



A FOCUS ON CONTINUOUS IMPROVEMENT

**Ontario Public Drug Programs
Annual Report**

2013–2014

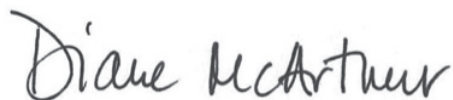
Letter from the Executive Officer

Last year, the theme of this report was “Tough Decisions, Made Responsibly,” an acknowledgement of the acute pressures the Ontario Public Drug Programs face when making drug funding decisions on behalf of Ontarians. As you will see in the material that follows, this theme remains central to what we experienced during 2013–14. If anything, the pressures that surround funding decisions were greater, especially in cases of contentious drugs. The decisions themselves were increasingly complex, both medically and economically. In a public drug system, the challenge of balancing public interest with clinical and fiscal values can only intensify. It is a challenge that we welcome.

Nevertheless this one theme is inadequate to describe the progress the Ontario Public Drug Programs made in 2013–14. We advanced on several fronts, from the reduction in response times under the Exceptional Access Program and dealing with ongoing drug shortages, to building better access to advanced drugs for cancer and rare diseases and doing a more thorough job of monitoring narcotics use. We are continually improving our public drug system, and contributing to the long-term sustainability of Ontario’s health care system.

A more appropriate theme might be “Continuous Improvement” because at Ontario Public Drug Programs, we are bettering our performance each year. Nowhere is this more evident than in the growing degree of collaboration Ontario has developed with other provinces and territories in working to ensure stable supplies of both brand name and generic drugs and to reduce costs. By working together, and gradually expanding our effort both in Canada and internationally, we will deliver more cost-effective medications to Canadians.

This will be my last report to you as the Ontario Public Drug Program’s Executive Officer. After four years in this job, I have left to take on another challenge in Ontario’s Public Service. I leave behind an extraordinary team whose commitment and professionalism have made my time with the Ontario Public Drug Programs both satisfying and rewarding. I would also like to thank my colleagues across Canada for their support and their tireless efforts to build better public drug systems. I am very proud of all that we have accomplished, and I know that there are many more achievements to come.



Diane McArthur

Assistant Deputy Minister and Executive Officer
Ontario Public Drug Programs

Introduction

In the year ended March 31, 2014, the Ontario Public Drug Programs (OPDP) provided drug coverage for nearly four million Ontarians, more than half of whom were seniors. Under OPDP's administration, the province's public drug system remains one of the most generous in Canada, with annual funding of approximately \$4.5 billion used to provide coverage for more than 3,800 drug products listed on the Ontario Drug Benefit (ODB) Formulary/Comparative Drug Index (Formulary), and a number of unlisted drug products on a case-by-case basis under the OPDP's Exceptional Access Program (EAP). Through its six operating programs, the OPDP not only provides drug coverage on an ongoing and exceptional basis, but also funding for specialty drugs for rare diseases and for newer intravenous cancer drugs.

Since it began operating seven years ago, the OPDP has worked consistently to balance responsible spending of taxpayer dollars on public drug programs with increased access for Ontarians to new therapies that are shown to be clinically effective. This management effort depends in part on a rigorous review process of requests for drug funding coupled with active negotiations with brand name and generic manufacturers, either alone or on a pan-Canadian basis in concert with other provinces.

Indeed, the template for the OPDP's actions goes back to Ontario's Drug System Transformation, an effort that began in 2005 with the intent to improve patients' access to drugs, promote the appropriate use of drugs, reward innovation and to strengthen Ontario's position as a customer. In the wake of reforms that were enacted in 2006 and 2010, OPDP has been able to save more than \$2.3 billion, all of which has been reinvested in Ontario's health care system.



OPDP's success in managing equitable and cost-effective access to drugs has not been without controversy. The program operates in an accountable and transparent fashion, and its work is often carried out under intense media and public scrutiny. Particularly in cases where lives appear to be in the balance, it requires extraordinary compassion, discipline and perspective to make funding decisions that will ultimately provide the greatest value to Ontarians.

About Ontario Public Drug Programs

OPDP was created by the *Transparent Drug System for Patients Act (TDSPA)* of 2006. The legislation was designed to fundamentally reshape the province's drug system by ensuring improved access to drugs for Ontarians as well as better value for every taxpayer dollar spent. The act also promoted the appropriate use of drugs as well as investment in innovative health system research. Equally, the *TDSPA* sought to strengthen accountability and transparency in Ontario's public drug system. Collectively, these goals form the OPDP's mission statement.

