



Health  
Canada

Santé  
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Health Products  
and Food Branch

Direction générale des produits  
de santé et des aliments

Marketed Health Products Directorate  
A.L. 0701L  
OTTAWA, Ontario  
K1A 0K9

August 02, 2018

18-106047-166

To whom it may concern,

**Re: Health Canada will publish a summary safety review regarding methadose and metadol-d**

As an ongoing commitment to openness and transparency, Health Canada would like to notify you that a summary safety review (SSR) will be published regarding methadose and metadol-d and the potential risk of serious harm to children exposed to methadone through breast milk (see attached document). The SSR is intended to provide Canadians with a sufficient understanding of the safety review conducted by Health Canada, specifically what was assessed, what was found and what action was taken. The SSR will be posted in subsequent days<sup>1</sup>.

**This advance notification is being sent for your information only.** A broader dissemination by associations to their members would be significantly appreciated.

Any question related to the SSR process or requests for further information on the safety review should be directed to the Marketed Health Products Directorate; e-mail: [MHPDSSRCoordinator@hc-sc.gc.ca](mailto:MHPDSSRCoordinator@hc-sc.gc.ca)

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<sup>1</sup> <http://www.hc-sc.gc.ca/dhp-mps/medeff/reviews-examens/index-eng.php>

Please feel free to contact us, should you require further information.

Sincerely,



Lisa Lange, BSc, MA

Director

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**Attachment:**

Summary Safety Review – methadose and metadol-d – Assessing the potential risk of serious harm to children exposed to methadone through breast milk