



Consulting on Proposed Amendments to the Patented Medicines Regulations Submission by the Multiple Sclerosis (MS) Society of Canada June 2017

About the MS Society of Canada

The MS Society provides services to people with multiple sclerosis and their families to enhance their quality of life, and funds research to find the cause and cure for this disease. We have a membership of 17,000 and are the only national voluntary organization in Canada that supports both MS research and services. Since our founding in 1948, the core support of the MS Society has been from tens of thousands of dedicated individuals, companies and foundations in communities across Canada.

Introduction

The MS Society of Canada is pleased to provide this submission to the consultation underway regarding the Proposed Amendments to the Patented Medicines Regulations.

MS impacts all Canadians - not only the affected individuals, but also their families. The unpredictability and episodic yet progressive nature of MS makes it particularly challenging in maintaining an adequate quality of life. This along with the challenges of living with a disability which has both visible and invisible symptoms and the barriers in our support programs across all levels of governments creates immense financial challenges for Canadian families who struggle to manage the realities of living with MS.

People living with MS are mothers, fathers, sisters, brothers, children, and friends. They are people who are impacted by this disease every day, every hour, and every minute. The needs of people with MS and their families should be at the centre of health and drug policy decisions. Therefore, their perspectives and experiences should be a top priority in this consultation.

Throughout our submission, we reinforce why equal and timely treatment and healthcare access, affordability, appropriate prescribing, and accountability is so important for Canadians living with MS. Firstly, we provide information and commentary based on our interactions with people affected by MS as well as a survey we launched to better understand what 'excessive' drug pricing means to Canadians affected by MS. Then, we describe the current environment of MS medications in Canada along with quotes from survey participants. Next, we comment on the proposed amendments to the Regulations.

Finally, we note that our response to the consultation questions is aligned with the perspectives of the Health Charities Coalition of Canada, of which the MS Society is a member.

MS is Canada's Disease

MS is a chronic, often disabling, disease of the central nervous system. Since that includes the brain, spinal cord and optic nerve, MS can affect vision, memory, balance, and mobility. It is the most common neurological disease affecting young adults in Canada. Most people with MS are diagnosed between the ages of 15 and 40. MS is three times as likely to occur in women as in men. The unpredictable effects of MS are physical, emotional, and financial and last for the rest of their lives.

Canada has the highest rate of MS in the world, and consequently, it is often referred to as "Canada's Disease."

Information gathering for this report

A targeted poll about MS medication use, including private insurance and public coverage, was developed and circulated via the MS Society's 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 most important challenges in terms of accessing MS medications in Canada. The findings from this poll formed the basis for the MS Society submission for the previous consultation "*Patented Medicines Pricing Review Board Rethinking the Guidelines.*"

In addition to this poll, we provide information below based on a MS Society initiative called "*Listening to People Affected by MS*" where we heard from more than 6,000 Canadians affected by MS allowing us to better understand the impact of multiple sclerosis on quality of life (QOL) needs, gaps and barriers. We heard from a broad range of people including those diagnosed with MS, people waiting for a diagnosis of MS, informal caregivers of a person with MS, family members and close friends of people with MS. MS Society's interactions with people affected by MS across Canada. We believe both sources of information provide a breadth of perspective to this consultation.

MS Medications: Disease modifying therapies in Canada

Health Canada has approved 13 disease-modifying therapies (DMTs) to treat relapsing forms of MS. They reduced annual relapse rates (ARR) by 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 in Canada for progressive forms of MS.

The annual cost of DMTs for MS range from approximately \$16,000 to \$30,000 for first-line therapies, and \$50,000 or more, for second or third line therapies. The vast majority of these drugs are included on some 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. Individuals with MS must meet certain criteria in order to be eligible for public reimbursement. Many people do not meet the necessary criteria for various reasons, including but not limited to, their doctor having filled the paperwork incorrectly, the patient having coverage under another plan; not being enrolled in the provincial plan; cancelled due to arrears in premiums, or the patient not meeting the specific medication criteria.

