Working Together for Change

Ontario Public Drug Programs Annual Report 2014–2015

Ontario

Letter from the Executive Officer

The front lines of nursing hold many life lessons, from the dedication and support of patients and their families to the care and commitment of health care providers at all levels. In my 17 years as a nurse in every area from acute care to rehabilitation, I witnessed the extraordinary on more occasions than I could count.

Yet my experience taught me other lessons too, many of them about the nature of our health care system and how it works and how it can work better. I learned that there are many ways to look at any given problem, and that it's important to grasp these different perspectives if you have any hope of reaching a balanced decision that serves patients' needs today, tomorrow, and in the more distant future. I learned that it's crucial to make choices based on good, hard evidence. I learned that, despite sometimes conflicting positions, it's vital for all stakeholders in the health care system to be accountable, and there must be clear and honest communication amongst them. I was convinced that, in every instance, the objective isn't just adequate care, but the best possible care for all the people of Ontario. And I learned that the best way to achieve this goal is through a cooperative effort.

Not quite a year into this job, I can see the virtue of those lessons learned and how they can help us change the way we function in order to produce a better public drug system. Despite rising demographic pressures and the phenomenal level of activity in the pharmaceutical sector as new and more specialty drugs emerge, two key factors are evident to me about the work of the Ontario Public Drug Programs. One is that the Ontario Public Drug Programs has reached a critical turning point where we cannot continue to keep growing at the rate we have. Simply put, it is not financially sustainable. Second, it is within our power to deal with this reality. To become sustainable in the face of rising demand, the Ontario Public Drug Programs and all its stakeholders need to think about drugs in new ways, so that we can all better understand the practical and clinical value of what is being offered and its financial worth.

Such an effort will require commitment, cooperation, and a desire for change that I have already witnessed in every corner, through the work of the pan-Canadian Pharmaceutical Alliance and in the developing relationships with drug manufacturers, both brand name and generic. I have seen the desire for change in the many meetings I have had with patient groups, practitioners and pharmacies. If we combine in good will, and ask hard questions about everything from reasonable costs for drugs to appropriate usage of those drugs, I believe that progress toward sustainability is inevitable. It's a great challenge that will be met against a background of rising patient needs, pharmaceutical innovation and intense public scrutiny.

Although I have been the Executive Officer only a short time, I have developed great admiration and respect for the Ontario Public Drug Programs team. These committed professionals stand ready to do their part in building a better public drug system for Ontarians and it is both an honour and a privilege to work with them.

SIGNATURE FPO

Suzanne McGurn

Assistant Deputy Minister and Executive Officer
Ontario Public Drug Programs

Introduction

In the year ending March 31, 2015, Ontario Public Drug Programs (OPDP) provided drug coverage for more than 3.8 million Ontarians, or nearly one third of all residents in the province. The OPDP is one of the most generous drug systems in Canada, using its annual funding – an estimated $4.7 billion in 2014-15 – to provide coverage for more than 3,800 eligible drug products listed on the Ontario Drug Benefit (ODB) Formulary/Comparative Drug Index (Formulary). The annual funding includes OPDP's Exceptional Access Program (EAP) as well as six other operating programs. These programs allow for funding of unlisted drug products (evaluated on a case-by-case basis), drugs for the treatment of specific diseases and outpatient administered intravenous cancer drugs.

Since it began operating eight years ago, OPDP has spent taxpayer dollars responsibly while providing increased access to new therapies that are shown to be clinically effective. The program's management effort depends on a rigorous review process of requests for drug funding coupled with active negotiations with brand name and generic manufacturers, through the pan-Canadian process in concert with other provinces and territories (PTs).

"The OPDP is one of the most generous drug systems in Canada."

Introduction Cont'd.

The template for the OPDP was set by Ontario's Drug System Transformation, an effort that began in 2005 to improve patients' access to drugs, promote the appropriate use of drugs, reward innovation, and strengthen Ontario's position as a customer. In the wake of reforms enacted in 2006 and 2010, OPDP has been able to save more than $3.3 billion, all of which has been reinvested in Ontario's health care system.

The management of equitable and cost-effective access to drugs can generate controversy. The OPDP 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 benefit to Ontarians.

Equally, the OPDP has a broad and diverse family of stakeholders whose interests can sometimes be at odds. The program continually works to understand and find consensus among patient groups and their advocates, brand and generic drug manufacturers, health care providers, pharmacies, various professional associations and agencies, the hospital sector, and other public drug programs from other PTs.

