

## STAFF REPORT ACTION REQUIRED

# Toronto Public Health Response to Removal of OxyContin™ from the Market

| Date:                | March 23, 2012            |
|----------------------|---------------------------|
| То:                  | Board of Health           |
| From:                | Medical Officer of Health |
| Wards:               | All                       |
| Reference<br>Number: |                           |

## **SUMMARY**

On March 1, 2012, Purdue Pharma stopped distributing the brand name opioid formulation OxyContin<sup>TM</sup> into the Canadian market and replaced it with OxyNEO<sup>TM</sup>, a tamper-resistant tablet. At the same time, the Ministry of Health and Long-Term Care implemented procedures restricting access to OxyNEO<sup>TM</sup>. Physicians are required to apply through the Exceptional Access and the Facilitated Access to Palliative Care Drugs programs in order for it to be funded under the Ontario Drug Benefit Program. This provincial decision came in response to significant increases in the rates of addiction and overdose deaths related to prescription opiates in Ontario.

Provincial action to reduce the harms of prescription drug misuse is needed. However, there are potential negative impacts of this policy change in the short and long term. Possible impacts include: increased demand for withdrawal management (detox) and other treatment services; increased overdoses as people transition to other, potentially more harmful, drugs; and, increased rates of crime as the street-level price of opiate drugs rises in response to the lack of OxyContin<sup>TM</sup> in the illicit drug market.

The purpose of this report is to highlight the potential health implications arising from the removal of OxyContin <sup>TM</sup> from the market, and to outline action being taken by Toronto Public Health and other stakeholders to help mitigate the impacts of this policy change.

#### RECOMMENDATIONS

The Medical Officer of Health recommends that:

1. The Board of Health urge the Minister of Health and Long Term Care to make Suboxone™ available through the Ontario Drug Benefit Program without requiring application through the Exceptional Access Program to ensure timely access to this treatment option.

### **Financial Impact**

There are no financial implications for the City of Toronto arising from this report.

#### **ISSUE BACKGROUND**

On March 1, 2012, Purdue Pharma stopped distributing the brand name opioid formulation OxyContin<sup>TM</sup> into the Canadian market and replaced it with OxyNEO<sup>TM</sup>, a tamper-resistant tablet. At the same time, the Ministry of Health and Long-Term Care implemented procedures restricting access to OxyNEO<sup>TM</sup>. Physicians are required to apply through the Exceptional Access and the Facilitated Access to Palliative Care Drugs programs in order for it to be funded under the Ontario Drug Benefit Program. This provincial decision came in response to significant increases in rates of addiction and overdose deaths related to prescription opiates. These outcomes were the result of overprescribing by physicians and widespread, non-medical use of OxyContin<sup>TM</sup>, often obtained through the illicit drug market. The United States and other Canadian provinces, including Quebec and Manitoba, have delisted OxyContin<sup>TM</sup> for some time.

OxyContin<sup>™</sup> is a brand name of oxycodone, which is an opioid pain reliever. Other opioids include codeine, morphine and heroin. OxyContin<sup>™</sup> is a strong, highly addictive drug. Individuals consuming high doses of this drug risk overdose as well as serious withdrawal symptoms if they discontinue use abruptly. OxyContin<sup>™</sup> is an oral medication, although some people crush and mix it into a form that can be injected intravenously.

While provincial action to reduce the harms of prescription drug misuse is welcome, there are concerns about potential negative impacts of removing OxyContin<sup>TM</sup> from the market, especially for people using this drug for non-medical reasons. Possible impacts include the following:

- Increased demand for withdrawal management (detox) and other treatment services such as methadone, which already have long waiting lists;
- Increased incidents of overdose as people transition to other, potentially more harmful opiates, such as heroin and fentanyl (a strong prescription opioid available as a skin patch, also available in the illicit drug market);
- Adverse effects of injecting or misusing OxyNEO™; and,
- Increased rates of crime as the street-level price of opiates rise in response to the lack of OxyContin™ in the illicit drug market.

The impact of the removal of OxyContin™ from the market has received considerable media attention. This report highlights concerns from a public health perspective and outlines action being taken by Toronto Public Health and other stakeholders to help mitigate the impacts of this decision for our community.

