Counter Drugs (OTCs): Considerations for Physical Therapy Practice in Canada

### Background

The use of medications or drugs by non-physician health professionals is evolving and is linked to collaboration and best use of resources to facilitate access to care. The use of drugs in clinical practice encompasses a wide variety of activities including: prescribing, compounding, dispensing, administering, advising and selling. For the purposes of this paper, these activities are defined as follows but may have slightly different meaning under provincial or federal legislation:

Prescribe = to advise and authorize the use of

Compound = to combine or mix

Dispense = to prepare and give out

Administer = to give or apply as a remedy

Advise = to recommend for use

Sell = to exchange or deliver for money or its equivalent

The activities of prescribing, compounding, dispensing, administering and selling drugs are restricted by provincial and federal legislation.

Health Canada is responsible for approving all drugs for sale in Canada and for regulating drug safety, quality, efficacy, importing, labelling and manufacturing. Health Canada maintains a drug product database and a licensed natural health products database, and is an important resource for advisories, warnings, recalls and safety alerts.

Provincial pharmacy regulators (i.e. the College of Pharmacists of a particular province) are responsible for the sale, dispensing and distribution of scheduled drugs. Where and how drugs can be sold in Canada depends on the national drug scheduling model established by the National Association of Pharmacy Regulatory Authorities (NAPRA). This model is based on the degree of risk involved (e.g. safety, toxicity, side effects, potential for abuse).

- Schedule I – greatest risk; prescription required, e.g. Tylenol #3
- Schedule II – must be kept behind the counter in a pharmacy and sold only upon pharmacist intervention, e.g. codeine containing products
- Schedule III – must be sold in a pharmacy where a pharmacist is available for consultation, e.g. Naproxen
- Unscheduled – available anywhere, e.g. Tylenol, Advil, Aspirin\* in limited package sizes

Despite this drug scheduling model, drugs and other substances (such as herbal supplements) that can be sold without a prescription are often referred to collectively as OTCs (OTC stands for “over the counter”).

In spite of their generally accepted low levels of risk, OTCs do present a number of risks if prescribed or administered incorrectly. Examples include:

- Acetaminophen: Acetaminophen can give rise to hepato-toxicity (especially when used concurrently with alcohol), cause urticaria and may adversely affect concomitant use of anticoagulants such as warfarin. Also, unlike salicylates which may cause significant gastrointestinal side effects, acetaminophen in greater than recommended doses shows a lack of

symptoms for a latent period making the identification and treatment of toxicity difficult and giving rise to life-threatening liver toxicity.

- Ibuprofen: Like salicylates, ibuprofen can cause gastro-intestinal (GI) side effects (including dyspepsia, GI bleeding, and peptic ulcer), fluid retention, hypertension, renal impairment and hypersensitivity. It may also affect coagulation times when given concurrently with warfarin/Coumadin and interact with lithium and the class of Selective Serotonin Reuptake Inhibitors (SSRI's) used to treat depression.
- Diclofenac: Diclofenac in oral dosage forms can interact with a number of cardio-vascular drugs such as diuretics, beta-blockers and ACE inhibitors and can also cause cardio-toxic events which recent research has suggested is not unlike those which caused Vioxx to be removed from the market some time ago. Other adverse effects may include tinnitus, confusion (especially in the elderly), skin rash, asthmatic reactions and severe GI side effects. Topical diclofenac, as noted, is much less likely to cause such effects but is not without possible adverse reactions chiefly related to skin rash and other allergic reactions.

Canadian physiotherapists/physical therapists (PTs) are not authorized to prescribe, compound, dispense or administer prescription drugs (although administering a substance by inhalation, such as oxygen, when ordered by a physician or other authorized individual, is permitted in some provinces). Whether PTs can administer, recommend or sell OTCs or other products in their practice varies from province to province. Some jurisdictions have restrictions, others do not.

### **Purpose**

This paper discusses important considerations for Canadian PTs contemplating whether to administer, recommend or sell OTCs. OTCs are defined as drugs or other substances (such as herbal supplements) that are available without a prescription and for self-selection by the public. This paper is an internal resource document of The Alliance for use by provincial physiotherapy regulators.

### **Evolving PT Practice**

The use of OTCs in PT practice has not been specifically studied in Canada. However, in provinces where there are no legislative restrictions on administering, recommending or selling OTCs, there is ample evidence that PT practice has evolved to include the use of OTCs. Typical examples of how PTs have implemented OTCs into their practice include:

- applying a topical NSAID or pain relieving cream as part of a therapeutic intervention
- recommending a muscle relaxant as a therapeutic adjunct
- selling vitamin supplements within a practice setting

Researchers in Australia report similar examples of PTs recommending OTC analgesics or oral NSAIDs (non-steroidal anti-inflammatory drug) and using topical NSAIDs as a therapeutic adjunct (Kumar and Grimmer, 2005). The authors highlight the potential for "medication misadventure" because PTs have limited knowledge about pharmacology, drug interactions and risks. They argue that PTs could be putting patients and themselves at risk. The study concludes that while the inclusion of NSAIDs in treatment plans has the potential to improve patient outcomes, it should be done in collaboration with an appropriate health professional such as a pharmacist or physician (Kumar and Grimmer, 2005).