The operational backbone of OPDP is its province-wide Health Network System (HNS). The HNS links more than 3,800 pharmacies, dispensing physicians and some hospital outpatient pharmacies to the ministry, processing up to 130,000 transactions per hour in peak periods for the ODB and the Narcotics Monitoring System. More than 225 million times a year, the HNS captures a wide range of information covering patients, the drugs they take, their physicians and their pharmacies. The HNS also supports claims for influenza immunization by pharmacists as well as pharmacy services such as MedsCheck, the annual patient medication review. In doing all these things, the system speeds the processing of ODB claims, as well as helping to ensure the proper and safe use of drugs. The HNS improves communication between pharmacies and the ministry and also provides the data to analyze and improve the OPDP.

Who is eligible for OPDP coverage?

Ontarians eligible for drug reimbursement coverage fall into five categories:

- Those 65 years of age and over
- People receiving social assistance through the Ontario Disability Support Program or Ontario Works
- Those living in Long-Term Care homes and Homes for Special Care
- Recipients of professional home care services (e.g., nursing, physiotherapy); and
- People registered in the Trillium Drug Program for those whose drug costs are high relative to household income

About Ontario Public Drug Programs

OPDP was created by the *Transparent Drug System for Patients Act, 2006 (TDSPA)*. 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 *TDSPA* 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 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 process involving many stakeholders, and a financial challenge, given that the province's spending on drugs amounts to roughly 8.5 per cent of all provincial health care expenditures.

The main program for public drug funding is the ODB Program. Funding is provided for drugs listed in the Formulary, a comprehensive listing of what has grown to include more than 3,800 drugs.

Funding recommendations for new drugs or new indications and uses approved by Health Canada are initiated through manufacturer submissions to the Canadian Agency for Drugs and Technologies in Health (CADTH)'s 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 CDEC or pERC 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. The CED review does not overlap that of CADTH's work rather it provides additional Ontario specific considerations. Further, the timeline for the CED review does not impact the timeline for the product to move through the pan-Canadian Pharmaceutical Alliance (pCPA, see following section) process for negotiations.

After the CDR/pCODR and CED complete their assessment, a recommendation is issued stating whether or not the drug product should be funded. The final decision to fund the product is made by the Executive Officer, based on a careful consideration of the CDR/pCODR and CED's recommendation, the overall budget and public interest.

On the whole, the drug funding approval process is dynamic and invariably results in a number of changes to the Formulary in any given year. In 2014-15, for example, 37 new brand name drugs were considered for funding through the Formulary, EAP, or New Drug Funding Program (NDFP) mechanisms. Another 15 drugs, including three under NDFP, were given expanded access through these programs. As well, 58 first-time generic drugs were added to the Formulary.

Ontario Public Drug Programs: Six ways to help Ontarians

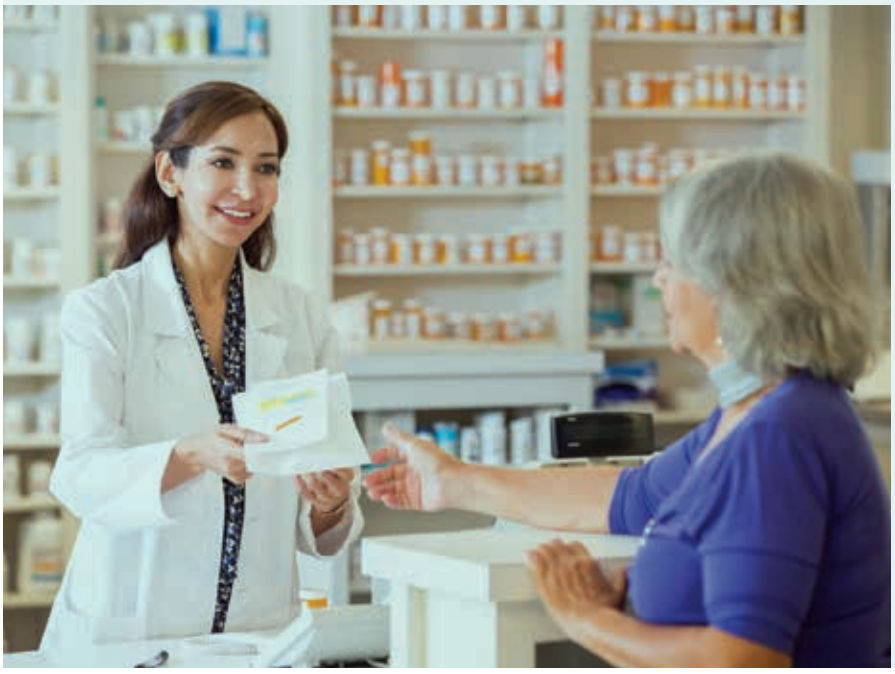
The OPDP includes six main programs which operate to provide access to drugs under a wide range of circumstances:

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, Homes for Special Care, recipients of professional home care services or social assistance and recipients of the Trillium Drug Program. Its components include:

   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. The program's coverage applies to drug products listed in the Formulary or individual requests for drug products that have been approved through the EAP.