OPDP was set up in April 2007 under the leadership of an Assistant Deputy Minister of Health and Long-Term Care who also serves as Executive Officer. The Executive Officer's duties include administering and making payments for the OPDP's six drug programs, maintaining and publishing the ODB Formulary, considering coverage for unlisted drugs through the EAP, and negotiating agreements with drug manufacturers. The Executive Officer ensures OPDP's focus on balancing access with value for taxpayer dollars spent by making difficult decisions with the broad public good in mind. This is a complex and often emotionally charged process, and a significant financial challenge, given that the province's spending on drugs amounts to roughly 9% of all provincial health care expenditures.

Funding is provided for drugs listed in the ODB Formulary, a comprehensive listing of what has grown to include more than 3,800 drugs. It contains only those drugs which have passed a rigorous evaluation process.

Funding recommendations for new drugs approved by Health Canada are initiated through the national Common Drug Review (CDR) or pan-Canadian Oncology Drug Review (pCODR) processes, with an overall assessment of the clinical, cost-effectiveness and patient evidence completed by the Canadian Drug Expert Committee (CDEC) or the p-CODR Expert Review Committee (PERC), respectively. Once the final recommendation has been issued, the ministry's expert advisory committee, the Committee to Evaluate Drugs (CED) reviews the summary reports and recommendation and considers any Ontario specific issues as well as the availability of other treatments funded under the OPDP.

Once the CED completes their assessment, a recommendation is issued stating whether or not the drug product should be listed in the ODB Formulary, or funded through the EAP on a case-by-case basis. The final decision to fund the product is made by the Executive Officer, based on careful consideration of the CED's recommendation, the overall budget and public interest.

Overall, the drug funding approval process is dynamic and invariably results in a number of changes to the Formulary in any given year. In 2013–14, for example, 25 new brand name drugs were considered for funding through the Formulary or EAP mechanisms, while another 11 drugs were given expanded access through these programs. As well, 120 generic drugs were added to the Formulary. Total government expenditures for 2013–14 are estimated at \$4.5 billion.

Ontario Public Drug Programs: Six ways to help Ontarians

The OPDP includes six main programs which operate to provide access to drugs under a wide range of circumstances:

1. Ontario Drug Benefit Program – the largest single program, it provides drug benefits for eligible Ontarians who are aged 65 and older, residents of long-term care homes or homes for special care, recipients of professional home services or social assistance and recipients of the Trillium Drug Program.
 - Trillium Drug Program – benefits Ontarians who face high prescription costs relative to their net household income, and those that do not qualify under any of the other plans.
 - Exceptional Access Program – facilitates patient access in exceptional circumstances to drugs not listed on the Formulary or where Formulary drugs are ineffective, not tolerable or where no listed alternative is available. These requests are reviewed on a case-by-case basis, according to criteria recommended by the CED.
 - Compassionate Review Policy – considers requests for drugs or indications in the absence of a CED review where there are rare clinical circumstances in immediately life-, limb-, or organ-threatening conditions.
2. Special Drugs Program – provides coverage for expensive outpatient drugs required for specific diseases such as end stage renal disease and cystic fibrosis.
3. New Drug Funding Program – designed to fund newer, injectable cancer drugs administered in regional cancer centres. Overall, it provides three quarters of injectable cancer drug funding with hospitals covering the rest.
4. Visudyne Program – covers the cost of Visudyne, a drug used to treat age-related macular degeneration through eight designated hospitals.
5. Inherited Metabolic Diseases Program – provides coverage of outpatient drugs, supplements and specialty foods for the treatment of specific metabolic disorders.
6. Respiratory Syncytial Virus Prophylaxis (RSVP) for High-Risk Infants Program – covers the cost of palivizumab, to treat infants who are at high risk for hospitalization and complications from a Respiratory Syncytial virus infection.

Engaging the Public to Inform Decision-Making

OPDP continues to value the insight of Ontarians in informing decision-making and guiding future policy direction, with the patient submission process and the Citizens' Council acting as two critical pathways for public engagement.

The patient submission process, which was put in place four years ago, invites patient groups to make submissions to the CED concerning drugs that the CED is reviewing for funding recommendations. OPDP understands that patients and caregivers can provide practical and valuable insight about their treatment experiences, and their real-world exposure is an important contribution to the overall decision-making process. Since implementation of the patient submission process in 2010, 110 patient submissions have been received from 82 patient groups, and all were given thorough consideration by the CED.

