Questions & Answers:
Risk-based Compliance and Enforcement Approach for Plain Language Labelling of Marketed Non-prescription Drugs

1.0 Purpose

The purpose of this Questions and Answers document is to provide information to address some questions regarding expectations of retailers and market authorization holders related to the implementation of the Plain Language Labelling (PLL) Regulations.

2.0 Overview

- As a part of the transition for the Plain Language Labelling (PLL) Regulations, Health Canada expects marketed non-prescription drugs are compliant at retail by June 30, 2021.
- However, as a result of the COVID-19 pandemic, and in conversations with market authorization holders and retailers, Health Canada acknowledges there may be limited circumstances where manufacturers will not be able to meet the retail deadline for some products.
- Given industry's progress to date to implement the PLL Regulations and Health Canada's commitment to fairness and transparency, the Department will retain the June 30, 2021, retail deadline date.
- Health Canada intends to continue to work directly with market authorization holders to support them as they develop compliance plans and work toward full compliance for all products by the deadline. Following the deadline, a risk-based approach to compliance and enforcement will be implemented as follows:
    - **July 1, 2021 to December 31, 2021:** Compliance and enforcement efforts will focus on companies that have not responded to Health Canada's request for a compliance plan, or those that have not filed any product labelling submissions.
      January 1, 2022 and later: Compliance and enforcement efforts will focus on companies that have submitted a compliance plan but are experiencing some delays in implementation, with efforts expanded to include all regulated parties.
- In general, retailers are not expected to take actions related to non-prescription drug compliance with the Plain Language Labelling Regulations. As part of the transition toward full compliance with the PLL regulations for all products, Health Canada has dedicated significant effort towards compliance promotion until the established deadline. Following the deadline, the Department will focus compliance and enforcement efforts at the manufacturer level in a two-phased approach, outlined above. A retailer may be expected to participate in risk mitigation measures, such as recalls, if non-compliances, in addition to those related to PLL requirements (e.g., quality or safety concerns) are identified.

3.0 Information for Retailers

3.1 Can retailers continue to accept non-prescription drugs that are not compliant with the PLL Regulations after June 30, 2021?

It is Health Canada's expectation that manufacturers and retailers work together to assess information related to existing stock and sales volumes, and make business decisions that align with the new regulatory requirements. Both manufacturers and retailers must strive to meet the compliance dates as outlined in the risk-based approach. However, Health Canada also acknowledges that there may be circumstances where manufacturers may not meet the retail deadline for compliance with PLL regulations for some products. Under these conditions, Health Canada encourages manufacturers and retailers to work collaboratively to avoid retail shortages of non-prescription drugs and realize this may necessitate accepting non-compliant product post June 30, 2021. The need to do so can be minimized, and even avoided, if manufacturers and retailers collaborate in planning efforts. In line with Health Canada's Compliance and Enforcement Policy, various factors will be considered when non-compliance is identified, including compliance history as well as user population. Health Canada will work directly with market authorization holders who are experiencing delays implementing the PLL Regulations.

3.2 Do retailers have to check incoming stock or ask their suppliers to provide evidence after June 2021 to ensure compliance with the PLL Regulations?

Health Canada does not expect retailers to implement additional measures to verify the compliance of incoming stock, nor to request evidence from manufacturers regarding the status of their compliance with the PLL Regulations. In cases where non-compliance with PLL is identified, Health Canada will work directly with manufacturers to help ensure compliance. Manufacturers are responsible for ensuring their products meet regulatory requirements. Health Canada does not have specific requirements in place for retailers to check incoming stock or verify compliance with their suppliers. A retailer may be expected to participate in risk mitigation measures when non-compliances arise (e.g., quality or safety concerns).

3.3 Will Health Canada require recalls for non-prescription drugs sold at retail that are non-compliant with the PLL Regulations?

Health Canada expects both manufacturers and retailers to strive to meet the compliance dates as outlined in the risk based approach. Health Canada also acknowledges that there may be circumstances where manufacturers may not meet the retail deadline for compliance with PLL regulations for some products.

As part of Health Canada's risk-based approach to compliance and enforcement, non-compliance with the PLL Regulations will be assessed on a case-by-case basis. Health Canada manages the risk posed to public health and safety by health products through various compliance and enforcement activities and determines the actions and tools that are most appropriate for the situation.

In line with Health Canada's Compliance and Enforcement Policy, various factors will be considered when non-compliance is identified, including compliance history as well as user

population. Health Canada will work directly with the market authorization holder to ensure compliance.

A retailer may be expected to participate in risk mitigation measures, such as recalls, when other non-compliances, in addition to PLL requirements (e.g., quality or safety concerns) are identified.

Health Canada will always reserve the opportunity to take action as required to ensure the health and safety of Canadians.

3.4 Are retailers expected to notify Health Canada of non-PLL-compliant products on their shelves after the June 2021 retail compliance date?

Retailers are not expected to notify Health Canada of non-PLL-compliant products on their shelves. Health Canada will verify the compliance status of products with the PLL Regulations and will work directly with market authorization holders to help ensure compliance. Should complaints be received, they will be triaged and could be used as an opportunity for compliance promotion.

3.5 After July 1, 2021, what should retailers do with on-hand inventory of non-prescription drugs that is not compliant with the PLL Regulations?

