Reckitt Benckiser Pharmaceuticals (Canada)

2014 Pre-Budget Consultations

Identifying priorities for the 2015 Federal Budget

Cameron Bishop -- Co-Chair, Legislation & Regulation Committee, National Advisory Council on Prescription Drug Misuse & Director of Health Policy & Government Affairs, Reckitt Benckiser Pharmaceuticals Canada

August 5, 2014

Executive Summary

Two of the government's themes will be addressed in these recommendations:

- **Supporting families and helping vulnerable Canadians by focusing on health, education and training; and,**
- **Improving Canada's taxation and regulatory regimes.**

Recommendations

- In accordance with the spirit of Recommendation 12 of the 2014 Study by the House of Commons Standing Committee on Health (HESA) entitled "Government's role in addressing prescription drug abuse", Budget 2015 should require that naloxone be added to all federal formularies in order to address overdose deaths from prescription opioids or illicit drugs[1]. Further, the federal government should direct funding from the 2015 Budget to support the expansion of community-based take-home naloxone programs nationwide.

  Legislative/regulatory action:
  a. Amend legislation to operationalize the addition of naloxone to federal formularies;
  b. Earmark a funding envelope to expand community-based naloxone programs;
  c. Reschedule naloxone under Canada's *Food & Drugs Act* to make it available without prescription; and,
  d. Legislate a requirement that naloxone be co-prescribed when a patient is prescribed an opioid analgesic for chronic pain treatment.

- The 2015 Budget should direct funding to the Canadian Institute of Health Information (CIHI) for the development, in cooperation with the provinces & territories, of a real-time pan-Canadian prescription drug monitoring & surveillance system. The system would be responsible for tracking patterns of prescriptions of drugs of abuse across provincial and territorial borders, providing governments at both levels with the information necessary to identify issues and trends that require attention, funding, research or intervention by governments, law enforcement, or other actors. This recommendation was first put forward in the March 2013 strategic plan released by the National Advisory Council on Rx Drug Abuse, "First Do No Harm"[2].

- The 2015 Federal Budget should allocate funding to the Canadian Centre on Substance Abuse to allow it to operationalize the recommendations contained in the "First Do No Harm" report, such as the conducting of a study to estimate the most recent health, social and economic costs of prescription drug misuse and harms in Canada.

---

[1] HESA, "Government's Role in Addressing Prescription Drug Abuse", Report of the Standing Committee on Health, April 2014: p.35.
[2] National Advisory Council on Prescription Drug Misuse, "First Do No Harm: Responding to Canada's Prescription Drug Crisis", March 2013: pp 42-45.

- The 2015 Federal Budget should provide funding, administered through the First Nations & Inuit Health Branch of Health Canada, to the development of culturally sensitive training locums in addiction treatment for health care practitioners who are willing to be deployed on ongoing rotations to rural and/or remote First Nations communities identified as high-need with respect to prescription drug abuse and dependence. These health practitioners would be trained in opioid dependence, the treatment of the disease, and after-care. The locum training would be open to family physicians, nurses, nurse practitioners, counselors, addiction specialists and other relevant health practitioners. The training locum program would begin as a one-year pilot project.

- The 2015 Federal Budget should direct the Canadian Institutes of Health Research to develop a research strategy to better understand the epidemic of prescription drug misuse and harms, including addiction, concurrent disorders, chronic pain, overdose and death[3].

- Roll back the provisions contained in Budget 2012 that decreased the tax credit rate of the Scientific Research & Experimental Development (SR&ED) Tax Incentive Program. In fact, Budget 2015 should increase the tax credit rate under the SR&ED Tax Incentive Program to 25%.

- As referenced in Recommendation 8 of the 2012 "Action Plan to Help Attract More Clinical Trials to Canada", Budget 2015 should also update Canadians on plans or progress towards improving the administration of SR&ED tax credit so that credits are received within an appropriate time frame to offset the costs of clinical trials[4].

[3] National Advisory Council on Prescription Drug Misuse, p. 54.
[4] Association of Canadian Academic Healthcare Organizations, "An Action Plan to Help Attract More Clinical Trials to Canada", March 30, 2012: p. 26.

On behalf of Reckitt Benckiser Pharmaceuticals (Canada), please accept, for consideration by the House of Commons Standing Committee on Finance, recommendations for inclusion in the 2015 Federal Budget. These recommendations will focus on the area of addiction & addiction treatment with the aim of seeing the federal government build on its 2014 five-year investment of $44.9 million to address prescription drug abuse & dependence in Canada, as well as its 2013 Speech from the Throne commitment.

