

TOUGH DECISIONS, MADE RESPONSIBLY

**Ontario Public Drug Programs
Annual Report**

2012–2013

Letter from the Executive Officer

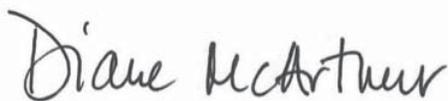
I am extremely proud to submit the Ontario Public Drug Programs 2012–13 Annual Report. This year we have broken with convention somewhat and chosen the name of our report not to reflect the progress we are indisputably making, but instead, to reflect the approach we take when we encounter challenges.

Tough Decisions, Made Responsibly. That is the name of our annual report and it is the story of our last five years of existence – 2012–13 being no exception. It is the job of Ontario Public Drug Programs (OPDP), and mine as Executive Officer (EO), to make extremely difficult decisions about what drugs should be funded and who should be eligible to receive them. Decisions like these are not uncommon in a publicly-funded health care system, but it may be the nature of our drug system and of how patients view drugs in particular, that drug funding decisions can seem particularly tough.

The obvious example of this kind of decision would be the case of patients who believe a certain expensive drug that no one could afford on their own, might save or at least extend their lives or the life of a loved one. This hugely expensive drug may not be funded, for the perfectly legitimate reason that research does not indicate it will do anything, or that it will do extremely little for those patients. The responsible decision that is in the best interest of all patients and citizens, clearly, is not to fund the drug. That doesn't make it an easy one.

Less obvious examples of the kinds of decisions that need to be made involve our relationship with drug manufacturers, with whom we have had to contend with pricing, and pharmacists, with whom we have had to contend with rebates. In all these cases, the decisions we have made have been the responsible ones, and all of them involved controversy and demanded extreme resolve on our part.

The past year has seen no shortage of those decisions, and it has also seen no shortage of positive developments in the Ontario drug system. As always, we were guided by a commitment to providing the best possible access for the greatest possible value, while building the very best possible drug system for Ontarians who rely on us.



Diane McArthur
Assistant Deputy Minister and Executive Officer
Ontario Public Drug Programs

Introduction

Ontario's public drug system is one of the most generous in Canada. Every year, an estimated 3.7 million eligible recipients receive benefits from one of this province's several different public drug programs. There are some 3,800 drugs listed on the province's Ontario Drug Benefit (ODB) Formulary. In addition, Ontario has an Exceptional Access Program (EAP) that facilitates patient access to drugs not listed on the ODB Formulary, in situations where no other option is available. There are currently more than 850 drugs available under that program.

Ontario Public Drug Programs (OPDP) was created in 2007 to administer the public drug system. Our mandate is to manage the expenditures of the public drug programs while maintaining access to new therapies that demonstrate clinical and cost effectiveness. To support this we actively negotiate agreements with drug manufacturers, make funding decisions, and determine which products should be paid for through taxpayers' dollars. This report covers our activities over the past year – a period we think of as constituting the second chapter in the life of OPDP. The first chapter – our first four years of existence – was covered in last year's report.



Our second chapter was a time of controversy and occasionally difficult, but always necessary, transformation. It was a time in which we fully committed to transparency and accountability in all that we do, allowing interested members of the public to have a voice in the operation of our drug system through the Ontario Citizens' Council. It was also a time in which we made a great many tough decisions, including continuing to lower generic drug prices, ending a rebate system that had existed for years, removing OxyContin from the ODB Formulary and launching a new narcotics monitoring strategy. Not all of these decisions were popular at the time, but each and every one of them was made responsibly, and time has proven that these were the right decisions to make.

About Ontario Public Drug Programs

Ontario Public Drug Programs was created by the *Transparent Drug System for Patients Act, 2006 (TDSPA)*, the legislation drafted by the Ontario government to enable a dramatic restructuring of the provincial drug system. The goal was to build a sustainable and transparent system that would help achieve positive health outcomes for patients, and also increase value for money. The five stated objectives of the TDSPA, which have in effect become a mission statement for OPDP, are as follows:

1. Improving patient access to drugs
2. Ensuring better value for money
3. Promoting the appropriate use of medications
4. Investing in innovative health system research
5. Strengthening transparency and accountability in the public drug system

Since 2006, drug system reforms managed by OPDP have generated approximately \$2.3 billion in savings, all of which have been reinvested in the system.



