Letter from the Executive Officer

As the Executive Officer of the Ontario Public Drug Programs, I am excited to present the 2015-16 annual report. The closing of a year is a good time to pause and reflect.

Following my degrees in Nursing Science and Masters of Public Administration, I’ve been working in health care for more than 30 years in a variety of settings from hospital to home care to industry, and a number of public policy roles within the Ministry of Health and Long Term Care. I’ve seen the difference health care providers, public administrators and pharmaceutical companies make every day in the lives of people.

I have witnessed over the years how necessary it is for people to understand their health information, to know how to access programs and services, and make informed decisions about their health. Health care professionals must work together to ensure that health information and services can be understood and easily accessible by the patients they look after. This annual report is intended to contribute to informing Ontarians by providing a detailed description of who we are and what programs we have available. Our objective isn’t just adequate care, but the best possible care for all the people of Ontario in a sustainable system for generations to come.

Creating such a system requires commitment and cooperation, with open and honest conversations to address public drug access and funding in refreshing ways. I continue to see the desire for change in the many meetings I have had with patient groups, clinicians, and pharmacists. If we combine our goodwill and ask hard questions about everything from reasonable costs for drugs to appropriate usage of those drugs, I believe that progress is inevitable. It’s a great challenge that involves a careful balance of patient needs and expectations, pharmaceutical innovation, intense public scrutiny and a rapidly evolving health care system. I look forward to working together towards this goal.

Throughout my career, I’ve been fortunate to have worked with many amazing people, and the skilled and dedicated team of the Ontario Public Drug Programs is no exception. Every day, they work diligently to ensure the programs are steadily improving patient access to more treatments while operating efficiently. I am very thankful for their efforts.

Original signed by

Suzanne McGurn
Assistant Deputy Minister and Executive Officer
Ontario Public Drug Programs
Ontario will have better and faster access to quality health services. They will have better information so they can make decisions that will help them live healthy and stay healthy. And their health care services will be protected for generations to come.

Patients First: Action Plan for Health Care, February 2015

In the year ending March 31, 2016, the Ontario Public Drug Programs (OPDP) provided drug coverage for more than 3.9 million Ontarians, or approximately 30 per cent of all residents in the province. Under the OPDP’s administration, the province’s public drug system remains one of the most generous drug systems in Canada, with an annual funding of approximately $5.1 billion in 2015-16. Through this funding, Ontario Drug Benefit (ODB) eligible recipients receive coverage for more than 4,400 eligible drug products listed on the Ontario Drug Benefit Formulary/Comparative Drug Index (Formulary). In addition, the OPDP covers unlisted drug products (on a case-by-case basis), drugs for the treatment of specific diseases and conditions, and intravenous cancer drugs.

The OPDP is spending health care dollars responsibly while providing increased access to new therapies that are based on clinical and cost-effectiveness. Management of the program 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). In February 2015, the Ontario government announced Patients First: Action Plan for Health Care. In this plan, the government made a commitment to put the needs of patients at the centre of the health care system. All parts of the health care system are aligning to focus on four (4) pillars:

**Improve Access** - providing faster access to the right care

**Connect** services - delivering better coordinated and integrated care in the community, closer to home

**Inform** people and patients - providing the education, information and transparency they need to make the right decisions about their health

**Protect** our universal public health care system - making decisions based on value and quality, to sustain the system for generations to come.

The Patients First: Action Plan for Health Care strengthened OPDP’s commitment to increase access to new drugs and services to patients, while maintaining costs to keep our publicly funded health care system sustainable, ensuring safe and appropriate drug usage for Ontarians.
The OPDP (as it is known today) was created by the *Transparent Drug System for Patients Act, 2006* (TDSPA). This legislation was designed to fundamentally reshape the province’s drug system by improving access to drugs for Ontarians as well as better value for every taxpayer dollar spent.

The 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 (EO). The EO’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 Exceptional Access Program (EAP), and negotiating agreements with drug manufacturers. The EO ensures that Ontario’s drug programs balance access with value for taxpayer dollars 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 nine 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 on the Formulary, a comprehensive listing of what has grown to include more than 4,400 drug products.

