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Leaders

Ontario Dietitians in
Public Health

July 24, 2019

Hon. Ginette Petitpas-Taylor
Minister of Health
House of Commons
Ottawa, Ontario K1A 0A6

Dear Minister Petitpas-Taylor,

Re: alPHa Resolution A19-7, Considering the Evidence for Recalling Long-Acting Hydromorphone

On behalf of the Association of Local Public Health Agencies (alPHa) and its member Medical Officers of Health, Boards of Health and Affiliate organizations, I am writing today to inform you of the attached resolution, which was passed by our membership at its recent Annual General Meeting.

Resolution A19-7 calls on Health Canada to review the scientific literature and other available data regarding potential harms associated with long-acting hydromorphone, particularly with respect to the risk it poses for the spread of infectious diseases among people who inject drugs; and if evidence of serious or imminent risk to health is found, that consideration be given to recalling the product or placing restrictions on prescribing.

More details are provided in the attached resolution as well as a briefing note that was provided by the resolution sponsor.

We hope that you will take this request into careful consideration, and we look forward to discussing it with you further as required. To schedule a meeting, please have your staff contact Loretta Ryan, Executive Director, alPHa, at loretta@alphaweb.org or 647-325-9594.

Yours sincerely,



Carmen McGregor
alPHa President

COPY: Dr. Theresa Tam, Chief Public Health Officer of Canada
Dr. David Williams, Chief Medical Officer of Health (Ontario)
Dr. Peter Donnelly, President and CEO, Public Health Ontario
Hon. Christine Elliott, Minister of Health & Deputy Premier (Ontario)
Dr. Dirk Huyer, Chief Coroner for Ontario
Dr. Robert Strang, Co-Chair, Public Health Network Council

Encl.

TITLE: **Considering the Evidence for Recalling Long-Acting Hydromorphone**

SPONSOR: **Kingston, Frontenac, and Lennox & Addington Public Health**

WHEREAS data from 2017 estimates 1,250 Ontarians died from opioid-related causes, representing a 246% increase in mortality from 2003 (Public Health Ontario, 2019); and

WHEREAS one in three people who died from an opioid-related cause had an active prescription for an opioid (Gomes, 2018); and

WHEREAS the harms associated with long-acting and high-dose formulations of opioids are well- characterized and include accidental overdose, cognitive impairment, falls, depression, and physical dependence (Bohnert, et al., 2011) (Juurlink, 2017); and

WHEREAS there is emerging evidence that long-acting hydromorphone is able to sustain HIV infectiousness due to the microcrystalline cellulose component of the drug and can infect people who inject drugs as a result of sharing equipment (Ball, et al., 2019); and

WHEREAS there is evidence that HIV persisted in long-acting hydromorphone residuals which may be used in “serial washes”, where the non-solubilized drug from an initial preparation for injection is reused; and

WHEREAS there is additional evidence that long-acting hydromorphone prescribing patterns are associated with an increased incidence of infective endocarditis among people who inject drugs (Weir, et al., 2019); and

WHEREAS the federal Minister of Health has the power under the Food and Drug Act to recall drugs that pose serious or imminent risk to health (Government of Canada, 1985); and

WHEREAS the known harms of opioids coupled with new evidence of additional risk of infectious disease uniquely associated with long-acting hydromorphone meet the threshold for action from the federal Minister of Health;

NOW THEREFORE BE IT RESOLVED that the Association of Local Public Health Agencies (alPHA) petition the federal Minister of Health and Health Canada to review the scientific literature and other available data regarding potential harms associated with long-acting hydromorphone, particularly with respect to the risk it poses for the spread of infectious diseases among people who inject drugs;

AND FURTHER that if evidence of serious or imminent risk to health is found, that the federal Minister of Health and Health Canada consider recalling or restricting prescribing of long-acting hydromorphone;

AND FURTHER that the Federal Minister of Health, the Minister of Health and Long-Term Care, the Chief Medical Officer of Health for Ontario, the Chief Coroner for Ontario, the CEO of Public Health Ontario, the Chief Medical Officer of Health for Canada, and all Chief Medical Officers of Health across all Provinces and Territories be so advised.

References – Resolution A19-7

Ball, L. et al., 2019. Heating injection drug preparation equipment used for opioid injection may reduce HIV transmission associated with sharing equipment.

Bohnert, A. B., Valenstein, M. & Bair, M. J., 2011. Association between opioid prescribing patterns and opioid overdose-related deaths. *JAMA*, Volume 305, pp. 1315-21.

Gomes, T., 2018. Contributions of prescribed and non-prescribed opioids to opioid-related deaths: A population-based cohort study in Ontario, Canada. *BMJ*.

Government of Canada, 1985. *Food and Drugs Act*. s.l.:s.n.

Herder, M. & Juurlink, D., 2018. High-strength opioid formulations: the case for a ministerial recall. *CMAJ*, Volume 190, pp. 1404-5.

