

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

Product: Pomalyst (pomalidomide) and Thalomid (thalidomide)

Potential Safety Issue: Progressive multifocal leukoencephalopathy, a rare but serious and potentially fatal brain infection.

Key Messages

- **Pomalyst (pomalidomide) and Thalomid (thalidomide) are authorized for sale in Canada to treat multiple myeloma.**
- **Health Canada reviewed the risk of progressive multifocal leukoencephalopathy (PML) with the use of Pomalyst or Thalomid. The safety review was triggered by international case reports of PML in patients taking Pomalyst.**
- **Health Canada's review of the available information concluded that there is a possible link between Pomalyst or Thalomid and the risk of PML, a rare, serious and potentially fatal brain infection.**
- **The Canadian product safety information for Pomalyst has been updated to include a warning for the risk of PML. Health Canada is working with the manufacturer to update the Thalomid Canadian product information to include this rare safety issue.**

Overview

Health Canada reviewed the potential risk of a rare brain infection known as progressive multifocal leukoencephalopathy with the use of Pomalyst or Thalomid following reported cases of PML in patients taking Pomalyst.

PML is an opportunistic infection in the brain caused by the John Cunningham (JC) virus. It is most frequently associated with a weakened immune system. PML is often fatal; therefore, it is important to detect it early so it can be appropriately managed.

Use in Canada

- Pomalyst and Thalomid are prescription drugs authorized for sale in Canada to treat multiple myeloma.
- Thalomid has been marketed in Canada since 2010 and is available as 50 mg, 100 mg and 200 mg capsules. Pomalyst has been marketed in Canada since 2014 and is available as 1 mg, 2 mg, 3 mg and 4 mg capsules.
- Between January 2015 and December 2020, there were about 492 prescriptions filled for Thalomid and 5,832 prescriptions filled for Pomalyst.

Safety Review Findings

- Health Canada reviewed the available information from searches of the Canada Vigilance database^a, the World Health Organization's Adverse Drug Reaction Database^b, published literature and information provided by the manufacturer.
- At the time of the review, Health Canada had not received any Canadian reports of PML related to Pomalyst or Thalomid use.
- The safety review assessed 25 international case reports of PML in patients treated with pomalidomide (16 cases) or thalidomide (9 cases). For pomalidomide, 15 cases showed a possible link between this medication and PML, and 1 case did not have enough information to be further assessed. For thalidomide, 6 cases showed a possible link, while 3 cases were unlikely to be linked.
- All cases had other contributing factors, such as other medications taken by the patients that could have been possible causes of PML, or medical conditions that could have affected the patients' immune system and/or infection risk. Multiple myeloma itself is a risk factor for PML.
- Health Canada's review of the scientific literature did not find a clear mechanism to explain how Pomalyst or Thalomid could lead to PML.

Conclusions and Actions

- Health Canada's review of the available information concluded that there is a possible link between Pomalyst or Thalomid and the risk of PML.
- The Canadian product safety information for Pomalyst has been updated to include a warning for the risk of PML. Health Canada is working with the manufacturer to update the Thalomid Canadian product information to include this rare safety issue.
- Health Canada will continue to monitor safety information involving Pomalyst and Thalomid, as it does for all health products on the Canadian market, to identify and assess potential harms. Health Canada will take appropriate and timely action should new health risks be identified.

Additional Information

The analysis that contributed to this safety review included scientific and medical literature, Canadian and international information, and what is known about the use of these drugs both in Canada and internationally.

For additional information, [contact the Marketed Health Products Directorate](#).

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- a. Canadian reports can be accessed through the [Canada Vigilance Online Database](#)
 - b. [World Health Organization's Adverse Drug Reaction Database VigiLyze](#)