The Board of Health sets and advocates for healthy public policy on a broad range of issues. Substance use, including prescription drug misuse, is an important health issue for Toronto and addressing the resulting harms is a responsibility of Toronto Public Health as set out in the provincial public health standards.

#### COMMENTS

This section provides a brief overview of the Toronto Drug Strategy, which is the City's policy framework for substance use issues, the role of harm reduction within this strategy, rates of drug use in Toronto with a specific focus on opiate use, and a summary of actions to help respond to the issues resulting from the removal of OxyContin™ from the market.

## **Toronto Drug Strategy**

The Board of Health and Toronto City Council approved the Toronto Drug Strategy (TDS) in 2005. The TDS is a comprehensive municipal drug strategy based on the integrated components of prevention, harm reduction, treatment, and enforcement. Governments around the world use this "four pillar" approach to address the harms of alcohol and other drug use for individuals, families and communities. A key TDS recommendation is to work with key stakeholders to help reduce the misuse of prescription drugs, and the diversion of these drugs into the illicit drug market. A progress report to the Board of Health on implementation of the TDS is planned for later in 2012. More information about the drug strategy is available at <a href="https://www.toronto.ca/health/drugstrategy">www.toronto.ca/health/drugstrategy</a>.

#### The role of harm reduction

Harm reduction is an integral part of Toronto's drug strategy working in concert with prevention, treatment and enforcement approaches. Harm reduction refers to actions that reduce the harms associated with substance use for individuals, families and communities. It is important to include harm reduction in the range of responses to drug use because some people do not want to stop or are unable to stop using drugs, and require access to services and supplies that reduce the associated harms.

As part of a comprehensive approach, we need to ensure health interventions are available for people wherever they are along the continuum of substance use. Harm reduction workers focus on providing necessary harm reduction supplies and educating people on how to reduce the harms of drug use (e.g., preventing disease transmission and overdose), building trusting relationships to keep people connected to the service system, connecting people to primary health care (e.g., wound care, immunization), and linking people with other supports and services in the community (e.g., drug treatment, housing).

Needle exchange programs are among the best-known forms of harm reduction. The spread of Hepatitis B and then HIV/AIDS among injection drug users in the 1980s prompted implementation of these programs around the world. Other examples of harm reduction include condom distribution, overdose prevention, nicotine patches, bar server intervention, and supervised consumption sites. In Toronto, community-based, government and institutional agencies deliver a wide range of harm reduction programs and services.

Research continues to demonstrate the efficacy of harm reduction in reducing the transmission of communicable diseases such as HIV/AIDS and hepatitis B and C, reducing overdose and death, connecting people to health and social services, reducing levels of drug use as well as public drug use [1,2]. Further, there is no evidence that the availability of harm reduction programs encourages substance use.

#### **Substance use in Toronto**

The majority of the population uses some form of psychoactive substance be it alcohol, tobacco, prescription or illicit drugs. The Centre for Addiction & Mental Health conducts longitudinal studies on the rates of substance use in adults and youth across Ontario. Key substance use rates for Toronto are as follows:

Substance use by adults over age 18 (reported use over past year): [3]

- 78% used alcohol
- 12% drank at harmful/hazardous levels
- 16% used cannabis
- 23% used opioid pain relievers; 2% for non-medical reasons. (*This could include OxyContin™*, *Percodet™*, *Percodan™*, *Demoral™*, *Tylenol #3™*, *or other products*).

Substance use by youth in Grades 7-12 (reported use over past year): [4]

- 47% used alcohol.
- 13% drank at harmful/hazardous levels
- 19% used cannabis
- 13% used opioid pain relievers for non-medical reasons.

  (This could include OxyContin™, Percodet™, Percodan™, Demoral™, Tylenol #3™, or other products).

These data reveal that the non-medical use of opioid pain relievers, including OxyContin™, is an issue for the population as a whole. Rates of use and associated harms are more significant for some groups, including people who are homeless or otherwise street-involved. A pan-Canadian study of people who inject drugs found that in the Toronto sample, 78% of injection drug users had injected opiates in the six months prior to the interview [5]. Of this group, 54% had injected OxyContin™. Thirty-four percent of participants in this study took oxycodone through non-injection methods [5]. A study of street-involved youth in Toronto found that 26% had (ever) injected opiates [6]. In this same study, 63% of young women reported using oxycodone to get high, as did 36% of young men [6].