Two of the government's themes will be addressed in these recommendations:

- **Supporting families and helping vulnerable Canadians by focusing on health, education and training; and,**
- **Improving Canada's taxation and regulatory regimes.**

Background

Reckitt Benckiser Pharmaceuticals (RBP) is an addiction treatment company that manufactures ^{N}Suboxone® (buprenorphine/naloxone) sublingual tablets -- the first opioid medication approved for the substitution treatment of opioid dependence in an office-based setting. Above and beyond that, RBP works extensively in partnership with government and key stakeholders to break down barriers to accessing treatment for patients; this includes addiction policy reform and legislative and regulatory proposals..

Opioid dependence, a chronic relapsing medical condition of the brain, is a well-recognized clinical and public health problem in Canada. Indeed, Canada is the second-highest per capita user of opioids in the world, after the United States[5]. A 2009 study by Popova et al indicated that there are between 321,000 and 914,000 non-medical prescription opioid (PO) users among the general population in Canada. Further, the estimated number of non-medical PO users, heroin users, or both, among the street drug using population, was about 72,000, with more individuals using non-medical PO than heroin in 2003[6]. Historically, heroin was the primary substance fuelling opioid dependence; the current reality is much more diverse and complex. In Canada, illicit opioid use encompasses a variety of prescription opioids including oxycodone, codeine, morphine, and hydromorphone. We also know that the drugs of abuse are evolving. As the supply of oxycodone contracts, other prescription opioids like fentanyl and hydromorphcontin are becoming increasingly linked to addiction and overdose, in no small part because of the easily-abusable formats these drugs are produced in.[7]

[5] Canadian Centre for Substance Abuse. http://www.prescriptiondrugmisuse.ca/wp-content/uploads/2010/01/CCSA-Media-Release-Prescription-Drug-Misuse.pdf
[6] Popova, S. "An overview of illegal opioid use and health utilization services in Canada", Journal of the Royal Institute of Public Health (2006) xx, 1–9
[7] Ramsay, J. "Drug users went to fentanyl when Oxy delisted". Ontario Pharmacists Association (February 2013).

We know the costs of addiction to the federal government. In 2002, the nationwide costs of counseling and psychosocial supports, treatment for comorbidities, and addiction's costs to the social welfare system and criminal justice system, were estimated at $39.8 billion.[8] In 2014 dollars, that amounts to over $48 billion, however, knowing that opioid abuse has surged since 2002[9], the real cost is certain to be much higher. As this epidemic continues to spread, we are looking at a unique and systematic drain on our economic resources. These figures do not include the annual costs to Canada's Non-Insured Health Benefits program associated with providing medication to treat opioid dependence, nor does it take in to account the expenditures on travel provided to opioid dependent patients to transport them to and from their communities in order for them to access some forms of opioid dependence treatment.

Supporting families & helping vulnerable Canadians by focusing on health, education & training

In light of the serious health and economic impacts of prescription drug misuse, abuse and dependence, we submit the following recommendations for consideration:

- In accordance with the spirit of Recommendation 12 of the 2014 Study by the House of Commons Standing Committee on Health (HESA) entitled "Government's role in addressing prescription drug abuse", Budget 2015 should require that naloxone be added to all federal formularies in order to address overdose deaths from prescription opioids or illicit drugs[10]. Further, the federal government should direct funding from the 2015 Budget to support the expansion of community-based take-home naloxone programs nationwide.

  Legislative/regulatory action:
  a. Amend legislation to operationalize the addition of naloxone to federal formularies;
  b. Earmark a funding envelope to expand community-based naloxone programs;
  c. Reschedule naloxone under Canada's *Food & Drugs Act* to make it available without prescription; and,
  d. Legislate a requirement that naloxone be co-prescribed when a patient is prescribed an opioid analgesic for chronic pain treatment.