Greater Access and Better Value – Running the Drug System More Effectively

Ontario's various drug programs are funded by the provincial government – which is to say, they are funded by the taxpayers of this province. That fact makes it our responsibility to ensure that while we are focused on obtaining the best access to the best drugs for the millions of vulnerable people who are served by our programs, we must also focus on getting the best value for the billions of taxpayer dollars that we are spending in the process. 2012–13 saw a great many examples of ways in which the OPDP was able to expand access to drugs that people need and strove to become more efficient, while still making necessary tough decisions in order to maintain value for taxpayers.

Ontario's Drug Formulary

A formulary is traditionally a list of medicines, or compounds, for making medicines. Today, this word is often used to describe a list of drugs approved for funding under a given insurance policy. Such is the case here. For the most part, drugs that are funded through Ontario Public Drug Programs must first be listed in the province's Ontario Drug Benefit Formulary/Comparative Drug Index. There are exceptions to this – notably the Exceptional Access Program and its Compassionate Review Policy (CRP) discussed later in this report – but the vast majority of drugs funded through the Ontario Drug Benefit Program are made available through the formulary system.

Ontario is a key supporter of the national Common Drug Review (CDR) which provides recommendations on drug funding to all governments except Quebec. In Ontario, the clinical information, cost information, public input and recommendations arising from the national CDR is reviewed by the Committee to Evaluate Drugs (CED), which is the Ministry of Health and Long-Term Care's expert advisory committee on drug-related issues. The CED then makes recommendations to the OPDP Executive Officer on whether drugs should or should not be listed on the ODB Formulary. The final decision on listing or designating a generic drug as interchangeable with a brand name drug rests with the Executive Officer. Over the past year the OPDP has been working to streamline the relationship between the CED and CDR, such that CDR recommendations are now generally reviewed within one month by the CED with no additional information required from drug manufacturers. This secondary review allows manufacturers and patient groups the opportunity to provide input on the CDR recommendation.

In 2012–13, 26 new brand name drugs were added to the ODB Formulary. In addition, 30 brand name drugs already on the ODB Formulary had their access increased. There were also 18 new generic drugs added. Despite these additions, spending by OPDP was down 1.8 per cent last year, from \$3.478 billion to \$3.414 billion.

Exceptional Access Program

A drug system without flexibility runs the risk of letting people in need fall through the cracks. In 2006, Ontario acted to increase the system's flexibility by introducing the Exceptional Access Program (EAP). This program facilitates patient access to drugs that are approved for sale in Canada, but are not listed on the ODB Formulary. The decision to make drugs available for funding under EAP is overseen by the Executive Officer, based on recommendations and guidelines from the CED.

In 2012–13, there were approximately 76,000 requests made for EAP consideration, of which approximately 57,000 were approved.



The EAP at Work

Two new drugs for the treatment of chronic Hepatitis C, boceprevir and telaprevir, were approved for funding under the EAP in 2013.

Although both drugs have been shown to be effective in treating Hepatitis C, they also carry an increased risk of side-effects such as anemia and/or serious life-threatening rash.

For telaprevir, the CED raised concerns about the risk of life-threatening rash and recommended very restrictive criteria. Although, patient groups and prescribers raised concerns about these restrictions, it was the right thing to do and ahead of changes made to the product monograph that highlighted this risk. The funding criteria provide access only to those patients who stand to benefit the most from treatment.

OPDP will continue to review new data as it becomes available. For example, based on a review of more recent available data, the EAP criteria for boceprevir were revised to include consideration of patients who are co-infected with Hepatitis C and HIV.

EAP Response Times

Over the past few years, OPDP has recognized the need to improve EAP response times, and taken action on several fronts. Steps taken have included increasing the automation of reviews, reducing the number of external expert reviews required, increasing the number of drugs considered through the Telephone Request Service (see below) and re-assessing staffing mix and duties.

In 2012/13, it became clear that progress on response times was indeed being made. The following are the overall average turnaround times in 2011/12 and 2012/13 fiscal years:

CLASSIFICATION	AVERAGE TURNAROUND April 1, 2011 – March 31, 2012	AVERAGE TURNAROUND April 1, 2012 – March 31, 2013
Stats (urgent i.e., compassionate review, antibiotics, cancer)	10.25 business days	6.7 business days
Rush	21.92 business days	14.3 business days
Biologics	26.17 business days	13.9 business days
Non-Rush	57.67 business days	21.5 business days

Telephone Request Service

As noted above, OPDP is increasing the number of EAP requests considered through the Telephone Request Service. This service was introduced in 2008, offering physicians another way to submit requests for drug funding. In 2012–13, approximately 12,300 requests were made through the Telephone Request Service, of which approximately 11,800 were approved.