In 2013-14, the Citizens' Council met on two occasions to address further policy questions related to the province's public drug programs and the broader drug system in Ontario. Topics of discussion included: *"To what degree should Quality Adjusted Life Years (QALYs) be utilized in drug funding decisions in Ontario?"* at the June 2013 meeting, and *"What are the factors that the ministry should consider in ranking or prioritizing the timing of drug funding reviews?"* at the November 2013 meeting. The Citizens' Council has prepared summary reports for each meeting, highlighting their values, opinions, and considerations that arose from their discourse on each topic. The reports have been submitted to the Executive Officer and are currently under consideration.



An Accommodating, Responsive System

One hallmark of a good public drug system includes the ability to respond to individual needs and circumstances. OPDP does so in two significant ways: through the EAP, and by utilizing the Compassionate Review Policy, where appropriate.

For the past eight years, the EAP has provided patients with drugs that, while approved for sale in Canada, are not listed in the ODB Formulary. Requests from doctors are handled on a case-by-case basis, and can arise for several reasons. It may be that treatment with a listed drug is proving ineffective and no alternative is available on the ODB Formulary. It could also be that a patient cannot tolerate a listed drug. Funding decisions are made using CED recommendations, with the intent of balancing patient needs with evidence of a drug's clinical effectiveness and cost-effectiveness.

There are many requests received by the EAP program, year after year. In 2013–14, for example, there were 64,200 unique requests for drugs ranging from treatments for anemia, Crohn's Disease and Multiple Sclerosis, to Rheumatoid Arthritis, and various forms of cancer. In all, 52,000 or 81% of these requests were approved. Of the overall total, some 11,800 requests for funding were made by physicians using the program's Telephone Request Service, a service offered for physicians to submit EAP requests for a group of selected drugs.

EAP response times continue to reduce considerably across all request classifications, as shown in the table below:

CLASSIFICATION	AVERAGE TURNAROUND April 1, 2012 – March 31, 2013	AVERAGE TURNAROUND April 1, 2013 – March 31, 2014
Stats*	6.7 business days	5.7 business days
Rush	14.3 business days	10.0 business days
Biologics	13.9 business days	9.2 business days
Non-rush	21.5 business days	11.3 business days

Efforts to optimize EAP response times are ongoing. The ministry continues to develop criteria-based application forms for EAP requests in consultation with key stakeholders, and EAP funding criteria for commonly requested drug products remain publicly posted to reduce the potential for incomplete requests that often result in longer response times. In addition, the ministry is constantly working to find efficiencies in managing fluctuations in request volumes in order to meet target turnaround times.

*(urgent i.e., compassionate review, antibiotics, cancer)

In life, limb or organ-threatening situations, or where a final funding decision is pending because of ongoing negotiation between the ministry and a manufacturer, requests for drugs that are currently under review or those that have yet to be reviewed by the CED, can be made under the Compassionate Review Policy (CRP) for hospitalized patients. In 2013–14, there were 257 such requests, of which 160 or 62% were approved for funding by the Executive Officer.

The Ongoing Problem of Drug Shortages

Periodic shortages of drugs are a common occurrence for a public drug system and occur in every jurisdiction across Canada. Issues contributing to drug shortages are complex with many causes including manufacturing problems, financial or marketing decisions related to individual products, communication problems related to distribution, unanticipated demand and regulatory/enforcement issues which may delay access to additional stock.

When a shortage does occur, it can quickly take on a dramatic character. The ministry has a limited role in the supply chain of drug ordering, procurement, supply or distribution but the ministry continues to work with its health system partners, as well as manufacturers and distributors, to assist in coordinating a response to emerging drug shortages. In 2013–14, for example, there was a sudden shortage of generic clobazam, an anti-convulsive drug used to treat epilepsy. The ministry only learned of it when the mother of a patient called the Executive Officer to say her that daughter was down to four day's supply of the drug. OPDP's reaction was swift and effective, and included checking with pharmacies, distributors and the manufacturer in order to locate a supply.

Experience has taught that the best way to anticipate and cope with shortages is for the ministry to maintain regular contact with health stakeholders and manufacturers about supply issues. At the federal level, Health Canada has the same ongoing communication effort with manufacturers to maintain continuity of supplies.

