PROPOSED PROCESS FOR SWITCHING PRESCRIPTION DRUGS TO NON-PRESCRIPTION STATUS IN CANADA

STAGE I
PRE-SUBMISSION / R&D

STAGE II
APPROVAL OF SWITCH AND SCHEDULING

STAGE III
CONSUMER ACCESS

KEY SOLUTIONS

1. Policy for temporary product-based switch: Adapting a two-stage switch process where products are switched first by the sponsor, followed by Health Canada switching the ingredient would enable the sponsor to proceed to market without delay while satisfying the World Trade Organization’s (WTO) notification requirements. After the product is switched and any period of data protection is completed, then Health Canada could proceed with the WTO’s 180 day notification process to switch the ingredient, enabling market access for second-entry products.

2. Regulatory provisions for data protection: Introducing provisions in regulations to provide three years of data protection for clinical trials that support new uses for existing products would give an opportunity for innovators to recuperate the costs of research and incentivize switch and innovation in Canada. New Non-Prescription Drug Regulations, as a part of the Consumer Health Product Framework is the ideal opportunity to opt in to these provisions for intellectual property protection in accordance with the Trans Pacific Partnership.

3. Process integration of the switch and scheduling decisions: Integrating the process for determining the conditions of sale of a non-prescription drug in a pharmacy environment with the federal decision approving the switch of a product to non-prescription status would significantly streamline the switch process. Decision makers would have access to more information, be able to recommend more options for mitigating risk, enable provinces to be consulted earlier, and result in nationally harmonized decisions. The Food and Drugs Act would be the governing legal statute for determining the conditions of sale, however both Federal and Provincial regulatory changes may be required to achieve this process.