Across Ontario, the use and dose of prescription opioids has increased substantially since 1991. At the same time, opioid-related deaths have doubled and are associated with the introduction of oxycodone to the provincial drug formulary. Addiction treatment services in Ontario also report an increasing proportion of individuals being treated for addiction to oxycodone [7].

## **Opioid-related deaths in Toronto**

Information about drug-related deaths is provided by the Office of the Chief Coroner for Ontario. The latest year for which information is available for Toronto is 2009. Preliminary analysis finds that between 2002 and 2009, a total of 229 deaths in Toronto were due to toxic amounts of oxycodone (out of 786 such deaths across Ontario). The number of oxycodone deaths has been increasing steadily, from 24 Toronto deaths in 2002 to a total of 52 in 2009. Province-wide, the total number of oxycodone-related deaths (including Toronto) went from 35 in 2002, to 143 in 2009. The majority (65%) of Toronto deaths were men, between the ages of 30 and 64.

## **Provincial response**

In early March, the Ministry of Health and Long Term Care took steps to respond to the growing concerns about the impact of the removal of OxyContin™ from the market for communities across Ontario. This included setting up an Expert Working Group on Narcotic Addiction charged with developing short, medium and long term recommendations to address potential impacts. On March 12, the Minister of Health announced several initial measures, including the following: [8]

- Partnering with the Centre for Addiction and Mental Health to create withdrawal and treatment guidelines to improve outcomes for people addicted to prescription pain medication.
- Working with the College of Physicians and Surgeons of Ontario to gather information from methadone programs to help identify communities in need of additional resources
- Alternative treatment options such as Suboxone<sup>™</sup> are also being made available, where appropriate. Suboxone <sup>™</sup> is similar to methadone and is used to treat opiate addiction.
- Working with ConnexOntario and its Drug and Alcohol helpline to monitor incoming calls regarding opioid addiction and wait lists for addiction treatment services.
- Reaching out to addictions programs through the Ontario Telemedicine Network to improve access to counselling services.
- Closely monitoring emergency departments to identify increased cases of withdrawal.
- Reaching out to the federal government through the Ministry of Aboriginal Affairs to address issues related to these changes emerging on First Nations Reserves.

## **Toronto Public Health response**

TPH staff is working with the provincial government and community and institutional stakeholders to help mitigate impacts for Toronto due to the removal of OxyContin™ from the market. These initiatives are outlined below.

## Identify local impacts

TPH staff in The Works/Methadone Works harm reduction programs are collecting information from clients about the impact of the removal of OxyContin™ from the market, and what individuals are doing to cope. This information is also being collected from harm reduction programs across the city, under contract with the City of Toronto, to help assess impacts on a city-wide basis. The Ministry of Health and Long Term Care is collecting similar information from health services across Ontario as part of a broader surveillance effort that includes acute care settings.

#### Increase access to treatment

Withdrawal symptoms from opioids such as OxyContin<sup>TM</sup> can be severe. With the removal of OxyContin<sup>TM</sup> from the legal and illegal drug markets, it is expected that the demand for withdrawal management (detox) and other treatment supports, such as methadone, will rise. Unfortunately, treatment services in Toronto are already stretched beyond capacity. It is difficult to get into withdrawal management, and the waiting lists for drug treatment can be six months or longer.

One immediate measure to help deal with an increased demand for treatment is to increase access to Suboxone<sup>TM</sup>. Similar to methadone, Suboxone<sup>TM</sup> is used to treat opioid addiction. It contains a combination of buprenorphine and naloxone. Buprenorphine is an opioid similar to methadone although it produces less euphoric effects and is considered to be less addictive and easier to withdraw from. Naloxone blocks the effects of opioids and is also used to reverse opioid overdoses. However, when taken orally as directed by a physician, naloxone does not affect the therapeutic actions of buprenorphine. Suboxone<sup>TM</sup> is also used for withdrawal management (detox) because people can get an effective dose immediately as opposed to gradually reaching an effective dose on methadone, which can take several weeks.

