

## Education

# Health policy obstacles in gaining access to safe and effective prescription medications

**Prescription medications\*** (ones that are proven through research to be safe and effective as determined by Health Canada) are an important part of treatment plans for many of the four million Canadians living with arthritis. Prescription medications – as one part of an overall treatment plan – can help a person function day to day and maintain the highest quality of life possible. As a result, health policy that enables a person with arthritis to access prescription medications is of great interest to them.

At present, there are four significant health policy obstacles preventing Canadians with arthritis from accessing the prescription medications they need, when and where they need them, and at a cost they can afford. These obstacles occur first at Health Canada, next, in the Common Drug Review process, and finally, in the provincial drug formulary\*\* review processes across Canada.

This issue of JointHealth™ monthly provides information about health policy related to prescription medications in Canada and views on developing a “consumer-centred” national pharmaceuticals strategy in Canada. It also includes a consumer report on the Consensus Conference on Systematic Autoimmune Rheumatic Disease Research held last December 2005. The topics covered in this issue are:

### Education

- Health policy obstacles in gaining access to safe and effective prescription medications
- Principles of a “national pharmaceuticals strategy” that serve the needs of people with arthritis
- Research into medication usage and the importance of consumer involvement in policy development

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### Obstacle 1 : The safety and effectiveness review process

Health Canada is considerably slower than other federal/national drug review agencies in granting licenses to manufacturers for patented prescription medications. A comparison study concluded that Canada’s review time from submission to issuance of a “Notice of Compliance” was 514 days compared to the UK at 433 days, and the US at 361 days. The net result is that even at the very beginning of Canada’s drug review process, Canadians wait longer for access to prescription medications than Americans or Britons, and these often lengthy waits result in untreated illness and disease.

### Obstacle 2 : The Common Drug Review process

The next step in the prescription medications review process is managed by a federal/provincial/territorial body called the Common Drug Review. Based on submissions from the manufacturers of prescription medications, the Common Drug Review assesses a particular medication’s “cost-effectiveness”. The Common

\* **Prescription medications:** a medication that is not available for purchase over the counter and requires a prescription from a physician

\*\* **Drug formulary:** an approved list of prescribed medications where cost to the consumer is covered either in full or is restricted, meaning certain criteria have to be met for full coverage.

Drug Review was formed several years ago to replace the highly varying review processes at the provincial level. The hope was that time savings could be achieved by creating a “common” drug review process and dismantling the individual provincial/territorial review processes.

However, this has not been realized as nearly all of the formularies maintained their own review process. In some provinces like British Columbia, the review process has grown along with review times and much poorer access to prescription medications for consumers and patients.

### Obstacle 3 : The provincial, territorial, private insurer review processes

At the end of its review process, the Common Drug Review issues a listing recommendation to provincial, territorial, private insurer drug formularies. Their recommendations can either be:

- **a full listing** – anyone with prescribing authority can prescribe the product and the formulary should cover its cost to the consumer or patient
- **a restricted listing** – anyone with prescribing authority can prescribe the product and the formulary should cover its costs as long as the consumer or patient meets specific criteria (such as, failure or intolerance to one or more older, usually less expensive medications)
- **do not list** – no coverage for cost to the consumer or patient.

Once formularies across the country receive the Common Drug Review recommendation for a particular prescription medication, they each embark upon their own highly varied review process. In many cases, these reviews fail to consult with experts from each disease/illness community or take into account “real world” patient experience, preferences and needs, and often, they lead to months and years of delay. Again, the people paying the price are Canadians with illness or disease who need timely, affordable access to the best, safest medicines.

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# Principles of a “national pharmaceuticals strategy” that serve the needs of people with arthritis

People with arthritis and other chronic diseases are directly affected by what prescribed medications are available to them depending where they live, and what public or private drug coverage they have. The goal of a national pharmaceuticals strategy (NPS) is to standardize the regulation and formulary drug coverage in Canada - nationally, provincially and territorially. Currently, health care is provided to Canadians under the Canada Health Act. However, there is no “act” for the provision of medications.