To have a new brand name drug approved for a particular indication or use, the manufacturer submits an application to the Canadian Agency of Drugs and Technologies in Health’s (CADTH) national Common Drug Review (CDR) or pan-Canadian Oncology Drug Review (pCODR) (for cancer drugs). Their expert committees assess the drug based on medical and scientific evidence, current clinical practice, cost-effectiveness, ethical considerations and impact on the patient and the public. Their recommendations inform whether a new drug should be reimbursed or covered for a certain use.
In the past, all recommendations made by CDR or pCODR were then further considered by the ministry’s expert advisory committee, the Committee to Evaluate Drugs (CED). During 2015-16, work was done as part of an effort to align Ontario’s drug review with national processes. Effective April 1, 2016, new brand name drugs approved by CDR or pCODR are no longer routinely reviewed by CED. Instead, the ministry seeks CED’s advice on a case-by-case basis. The CED continues to review brand name drugs that are not accepted for the CDR or pCODR review process as well as some generic drugs. The CED also provides important evidence-based advice to the ministry on important initiatives such as formulary modernization and drug class reviews.

The EO makes the final decision about whether or not a new brand name or generic drug should be added to the Formulary, funded on a case-by-case basis through the EAP or funded through the New Drug Funding Program (NDFP). The EO makes that decision based on the recommendations from the CDR, pCODR and/or CED as well as public interest, the overall OPDP budget, and the Ontario context.

Who is eligible for OPDP coverage?

Ontarians eligible for drug reimbursement coverage fall into five categories:

- People 65 years of age and over
- People receiving social assistance benefits through the Ontario Disability Support Program or Ontario Works
- Residents of Long-Term Care homes and Homes for Special Care
- Recipients of professional home and community 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.
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 and Homes for Special Care, recipients of professional home and community care services or social assistance, and people enrolled in the Trillium Drug Program.

Trillium Drug Program – benefits Ontarians who face high prescription costs relative to their net household income and do not qualify for the ODB Program under any of the other categories. The program’s coverage applies to drug products listed on the Formulary or individual requests for drug products that have been approved through the EAP.

2. New Drug Funding Program – funds intravenous cancer drugs administered in an outpatient setting in hospitals or cancer care facilities.

3. Special Drugs Program – provides coverage for certain outpatient drugs required for specific diseases such as end-stage renal disease, cystic fibrosis, schizophrenia or organ or bone marrow transplants for outpatients of a hospital.

4. Inherited Metabolic Diseases Program – provides coverage of outpatient drugs, supplements and specialty foods for the treatment of specific metabolic disorders.

5. 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.

6. Visudyne Program – covers the cost of Visudyne, a drug used to treat certain eye conditions that may lead to vision loss such as choroidal neovascularization, age-related macular degeneration, pathologic myopia and presumed ocular histoplasmosis.

A financial ‘snapshot’ in FY2015/16 of the Ontario Public Drug Programs is shown in the following diagram (page 6).
FY 2015/16 Expenditures: $5,089.81M

- $0.1 million, 0% Visudyne Program
- $20.29 million, 0% Respiratory Syncytial Virus Program
- $32.45 million, 1% Inherited Metabolic Diseases Program
- $136.32 million, 3% Special Drugs Program
- $355.00 million, 7% New Drug Funding Program
- $1,160.68 million, 23% Ontario Drug Benefit Program (MCSS)
- $3,384.96 million, 66% Ontario Drug Benefit Program (MOHLTC)

Source: Public Accounts 2015/16

ODB Program (MOHLTC) expenditures include seniors, residents of Long-Term Care (LTC) homes and Homes for Special Care, recipients of professional home and community care services, people enrolled in the Trillium Drug Program, and Rebates. ODB Program expenditures paid by the Ministry of Community and Social Services (MCSS), for people receiving social assistance benefits (Ontario Disability Support Program and Ontario Works), are shown separately.
In 2015-16, the OPDP took several significant steps to cover more drugs for more Ontarians.

MORE DRUGS AVAILABLE

The OPDP actively works to ensure that evidence-based or clinical and cost-effective drugs covered by our publicly funded drug programs keep pace with advances in treatment and changes in clinical practice based on evidence. Each year, new drugs are added to the Formulary, or are funded through the EAP. The OPDP also adds new evidence-based indications or uses for drugs already on the ODB Formulary. Information on new drugs added to the Formulary can be found by searching www.ontario.ca/page/check-medication-coverage.

In 2015-16:

- 20 new brand name drugs were added to the Formulary, including:
  - Holkira Pak, a new drug used for the treatment of Hepatitis C, which is now funded according to criteria through the ODB’s EAP.
  - Eylea, a new drug that can help prevent blindness in patients with age-related macular degeneration, macular edema secondary to central retinal vein occlusion, and diabetic macular edema.

