



Health
Canada

Santé
Canada

2020-11-30

Dear Stakeholder:

Re: Health Canada's Risk-Based Compliance and Enforcement Approach for Plain Language Labelling of Marketed Non-prescription Drugs

We are following up on correspondence issued in January 2019 on behalf of Tina Green, Assistant Deputy Minister of the Regulatory Operations and Regions Branch (now the Regulatory Operations and Enforcement Branch), regarding Health Canada's commitment to inform stakeholders of the compliance and enforcement approach for Plain Language Labelling (PLL) post June 30, 2021.

Promoting clear and legible labelling of over-the-counter (OTC) medications has been a priority for Health Canada for several years, and is a joint responsibility with industry. Our goal remains to deliver on this priority for Canadians to reduce the potential for medication errors and product misuse. This is particularly important in the current environment, where some consumers may be avoiding pharmacies and pharmacist interaction for fear of COVID-19 exposure, and relying more on labelling for proper use of medications.

It is Health Canada's position that the OTC industry and retailers play a strong and visible role in this regard. Given this initiative involves a multi-year transition period, and the important patient safety objectives, Health Canada continues to expect the industry to maintain its best efforts to ensure that OTC products will be PLL compliant at retail as of July 2021.

That said, we understand that the current extraordinary environment created by COVID-19 may impact the ability of certain regulated parties to comply with the retail deadline. We would like to reassure you that the current context will be taken into consideration by Health Canada when addressing identified non-compliance post June 2021.

As a result of the current exceptional context, and in line with the risk-based approach outlined in the Compliance and Enforcement Policy (POL-001) and communicated earlier for this initiative, the compliance and enforcement approach that will be applied is as follows:

- From July 1, 2021 to December 31, 2021, compliance and enforcement efforts will focus on companies who have not responded to Health Canada's request for a compliance plan, or those who have not filed any product labelling submissions.
- From January 1, 2022 and ongoing: compliance and enforcement efforts will focus on companies who have submitted a compliance plan but are experiencing some delays in implementation.

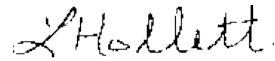
Through collaboration and transparency with industry stakeholders, Health Canada has prepared a *Questions and Answers* document that aims to address common concerns related to the compliance and enforcement approach described above.

We look forward to your continued collaboration on this important initiative for Canadians.

Sincerely,

Handwritten signature of Robin Churchill in blue ink.

Robin Churchill, PhD
A/Director General,
Natural and Non-prescription Health Products
Directorate
Health Products and Food Branch

Handwritten signature of Linsey Hollett in blue ink.

Linsey Hollett
A/Director General,
Health Product Compliance
Regulatory Operations and Enforcement
Branch

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