Feedback submitted to the Patented Medicines Pricing Review Board from the Multiple Sclerosis Society of Canada related to Excessive Drug Pricing in Canada

Deadline:	**Monday, October 24, 2016**
Submitted to:	Patented Medicine Prices Review Board (Rethinking the Guidelines) E-mail: PMPRB.Consultations.CEPMB@pmprb-cepmb.gc.ca
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Background

Multiple sclerosis is an unpredictable, often disabling disease of the central nervous system. In Canada, there are approximately 100,000 people living with MS. Eighty-five to ninety per cent of all people living with MS have relapsing MS, which is characterized by neurological attacks (relapses) followed by periods of near or full recovery (remission). The remaining ten to fifteen per cent of people live with a progressive form of the disease, which follows a course of slow accumulation of disability without relapses.

The most commonly reported MS symptoms include fatigue, difficulty in walking, visual impairment, memory or attention problems, depression, bladder problems, paresthesia, heat intolerance and sensitivity, and pain. MS can occur at any age, but is usually diagnosed between the ages of 15 to 40, and has been diagnosed in children as young as two years old, and adults over 50.

MS can significantly affect employment, education, physical activity, family commitments, interpersonal relationships and social and recreational life. MS varies considerably from person to person, and in the severity and course of the disease. It is impossible to predict what course the disease might take and how individuals will be affected over time.

Information gathering for this report

To better understand what ‘excessive’ drug pricing means to Canadians affected by MS, a short poll about MS medication usage, including cost coverage, was developed and posted on our social media channels. We received 232 responses in English and French. Most respondents were employed full-time and accessed their medications through private insurance offered as part of their employee benefits program. More than eighty percent of all respondents stated that they would be unable to continue treatment if they did not have access to an insurance plan (private or public). ‘High cost’, followed by ‘standardized access and cost of drugs’ were identified as the top two areas of improvement required in terms of accessing MS medications in Canada.

MS Medications: Disease modifying therapies in Canada

Health Canada has approved eleven drugs to treat relapsing forms of MS, collectively referred to as disease-modifying therapies, or DMTs. These medications have shown to be efficacious and safe in reducing annual relapse rates (ARR) between 30 and 70 per cent, depending on the agent being used. These drugs are also effective in slowing disability progression and reducing the number or new or enhanced lesions (as seen on MRI). Currently there are no approved MS medications for progressive forms of MS.

The annual cost of DMTs range from approximately $16,000 to $30,0000 for first-line therapies, and $50,0000 or more, for second or third line therapies. The vast majority of these drugs are included on provincial, territorial and federal formularies, overseen by ‘special’ or ‘exceptional access’ drug programs that require a case-by-case approval for reimbursement due to their high cost. Certain criteria must be met in order to be eligible for public reimbursement or coverage of these drugs. Many people do not meet the necessary criteria for various reasons including but not limited to: their doctor filled the paperwork incorrectly, the patient is covered under another plan; not enrolled in the provincial plan; cancelled due to arrears in premiums, or the patient does not meet the specific medication criteria.

Private health insurance, either group or individual plans, and some pharmaceutical company assistance plans also cover the cost of these drugs. Most of the MS medications cost the same as or exceed an average annual salary. Without drug plans in place (public, private or industry), financial access to these drugs would be unattainable by the vast majority of Canadians who live with relapsing MS. Some individuals have gone in to debt to afford their medications, and as a result some have lost their homes. Many people equate the excessive cost of the drugs to a mortgage payment.

> *‘The cost of the medicine is more than I make a month, without my company drug plan this would be financially impossible.’*
>
> *‘The monthly cost of these drugs is equal to a small mortgage, except it's a mortgage that you pay your entire life. Even at 90% coverage, my family has to make sacrifices. I can't imagine what someone without a good plan would do.’*

> *'The cost of my drug comes in to my pharmacy at just under $1,800 for a 28-day supply. That's more than my mortgage.'*
>
> *'Without my drug plan through work there is no way I could afford my medicine. The cost of my meds each month is only a few hundred dollars less that I make a month working fulltime. If I had to pay for my meds myself, we would not be able to pay the bills.'*

In addition to the high cost of medications, the episodic nature of multiple sclerosis creates unique employment issues. Many people are unable to maintain stable jobs or remain in the workplace due to relapses, symptoms, medication side-effects and disability progression. This often results in loss of employment benefits including private group insurance plans that cover partial or full cost of MS medications, forcing people to apply for public reimbursement and in some provinces the cost of these medications is not covered one hundred per cent. Many Canadians are therefore left out of pocket or unable afford the medications at all.