Compassionate Review Policy

The Compassionate Review Policy allows the Executive Officer to consider funding requests on a case-by-case basis, for drugs or indications in circumstances where there are immediate life, – limb or organ-threatening conditions for which the CED has not reviewed or where a product has been reviewed by the CED but the Executive Officer has not made a final funding decision due to protracted negotiations between the ministry and the manufacturer related to the funding of that product. In all cases, no consideration will be given for a CED-reviewed drug or indication where the Executive Officer has decided not to fund.

In 2012–13, 263 requests were received under the Compassionate Review Policy. Of these, 186 were approved for funding by the Executive Officer.

Trillium Drug Program

The Trillium Drug Program (TDP) is intended for Ontario residents who have a valid Ontario Health Card and who have high prescription drug costs in relation to their net household/individual income. The TDP provides coverage for products listed on the ODB Formulary. Drug products that are not listed on the Formulary may be considered for coverage through the ministry's Exceptional Access Program (EAP), on a case-by-case basis.

The program is an annual program requiring application by the household. The TDP benefit year runs from August 1 to July 31 of the following year. Before a person receives coverage for ODB benefits, their household must pay a set amount out-of-pocket for eligible prescription purchases, otherwise known as the "deductible". The deductible is paid on a quarterly basis every year starting August 1.

The program is an application based program. Ontario residents can apply at any time throughout the benefit year (August 1 to July 31) and renew on an annual basis. Recipients pay a deductible which is based on household income. In 2012/13 there were 139,310 households eligible for benefits through the ODB Program and of those, there were 187,562 recipients receiving drug benefits. The beginning of the 2012/13 year saw some application and receipt processing slow down due to system issues; however, significant strides were made in processing times toward the middle of the year and continue to remain at usual processing times – which is within 17 days.

Seniors Co-payment Program

Ontario residents aged 65 or older are eligible for ODB benefits. ODB eligible seniors are asked to pay an annual \$100 deductible in prescription expenses and up to \$6.11 co-payment per prescription. Single seniors (aged 65 or older) who have an annual income of less than \$16,018 or senior couples with a combined annual income of less than \$24,175 may apply, under the Seniors Co-Payment Program (SCP), to have the \$100 deductible waived and pay up to \$2 per prescription instead of \$6.11.

In 2012/13 there were 18,389 applications submitted to the SCP.

Patient Submission Process

In 2010, OPDP established a process that allows patient advocacy groups to make submissions about new drugs that are under consideration for funding by the CED. Like the Ontario Citizens' Council, it was part of our commitment to transparency and accountability and reflected our understanding that patients and caregivers have valuable insights to offer. Public forums also give people more confidence in a system in which they have a voice.

Last year, 19 submissions from 13 different patient groups were received and considered by the CED. To help inform our recommendations in cases where an Ontario specific submission was not received, we relied on the information that was included in the patient submissions provided to the Common Drug Review (CDR) and/or the pan-Canadian Drug Review (pCODR) processes.

Drug Shortages

From the point of view of an organization committed to ensuring access to patients in need, of the most alarming things with which we have to deal at OPDP is our dependence on outside organizations to supply us, and our patients, with the drugs that they need. 2012 was a year in which the potential unpleasant consequences of that dependence were made evident.

In February 2012, Sandoz Canada Inc. announced that as a result of failed inspections by the U.S. Food and Drug Agency and the closure of several U.S. plants, distribution of over 200 injectable drugs at their Boucherville, Quebec facility would need to serve both Canada and U.S. customers, thus impacting drug availability. Sandoz is the main manufacturer of many injectable drug products, 40 per cent of which are not made by any other manufacturer in Canada, and availability for a number of these critical products was reduced for a protracted period in 2012.

Working with partners in the health care system, Ontario put in place a plan to ensure any effect on patients was minimized. OPDP and the Ministry of Health and Long Term Care implemented an Action Plan to address the drug shortage issue, key pillars of which were inventory/impact assessment, inventory management, procurement, modification of services, and communications. Inventory levels and backorder drug issues are currently being monitored at the hospital and Local Health Integration Network (LHIN) level. The health sector has been asked to consider backorder issues within the planning for health service delivery. To date, no hospital has reported the need to alter service delivery by cancelling surgeries.