   Exceptional Access Program – facilitates patient access in exceptional circumstances to drugs not listed on the Formulary where Formulary drugs are ineffective, not tolerated 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.



Ontario Public Drug Programs: Six ways to help Ontarians Cont'd.

2 **Special Drugs Program** – provides coverage for certain outpatient drugs required for specific diseases such as end-stage renal disease and cystic fibrosis.

3 **New Drug Funding Program** – designed to fund, intravenous cancer drugs administered in an outpatient setting in hospitals or cancer care facilities. Overall, it provides approximately half of intravenous cancer drug funding in Ontario.

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 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.

Ensuring access, availability and safety

The following updates cover key developments in OPDP's operations during the 2014-15 year. The common theme in every case is the ongoing effort not only to increase access to new drugs and service to patients, but to ensure safe and appropriate drug usage for Ontarians to optimize health outcomes.

Working collectively to lower drug prices

On its own, Ontario has had some past success in lowering the cost of drugs covered by OPDP's Formulary. In 2010, reforms to the prescription drug system reduced the cost of generic drugs sufficiently to produce annual savings of some $500 million, funds which could then be applied to the funding of new drugs. In 2010, Ontario joined with other PTs – with the exceptions of Quebec and Nunavut – to work together to achieve greater value for brand name and generic drugs for publicly funded drug programs. These initiatives, formerly known as the pan-Canadian Pricing Alliance and the Generic Value Price initiative, are now encompassed under the pan-Canadian Pharmaceutical Alliance (pCPA). In addition to cost savings, this common front aims to improve access to drugs, reduce duplication, improve the use of resources and increase consistency in decision-making across jurisdictions.

Health Ministers announced on September 30, 2014 that a new office to support the work of the pCPA would be established. The decision to establish an Office of the pCPA (Office) was informed by the work completed by IBM Canada Ltd. based on a review of international practices and broad consultation with both internal and external stakeholders. The report is titled "Pan Canadian Drugs Negotiation Report" and can be found at: www.canadaspremiers.ca/en/initiatives/358-pan-canadian-pharmaceuticalalliance. It was also confirmed at the September 30 meeting that Ontario will host the Office. Ontario has been working with their pCPA counter-parts in Nova Scotia and Saskatchewan to launch the new Office for September 2015.

For brand name drugs, by March 31, 2015 with Ontario and Nova Scotia taking the lead, the pCPA had completed negotiations for 63 products, resulting in estimated yearly savings of approximately $300 million for all pCPA members. In 2014-15 alone, the pCPA completed 26 negotiations with Ontario leading or co-leading nine of these on behalf of pCPA participating jurisdictions.

Since 2013, the PTs have been using the Generic Value Price Initiative to establish a price point of 18 per cent of the brand name product for six of the most commonly prescribed generics, resulting in an estimated annual savings of $100 million for all members. At the beginning of 2014, the prices of another four generic products were also reduced to 18 per cent of their brand name product. The 2015-16 fiscal year will continue this trend and reduce the price of another four generics to

18 per cent of the brand name product's price. For Ontario alone, these successive rounds of cooperative price reductions will amount to cumulative savings of $104 million a year, funding that is reinvested in the province's drug system. In May 2014, pCPA member PTs reached an agreement and signed a letter of intent with the industry's Canadian Generic Pharmaceutical Association to implement a tiered pricing framework for generic drugs. This agreement is initially for three years, at the end of which there will be an evaluation and further assessment.

The price tiers are based on the number of generics available on the Canadian market for a specific drug product. In 2015, updated regulations came into effect in Ontario to enact the agreement and its price tiers. The Generic Pricing Framework is designed to build on the Generic Value Price Initiative by developing a more consistent, transparent and predictable nation-wide approach to generic prices, as well as improving stability in the generic drug marketplace.