> *'My medication is extremely expensive and I simply wouldn't be taking it if I ever lost my job and wasn't covered under their drug plan.'*
>
> *'The cost of the medicine is more than I make a month, without my company drug plan this would be financially impossible.'*
>
> *'If I was not working for a company with benefits, I would not be able to take the drug. It's way too expensive... it's pretty easy to see that.'*

According to a 2013 report, *Comparative Clinical and Cost-Effectiveness of Drug Therapies for Relapsing-Remitting Multiple Sclerosis*, published by the Canadian Agency for Drugs and Technologies in Health (CADTH), the cost of a mild to moderate relapse can cost the health care system upwards of $6,400 while an acute relapse could cost up to $15,000. Without treatment, those with relapsing forms of MS would likely continue to experience relapses ranging in severity, requiring hospitalization and treatment with other medications. Ultimately this incurs a much higher cost to health care systems overall.

In a recent report published by the Conference Board of Canada, *The Value of Specialty Medications: An Employer Perspective*, societal benefits of specialty medications include a decrease in caregiving needs of working relatives and reduced use of healthcare resources, which total an estimated $10,700 to $17,000 per employee in benefits depending on the disease.

MS therapies cost a minimum of $16,000 annually, which can go up to approximately $50,000(or more). Second line therapies, which are taken after a patient has failed on an initial or first line therapy, are more therapeutically aggressive but are highest in cost. Of the eleven approved therapies, three are second line options.

There is no ‘standard’ MS medication. Although several MS medications have similar mechanisms of action, dosing and administration are not the same and therefore the options available to people are selected based on tolerance, known (expected) side-effects, lifestyle choices, disease course and cost. It is common for one treatment to work well in one individual, and fail in another.

Although there is a growing number of options, the cost of newer therapies is also increasing. Both public health insurance plans and private payers require that individuals meet specific criteria before they will cover the cost of an MS medication, or require a higher co-pay. Some people are denied their applications for drug coverage, while others cannot afford the co-pay.

> *‘The provincial co-payment is significant enough that the cost is too prohibitive when other expenses are accounted for (i.e. child care).’*
>
> *‘*
>
> *The coverage will not cover the full cost of the drug and will still cost thousands to go on [continue treatment].’*

Pharmaceutical Companies and MS Medications

Although marketed under different brand names, the same treatments for multiple sclerosis are available in other developed countries. Of the eleven MS medications approved in Canada, four are marketed by the same pharmaceutical company, who have another MS medication currently pending approval with Health Canada, and three other agents in their product pipeline. Two other large pharmaceutical companies in multiple sclerosis therapeutics each have two MS medications on the market and the remaining three companies each have one MS medication on the market.

In Canada, pharmaceutical companies that market MS medications set list prices for first line MS medications competitively, ranging between $16,000 and $24,000. At this time, there is no Health Canada approved generic or biosimilar available for treatment of MS, however a generic MS medication has been developed and is pending Health Canada approval. The brand name counterpart of the generic drug pending Health Canada approval has been identified by CADTH (*Comparative Clinical and Cost-Effectiveness of Drug Therapies for Relapsing-Remitting Multiple Sclerosis)* as the most cost-effective MS medication, and was is the most widely used medication among the respondents in our poll. Once the generic version of this medication is available in Canada, the landscape for prescribing MS medications, including public and private payer criteria and decision making, will be impacted. It is possible that the cost of the drug, according to a payer, may play a much larger role in determining what is best for an individual therapeutically.

Conclusion

The MS Society appreciates the opportunity to provide feedback to the Patented Medicine Prices Review Board (PMPRB)’s consultation with stakeholders. The MS Society is committed to ensuring that Canadians have timely and standardized access to MS medications. The cost of these medications is not possible for most individuals to cover on their own, however the costs should not be so excessive that public payers are forced to tighten criteria for reimbursement leaving many people unable to qualify for coverage, or so high that provinces will not include medications on their formulary.

Overall, MS Society believes that:
Governments need to ensure people with MS have timely access to affordable treatments.

- The provincial and territorial governments need to provide timely access and public reimbursement to all Health Canada-approved MS therapies.
- The federal government should establish nation-wide access standards for drugs needed to treat multiple sclerosis.

The high cost of patented medicines in MS has been an area of concern for people living with MS and public payers since the first disease-modifying treatments for MS entered the Canadian market over twenty years ago. Now, with eleven MS medications on the market, and several others pending approval, including one generic, cost of MS medications will become a greater issue.

The MS Society of Canada supports the role of PMPRB in setting the ceiling price for patent medicines. We will also recommend that the PMPRB seek opportunities to meaningfully and continuously engage patient representatives in their decision making and regulatory processes.