As allocation levels have increased and products are anticipated to return to normal supply status, the drug shortage of Sandoz products has moved from a crisis requiring acute management to longer-term maintenance of drug shortage issues. The ministry and OPDP are currently engaging with stakeholders in regards to ongoing strategies for the management of drug shortages in the province. In addition, Ontario is actively working with other provinces to develop a coordinated plan to deal with future drug shortage issues.

Brand Name Drugs – Pan-Canadian Pricing Alliance

Ontario has been co-leading with Nova Scotia the design and implementation of the Pan-Canadian Pricing Alliance. The alliance was established in 2010 after Canada's premiers agreed that all provinces and territories (PTs) would benefit from a common approach to the procurement of brand-name drugs. This approach capitalizes on the combined negotiating power of public drug plans across multiple jurisdictions, resulting in lower drug costs and increased consistency and access for patients to badly-needed treatment options. As of April 1, 2013, negotiations were completed for five brand name drug products and another 17 products were being negotiated.

The next challenge to be dealt with is one of governance. To date, all of the successful negotiations have been achieved on a case-by-case basis, thanks to the commitment of one or more of the provinces or territories. There is no dedicated governance structure or resourcing in place to guide negotiations. In an effort to change that, an external organization is reviewing the current processes to develop recommendations on a formal operating structure for the pricing initiative which will include brand and generic drugs.



Generic Drugs – Competitive Value Price Initiative

The fight to achieve better value in generic drug pricing helped define the early years of Ontario Public Drug Programs. Now Ontario is helping with that fight on a national level, joining other provinces and territories, through the Council of the Federation in what is being called the Value Price Initiative. By using their collective purchasing power, the provinces and territories are negotiating with manufacturers to achieve the best possible prices for generic drugs.

April 1, 2013, marked the achievement of a significant victory in this campaign. A price point of 18 per cent of the equivalent brand name price was established for six of the most commonly used generic drugs. They are:

- Atorvastatin, used to treat high cholesterol
- Ramipril, used to treat blood pressure and other cardiovascular conditions
- Venlafaxine, used to treat depression and other mental health conditions
- Amlodipine, used to treat high blood pressure and angina
- Omeprazole, used to treat a variety of gastrointestinal conditions
- Rabeprazole, used to treat a variety of gastrointestinal conditions

The price point was chosen as it is close to the median international price for several of the selected drugs.

Value Price Initiative

This agreement yielded the lowest generic prices achieved to date by any provincial-territorial (PT) drug plan. The initial six drug products represent approximately 20 per cent of total spending by participating jurisdictions on generic drugs.

Total aggregate savings for participating PT drug programs for this initial one-year price setting phase are estimated to be approximately \$100 million.

Going forward, a working group of senior officials from the four lead provinces working on the pharmaceutical file (Ontario, Alberta, Nova Scotia, and Saskatchewan) have come together to develop a more strategic, comprehensive and coordinated approach to pharmaceutical management in Canada, including both generic and brand name drug products.

This working group will be informed by the outcomes of an Ontario-led initiative to develop a permanent model to facilitate negotiations for brand name drug products and achieve better value for money for generic drugs.

Quality First – Building a Better System for Ontarians

Access and value for money will always be the things by which organizations like Ontario Public Drug Programs are judged, and that is as it should be. Here at Ontario Public Drug Programs, however, we also place huge importance on the success we are achieving in building a high-quality public drug system for the people of Ontario – one that is fair, responsive, accountable, focused not just on access but also on safety, and we are determined to improve all of the ways in which Ontarians interact with the system.

Expanded Role for Pharmacists

2012–13 was the first full year in which pharmacists were supported in offering expanded services to their clients. As part of our commitment to leveraging the abundant knowledge and skills of Ontario pharmacists, we expanded their scope of practice in late 2012.

Ontario pharmacists are now able to:

- Administer the flu vaccine to patients five years of age and older
- Prescribe smoking cessation medication
- Renew some prescriptions without consulting with a doctor
- Adapt certain prescriptions by changing dosage amounts or excluding narcotics without consulting with a doctor
- Give injections or inhalations to patients for education or demonstration purposes
- Perform procedures on tissue below the dermis for the limited purposes of patient self-care education and chronic disease monitoring (e.g., blood glucose monitoring).

Some examples of the benefits to Ontarians include not running out of medication for chronic conditions and easier access to flu vaccines.

