



Health  
Canada

Santé  
Canada

Health Products  
and Food Branch

Direction générale des produits  
de santé et des aliments

Marketed Health Products Directorate  
A.L. 1906 C  
OTTAWA, Ontario  
K1A 0K9

May 26<sup>th</sup>, 2021

21-106578-783

To whom it may concern,

**Re: Health Canada will publish a summary safety review regarding Pomalyst (pomalidomide) and Thalomid (thalidomide)**

As an ongoing commitment to openness and transparency, Health Canada would like to notify you that a summary safety review (SSR) regarding Pomalyst (pomalidomide) and Thalomid (thalidomide) and the potential risk of progressive multifocal leukoencephalopathy (PML) will be published (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 to your members would be greatly 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: [hc.mhpdssrcoordinator-dpscreicoordinateur.sc@canada.ca](mailto:hc.mhpdssrcoordinator-dpscreicoordinateur.sc@canada.ca)

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

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

Sincerely,

E-signed by

Jason Berg  
Associate Director  
Office of Policy, Risk Advisory and Advertising  
Marketed Health Products Directorate  
Health Canada  
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**Attachment:**

Summary Safety Review – Pomalyst (pomalidomide) and Thalomid (thalidomide) – Assessing the potential risk of progressive multifocal leukoencephalopathy