- 10 new brand drugs or new indications for existing drugs were funded through EAP for non-cancer treatment, including:
  - Diacomit, a drug used in the treatment of the rare disease, Dravet syndrome, for infant patients with severe myoclonic epilepsy.
  - Firazyr, a drug used for the treatment of acute attacks of hereditary angioedema in adults with C1-esterase inhibitor deficiency.

- 15 new cancer drugs or indications were either listed on the Formulary or made available through the EAP or the NDFP, including:
  - Xalkori, a drug used for the treatment of advanced non-small cell lung cancer is now funded through the EAP according to specific criteria.
  - Avastin, a drug used for the treatment of metastatic, persistent, or recurrent carcinoma of the cervix is now funded through the NDFP according to specific criteria.
9 drugs either had new indications added or were moved to a general benefit, including:

- Rituxan, Remicade, Humira, and Mycophenolate mofetial, already funded through the EAP, had a new indication funded. Mycophenolate mofetil is now funded according to the criteria for the treatment of severe non-infectious ocular inflammatory disease.

- 118 new generic drugs were added to the Formulary, of which 18 were first-time generic drugs.

- 52 new multiple source drug products were approved for Off-Formulary Interchangeability (making cheaper, but equally effective generic products more accessible to Ontarians covered through private drug plans or paying out of pocket), including:
  - Apo-Tadalafil, a drug used for the treatment of pulmonary arterial hypertension.
  - Auto-Entecavir, a drug used for the treatment of hepatitis B.

**MORE EFFECTIVE HEPATITIS C TREATMENTS**

Over the past few years, the landscape to treat hepatitis C has evolved rapidly. In 2015-16, new hepatitis C treatments, which have the potential to cure patients, became available in the Canadian market. Public prices for these effective drugs range from $30,000 to over $100,000 per patient per course of treatment, depending on the drug and length of treatment.

Ontario has invested in making these treatments available to Ontarians in greatest need. Over 3,700 Ontarians have benefited from public drug program funding of these new drugs in 2015/16, at a cost of almost $300M.¹ The ministry supports expanding funding to all patients with chronic hepatitis C regardless of liver disease status. The OPDP is working closely with health care providers and with other PTs to address issues related to the effectiveness, safety and affordability of hepatitis C treatments, and to explore ways to treat more people while ensuring sustainability.

¹Note that government expenditures reflect the publicly available price of drugs, and may not reflect the government’s actual costs based on confidential list prices or rebates negotiated as part of Product Listing Agreements.
MORE COVERAGE FOR BLOOD GLUCOSE TEST STRIPS

Since August 2013, the OPDP provides coverage for blood glucose test strips based on a patient’s clinical need and in alignment with the Canadian Diabetes Association, and research conducted by the Ontario Drug Policy Research Network and CADTH. In December 2015, the OPDP reduced the amount that patients pay out-of-pocket, increasing coverage for ODB recipients. The only cost patients now incur is the up to $2.00 or up to $6.11 co-payment per prescription.
While the OPDP works to improve access to effective drugs treatments, it also strives to make the best use of public resources.

The OPDP is committed to collaborating with ministry partners to modernize and streamline processes, manage fiscal challenges, reduce administrative costs and make decisions about which drugs to cover based on the best available evidence. The goal is to improve the patient experience while being accountable to the people of Ontario for spending wisely.

The strategies used to protect the system and uphold value, and the progress made in 2015-16, include:

COLLABORATING WITH PHARMACY PROFESSIONALS TO MAKE DRUG PROGRAMS EFFICIENT AND SUSTAINABLE

Changing Pharmacy Payments
In October 2015, the OPDP made a number of changes to pharmacy payments and practices which are based on evidence, and account for getting good value for money spent and achieving better outcomes.

Ontario supports pharmacies in acquiring medications through a mark-up that is added to each prescription covered through the public drug programs, which was previously set at 8 per cent for all prescriptions. Under the new regulations, pharmacies continue to receive an 8 per cent mark-up on prescriptions that cost less than $1,000 and now receive a 6 per cent mark-up on prescriptions that cost $1,000 or more.