Expanding the scope of practice for pharmacists has been an OPDP focus for several years. It was also one of the recommendations in last year's Drummond Report and the Ontario Action Plan for Health Care. Ontario is not alone in pursuing an expanded role for pharmacists. All other Canadian provinces are at some stage of implementing an expanded scope of practice for their pharmacists.

MedsCheck Program

Pharmacists deliver these new services through the MedsCheck Program, which was created in 2007. Ontario was looking to redefine the role pharmacists were able to play, not just within the drug system but within the broader health care system, and the MedsCheck program was the vehicle for making that happen. It leverages the skills and expertise of pharmacists, compensating them for regular consultations with patients who take multiple chronic prescription medication, patients with diabetes, Ontarians who are home-bound and residents of long-term care homes.

The ministry is working with the Ontario Pharmacy Council, co-led by the Ontario Pharmacists Association, to review the existing program to ensure it continues to meet the high quality standards as intended when this program was first announced. Various bodies are examining the various services across the provinces to help measure outcomes and to ensure that the recommendations are communicated within the health care team as appropriate.

In 2012–13, about 1.9 million Ontarians received a *MedsCheck* service with a pharmacist, helping to ensure that they were taking the right medications at the right times and in the right amounts.

In addition, as noted above, pharmacists began fulfilling their new roles in the past year. They delivered about 247,000 flu shots, and more than 47,000 Ontarians received services under the Pharmacy Smoking Cessation program.

Narcotics Monitoring System

In April 2012, Ontario's Narcotics Monitoring System (NMS) was activated. The system was created in response to the growing problem of prescription narcotics abuse, which in recent years has been plaguing jurisdictions in Canada and around the world. The NMS collects dispensing information from pharmacists across the province in relation to all of the prescription narcotics and other controlled drugs that they dispense to their clients.

The information being collected by the Narcotics Monitoring System is being used to ensure appropriate prescribing, dispensing and use of narcotics and other controlled drugs. The NMS acts as a safety buffer against abuses of the system such as double-doctoring (where a patient obtains the same prescription from several doctors) or poly-pharmacy visits (where a patient takes the same prescription to several pharmacists). NMS has been designed to detect these kinds of abuses and to issue an immediate alert to the pharmacist before the prescription can be filled.

Narcotics Monitoring System

All of Ontario's more than 3,500 pharmacies are now submitting dispensing data to the NMS. As of March 31, 2013, the NMS had received approximately 22.6 million submissions for almost 2.5 million patients.

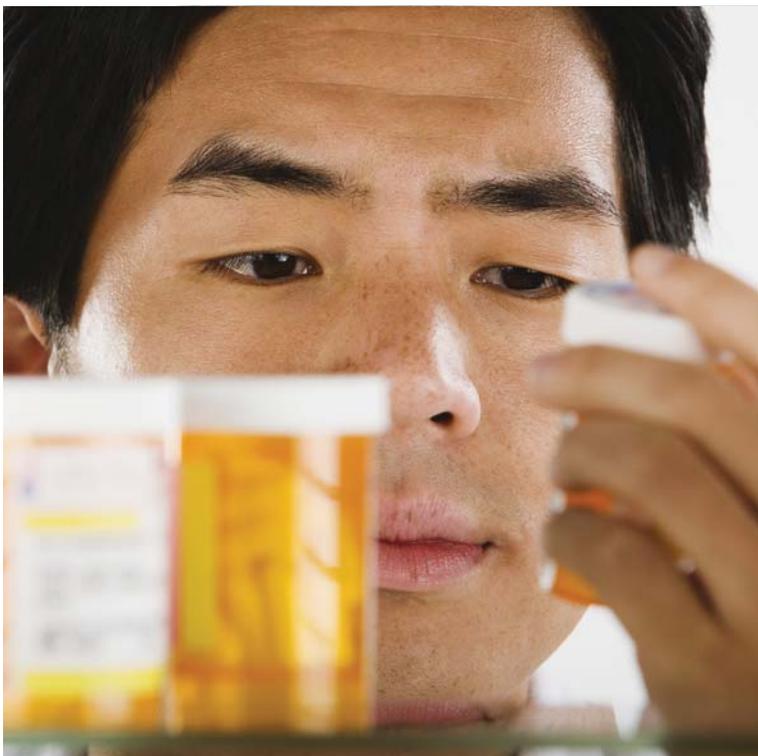
Pain Medication Formula Review

The problem of OxyContin CR addiction and abuse was one of the key factors in the creation of a Narcotics Strategy several years ago, and of the NMS last year. OxyContin CR (oxycodone) is an opioid generally prescribed for the relief of moderate to severe pain but it can also, when crushed and snorted or injected, produce an extremely quick and powerful “high.” Between 1991 and 2009, hundreds of deaths were attributed to OxyContin CR abuse, and the number of addiction cases, particularly in remote First Nations communities, became a national concern.