From Ontario's perspective, this system of voluntary notification isn't enough. In the absence of federal willingness to move on mandatory notification, the ministry has been working with other provinces to develop coordinated plans to deal with shortages. Along with collaboration with Health Canada, this includes activities such as identifying alternatives to products in short supply, working jointly to seek alternative suppliers, sharing information, and participating in a Multi-Stakeholder Steering Committee on drug shortages.

Ontario will also soon be rolling-out a collaborative, exception-based reporting solution that builds upon the voluntary shortage reporting system in place in the province. The Drug Stock Monitoring System¹ will be used by OPDP staff to monitor and manage drug shortages with input from Local Health Integration Networks and hospitals.



¹ Roll-out of the Drug Stock Monitoring System began in winter 2014.

Dealing with the Unexpected

In the spring of 2013, hospitals in Ontario and New Brunswick received compounded chemotherapy solutions from an Ontario firm that contained proportionately more saline solution than the hospitals realized. As a result, more than 1,200 cancer patients in these two provinces were under-dosed.

In response, Dr. Jake Thiessen was appointed as an independent investigator to review the incident to determine the cause and provide recommendations to prevent future incidents. In terms of the cause identified, Dr. Thiessen identified the following key findings:

- the compounding facility that compounded the chemotherapy solutions used prefilled normal saline bags that had overfill, but did not account for this overfill when labelling the final product;
- the Group Purchasing Organization (GPO), in awarding the contract to the facility, did not require finished product concentrations; and
- in the absence of clarifying patient-related instructions from the compounding facility to the hospitals, the hospitals did not adjust doses to factor in the overfill, because they were unaware of the lower concentrations.

The OPDP, working with the ministry's Health System Accountability and Performance Division and the Health Human Resources Strategy Division, spent a great deal of time and resources to address the problem in a joint effort with many other stakeholders. In addition to appointing Dr. Thiessen, the ministry also undertook several other initiatives such as:

- appointing an Implementation Taskforce to oversee implementation of Dr. Thiessen's recommendations;
- requesting that drug compounders declare their regulatory framework, their accreditation, and their quality assurance practices; and
- establishing requirements for hospitals with respect to the purchasing and obtaining of drugs, and giving new authority to the Ontario College of Pharmacists to inspect drug preparation premises, through new regulations.

Additionally, legislation was drafted to respond to a recommendation made by Dr. Thiessen to provide the Ontario College of Pharmacists the authority to license and inspect hospital pharmacies.²

² Although this legislation did not pass before the Legislature was dissolved in spring 2014, it was re-introduced in July 2014 as part of Bill 21, Safeguarding Health Care Integrity Act, 2014. Bill 21 passed third reading on December 10, 2014.

Accessing New Cancer Drugs

Given the increasing range and complexity of cancer diagnoses, it is vital that OPDP and the ministry do as much as possible to optimize Ontarians' access to new, clinically effective therapies.

Cancer drugs are funded through two main mechanisms under the OPDP: the ODB program for oral cancer drugs and the New Drug Funding Program (NDFP), administered by Cancer Care Ontario (CCO), for injectable cancer drugs. In the last five years, OPDP has approved funding for 67 cancer products for multiple indications. In 2013–14 alone, the ministry has approved funding for eight cancer drugs for a total of 18 indications. Cancer drug expenditures for 2013–14 are estimated to be approximately \$547 million, which includes both ODB and NDFP funded products. To further strengthen to these programs, CCO partnered with the ministry to develop the Evidence Building Program (EBP) in May 2011. The EBP is designed to provide conditional coverage of cancer drugs that have evolving but incomplete evidence of benefits. A given drug is funded on a time-limited basis to collect real-world data on its clinical- and cost-effectiveness. This data will be used by the ministry to help inform a final change to existing funding criteria. To date, two drugs have been funded under the EBP; Herceptin (trastuzumab) for the treatment of a specific type of breast cancer and Eloxatin (oxaliplatin) for the treatment of metastatic colorectal cancer.

CCO has also worked with the OPDP to introduce a policy similar to the CRP to evaluate the reimbursement of cancer drugs not considered for funding under the EAP. CCO's Case-by-Case Review Program (CBCRP) applies CRP principles to all types of cancer drugs, including therapies taken in hospitals, cancer care centres or at home.

