

**MULTIPLE SCLEROSIS SOCIETY
OF CANADA**

**BRIEF TO THE HOUSE OF COMMONS STANDING
COMMITTEE ON HEALTH**

**STUDY ON PRESCRIPTION DRUGS
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INTRODUCTION

The Multiple Sclerosis Society of Canada is pleased to have this opportunity to provide input to the Standing Committee on Health on issues related to prescription drugs that are of concern to people who are affected by multiple sclerosis (MS).

In our submission the Multiple Sclerosis Society of Canada will focus on the high cost of drugs, access to drugs for people with MS and the need for improving post-market surveillance. We will also make some comments on the importance of ongoing health research in the battle against multiple sclerosis, an often disabling disease of the central nervous system. (Please see the appendix for more information about MS and the Multiple Sclerosis Society of Canada.)

HIGH COST OF PRESCRIPTION DRUGS

Drugs to actually affect the course of MS became available only in the mid 1990s. There are now four federally approved prescription drugs available for people with the most common form of multiple sclerosis. There is agreement among clinicians that people with MS benefit from early treatment with drugs that can reduce the frequency and severity of attacks and slow the progression of disability. In September, Health Canada extended the labeling for one of the drugs for people who have had one clinical attack and MRI-detected brain lesions consistent with multiple sclerosis.

Unfortunately, drugs to treat MS are very expensive, and therefore, economic barriers prevent far too many people with MS in accessing proven therapies. The drugs range in cost from \$12,000 to \$24,000 a year. Currently provincial and territorial drug programs provide uneven access and compensation as illustrated by the attached chart showing current provincial criteria and reimbursement for the four therapies.

The MS Society welcomed the promise in the 2003 First Ministers' Accord on Health Care Renewal to provide reasonable access to catastrophic drug coverage by the end of 2005/06. We urge the government, on behalf of people with MS waiting for drug coverage, to speed up this timetable.

ACCESS TO PRESCRIPTION DRUGS

In June 2003, the Multiple Sclerosis Society of Canada joined more than 50 stakeholders at a two-day session organized by the Public Policy Forum on Improving Canada's Regulatory Process for Prescription Drugs. We support the directions that emerged from this meeting, particularly:

- There must be a real commitment to openness and transparency by the therapeutic products regulator;
- Facilitating informed choices by people who require drug therapy should be an underlying principle of the regulatory process. Voluntary health organizations can and should play an important role in public education.

- Health Canada has a responsibility to facilitate access to therapeutic products for Canadians – for many people who require drug therapy accessibility is about ensuring the availability of safe, effective and affordable therapeutic products in a timely fashion.

Transparency and Timeliness

Health Canada's Therapeutic Product Directorate must do its part and have the resources available to it to carry out timely reviews to ensure that beneficial therapies are available to people who need them in a reasonable timeframe. It is also important that this process be transparent to all stakeholders. Transparency needs to be a paramount principle within the TPD. This involves everything from simply having information available to the public as to whether a particular product is under review to more detailed information about whether the review is on target. Presently, TPD is not allowed to provide to the public the status of drugs under review. Instead, it is left to the pharmaceutical company to provide that information if it so wishes.

Timeliness is vital to Canadians who rely on prescription drugs. Today, it takes on average of 717 days for new drugs to be approved in Canada. This is more than double the target of 355 days the federal government has set for itself. The government should strive to ensure Canadians who need prescription drugs and their health care professionals have faster access to better and new drugs through a regulated review and approval system that is efficient, well resourced, rigorous and comprehensive.

As a member of the Best Medicines Coalition, we join in calling on the federal government to provide all Canadians, with timely and consistent access to the best medicines by dramatically improving the drug review system for new drugs, and the process for ensuring that effective old drugs remain accessible on the market.

Provincial Differences in Access

While improvements to the drug approval process at the federal level is a very important aspect of enhancing the access of Canadians to prescription drugs, it is equally important to understand that issues at the provincial level can have a significant impact on how people access the medicines that they need. Access to drugs for people with MS should be universal and comprehensive across Canada. This access should not depend on where a person lives in Canada.

We are aware that provincial matters are outside of the Committee's mandate, however we would like to note that improvements in provincial reimbursement programs, prompt listing of drugs on provincial formularies and ensuring that the Common Drug Review speeds up the drug review process at the provincial level would greatly enhance access to prescription drugs. It is important that the Common Drug Review not become just another layer of review and delay.

We would also like to reiterate that the timetable to provide reasonable access to catastrophic drug coverage across Canada should be speeded up.