### **Patients as enlightened consumers**

There are a number of factors at play: 1) access to information means patients are more informed and empowered to ask for additional information and 2) PTs are primary care providers, and as the first and sometimes only point of contact, PTs are being asked for advice related to OTCs. Because OTCs do not require a prescription, they are often seen as being less risky and many PTs believe their education and experience is either adequate to provide advice or at a minimum is better than nothing.

With OTCs, consumers are expected to make decisions about self care; and when they do so, they assume personal responsibility. When a health care provider such as a physiotherapist makes a recommendation about an OTC, not only is greater credence is given to the advice, but the PT as a regulated health professional, assumes responsibility and accountability for such recommendations.

### **Essential principles to understand and manage risk**

PTs are an obvious resource for patients, especially when the OTC relates to a condition for which the patient is seeing a PT; but OTCs are not risk free. When considering whether to incorporate OTCs into clinical practice, PTs should:

- conduct an assessment to evaluate need and ensure appropriateness
- focus on issues of safety, quality and accountability
- ensure competence and ability to manage negative consequences
- comply with labelling, storage and disposal requirements for OTCs

### *Assessment*

When a regulated health care provider recommends or administers any course of therapy it should be as a result of an assessment and be grounded in therapeutic appropriateness. There are also clinical and technical aspects to consider (right therapy, right frequency, right intensity etc.). With any drug - even non-prescription OTCs - physiotherapists may have incomplete knowledge about the medical or medication history of the patient to determine the efficacy, effectiveness, dosage, chemical and therapeutic profile, and interactions etc. to ensure appropriate assessment.

### *Safety*

Certain OTCs can be useful for a number of conditions treated by physiotherapists. Despite the fact that no prescription is required, and there may be no restriction on who can sell them, OTCs are not without adverse effects especially in vulnerable patients. Developing risk protocols to ensure safety is essential.

### *Quality/Competence*

Linked to both safety and assessment is the concept of quality and competence. Extensive education and training are required to ensure knowledge, skill and judgment for safe, competent care. Practising within the scope of practice of the profession, providing quality care and ensuring competence for all aspects of care that is provided is an expectation for all health care professionals.

### *Accountability/Liability*

All health professionals are also held to a standard of care when practicing their profession. Competence and judgment are cornerstones of accountability and informed consent continues to apply. The wide margin of safety for OTCs does not preclude harm to patients or exemption from liability for PTs should harm occur. Although patients can self select OTCs, accountability is much higher should a health professional decide to recommend a product. Best advice is to exercise care and good judgment; practice collaboratively and refer to other health care providers when appropriate.

### *Logistics*

A final but important component relates to ensuring compliance with the requirements for labelling and storage of all drugs, including OTCs. Anyone who compounds, dispenses or sells drugs is expected to comply with provincial regulations in place to ensure only quality products from bona fide Canadian drug wholesalers end up in the public domain. This includes expectations for monitoring expiry dates and ensuring appropriate disposal of unused or expired medications.

### **Summary**

- PTs are administering, recommending and selling OTCs (to varying degrees across Canada) and patients are requesting these activities
- If a PT is considering these activities (and their provincial legislation does not prohibit it) there are multiple risks and obligations to be considered
- PTs should assess and be prepared to manage the risks; ensure safety, quality and accountability; practice collaboratively and above all, always act in the best interest of patients

## **Appendix 1: Considerations and Questions**

### **Considerations:**

1. Some jurisdictions prohibit administering, recommending and/or selling OTCs (British Columbia, Manitoba and Nova Scotia).
2. If your jurisdiction does not prohibit administering, recommending, and/or selling OTCs, this does not mean you should do it just because you can - consider patient interests over your own interests
3. If you do decide to administer, recommend and/or sell OTCs, consider your scope of practice, your personal competence, patient risk, professional liability and appropriateness – collaboration with other health professionals is recommended
4. Always use judgment and apply reasoning - patient safety should be the primary focus

### **Questions to ask yourself before administering, recommending or selling OTCs in your practice:**

- Does my jurisdiction permit the activity?
- Is this activity within my scope of practice?
- Am I competent to do this activity?
- What additional education or training do I need?
- Am I the right person to be doing this activity?
- Is this activity in the best interest of my patient?
- Is it the right thing to do?
- Who can I access for advice/assistance?
- Is it better to refer to another provider?
- Have I done a complete assessment?
- Have I evaluated all the risks?
- Do I have appropriate protocols in place to manage the risks and ensure safety?
- Do I have appropriate liability insurance? Does the policy cover the activities I am planning to do?

## References

Health Professions Regulatory Advisory Council (HPRAC). *“Prescribing and Use of Drugs by Non-Physician Health Professionals: A Jurisdictional Review of the Profession of Physiotherapy.”* November 2008. Available at [www.hprac.org](http://www.hprac.org)

Kumar, S. and Grimmer, K. (2005). *“Nonsteroidal anti-inflammatory drugs (NSAIDs) and physiotherapy management of musculoskeletal conditions: a professional minefield?”* Ther Clin Risk Mgmt: 1(1) 69-76.

National Physiotherapy Advisory Group (NPAG). *“Essential Competency Profile for Physiotherapists in Canada.”* October 2009. Available at [www.alliancept.org](http://www.alliancept.org)

Williams, D., *“Use of Drugs in Physiotherapy: Review and Options.”* Prepared for the Canadian Alliance of Physiotherapy Regulators, October 2011.