In early 2012, OxyContin CR was removed from the ODB Formulary. It was replaced by a drug called OxyNeo, a new tamper-resistant formulation, which is only funded through the EAP and Facilitated Access to Palliative Care Drugs mechanisms. Following that transition, a subcommittee of the Committee to Evaluate Drugs was asked to conduct a review of all opioids and other pain medications.

The subcommittee has membership from the CED, as well as external experts including a clinical pharmacist and physicians specializing in the treatment of pain, addictions, palliative care, cancer pain and family medicine. They have been asked to evaluate the efficacy, safety, abuse liability, place in therapy and utilization trends of different pain medications, and to provide advice on which pain drugs should be added or removed from the ODB Formulary.

The work of this subcommittee will help inform how the ODB Program funds and approves pain medications. Recommendations are expected by Fall 2013.



Pharmacy Audits

Under the public drug system, pharmacists bill the Ontario Drug Benefit Program for various drugs and services. They are then compensated with what are, in effect, taxpayer dollars. It is therefore incumbent on OPDP, as overseers of the drug program, to ensure that the rules are being followed. To that end, inspectors appointed by the Minister of Health and Long-Term Care conduct routine reviews of pharmacies to assess their compliance with the Ontario Drug Benefit Act and their adherence to the terms and conditions of the pharmacy's Health Network System Subscription Agreement with the ministry.

The inspectors analyze the claims submitted by over 3,500 pharmacies across Ontario and identify issues for inspection and audit. Billing irregularities may also be identified through external contacts or through internal ministry drug utilization review and policy/program management analyses. Over 100 inspections are completed annually. Since 2008, 35 pharmacy operators have had their billing privileges revoked and their right to receive payment suspended.

In 2012–13, as a result of OPDP referrals to the Ontario College of Pharmacists, the following disciplinary actions were also laid which impacted pharmacists' licenses:

In April 2013, a pharmacist from Vanguard Pharmacy was penalized for professional misconduct relating to falsification of claims records for billings to the ODB program. The College imposed a 10 month suspension with one month being remitted on condition of remedial training, as well as a three year prohibition of having a proprietary interest in, being a designated manager of, or receiving remuneration other than remuneration based on hourly or weekly rates.

In May 2013, a pharmacist from Tamimi Pharmacy was penalized for falsification of claims records for billings to the ODB program. The pharmacist has resigned permanently, irrevocably surrendered his Certificate of Registration, and will no longer work or be employed in a pharmacy in any capacity whatsoever, in Ontario.

In addition, as a result of an OPDP referral to the OPP Fraud Unit, a charge of fraud over \$5,000 was laid in May 2012 against a pharmacist of Lighthouse Pharmacy, for billing ODB for drug products that were not purchased or sold to clients. The pharmacist, who entered a plea of guilty to Section 15(1)(b) of the ODBA, was fined and a restitution order was made. The pharmacist was placed on probation for a period of 12 months with conditions to keep the peace and be of good behaviour, not possess any proprietary interest in any pharmacy and to obey all orders of the OCP with regard to professional obligations.

Conclusion

Looking ahead to 2013–14, we will continue to guide Ontario’s public drug system with an eye to providing the best access to the highest possible number of effective prescription drugs, while protecting the interests of the taxpayers who fund our program. We expect challenges, we expect setbacks and we expect successes. And we know, without a shadow of a doubt, that we will have tough decisions to make.

This past year, we wrestled with what to do about boceprevir and telaprevir, the Hepatitis C drugs. It is always agonizing to reject a drug, even one where there is no scientific evidence in favour of funding it,

when we know that there are patients who believe it might help them. Disagreements with drug manufacturers, auditing pharmacies, conflicts with other PTs – all are difficult, and all involve making tough decisions.

Inevitably, there will be tough decisions that need to be made. And yet, there still will always be drugs that we cannot in good conscience fund and issues with pharmacies and manufacturers on which we cannot, in good conscience, back down. There will be tough decisions, to be sure, but Ontarians should know that these decisions will be made responsibly and based on the best available evidence, each and every time.