It is Health Canada's expectation that manufacturers and retailers work together to assess information related to existing stock and sales volumes, and make business decisions that align with the new regulatory requirements. Both manufacturers and retailers must strive to meet the compliance dates as outlined in the risk-based approach. However, Health Canada also encourages manufacturers and retailers to work collaboratively to avoid retail shortages of non-prescription drugs and realize that may necessitate continuing to sell on hand, non-compliant inventory. The need to do so can be minimized, and even avoided, if manufacturers and retailers collaborate on planning efforts. In line with Health Canada's Compliance and Enforcement Policy, various factors will be considered when non-compliance is identified, including compliance history as well as user population. Health Canada will work directly with market authorization holders to ensure compliance.

3.6 Will Health Canada inspectors be examining non-prescription drugs on store shelves for compliance with the PLL Regulations?

Health Canada monitors compliance, undertakes enforcement activities and works towards preventing non-compliance. Regulated parties are responsible for ensuring their health products comply with the laws and regulations. Health Canada inspectors will be looking for product compliance with all relevant Health Canada requirements. With respect to the PLL regulations, from July 1, 2021, to December 31, 2021, Health Canada will focus compliance monitoring activities on market authorization holders who have not submitted compliance plans or filed submissions to comply with the PLL Regulations. Proactive compliance monitoring activities could include sampling at the retail level or other market surveillance activities. Products determined to be non-compliant with the PLL regulations will be assessed on a case-by-case basis according to the risk-based approach outlined above. Health Canada will work with the market authorization holder to help ensure compliance. In general, responses to instances of

low risk non-compliance do not include requests to stop sale and/or recall at retail, however, these actions may be warranted at various levels in the supply chain, consistent with Health Canada's regulations, policies, and procedures.

3.7 What if retailers or wholesalers have questions about the risk-based approach to the compliance and enforcement of the PLL Regulations?

Retailers and wholesalers can contact the Regulatory Operations and Enforcement Branch, Health Product Compliance and Risk Management Division at hc.hpce-cpsal.sc@canada.ca.

4.0 Information for market authorization holders

4.1 What are compliance plans?

The *DIN-Specific PLL Submission Plan* is a form that Health Canada shared with all non-prescription drug market authorization holders in May 2019. Health Canada requested the voluntary completion of a *DIN-specific PLL Submission Plan* for marketed products, which outlines information on submissions that are scheduled to be filed with Health Canada. As some products do not require a submission to comply with the PLL Regulations (i.e., those applying a Standard Drug Facts Table, and those applying flexibilities provided for Self-Care Framework Category I products), Health Canada sought information on those situations as well. Market authorization holders responded to these requests in a variety of ways including the completion of a specified template or providing information via email. All of these forms of communications are acknowledged as fulfilling requests for compliance plans to provide updates on progress towards compliance with the PLL Regulations.

Note: Compliance plans are not necessary for new products due to the standard review process already in place to ensure compliance for submissions filed after June 13, 2017.

4.2 Will Health Canada be requesting more information on compliance plans?

There are no plans at this time to request additional information from market authorization holders. Health Canada recognizes that the compliance plans submitted in 2019 may have changed because of the pandemic, and other process changes recommended by Health Canada. Market authorizations holders are responsible for being transparent and working collaboratively with Health Canada to resolve any issues with delays in meeting the compliance deadline of June 30, 2021. Market authorization holders seeking to provide updated compliance plan information should contact the Label Review Coordinator at the Non-prescription Drugs Evaluation Division at hc.nded-demvso.sc@canada.ca.

4.3 How will the risk-based approach to compliance and enforcement of the PLL Regulations address non-prescription drug market authorization holders who have not filed a compliance plan but who have continued to file submissions?

Market authorization holders who have not filed a compliance plan but have continued to file submissions and demonstrated a coordinated approach to complying with the PLL requirements

will not be a focus of compliance and enforcement as of July 1, 2021. Should complaints be received, they will be triaged and could be used as an opportunity for compliance promotion.

4.4 What actions will Health Canada take with market authorization holders who have not submitted compliance plans or not filed submissions to comply with the PLL Regulations?

Until June 30, 2021, Health Canada will continue to promote compliance with the PLL regulations, through education and information sharing. Following June 30, 2021, compliance monitoring efforts will focus on market authorization holders who have not submitted compliance plans or filed submissions to comply with the PLL Regulations. From July 1, 2021 to December 31, 2021, Health Canada will focus on compliance monitoring and address complaints by working with market authorization holders who have not submitted compliance plans or filed submissions to comply with the PLL Regulations. Compliance monitoring projects could include sampling at the retail level or other market surveillance activities. Health Canada will take a risk-based compliance and enforcement approach to the implementation of the PLL regulations in which products that have not yet come into compliance with the PLL regulations will be assessed on a case-by-case basis according to the risk-based approach outlined above. Various factors will be considered in accordance with Health Canada's Compliance and Enforcement Policy. Health Canada will work directly with the market authorization holder to help ensure compliance.

4.5 What will Health Canada's actions be after January 1, 2022?

After January 1, 2022, Health Canada will continue to work with manufacturers to bring non-prescription drugs into compliance with the PLL Regulations. Proactive compliance monitoring will focus on companies experiencing delays implementing the PLL Regulations. These proactive compliance monitoring projects could include sampling at the retail level or other market surveillance actions. Health Canada will take a risk-based compliance and enforcement approach to the PLL regulations in which products that have not yet come into compliance with the PLL regulations will be assessed on a case-by-case basis according to the risk-based approach outlined above. Various factors will be considered in both the phases including compliance history as well as the user population. Health Canada will work directly with the market authorization holder to help ensure products are compliant with PLL regulations. In general, responses to instances of low risk non-compliance do not include requests to recall at retail, however, market action may be warranted at various levels in the supply chain, consistent with Health Canada's regulations, policies, and procedures.