

The Canadian Arthritis Patient Alliance Position on the use of COX-2 Inhibitors, Patient Perspective May 2005

The Canadian Arthritis Patient Alliance is pleased to present CAPA's position on Selective COX-2 Inhibitors NSAIDs for consideration by the Expert Advisory Panel convened by Health Canada.

Background

Since September 2004, beginning with the manufacturer's withdrawal of Vioxx, there has been much discussion surrounding the use of other COX-2 selective inhibitors, Celebrex and Bextra. While Merck withdrew Vioxx when studies showed increased incidences of adverse cardiovascular events, Health Canada requested that the manufacturer remove Bextra from the market on the evidence that it can produce a potentially life threatening skin reaction. Understandably, the approvals and subsequent withdrawals of medications valued by patients have created concern and confusion for individuals taking them. The cessation of effective treatment has reversed improvements in disease management and the quality of life of many patients.

Position Statement

Importance of this Panel and its recommendations.

- The withdrawal of some coxibs from the market and the uncertainty around coxibs in general have created alarm and confusion leaving thousands of Canadian patients in limbo for many months, waiting for resolution and clear government direction.
- The Expert Advisory Panel (EAP) must act to protect and promote the health of all people with arthritis, including those for whom there is no satisfactory alternative to a specific coxib. A viable solution that satisfies the needs of patients dependent on coxibs for disease management and that addresses the potential serious adverse effects of the medication must be found, recommended and implemented by the EAP without delay.

Summary statement regarding access to coxibs and to arthritis medications:

- Arthritis patients must have access to treatments that provide the greatest relief from pain, inflammation and stiffness and that slow or prevent the progression of their illness. Treatment access is paramount to disease management. Many patients do not need the newest and most expensive medications. Their disease is managed well with traditional medications. Others have had little or no success with traditional medications. Regardless of the medication prescribed, the most appropriate treatment is a decision

reached by the patient and the physician **based on the health status of the patient and after weighing the alternatives including potential benefits and possible adverse side effects. Medications and other treatments that have been shown to be helpful in treating arthritis must be available to Canadians living with arthritis, along with all available information on potential benefits and possible adverse side-effects.**

Why is access to COX-2 inhibitors needed?

- Thousands of Canadians have derived significant improvement in their disease activity from coxibs. For many, coxibs worked well for years, with mild, manageable or no adverse reactions.
- Although COX-2 inhibitors have potential adverse side-effects, many patients, after weighing the risks, still want these medications. Every day, patients who have been taken off the coxibs voice their complaints and concerns about having to forego a treatment they found beneficial.

Which Cox-2 inhibitor is better?

- No two patients are completely alike - they differ in many ways. The medication that manages the disease of one, won't necessarily have the same positive (or negative) effect for the other. For this reason, patients need more than one option in a drug class.

What about the adverse reactions to coxibs?

- Some Canadians have suffered adverse drug reactions related to taking coxibs. Distinguishing between the reactions that the informed patient was aware could occur, and those which occurred that could not be foreseen because of inadequate information must be recognized and considered.
- People with inflammatory arthritis commonly take multiple medications for many years, if not for life. Many of these drugs have the potential to cause serious health problems, including, but not limited to, liver/kidney failure, blood disorders, cataracts/glaucoma, bone disorders and GI incidents. Nevertheless, patients choose to take these medications to suppress disabling disease activity which enables them to carry out the normal aspects of daily living with a reasonable quality of life.
- Both Health Canada and the pharmaceutical industry have a responsibility to disclose all information that might influence patient/physician decision-making and the appropriateness of a medication, and to keep this information current.
- Patients and physicians have a responsibility to carefully monitor for adverse reactions to any medication.

Who decides whether or not to use a COX-2 inhibitor?

- The patient is ultimately responsible for treatment decisions but the best decisions are made in consultation with a qualified health professional or health care team.
- Patients and their physicians have a responsibility to be as informed as possible about any prescription or non-prescription drug or other therapy to treat their disease.
- All medications, whether prescription, over-the-counter, or "natural" remedies, have potential side effects. Whenever a patient and physician act together to decide on a particular treatment, they should look at alternatives and weigh the potential risks and benefits before determining the appropriate treatment.

Conclusion:

- Contradictory studies and conflicting data have made patients fearful and wary of Health Canada approvals and physicians' treatment recommendations. Canadians living with arthritis, health professionals, care givers and the public need a clear position on the COX-2 Selective Inhibitors. The EAPs recommendation(s) and subsequent government action are urgently needed. It is imperative that they reflect an understanding of the present situation in which patients experience a decline in their health because the coxib medication prescribed is no longer available. The right of patients to choose their treatment, in consultation with health professionals, must be respected.

Recommendation:

The Canadian Arthritis Patient Alliance recommends that the COX-2 Inhibitors previously approved by Health Canada again be made available to Canadians with arthritis. Information about all coxibs must be conveyed to patients along with benefit and risk data that is balanced and easily understood so that patients can make an informed decision about whether or not to use a COX-2 to help manage their arthritis. Warnings must be included on labels.

Related issues:**Patient information**

- There must be more emphasis on patient education, roles and responsibilities in the management of their disease.
- Patients need clear information to assess potential risks versus possible benefits, and make informed decisions.
- Up-to-date comparative studies such as those of the Cochrane Musculoskeletal Review Group are needed, along with evidence-based decision aids. International standards for patient decision aids are being developed which

- deal with such issues as the balanced and understandable presentation of data and should be used when patient information is prepared and disseminated.
- Patients must be encouraged to discuss concerns regarding their medications and other treatments with their health care team.
 - Health professionals must be trained in how to listen and communicate with patients so that treatment decisions are based on the patient's determinants and values as well the professional's expertise.
 - Physicians must be informed about current drugs and familiar with best practice prescribing recommendations for each arthritis medication.

Direct-to-consumer advertising (DTCA)

- Direct-to-consumer advertising leads to mis-information, misguided demand for prescription drugs and inappropriate prescribing of medications. Direct to consumer advertising spilling over from the United States, and drug promotions made to health professionals in Canada, contributed to the over-prescribing of coxibs.

Disclosure of clinical trials

- Health professionals and patients cannot make appropriate choices unless there is full and fair disclosure of the results of clinical trials. The coxib experiences of the past year clearly demonstrate the weakness of the present system. All parties – Health Canada, even industry itself, and, most importantly patients and the public - are paying a heavy price.

Post-market Surveillance

- The majority of reports of adverse reactions to medications occur soon after a drug is placed on the market. Canada must implement a patient centered, effective, post-market drug surveillance program that involves all stakeholders, including patients, health care providers, government and industry. In addition to, or instead of, expanding the burden of reporting by physicians on adverse drug reactions (ADRs), systematic reporting by patients directly to the newly created Canadian Adverse Drug Reaction Information System should be part of the ADR reporting system.