[Overview of provincial government coverage for MS disease modifying therapies]

POST-MARKET SURVEILLANCE

With MS therapies now having been available for several years, some individuals are starting to report issues with taking them that need to be captured by a robust post-market reporting system.

We are encouraged by the creation of Health Canada's Marketed Health Products Directorate with the mandate to coordinate the monitoring, collection and analysis of adverse reaction and medication incident data. We encourage a more active public education component so that the people who are taking medications have a clear understanding of the adverse reaction reporting process, how they can provide information about adverse reactions and how they can obtain up-to-date and accurate information about their medicines.

Therefore, we urge the government to ensure active post-market monitoring strategies and standards are in place that allow safety and effectiveness of drugs to be evaluated in a timely, appropriate and accurate manner and that information is communicated to consumers.

HEALTH RESEARCH

People living with multiple sclerosis today need access to treatments that can modify the course of the disease. But to have even better treatments and to find the way to prevent future generations from developing this devastating disease, they also need a robust, federally supported research program that will be an integral part of solving the MS problem. The Multiple Sclerosis Society of Canada supports its own large research program which is targeted at finding the cause of MS, ways to prevent it, discover better treatments and ultimately discover the cure. Key to the success of health research in Canada is a well-funded and stable federally funded research strategy that can complement the research program supported by the MS Society.

The creation of the Canadian Institutes of Health Research several years ago signalled that the Government of Canada recognized the importance of research to the overall future health of Canadians. We urge that this important investment continue and be expanded in the coming years to provide the needed stability for health research.

In particular, we note that stem cell research has great potential for people with multiple sclerosis, because of the real possibility for breakthroughs that will lead to a cure for multiple sclerosis. We applaud the government for having introduced legislation that will provide a regulated framework for stem cell research in Canada.

CONCLUSION AND RECOMMENDATIONS

The Multiple Sclerosis Society of Canada is grateful for this opportunity to present our views on this important topic. In summary, we recommend that:

- The timetable in the 2003 First Ministers' Accord on Health Care Renewal to provide reasonable access to catastrophic drug coverage by the end of 2005/06 be speeded up by a minimum of 12 months.
- The direction of the recommendations from the consultation facilitated by the Public Policy Forum on improving the regulatory process for prescription drugs should be followed without delay.
- Transparency in reporting to all stakeholders from the Therapeutic Products Directorate or any future drug regulatory body must be a primary principle.
- Reviews of therapeutic products must be carried out in a timely and efficient manner to ensure that Canadians have access to proven and safe medications. Public performance targets should be set to ensure success.
- Access to drugs in Canada should be universal and comprehensive and not dependent upon where a person lives.
- The government must ensure active post-market monitoring strategies and standards are in place that allow safety and effectiveness of drugs to be evaluated in a timely, appropriate and accurate manner and that information is communicated to consumers.
- The federal government should provide stable and adequate funding for health research to enable Canadian researchers to advance knowledge leading to new and better treatments for diseases.

APPENDIX

BACKGROUND ABOUT MULTIPLE SCLEROSIS AND THE MULTIPLE SCLEROSIS SOCIETY OF CANADA

Multiple sclerosis is a chronic disease of the central nervous system that unfortunately often leads to severe disability. Studies indicated that Canada has one of the highest rates of MS in the world. Usually diagnosed between the ages of 20 and 40, MS is the most common disease of the central nervous system affecting young adults in Canada.

MS attacks the protective myelin covering of the nerves, causing inflammation and often the destruction of the myelin in patches. This interrupts the normal flow of nerve impulses. The results often include vision problems, numbness, loss of balance, extreme fatigue and even paralysis. Periods of spontaneous recovery are interrupted by unpredictable attacks that over time result in most people with MS becoming disabled.

The MS Society of Canada is the only national voluntary organization in Canada that supports both multiple sclerosis research and services for people with MS and their families. In addition to the national organization, there are seven regional divisions and more than 120 chapters across Canada. More than 1,500 individuals serve on the national, division and chapter boards and 13,500 individuals organize and deliver service programs, fund raising events, public awareness campaigns and social action activities. Eighty percent of the Society's net revenue goes directly to fund MS research, client services and other programs for people with MS and their families while administration and fund raising costs account for just twenty percent.

The Multiple Sclerosis Society of Canada is a major funder of MS research in Canada. The MS Society was founded in 1948 and less than a year later was able to provide its first research grant of \$10,000 to the Montreal Neurological Institute. Today, the MS Society supports a research program that totals approximately \$6 million each year.