Juurlink, D. N., 2017. Rethinking "doing well" on chronic opioid therapy. *CMAJ*, Volume 189, pp. 1222-

3. Public Health Ontario, 2019. *Interactive Opioid Tool*. [Online]

Available at: <https://www.publichealthontario.ca/en/data-and-analysis/substance-use/interactive-opioid-tool#/dTrends>

Weir, M. A. et al., 2019. The risk of infective endocarditis among people who inject drugs: a retrospective, population-based time series analysis. *CMAJ*, Volume 191, pp. 93-9.

Considering the Evidence for Recalling Long-Acting Hydromorphone

Issue:

- In addition to the risk of opioid addiction and accidental death by overdose common to all opioid medications, long-acting hydromorphone poses an additional safety risk to the community
- Recent research has linked prescribing of long-acting hydromorphone to an increased incidence of blood borne infectious diseases among people who inject drugs
- A resolution was passed by the Association of Local Public Health Agencies (alPHA), June 10th, 2019 supporting a review of the evidence for recalling hydromorphone from the Canadian market

Background:

- There is emerging evidence that the long-acting formulation of hydromorphone, or hydromorph contin (HMC) is associated with an increased incidence of bloodborne infections such as HIV and hepatitis C (HCV).¹
- Unlike the immediate-release formulations, HMC contains a microcrystalline cellulose which is a competent growth medium for HIV and HCV.
- Experimental evidence demonstrated that HIV persisted in HMC residuals, which are used for “serial washes” where the non-solubilized drug from an initial preparation for injection is reused.
- HIV also persisted on injection drug preparation equipment meaning that items such as filters and cookers are potential vectors.
- Furthermore, a time-series analysis published in January 2019 showed that infective endocarditis is an increasingly common diagnosis among people who inject drugs, with a temporal association between increasing prescriptions for HMC following the removal of oxycodone from the Canadian market and increased hospitalizations for infective endocarditis.²
- While the prescribing rates of HMC have stabilized, there are over 60,000 individuals who have been dispensed long-acting hydromorphone in Ontario in the last year alone.³
- Long-acting formulations of opioids also pose well-characterized risks including accidental death by overdose, cognitive impairment, falls, depression, and physical dependence.⁴⁻⁶
- There have been calls for Health Canada to intervene to reduce the harms associated with long-acting opioids as recently as December 2018.⁷
- The Federal Minister of Health would have the power under the Food and Drugs Act to recall HMC from the Canadian market should the Minister believe serious or imminent risk of injury exists.⁷ The long-established risks of long-acting formulations of opioids coupled with emerging evidence of harm related to infectious disease uniquely associated from HMC would meet this threshold.
- A recall is not without risks or unintended consequences, as was demonstrated by the removal of oxycontin from the Canadian market. These risks could be proactively identified and managed by providing reasonable substitutions for patients currently using HMC; by requiring the manufacturer to remove the microcrystalline cellulose from the product; or by restricting prescribing to particular practice settings, for example palliative care.
- In the interim, the Province of Ontario could engage in harm reduction campaigns, including advising those who inject HMC to heat their residuals in order to reduce the risk of HIV, HCV, and infective endocarditis transmission. Similar “Heat Your Wash” campaigns have been effective at reducing transmission and would be a reasonable first step to protecting the public.

Recommendations:

- Collaborate with health system partners, including the Ontario Ministry of Health, Public Health Ontario, and the office of the Chief Coroner of Ontario to review the scientific literature and available data about potential harms related to HMC and take appropriate public health action.
- Ask the Federal Minister of Health and Health Canada to consider the evidence for recalling or restricting prescribing of long-acting hydromorphone.
- Take immediate action to reduce the harm to Ontario's population by working with the Province of Ontario on a comprehensive harm reduction campaign that includes messaging about the risks associated with long-acting hydromorphone and targeted interventions for people who inject drugs, specifically including recommendations to "heat your wash" which have been effective in reducing the spread of infectious diseases in this population.

References:

1. Ball, L. et al., 2019. Heating injection drug preparation equipment used for opioid injection may reduce HIV transmission associated with sharing equipment.
2. Weir, M. A. et al., 2019. The risk of infective endocarditis among people who inject drugs: a retrospective, population-based time series analysis. *CMAJ*, Volume 191, pp. 93-9.
3. Public Health Ontario, 2019. *Interactive Opioid Tool*. [Online]
Available at: <https://www.publichealthontario.ca/en/data-and-analysis/substance-use/interactive-opioid-tool#/dTrends>
4. Bohnert, A. B., Valenstein, M. & Bair, M. J., 2011. Association between opioid prescribing patterns and opioid overdose-related deaths. *JAMA*, Volume 305, pp. 1315-21.
5. Gomes, T., 2018. Contributions of prescribed and non-prescribed opioids to opioid-related deaths: A population-based cohort study in Ontario, Canada. *BMJ*.
6. Juurlink, D. N., 2017. Rethinking "doing well" on chronic opioid therapy. *CMAJ*, Volume 189, pp. 1222-3.
7. Herder, M. & Juurlink, D., 2018. High-strength opioid formulations: the case for a ministerial recall. *CMAJ*, Volume 190, pp. 1404-5.