Speaking Notes on Off-Label Use
Senate Committee on Social Affairs, Science and Technology
February 27, 2013

Thank you for providing this opportunity for the Canadian Pharmacists Association (CPhA) to appear before the Committee as part of your ongoing deliberations into prescription pharmaceuticals in Canada, and in particular, the issue of off-label use.

As you know, CPhA represents the interests of the pharmacy profession in Canada. Through its publications, CPhA also supports clinical decision-making through evidence-based drug and therapeutic information.

Off-label use refers to the use of medications for indications that have not received regulatory approval from Health Canada. It is different from use of an unauthorized medicine or unlicensed use.

Off-label use is a fairly common practice amongst health care providers. Estimates indicate that approximately one third of all prescriptions were for off-label use, although they vary from 11% to 50% of prescriptions, depending on the scope of the study. For certain patient groups, such as children and the elderly, and in certain diseases such as cancer, off-label use is common.

Overall, CPhA is supportive of off-label use, when clinical and scientific evidence has suggested that beneficial patient outcomes may outweigh potential risks. Patient safety should always remain the top priority of health care providers.

Guidelines and educational programs are being developed to support the appropriate use of off-label use in order to reduce any risks. However, despite guidelines, there remain challenges associated with off-label use that need to be addressed, which include:

- A lack of valid scientific evidence to support the off-label prescription. A 2012 McGill University Study found that of drugs prescribed off-label, 79% lacked strong scientific evidence. This lack of evidence could put patients at higher risk for inappropriate exposure to medication and potential side effects.

- There is no formal monitoring mechanism in place to monitor the impacts or effectiveness of off label use. This inhibits the ability of health regulators from being able to track or record the effects of off label use.

- It is possible that practitioners could be held liable for off label use, if it can be demonstrated that the prescribed treatment of care was not supported by evidence and a patient was shown to be harmed by being exposed to the treatment.

- With certain drugs that are reimbursed by private and public drug plans and classified as limited or exceptional use products, there may be restrictions on payment regarding off-label use.

In order to reduce the risks associated with off-label use, and to promote best practices associated with off-label use, CPhA would recommend the following:

1. Health providers should only prescribe medications for off-label uses when there is valid, scientific information to support the use of the medication for that indication, and the potential benefits to the patient clearly outweigh the risks. Liability insurance should cover health care practitioners prescribing drugs off-label unless there is evidence of negligence or use has an insufficient scientific basis.

2. Better guidelines and educational support for health care providers should be developed to support off-label use. Health providers, including physicians and pharmacists, need to disclose to patients when medications are being prescribed off-label, and discuss any potential pitfalls associated with off-label prescribing. Informed consent should be obtained.

3. Physicians and pharmacists should report on adverse events or side effects by the use of off-label prescriptions to Health Canada who should in turn make information available to health care providers to better inform clinical decisions.

4. Support needs to be given to implementing e-prescribing and e-health systems so that information can be more readily shared between physician and pharmacist in the event of an off-label prescription. Off-label prescription use should be clearly documented in the patient's medical record.

5. When pharmaceutical companies learn of off-label use of their products, they should be encouraged to conduct research to determine efficacy for the indication and ideally to submit to Health Canada for formal recognition of the use of the drug for that indication. Consideration should be given to incentives to support this type of research by industry.

6. A dialogue should occur between payers, health providers, and governments to determine eligibility and reimbursement policies with respect to medications issued for off-label use. In general, reimbursement policies should cover off-label use that is medically appropriate.

CPhA would be happy to work with governments and other stakeholders to implement policies and programs that would improve the use of off-label prescribed medications and reduce the associated risks.

CPhA appreciates the opportunity to appear before the Senate Committee and we look forward to answering any questions.

Jeff Poston
Executive Director, CPhA