### Consumers involved in the national pharmaceuticals strategy policy development

Arthritis Consumer Experts is a member of the Best Medicines Coalition (BMC) that is working to put patients first with decision-making around health policy related to the availability and management of prescription medications. This grassroots group of consumer and advocacy organizations focuses on the reform of Canada’s drug review process to ensure access to best evidence-based medicines and to advocate for an effective system to monitor the safety of drugs once they have been approved and are in the market place.

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### Prescriptions

#### Obstacle 4 : Formulary reimbursement criteria varies from jurisdiction to jurisdiction

The last obstacle in the prescription medication review process is that formularies offer different levels of reimbursement for cost, making access inconsistent across Canada. For example, in British Columbia, there are many reimbursement plans that provide different levels of coverage. Certain plans make it such that patients cannot even afford to get the first prescription filled because simply filling the first prescription in a year’s course of treatment is too expensive. Other provinces have similar obstacles. These four obstacles, among many others, are significant and Canadians deserve the “universal” health care they are being promised and are paying taxes to get.

If you would like to share your views about access to prescription medications, or have experienced challenges getting reimbursed for your prescription medications, please write or email ACE at:

[info@arthritisconsumerexperts.org](mailto:info@arthritisconsumerexperts.org) <

The BMC took an in depth look at the pros and cons of how other countries developed and implemented their national pharmaceuticals strategies with respect to prescription medications and compared them to British Columbia’s prescription medications policies. What they discovered was alarming.

### Failed Policies

In British Columbia, to combat the high cost of prescription medications, the PharmaCare program has remodeled their policies after New Zealand’s program, that uses reference-based pricing, or “RBP”, and therapeutic substitution. Reference-based pricing groups medications together into a single group that either treat one disease or react similarly in the body. They then take the lowest priced medication in the group and set that amount to be reimbursed on the formulary. For patients, this means that although it saves the drug plan money, there is more out-of-pocket expense for individuals taking other prescribed medication in this group or limited access to the medications they need.

Another step BC made to save on the high cost of prescription medications was to impose rules to use generic drugs when possible through therapeutic substitution. This is effective if the generic medication is an exact copy of the patented one. However, some generic medications are similar but not exact but are ruled as being the same by the government. If a patient medication treatment plan is more effective with the patented medication to the therapeutic substitute, then the patient has to pay for the cost of treatment themselves or take a less effective medication.

New Zealand and Australia use cost-effective criteria for decisions around prescription medication approval and access in their countries. In Australia, they have the Pharmaceutical Benefits Scheme that approves and purchases all medications, including prescription drugs. The physicians have to get government approval for newer medications or ones that have a high cost. Even when government approval is not required, each prescription has a fee of \$28.60.

In New Zealand approved prescription medications are purchased by the government through the Pharmaceutical Management Agency through a bid system, where the lowest bid wins. In addition, the drug manufacturers offer package deals to sell two different prescription medication products together for a good price. This seems to put money first and not

patient needs.

The result of both New Zealand and Australia’s programs for access to prescribed medications is a cost-effective system for their governments, but not necessarily optimal for patient treatment plans. The research suggests that although these countries saved on pharmaceutical costs in the short-term, poorer health outcomes resulted in increased health costs overall with patients affected by these cost cutting measures for prescribed medications.

Norway and Sweden changed from reference-based pricing about five years ago because it did not produce the expected cost-savings, and affected both the physician’s ability to prescribe appropriate medication, and the quality of life for the patient. Now, Norway has a similar system to Canada’s with international competition for price regulation and more than one decision-making body for approval and access of prescribed medication.

### Where to go from here

Canada needs to develop a system that is both cost-effective and optimal for all Canadians with respect to access and coverage for prescription medications, especially for people with chronic illnesses, where medications make a difference of functioning on a day to day basis, along with a quality of life. Looking at the experiences of other developed countries can help work towards making Canada’s national pharmaceuticals strategy and implementation the best it can be.