Leading the Way on Rare Diseases

Starting in late 2007, Ontario pioneered the development of a framework to review and fund drugs for the treatment of rare diseases. At that time, OPDP set up the Drugs for Rare Diseases (DRD) Working Group consisting of clinicians, an international expert in genetic medicine, two health economists, and an ethicist. This group developed an innovative evaluation framework that considers best achievable evidence for drugs for rare diseases.

Thus far, the DRD Working Group has conducted seven drug reviews using the framework. Of these, five drugs have been given funding, one was rejected, and one was turned down for lack of data but given funding consideration on a case-by-case basis.

Making Difficult Decisions on Contentious Drugs

In the fall of 2013, the Minister met with a patient suffering from Glioblastoma Multiforme (GBM), a rare and aggressive form of brain cancer. The meeting was a very public effort to convince the ministry to advance funding for Avastin (bevacizumab), a drug produced by Hoffmann-La Roche that seeks to prolong life by reducing brain tumours. The question of a drug's approval for funding had morphed from a scientific, evidence-driven decision into a very personal and well-publicized story.

In 2010, Health Canada had given the drug conditional approval to treat cases of GBM where previous therapy had proved ineffective, and three provinces, British Columbia, Manitoba and Saskatchewan, had approved funding for the drug for this indication.

Following a careful review of the clinical evidence, OPDP could not support funding for Avastin. The evidence was not at the same level provided by other funded therapies and did not show the drug improved overall survival or quality of life. Starting in 2010, the manufacturer made the first of three submissions to the CED; none consisted of convincing clinical evidence that Avastin would improve overall survival or quality of life for patients with recurrent GBM. The last submission was also reviewed by the Ontario Steering Committee of Cancer Drugs (OSCCD), an expert oncology drug advisory committee established by the OPDP and CCO in late 2013. The Executive Officer accepted the CED's and OSCCD's recommendations and decided against funding.

Similar personal stories have gained significant media attention for other contentious drugs. Twice in early 2014, attention focused on funding approval for Kalydeco (ivacaftor), a drug that could possibly reverse lung damage in people with a specific genetic mutation of Cystic Fibrosis (CF).



Health Canada approved the drug for this indication in late 2012, and the Canadian Drug Expert Committee (CDEC) of the national CDR recommended funding for Kalydeco in a specific subset of CF patients. But the drug is extremely expensive, with an annual cost of approximately \$360,000 per patient. CDEC's recommendation came with a provision that a significant price reduction should be granted by the manufacturer, U.S.-based Vertex Pharmaceuticals, to ensure cost effectiveness. With Alberta taking the lead, the pan-Canadian Pricing Alliance (pCPA)³, a joint effort amongst participating jurisdictions to negotiate equitable drug prices with manufacturers, has been in ongoing talks with Vertex. In the meantime, the CED recommended against funding for Kalydeco and showed concern about its cost-effectiveness. The Executive Officer accepted this recommendation and as of March 2014 Kalydeco was not approved.⁴

A third drug that received media coverage and petitions from Members of the Legislative Assembly in 2013-14 was Esbriet (pirfenidone), a drug used to treat a severe lung disease called idiopathic pulmonary fibrosis (IPF). The drug was turned down for listing in April 2013 by CDEC for a number of reasons including inconsistent patient outcomes in clinical trials and a lack of evidence of clinical benefit and improved patient quality of life. A month later, Ontario's CED recommended that Esbriet not be included in the Formulary or funded through the EAP, essentially for the same reasons cited by CDEC. Shortly after, the Executive Officer decided against funding for the drug.

Esbriet's story continues, however, in part because it stands as the only potential effective therapy for IPF. The alternative has been to treat the symptoms of the disease with corticosteroids and immunosuppressants, generally with limited success. The manufacturer, InterMune, said it would release the findings of a new clinical study in May 2014, and that the new information would be presented to the national CDR.⁵

³The pan-Canadian Pricing Alliance is now referred to as the pan-Canadian Pharmaceutical Alliance.

⁴Effective June 20, 2014, Kalydeco is funded under the ODB's EAP according to specific clinical criteria.

⁵Effective August 19, 2014, Esbriet is funded under the ODB's EAP according to specific clinical criteria. New clinical data from the drug's manufacturer is currently under review by the national CDR.

Further Gains in Narcotics Monitoring

In 2013–14, 16 prescriber profiles were referred to the College of Physicians and Surgeons of Ontario while 10 pharmacy files were reviewed by the Ontario College of Pharmacists.