The Centre for Addiction and Mental Health finds that Suboxone™ is "of comparable effectiveness to methadone, and the choice between the two is a joint decision of patient and doctor" [9]. Individuals who are in receipt of Ontario Drug Benefits are only eligible for Suboxone™ under the Exceptional Access Program, which requires physicians to request coverage. This treatment is recommended for people "who have failed, or have a significant intolerance or contraindication, or who are at high risk for toxicity with methadone; or, when methadone programs are unavailable or accessible" [9].

As noted above, the Minister of Health announced that Suboxone<sup>TM</sup> will continue to be made available, "where appropriate." However, there are issues related to accessing Suboxone<sup>TM</sup>. This drug is only available through the Exceptional Access Program, which is cumbersome and restrictive, and can take up to three months for approval. It is therefore recommended that the Board of Health urge the Minister of Health and Long Term Care to make Suboxone<sup>TM</sup> available through the Ontario Drug Benefit Program without requiring application through the Exceptional Access Program to ensure easy and timely access to this treatment option.

## **Expand overdose prevention efforts**

The removal of OxyContin™ from the drug supply may increase the risk that people will move to other, potentially more harmful, opiates which in turn may lead to more overdoses and deaths. Recently, The Works harm reduction program in TPH initiated the POINT (Preventing Overdose in Toronto) Program as part of a comprehensive plan to reduce overdose deaths. This action advances a Toronto Drug Strategy recommendation to expand overdose prevention initiatives in the city. POINT is a peer-based program in which people who use drugs are trained to administer naloxone during an opiate overdose. To date, about 200 people have been trained in this program, and naloxone has been administered with positive outcomes over 10 times.

Naloxone is an opiate antagonist that works by displacing opioids from their receptor sites. Naloxone can reverse the effects of overdose immediately if used within a short period following an opioid overdose. In Canada, naloxone is a prescription drug most commonly used by paramedics and hospital health care providers. Evidence has demonstrated the effectiveness of naloxone used in a community setting to prevent overdose deaths. The Chicago Recovery Alliance began its program in 1999. Between 1999 and February 2006, more than 4600 trainings/prescriptions of naloxone were distributed, with 416 overdose reversals reported. This translates to about one overdose reversal for every 11 kits given out.

The Ontario Harm Reduction Distribution Program has approached TPH staff at The Works to provide training for nurses at community health centres, hospitals, jails, First Nations communities and methadone programs across Ontario on naloxone prescription and distribution. Training and consultation will also be provided to relevant agency administrators.

## **Develop an intersectoral response for Toronto**

The Toronto Drug Strategy Secretariat and the Toronto Central Local Health Integration Network are convening an intersectoral meeting on this issue in late March. Attendees include public health and community health care providers, harm reduction services, drug treatment services, emergency departments, police, and people who use drugs.

The purpose of the meeting is to identify immediate and anticipated impacts and risks, strategize on ways to help mitigate these risks across the service system in Toronto, and determine how best to monitor the situation over time to enable effective responses to issues as they emerge. These efforts will build on what is happening already at the local and provincial levels.

## Develop harm reduction materials for OxyNEO™

The introduction of OxyNEO™ is intended to ensure opioid pain relievers are available through physicians as part of pain management plans. Access to this drug is accompanied by stricter prescribing guidelines in an effort to prevent negative outcomes similar to that of OxyContin™. The drug has been formulated to be harder to break down for use as an

injection drug. However, information is already being circulated on how to prepare OxyNEO<sup>TM</sup> for injection, snorting, etc.

The potential health harms associated with the non-medical use of OxyNEO™ are uncertain. TPH staff in The Works are monitoring the situation and will develop harm reduction resources for Toronto. They will draw on the expertise of public health professionals in the United States where OxyNEO™ has been available for some time.

#### Conclusion

OxyContin<sup>™</sup> is no longer distributed in Ontario. In its place, OxyNEO<sup>™</sup> has been introduced accompanied by stricter prescribing guidelines. There are concerns about potential negative impacts of this policy change in the short and long term. This report highlights the potential health implications arising from the removal of OxyContin<sup>™</sup> from the market, and outlines action being taken by Toronto Public Health and other stakeholders to help mitigate the impacts of this policy change.

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#### **SIGNATURE**

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