The Best Medicines Coalition is committed to working together with government to ensure safe, timely and equitable access to the best medicines for all Canadians. The BMC bases the positions it takes regards drug formulary decision-making in Canada on the following principles:

- Individuals need access to drugs through an effective and efficient drug review and approval process.
- There needs to be an effective and responsive post-approval monitoring or surveillance system for drugs once they are released into the market and prescribed to individuals.
- The cost and access to drugs/medicines must not be a burden to individuals.
- Public participation/involvement and engagement in the various aspects of reforming Canada’s drug review, approval and monitoring systems is critical to ensuring optimal outcomes. <

## Listening to you

### A consumer perspective.....

Patient involvement is critical in decision-making around issues that directly affect them like health policy and health research. Arthritis Consumer Experts is pleased to share with you Ms. Louise Bergeron thoughts on the SARDS conference, where she participated as a person with lupus.

### Consensus Conference on Systemic Autoimmune Rheumatic Disease Research

## A research Forum on: Lupus, Scleroderma, Sjögren's Syndrome, Myositis and Vasculitis

By: Louise Bergeron

*I am a person who has been living with systemic lupus erythematosus for 10 years. My sister has been recently diagnosed with scleroderma. I am on the steering committee of the Canadian Arthritis Patient Alliance (CAPA) as co-chair of research and a board member of Arthritis Montreal Arthritis.*

### The Consensus Conference on Systemic Autoimmune Rheumatic Disease (SARDS)

**Research** was held in Toronto last December 3 and 4, 2005 with a consumer education day held December 2nd. Many stakeholders attended such as patients, basic and clinical researchers, pharmaceutical representatives, funding agencies and health care policy makers. SARDS includes lupus, scleroderma, Sjögren's syndrome, myositis and vasculitis diseases which cause daily

debilitating pain and fatigue with a survival rate significantly worse than the general population.

Some of the Conference objectives were:

- To create an opportunity for patients to participate in setting the research agenda.
- To provide an opportunity for funding research agencies to consult with consumers regarding priority national research themes for improved diagnosis, understanding, and management of these diseases.
- To help define a vision for Canadian research in systematic autoimmune rheumatic diseases.

The consumer education day was held prior to the conference, on December 2, 2005, chaired by Dr. Paul Fortin - who is currently chair of CaNIOS (Canadian Network for Improved Outcomes in Systemic Lupus Erythematosus). Presentations from various experts in the field of research gave an overview on research, research funding and advocacy. This day benefited many of the patient participants as it was the first time they have participated in a research conference. The information day gave us all a greater understanding about patient advocacy and what is involved in health research. It was also an opportunity for different SARDS patient groups to network and bring their concerns to the forefront.

During the scientific conference there were small breakout groups that discussed research priorities. Each group included at least one patient who was part of a team of diverse stakeholders. Even though we all came with different agendas there was little disagreement about one priority. For all, the priority is research into the outcomes of people suffering from SARDS, so better treatment options could be found for a better quality of life.

Some of the main highlights of the conference were:

- A topic of discussion was to research Lupus, Scleroderma, Myositis, and Vasculitis as a group in a collaborative approach because of the overlapping features of these diseases.
- A registry of all SARDS cases to measure the burden of disease on Canadian Society has been proposed.
- The CaNIOS (Canadian Network for Improved Outcomes in Systemic Lupus Erythematosus) approach to collaborative research was proposed as a model for the research of SARDS.

As a lupus patient, what I hope to see as an outcome of this conference is a concerted effort in research that will find a cure and better treatment options for SARDS patients, with the outcome of a better quality of life. One of the great problems with SARDS is the time it takes from diagnosis to treatment so continuing research may solve this problem. I would also like to see more awareness in the community on how SARDS impacts the lives of people who have to live with it. This group of diseases carries a high incidence of morbidity, disability, and mortality so research is necessary because people's lives are at stake. <

## Education

### Research into medication usage and the importance of consumer involvement in policy development

Canadians are living longer largely due to better health care including medications and surgical procedures. However, prescription medication usage and cost both have increased over the last twenty years. The rise in costs of prescription medications is largely due to the baby boomer generation, with half this group now over 50 years old.