Building the evidence for Drugs for Rare Diseases

In 2014-15, Ontario contributed to a series of national efforts to evaluate and regulate drugs for rare diseases (DRDs). They are often referred to as "orphan drugs" because the patient numbers they target are small. Generally, DRDs are expensive.

The PTs are working with the federal government to develop a regulatory framework for DRDs. Broadly, the objective is to stimulate research and seek ways to get new DRDs to the Canadian market. Most importantly, such a framework should also address the need to incorporate meaningful clinical evidence in funding decisions. Insufficient data is a serious concern for all public drug programs that struggle to justify the high costs of these specialized drugs. Canada is not alone among industrialized countries in lacking such a framework, and the joint effort to produce one has been ongoing since 2012. Early in 2014, the PTs submitted their feedback to a draft discussion paper on the framework that had been prepared by Health Canada. As this report was written, further federal-provincial consultations were planned to develop the necessary regulations.

Efforts to review DRDs also received a boost in 2014-15 through the continuing work of a joint federal-provincial-territorial body, CADTH. Following consultations that began in late 2013, CADTH said it would review DRDs through the CDR using an enhanced process that obtains additional specialist expertise as well as patient consultation.

In addition to working through the pCPA to negotiate better value for DRDs, Ontario and other PTs are collaborating with one another on a number of DRD issues. In September 2014, Health Ministers recommended establishing a PT working group, which is being led by Alberta, British Columbia, and Ontario, to explore how to manage the cost of DRDs with evidence-based approaches. As growth rates for the worldwide orphan drug market are expected to double that of the overall prescription drug market by 2018, the ministers discussed how provincial territorial drug plans can approach this challenge.

Pharmacists make a difference

One of the most successful contributions by community pharmacists is participation in Ontario's Universal Influenza Immunization Program (UIIP) – a program that can prevent up to 30,000 costly visits to the hospital emergency rooms. Since the UIIP included pharmacists in October 2012, this effort has grown from approximately 600 pharmacies providing about 250,000 flu shots annually to approximately 2,400 pharmacies giving about 901,400 flu shots in the year 2014-15. The total cost of this preventive effort was $6.7 million, a fraction of the amount the health care system would have expended without it.

Pharmacist Professional Services have been a growing contributor to the health care of Ontarians since the MedsCheck program, the annual patient medication review, was launched in 2007. Considering their annual cost, $98.5 million in the 2014-15 year, there is an ongoing commitment to improving and assuring the value of these services. As this report was written, a review of the five MedsCheck program components by the Pharmacy Council, the ministry's advisory group, was nearing completion. As well, a broader three-year evaluation of Pharmacist Professional Services was underway by the Ontario Pharmacy Research Collaboration with a report due in 2016.

Exceptional Access Program Branch Service Enhancements

More than 404,000 Ontarians benefitted from the Trillium Drug Program in 2014-15, an increase of one per cent from the previous year. Given the number of eligible recipients, the program involves a great deal of processing and through new measures put in place, administration efficiencies have improved markedly during 2014-15. Between 125 and 150 new applications came in every day and the target for the year was to process every one of them within 17 business days. In addition, some 700 telephone inquiries were received each day and the aim was to be able to respond within an average of 60 seconds. By the end of the 2014-15 year, all of these targets had been achieved.

To recognize the unique health care needs of those Ontario patients whose closest physicians are located in two bordering provinces, Manitoba and Quebec, in February 2015, the Exceptional Access Program Branch (EAPB) started accepting EAP funding requests from licensed physicians from these two border provinces. All drugs, indications and reimbursement criteria are the same as those requests received from Ontario physicians, and any drugs prescribed must be dispensed by a registered Ontario pharmacy.

During 2014-15, the EAPB has taken on a review of cases where EAP funding decisions are appealed because either our policies or EAP criteria were not met, but where there was clinical evidence that funding the drug would provide a direct health benefit to the patient. Based on this work, the EAPB intends to bring forward changes to our current processes in early 2016 to support these areas of common or unique concern.

Emerging Trends

Whether it's a new cancer drug or one designed to treat a rare disease, the Executive Officer must make evidence-based decisions about funding that balance Ontarians' health care needs against sustainable management of the public drug system. The following were notable emerging trends during 2014-15:

Coping with new cancer drugs

Ongoing pharmaceutical development has greatly expanded the number of anti-cancer drugs funded in Ontario. Over the past five years, 73 cancer drugs have been added to the ODB and NDFP. In 2014-15 alone, the ministry approved funding for 12 new cancer drugs, including everything from Kadcyla for the treatment of breast cancer, to Giotrif, for lung cancer, to Pomalyst, to treat multiple myeloma, a blood cancer.