In less than two years of operation, Ontario's Narcotics Monitoring System (NMS) has built an extensive central database tracking the dispensing and utilization of prescription “monitored drugs” including narcotics and other controlled drugs. The NMS has been advancing the province's Narcotics Strategy, which in turn stems from *The Narcotics Safety and Awareness Act* passed in 2010. The province's more than 3,600 pharmacies have been submitting dispensing data to the NMS since May, 2012. Since then, the ministry has received more than 51 million submissions covering approximately 3.8 million people. These submissions are attributed to over 57,000 different prescribers.

NMS is effective at identifying potential drug misuse and providing front-line pharmacists with appropriate warning messages. Early NMS submissions were reviewed by ministry staff in order to identify patients who might be obtaining prescriptions for narcotics or other controlled substances from more than one physician, a practice referred to as double-doctoring. While this work produced a number of referrals to the Ontario Provincial Police, a more thorough approach was needed. As a result, the ministry established the Narcotics Monitoring Working Group with representation including physicians and pharmacists, the respective colleges and professional associations. This short-term working group has been reviewing narcotic and controlled drug use in order to recommend potential educational strategies and other actions. In 2013–14, 16 prescriber profiles were referred to the College of Physicians and Surgeons of Ontario while 10 pharmacy files were reviewed by the Ontario College of Pharmacists. The working group's goal is to give physicians better information about potentially concerning prescribing patterns, and ultimately, it will recommend a permanent on-going process to review and utilize NMS data for the benefit of any health care provider prescribing or dispensing narcotics.

Related to this broader effort, a subcommittee of the CED held five meetings between June 2012 and September 2013 to conduct a formulary review of pain medications. The subcommittee provided listing recommendations on the currently funded opioid drug products and newer agents that have previously been reviewed by the CED. It also put forward a recommendation for a new reimbursement strategy for long-acting opioids. These recommendations were presented to the CED in November and December 2013 and a final set of recommendations have been developed for consideration by OPDP's Executive Officer.

Our work on narcotics is also helping us to understand the opportunities on improving appropriate use of all medications. In collaboration with research groups such as the Ontario Drug Policy Research Network (ODPRN) and the Drug Safety and Effectiveness Network (DSEN), as well as

the CED, the ministry will continue to identify areas where patients and practitioners can be more engaged in the effective use of medications. These include promoting better adherence, decreasing adverse interactions resulting from the use of multiple medications and lifestyle, and reducing the use of unnecessary drugs. This is also an area where Ontario can learn from the initiatives put in place in other provinces and leverage its strengthened relationships developed through the pCPA.

Working Together for Better Access and Pricing

Important progress was made on drug access and pricing in 2013–14 thanks to the combined negotiating efforts of provinces and territories (P/T). The pCPA, in a joint effort to leverage combined buying power for brand name drugs that began in 2010, had completed negotiations for seven brand name products as of March 31, 2013. Then, talks moved into high gear. By March 31, 2014, the number of successfully completed brand name drug negotiations totalled 33, with another 12 negotiations ongoing. Cost savings for public drug programs as a result of this combined effort promise to be substantial. As of March 31, 2014, it was estimated that the average annual savings across the country from agreements on the 33 brand name drugs completed at that point were in the area of \$80 million a year.

The Alliance's work, which has been driven primarily by Ontario and Nova Scotia, has set a precedent for increased transparency with the launch of the pCPA webpage on the Council of the Federation website on February 19, 2014. Stakeholders can visit the webpage to learn which products are in active negotiations or have completed negotiations.

The increasing number and pace of talks has also highlighted the need for a more formal operating structure to guide the Alliance's negotiating process. As noted in last year's annual report, IBM Corporation was commissioned to review the Alliance's operating processes and provide recommendations for a formal governance structure. IBM's final report was received by the pCPA in March 2014, and will be brought forward to P/T Health Ministers for direction.^{6,7}

Lower prices, in this case for generic drugs, and major savings for Ontarians are also resulting from another cooperative effort, the pan-Canadian Generic Value Price Initiative. Formed in early 2013 under the Council of the Federation's Health Care Innovation Working Group, the Value Price Initiative soon established a price point for six common generic drugs at 18% of their brand name equivalents effective April 1, 2013 yielding an estimated average annual combined savings of \$100 million for P/T drug plans. Driven by the knowledge that Canadian generic drug prices remain significantly higher than international prices, the Value Price Initiative has, since October 2013, agreed with generic manufacturers to reduce the price of a further 12 drugs to 18% over three years (4 drugs per fiscal year) beginning April 1, 2014.