Canadians with chronic diseases like inflammatory arthritis, waiting for prescription medication review and approval, can have life changing events with irreversible joint damage and permanent deformities. Social costs also need to be considered like the effects on people living with pain, loss of mobility, ability to work and the emotional stress not only on the person with the disease but their families, formal and informal caregivers, too.

Most Canadians benefit from the prescription medications they take in that they feel better and live longer. However, it is important that prescription medications are properly managed by monitoring the benefits and adverse affects of approved prescription medications. This type of research involves the input of Canadian consumers taking prescription medications.

Research is needed to look at the benefits of people taking prescription medications that include cost savings in areas like surgery, work loss, hospital and long-term care costs, and doctor visits. For example, one of the

most common reasons people have to stop work in Canada is due to arthritis and muscle and bone issues, with a cost of about \$13.6 billion per year (Economic Burden of Illnesses in Canada, 1998). To date there is not enough concrete data to suggest that the above cost savings are greater than the cost of the prescription medications to governments.

If a person is given the right prescription medication and other medically necessary services, it may decrease total health costs and improve health outcomes for the consumer. This is important to both government and consumers in Canada, especially those with chronic diseases like arthritis.

Consumers should play a role in determining what they need from health policy related to prescription medications. Consumer participation in the drug regulatory system would add a new and necessary dynamic to the decision-making process around drug review and issues related to access, reimbursement coverage, and safety and monitoring of health outcomes for prescription drugs. Consumers that are affected by decisions such as drug regulations, including withdrawal of drugs, should be represented at the decision-making table because these decisions directly affect them. In other words, health policy development should follow The International Alliance of Patient Organizations motto, "Nothing about us without us". <

## Arthritis Consumer Experts

### Who we are

Arthritis Consumer Experts (ACE) provides research-based education, advocacy training, advocacy leadership and information to Canadians with arthritis. We help empower people living with all forms of arthritis to take control of their disease and to take action in health care and research decision making. ACE activities are guided by its members and led by people with arthritis, leading medical professionals and the ACE Advisory Board. To learn more about ACE, visit

[www.arthritisconsumerexperts.org](http://www.arthritisconsumerexperts.org)

### Guiding principles and acknowledgement

#### Guiding Principles

Health care is a human right. Those in health care, especially those who stand to gain from the ill health of others, have a moral responsibility to examine what they do, its long-term consequences and to ensure that all may benefit. The support of this should be shared by government, citizens, and non-profit and for-profit organizations. This is not only equitable, but is the best means to balance the

influence of any specific constituency and a practical necessity. Any profit from our activities is re-invested in our core programs for Canadians with arthritis.

To completely insulate the agenda, the activities and the judgments of our organization from those of organizations supporting our work, we put forth our abiding principles:

- ACE only requests unrestricted grants from private and public organizations to support its core program.
- ACE employees do not receive equity interest or personal "in-kind" support of any kind from any health-related organization.
- ACE discloses all funding sources in all its activities.
- ACE identifies the source of all materials or documents used.
- ACE develops positions on health policy, products or services in collaboration with arthritis consumers, the academic community and health care providers and government free from concern or constraint of other organizations.
- ACE employees do not engage in any personal social activities with supporters.
- ACE does not promote any "brand", product or program on any of its materials or its web site, or during any of its educational programs or activities.

### Thanks

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### Disclaimer

The material contained in this newsletter is provided for general information only. It should not be relied on to suggest a course of treatment for a particular individual or as a substitute for consultation with qualified health professionals who are familiar with your individual medical needs. Should you have any health care related questions or concerns, you should contact your physician. You never disregard medical advice or delay in seeking it because of something you have read in this or any newsletter. ◀

  
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