# Written Input to Health Canada's Cox-2 EAP

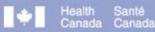
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#### **Presented by:**

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### **Agenda**

- About the process
- Who we heard from
- What we heard
  - Key themes and messages





#### **About the Process**

- The written input process was designed to complement the in-person Public Forum
  - An opportunity to broaden scope of public participation beyond in-person presentations
  - Both online and paper-based processes
- Voluntary Statement of Information included as part of the process to enhance transparency
- Participation was self-selected (not a representative sample)







#### Who we Heard From

- A total of 48 presentations were submitted (44 online and 4 by fax)
- 45 out of 48 contributors identified themselves as individuals (versus representing organizations)
- A significant majority of the participants identified themselves as patients (almost 90%)
- The remaining participants identified themselves as health care professionals or part of the general public





# What we Heard – Quality of Life

- A majority of contributors (40 out of 48) felt strongly that the benefits they experienced outweighed the risks associated with the drugs:
  - 28 individuals made a direct appeal for the return of a drug currently not on the market.
- The key theme from this group was a marked improvement in their quality of life while using Cox-2 inhibitors:
  - Pain control
  - Productive member of society







# **Input Excerpts – Quality of Life**

"My physician has put me on such a strong pain killer that I have been pulled off my job to try and adjust to all the side effects. I have lost my ability to be a productive member in our society at this time."

Cherylynn Burdeyney - General Public

"Today, I have to live with joint stiffness, with almost constant pain and I had to start using my cane again. I seriously ask myself whether I am better to live a shorter life with a product that improves my quality of life, or whether I will live longer in pain and discomfort. Honestly, the first of the two makes me laugh inside. Please leave us our quality of life. Thanks."

Raynald Morand - Patient





#### What we Heard – Safety

- Despite strong support for access to Cox-2s, almost one half of the participants (22 out of 48) identified requirements to better monitor the safety and safe use of this class of drugs:
  - A need to improve clinical studies standards
  - Regulations to support greater transparency of pre-market study and trial results
  - On-going surveillance of drug safety after market approval





# Input Excerpts – Safety

"I suggest it would be useful if a clinical study could be carried out with the following parameters: Select two groups of aging people who all have indications of heart problems as well as severe osteoarthritis which affects their capacity for physical activity: GROUP 1: People who have chosen to accept the reduction of physical activity, and do not use cox2 medication. GROUP 2: People who use cox2 medication to enable them to maintain vigorous physical and fitness activities."

Erik Hoel - Patient

"There should be regulations regarding the transparency of testing the companies do so that Health Canada has access to all tests regarding all drugs. The doctors and scientists that write about these drug tests in journals should not be on the payroll of the companies producing the drugs nor should they be ghost writers, as has been proven recently."

Marie Belliveau - Patient





#### What we Heard – Information and Choice

- The importance of individualized decision-making about risk and benefit at the patient/physician level was an important theme identified in a majority of the contributions (36 out of 48)
- Specifically, participants felt:
  - Access to better information is required for patients and physicians (20 out of 36)
  - Decisions should be made jointly by patient and physician (16 out of 36)
  - Individual risk should be evaluated on a case-by-case basis (14 out of 36)





### Input Excerpts – Information and Choice

"Make users aware of the issues. Let them weigh the risks with the advice of their physician."

**Greg Dorbeck - Patient** 

"My hope is that the solution will be a set of guidelines (drawn up by clinicians and Health Canada) which set specs on dosing, treatment indication and patient health status"

Islay Campbell - Patient





## **Summary**

- The input received was for the most part anecdotal (or experiential) in nature
- 3 key themes we heard:
  - Quality of life is a big issue that determines the public's position on accessibility and parameters for use
  - 2. Access to Cox-2s is predicated on availability of more and better quality information about safety and safe use
  - 3. Ultimately decision on use should be left to the individual and physician