Promoting Pharmacy Best Practices
For ODB recipients who take medications for chronic conditions, it can be inconvenient to pick up their prescriptions every month. With a co-payment up to $6.11 per prescription, the amount that patients may pay out of pocket can add up. To encourage pharmacies to dispense three-month supplies of medications for ODB recipients who are stable on their medication and do not require more frequent dispensing for clinical reasons, the OPDP now pays a maximum of five dispensing fees a year for certain categories of medications used to treat chronic (ongoing) illnesses. This change saves patients their time and money, and reduces administrative costs for the OPDP.
Reducing Dispensing Fees on Prescriptions for People in Long-Term Care Homes

Pharmacies that supply drugs to residents in Long-Term Care (LTC) homes are also paid a dispensing fee each time a prescription is filled. In LTC homes, most drugs are dispensed in small amounts weekly to address patient needs and safety concerns for LTC home residents. In 2015-16, the dispensing fee was reduced for each prescription dispensed for LTC home residents by $1.26, which amounts to a reduction of approximately $5.00 per month for each prescription. This change assists those experiencing the frequent dispensing costs that typically occur in LTC homes.

Generic brands first

The OPDP made changes to the “no substitution” policy to increase the use of safe and effective generic alternatives to brand name products. In other words, when both generic and brand names are available, the ODB program pays for the one that costs less. A “no substitution” prescription allows ODB recipients to receive a higher-cost brand name drug only when it is required for medical reasons, including cases where an ODB recipient has had a bad reaction (i.e., allergic) to interchangeable generic products listed on the Formulary.

COLLABORATING WITH OTHER GOVERNMENTS TO DESIGN BETTER DRUG REVIEW PROCESSES

Developing a Collaborative Approach to Approving and Listing Expensive Drugs for Rare Diseases

Rare or “orphan” diseases affect a very small number of people and are considered debilitating and/or life threatening. Treatments for these rare conditions are becoming more readily available. However, since only a small percentage of the population is impacted by these conditions, it is often hard to generate evidence to determine whether these drugs (usually high cost) are clinically more effective than the current treatment regimes.

To improve access to drugs for rare diseases, as well as to keep sustainability and align the public drug funding decisions across Canada, Ontario is part of a federal/provincial/territorial (FPT) working group that is discussing the approval and listing of these drugs. In Ontario, these types of drugs are typically available through the EAP on a case-by-case basis.

New in 2015, Ontario began providing funding for Diacomit through the EAP. It is used to treat the rare condition Dravet syndrome.
Establishing an Abbreviated Approval and Review Process for Subsequent Entry Biologics

Biologics, one of the fastest growing categories of new drugs, are derived from living organisms and can be expensive, costing tens of thousands of dollars per patient per year.

The patents on several biologics have now expired and more biologics will be coming off patent over the next few years. This provides an opportunity for significant cost savings through the entry of subsequent entry biologics (SEBs) or biosimilars.

Ontario supports increasing the use of SEBs. The OPDP is committed to work with other jurisdictions to support listing and utilization of SEBs where the evidence supports these decisions.

COLLABORATING WITH OTHER GOVERNMENT PARTNERS TO LOWER DRUG COSTS

Although Ontario is Canada’s largest province, it is still considered a small market for prescription drugs. To increase its negotiating power, Ontario, in collaboration with other PTs, has developed a number of strategies to manage drug costs and ensure value for money.

Negotiating Brand Name Drug Prices through the pan-Canadian Pharmaceutical Alliance

Since 2010, Ontario’s partnership with other PTs has been achieving greater value for brand name and generic drugs through the publicly funded drug programs. These initiatives, formerly known as the pan-Canadian Pricing Alliance and the Generic Value Price Initiative, are integrated under the pan-Canadian Pharmaceutical Alliance (pCPA) that is tasked to:

- increase access to clinically effective and cost-effective drug treatment options;
- improve consistency of decisions among its members;
- achieve consistent and lower drug costs; and
- reduce duplication of effort and improve use of resources.

Now all brand name drugs recommended by the Canadian Agency for Drugs and Technologies in Health (CADTH) national review processes, which includes the Common Drug Review (CDR) and the pan-Canadian Oncology Drug Review (pCODR) and Quebec's Institut national d'excellence en santé et en services sociaux, are considered for negotiation through the pCPA.

Quebec joined the pCPA in October 2015 and the federal government joined in 2016. This means the pCPA now includes all provincial, territorial and federal public drug plans.
Ontario plays several key roles in the pCPA that includes:

- hosting the pCPA office, which opened in September 2015;
- during this fiscal year, serving as a co-lead with Nova Scotia for the brand name drug initiative; and
- in 2015-16, Ontario participated in 36 completed negotiations, leading seven and co-leading two others.