- The 2015 Budget should direct funding – whether new or previously earmarked – to the Canadian Institute of Health Information (CIHI) for the development, in cooperation with the provinces & territories, of a real-time pan-Canadian prescription drug monitoring & surveillance system. The system would be responsible for tracking patterns of prescriptions of drugs of abuse across provincial and territorial borders, providing

[8] Rehm, Fischer & Kalousek, "Illicit Opioid Use, Treatment and Economic Costs, and Options for Cost Reduction: An Overview and Estimations," Report to the City of Vancouver's Drug Policy Program, December 8, 2006.
[9] Lynch & Fischer, "Prescription opioid abuse: What is the real problem and how do we fix it?" *Canadian Family Physician*, November 1, 2011 57:1241-1242.
[10] HESA, "Government's Role in Addressing Prescription Drug Abuse", Report of the Standing Committee on Health, April 2014: p.35.

governments at both levels with the information necessary to identify issues and trends that require attention, funding, research or intervention by governments, law enforcement, or other actors... This recommendation was first put forward in the March 2013 strategic plan released by the National Advisory Council on Rx Drug Abuse, "First Do No Harm"[11]. The aforementioned 2014 HESA report reinforced the need for this recommendation: *"Health care practitioners also explained that there is need for an interoperable real-time monitoring and surveillance system to prevent the inappropriate prescribing of medications and abuse of the health care system to obtain prescription drugs. For example, the Committee heard that the absence of real-time data available through a pan-Canadian interoperable system means that health care practitioners are unable to look up the medical history of a patient to determine whether he or she has received the same prescription from another practitioner from within the same community or from another jurisdiction, in order to prevent double doctoring"*[12].

- The 2015 Federal Budget should allocate funding to the Canadian Centre on Substance Abuse to allow it to operationalize the recommendations contained in the "First Do No Harm" report, such as the conducting of a study to estimate the most recent health, social and economic costs of prescription drug misuse and harms in Canada;

- The 2015 Federal Budget should provide funding, administered through the First Nations & Inuit Health Branch of Health Canada, to the development of culturall sensitive training locums in addiction treatment for health care practitioners who are willing to be deployed on ongoing rotations to rural and/or remote First Nations communities identified as high-need with respect to prescription drug abuse and dependence. These health practitioners would be trained in opioid dependence, the treatment of the disease, and after-care. The locum training would be open to family physicians, nurses, nurse practitioners, counselors, addiction specialists and other relevant health practitioners. The training locum program would begin as a one-year pilot project.

- The 2015 Federal Budget should direct the Canadian Institutes of Health Research to develop a research strategy to better understand the epidemic of prescription drug misuse and harms , including addiction, concurrent disorders, chronic pain, overdose and death[13]. This recommendation was also first put forward in the March 2013 "First Do No Harm" report.

The federal government is to be commended for the work it is doing, and has done, on the issue of prescription drug abuse. Still, more comprehensive action is needed in order to realize demonstrable results.

[11] National Advisory Council on Prescription Drug Misuse, "First Do No Harm: Responding to Canada's Prescription Drug Crisis", March 2013: pp 42-45.
[12] HESA, April 2014: pp. 21-23.
[13] National Advisory Council on Prescription Drug Misuse, p. 54.

Improving taxation and regulatory regimes

The federal government should be commended for their April 2014 announcement of the creation of the Canadian Clinical Trials Coordinating Centre. In order to further encourage businesses to conduct research and development activities in Canada, Budget 2015 should:

- Roll back the provisions contained in Budget 2012 that decreased the tax credit rate of the Scientific Research & Experimental Development (SR&ED) Tax Incentive Program. In fact, Budget 2015 should increase the tax credit rate under the SR&ED Tax Incentive Program to 25%. In so doing, the federal government will encourage greater investment from all business sectors, and could – as referenced in the November 2012 report by the Senate Standing Committee on Social Affairs, Science & Technology – help promote Canada as a favourable environment in which to conduct clinical trials for new drug products[14].

- As referenced in Recommendation 8 of the 2012 "Action Plan to Help Attract More Clinical Trials to Canada", Budget 2015 should also update Canadians on plans or progress towards improving the administration of SR&ED tax credit so that credits are received within an appropriate time frame to offset the costs of clinical trials[15].

Thank you for your consideration of these recommendations as the government moves towards a balanced budget that will improve opportunity – both economic and social – for all Canadians.

[14] Senate Standing Committee on Social Affairs, Science & Technology, "Canada's Clinical Trial Infrastructure: A Prescription for Improved Access to New Medicines", November 2012, p.28.
[15] Association of Canadian Academic Healthcare Organizations, "An Action Plan to Help Attract More Clinical Trials to Canada", March 30, 2012: p. 26.