This growth is not without its challenges. The appearance of new products has generally been accompanied by higher product prices as well as the development of treatment regimens that add new therapies or combine a greater number of drugs, and increased treatment regimens that incorporate additional rounds of maintenance. All of these factors resulted in overall cancer drug expenditures (intravenous and oral) of $650 million in 2014-15, an increase of 19 per cent over the previous year.

Funding is available through two channels. Oral cancer drugs are covered under OPDP's ODB program which includes the EAP; injectable cancer drugs are funded under the NDFP. The NDFP is operated by the ministry's primary advisor on adult cancer services, Cancer Care Ontario. Growth in cancer drugs has been challenging. Spending on injectable drugs under the NDFP rose 18 per cent to $329 million in 2014-15, while oral cancer drugs increased 20 per cent to $323 million under the ODB. Over the past four years, spending under the NDFP has grown at an average rate of 12 per cent.

As 2014-15 demonstrated, the review process for specialty drugs can be challenging. Often, the level of evidence for such drugs is less than for commonly known products; with variable clinical impact, the incremental cost in relation to the small number of patient users is high. This often leads to difficult funding decisions.

As an example, Soliris is a drug used to treat a rare genetic disorder called atypical hemolytic uremic syndrome (aHUS). It can also be used to treat paroxysmal nocturnal hemoglobinuria, a rare blood disorder. The evidence supporting the clinical impact of Soliris for aHUS is limited. Also, the diagnosis of the condition is complex and optimal duration of treatment is unknown, making the funding decision hard.

Promising drugs for the potential cure of hepatitis C have met with a positive funding response. In August 2014, CDEC recommended that Sovaldi, the first of a new generation of oral hepatitis C agents, be funded according to clinical criteria, a recommendation that was conditional on a price reduction. Sovaldi is part of a dual or triple therapy regimen used to treat chronic hepatitis C infection. By February 2015, the drug was approved for reimbursement on a case-by-case basis through the EAP. A second drug for hepatitis C was approved by Health Canada. At the end of the 2014-15 year, after the review by the CDR, this new interferon-free oral drug became available to chronic hepatitis C sufferers through the EAP. Still other new hepatitis C drugs are moving through the approval process. Given the overall total budget impact of these drugs, they raise affordability considerations given the number of patients with hepatitis C in Ontario.

"Ontario and other provinces and territories (PTs) are collaborating with one another on a number of drugs for rare diseases (DRD) issues."

The OPDP is also dealing with the emergence of subsequent entry biologics (SEBs), also called biosimilars, the new alternative to brand name biologics. In 2014-15, Inflectra, a SEB to Remicade, that can treat rheumatoid arthritis, was being negotiated through the pCPA. Others are likely to follow, given predictions such as the one made in early 2014 by the CADTH that biologics in general may constitute 20 per cent of the pharmaceutical market over the next decade. The OPDP supports the optimal use of SEBs and is committed to working with our partners in other PT drug programs to fund new SEBs where the clinical evidence justifies funding.

Looking ahead – Growing challenges demand greater cooperation

Growing financial pressures on the public drug system and the need to have sustainable budgeting clearly identify the importance of the pan-Canadian cooperation. Further discussion paired with more analysis by engaging stakeholders and PTs on such issues would be needed. This seems obvious in relation to key developments, starting with the growing dialogue over a national pharmacare policy. In October 2014, Ontario's health minister raised the need for a national pharmacare program at a meeting of provincial health care ministers. Canada, he noted, is the only industrialized country with a universal health care system, but no concomitant national pharmacare policy. One such paper, A Roadmap to a national pharmacare policy in Canada, published by The Canadian Federation of Nurses Unions, suggests that a national pharmacare plan could produce annual savings on the order of $11.4 billion. The establishment of pharmacare would no doubt require a concerted national effort.

It is clear that the pan-Canadian cooperation has come a long way since the establishment of the pCPA in 2010. As this work continues, financial pressures will build, which will test the long-term sustainability not only of Ontario's, but all of the country's public drug systems. It is only reasonable to think that a broader effort linking the federal government with the PTs could make more advances in providing all Canadians with cost-effective access to drugs.

Whatever form the public drug system takes in the future, there will always be new developments on the horizon. The challenge of cancer drugs, SEBs, and specialty medications will no doubt be met with the strength and commitment of our health care providers, industry, and OPDP to provide the best outcomes for the people of Ontario.

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