**Setting Consistent Prices for Generic Drugs Using the Tiered Generic Pricing Framework**

Provincial public drug plans strongly support the use of lower-cost interchangeable generic drugs once the patent on a brand name drug has expired. In 2014, to provide a more consistent approach to pricing generic drugs, the members of the pCPA and the Canadian Generic Pharmaceutical Association jointly developed a common, national Tiered Generic Pricing Framework. This framework was implemented across the country in 2015 and aims to further lower the cost of generic drugs for all Canadians, regardless of whether or not they are covered through a public drug program.

In 2015-16, the pCPA’s efforts continued its goal in lowering generic drug prices through the pan-Canadian Generic Value Price Initiative, leading to additional savings for provinces and territories.
DELIVERING SAFE AND EFFICIENT DRUG PROGRAMS

The OPDP continues to improve the efficiency of information systems to expand services and enhance drug safety.

Managing Claims and Monitoring Transactions

In 2015-16, the ministry’s Health Network System (HNS) processed 238 million transactions submitted by pharmacies across the province for prescriptions dispensed to over 2.9 million Ontarians. This includes approximately 39 million transactions submitted through the Narcotics Monitoring System (NMS) to record the dispensing of narcotics and controlled substances (monitored drugs) to about 2.7 million Ontarians. The Health Network System, which includes the NMS, manages up to 130,000 transactions an hour at peak times, and is one of the largest and busiest real-time 24/7 and 365 days a year transaction processing systems in the Ontario government.

The HNS processes claims quickly in real-time, which can help with providing safe and appropriate drug use so Ontarians have the best health outcomes.

- For patients who are taking two or more drugs, it can identify potentially dangerous drug interactions.
- For the health system, the HNS can be used to prevent fraud and abuse by alerting pharmacists about anyone who receives potentially dangerous drugs from different prescribers or pharmacies.
- For researchers, the HNS can provide data on drug use patterns and trends, which is information that can be used to strengthen and inform current OPDP initiatives.

OPDP will continue to use HNS data to forecast and plan for future drug program needs. OPDP will also enhance the capacity to analyze the data and plan for patient-centred drug programs.

Monitoring Narcotic Use

Physicians prescribe opioids, narcotics and/or other controlled drugs/substances for purposes of treatment to help people manage their pain. However, narcotics are addictive and can be abused. One of the most effective ways to avoid the potential harms caused by narcotics and opioids is to carefully monitor and manage their use.

Beginning in April 2012 pharmacies began recording information in the Narcotics Monitoring System (NMS) every time they dispensed a drug listed in the federal Controlled Drugs and Substances Act. Information from the system can be used to educate physicians, pharmacists and the public about evidence-based prescribing practices and safer use of medications to manage pain.
The OPDP is proud of the progress made in 2015-16 that has improved access to effective drugs for patients.

This is a dynamic and changing field. Each year, new drugs come to market. Some are breakthrough discoveries that lead to innovative ways of treating a health condition. Others improve on existing drugs by having fewer side effects or by being easier to administer and use. Some may improve health for tens of thousands of people; others may help only a handful of people with a rare disease. Decisions on public drug funding must be made wisely by considering the health care needs of all Ontarians.

The OPDP’s approach to the ongoing challenges is to seek better and smarter ways to strengthen the drug review and negotiation processes while managing and delivering drug programs. With the success of the pCPA, Ontario’s public drug programs are strong and excel when cooperating with other PTs to achieve common goals.

The next crossroad is to search for opportunities to achieve more comprehensive and inclusive public drug programs that will benefit Canadians across the country.

In June 2015, the province took first steps to start the conversation. The Honourable Dr. Eric Hoskins, Ontario’s Minister of Health and Long-Term Care, hosted a roundtable on Pharmacare. In attendance were the ministers of health from seven of Canada’s PTs that included British Columbia, Saskatchewan, Manitoba, Ontario, New Brunswick, Newfoundland and Labrador, and the Northwest Territories.

At a Health Ministers meeting held in January 2016, the FPT partners agreed to work together to explore opportunities to improve access, affordability and appropriate use of prescription medications. Ontario is now co-leading a working group with Health Canada, British Columbia and Alberta to advance collaboration in pharmaceutical policy.

In continuing to forge new relationships and partnerships on many levels, the OPDP is committed to put patients first through various means, including better access to evidence-based drug treatments to enhance the health and lives of Ontarians.