⁶The IBM report was posted in October 2014 to the Council of the Federation website at: http://www.councilofthefederation.ca/phocadownload/pcpa/pan_canadian_drugs_negotiations_report_march22_2014.pdf

⁷The IBM report was brought forward to P/T Health Ministers at the Federal-Provincial-Territorial meeting in September 2014. At that meeting, the Ministers of Health agreed to set up a permanent pCPA office to be housed in Ontario.

Leveraging the Contributions of Pharmacists

In the 2013-14 flu season, 765,836 shots were administered in over 2,000 pharmacies and \$5.7 million was paid to pharmacists for providing this service. This is compared to 247,030 shots administered, \$1.84 million paid to pharmacists operating out of about 600 pharmacies in the previous year.

Ontario has long recognized that pharmacists can, and should be, more active in the delivery of primary care and has sought to broaden their professional scope of practice. Starting with the MedsCheck program in 2007, an annual review of individual patient's prescriptions, including over-the-counter drugs and natural health products, the allowable scope of professional services have expanded to include the prescribing of smoking cessation drugs, administration of flu shots, and other educational services relating to injections, inhaled substances and chronic disease monitoring.

Pharmacists are compensated for their expanded services and growing use of professional expertise and discretion. Each year, the ministry allocates \$150 million to cover these services. And given the expansion of services – MedsCheck grew in 2010 to cover medication reviews in private homes, long-term care facilities and for patients with diabetes – the actual amount paid has grown substantially. In 2013–14, the ministry paid approximately \$95 million for MedsCheck and pharmaceutical opinion services to over 3,800 pharmacies.

Before the range of professional pharmacy services can be expanded further, the ministry needs to ensure that the amount of money already being spent is producing the expected value. In 2013, the ministry's advisory agency on these matters, the Pharmacy Council, reviewed MedsCheck to determine overall levels of consistency and quality. That review, completed in the fall, gave the Executive Officer 17 recommendations to make MedsCheck more efficient, including the introduction of more standardized processes, fine tuning the medication therapy review process to resolve problems, especially with multiple prescription users, and suggestions for new ways to share patient information between pharmacies and the patient circle of care.

Additionally, in May 2013, the ministry announced a Health System Research Fund grant of \$5.7 million over three years to the Ontario Pharmacy Research Collaboration (OPEN) towards the proposal: *Fostering innovation and evaluating the effectiveness of Ontario pharmacist-led medication management programs*. OPEN's objectives include providing evidence of the quality, outcomes and value of recent and emerging medication management services provided by pharmacists and this research will inform future policy development for MedsCheck services in Ontario.



Looking Ahead

For a public drug system like Ontario's, the challenge to improve only intensifies from year to year. There is always the promise and uncertainty of the new. There are innovative drug submissions for funding consideration, and a broader and more informed group of stakeholders to be consulted. Working relationships must continually be improved with manufacturers, patient and professional groups and with other collaborating provinces and territories. Contentious and potentially life-altering drugs emerge, usually with increased pressure due to media coverage. As an example, OPDP is reviewing new drugs that hold the promise of a cure for Hepatitis C. These drugs are expected to be expensive, and it is likely that there will be great demand for them if they are approved for funding.

OPDP believes the best way to respond to these challenges is to be consistent and dedicated to improvement. This means a couple of important things. The first is a continuing commitment to making thoughtful, disciplined decisions about drug funding, bearing in mind the health interests of all Ontarians balanced against the best, most efficient use of taxpayer dollars. The second is an ongoing effort to do a better job, either alone or in collaboration with other provinces and territories, in leveraging our influence and buying power to provide increased access and affordable drug prices for patients across Canada. The main focus of this work relates to negotiations with generic drug producers. Our goal is stability of supply for generics as well as reasonable prices. Alone, or together, we should also use our buying power to convince international producers of new drugs, particularly rare and highly expensive drugs, to be more transparent about their costs of development and production as well as their profit margins. Provinces such as Ontario represent the most stable part of international drug companies' revenue streams, and it is fitting to use this fact to help restrain prices for the benefit of Ontarians. Particularly with more expensive, highly targeted therapies, a global effort is likely necessary to ensure reasonable prices that will allow us to maintain a sustainable public drug system.