Group or individual private health insurance plans, and some pharmaceutical company assistance plans, may also cover the cost of these drugs. Most MS medications cost the same as or exceed an average annual salary. Without drug plans in place (public, private or industry), financially, access to these drugs would be unattainable by the vast majority of Canadians who live with relapsing MS. Some individuals have gone into 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 than I make a month working fulltime. If I had to pay for my meds myself, we would not be able to pay the bills.'

We hear from people who are frustrated with the inequality of publicly funded treatments across the provinces/territories. There is unequal access when one province covers the cost for a certain drug that other provinces do not, and that individuals in those provinces may worsen in their disease because of this. As a result, we've heard of people having to move provinces simply to access a drug; this is disruptive to their lives and could have serious health implications (changing doctors, stress, loss of support systems, etc.).

In addition to the high cost of medications, the episodic nature of MS creates unique employment issues. Many people are unable to maintain stable jobs or remain in the workplace due to relapses, symptoms, medication side-effects, disability progression, and psychosocial and cognitive issues. 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. 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.

DMTs for MS can 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 13 approved DMTs, four 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 there are various options available, from which people with MS and their healthcare providers can make decisions 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 drug plans and private payers require that individuals meet specific criteria before they will cover the cost of a MS medication, or require a higher co-pay. Some people are denied their applications for drug coverage, while others cannot afford the co-pay. There is also a time delay for public drug plans to list MS medications on their formularies with cost being a concern.

'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].'

Proposed amendments to the Regulations

We agree that a pharmaeconomic evaluation would be valuable to help better regulate excessive drug pricing in Canada, however this evaluation should only be used if it is complimentary to the Canadian Agency for Drugs and Technologies in Health (CADTH)/ l'Institut national d'excellence en santé et en services sociaux (INESS) quality-adjusted life year (QALY) evaluation, and not in addition to CADTH or INESS. The important role and relevance of CADTH and INESS should not be duplicated.

Cheaper drugs does not mean improved access to drugs. Access is a key challenge and an important priority for people living with MS. The QALY evaluation does not include some metrics that are important to patients, the lived experience. Ensuring the patient voice is a part of the equation is key.

The proposed amendments to the regulations must be neutral to the market launch of drugs. Market launch times must not be affected by the amended regulations. Timely access to medications is vital to many individuals living with MS, especially for those who are unable to tolerate the current medications that are available to them.

Like many Canadians with rare diseases or disorders, people living with MS face significant challenges in gaining access to therapies. As discussed in the consultation document, the government must acknowledge that one medication may not meet the needs of all patients living with a certain disease or condition. This is especially true for a disease like MS where no two patients have the same course of the disease and/or respond in the same way to the same medication.

While we appreciate the fiscal realities, we are concerned about the potential impact that a cost-containment environment will have on the private sector and we would be supportive of the federal government seeking opportunities to work with the private sector to advance research and find opportunities to incentivize innovation in Canada.

Conclusion

The MS Society believes that the Government of Canada should ensure people with MS have equitable and timely access to treatments based on the best possible health outcomes rather than the ability to pay. An effective and sustainable drug approval process and regulatory framework for evaluating drug pricing are key in providing timely and affordable access to medicines for Canadians. The PMPRB plays an important role in this landscape and we commend their efforts to review and revise regulations on patented drug pricing in Canada.

In summary, we recommend:

- In making decisions around approval and access to MS treatments we should take into account the perspectives of people with MS. This is of utmost importance in addition to the most current scientific knowledge available and acknowledges the importance of their quality of life.
- Changes only if they are in alignment with the position that Canadians deserve affordable, high-quality therapies and services that are appropriate for their individual lifestyles and needs.
- That any changes need to support timely and affordable access to interventions that are the most efficacious early in the disease, considering the variability that exists in the MS population, as well as the importance of choice.



- These amendments must ensure timely access to medications which is vital to many individuals living with MS, especially for those who are unable to tolerate the current medications that are available to them.
- These amendments do not duplicate the current work of other agencies involved in the drug approval process in Canada.

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