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Pharma in brief - Canada

Health Canada releases Draft Guidance Document – Drug Facts Table for Non-prescription Drugs for consultation

Summary

On February 20, 2017, Health Canada released the Draft Guidance Document – Drug Facts Table for Non-prescription Drugs for comment. Interested stakeholders, including industry, consumers and healthcare professionals, may provide comments on the draft guidance document by email to nnhpd_consultation_dpsnso@hc-sc.gc.ca. The consultation period is open until **April 21, 2017.**

Overview

As part of Health Canada's Plain Language Labelling Initiative (reported here), Health Canada released the Draft Guidance Document: Drug Facts Table for Non-prescription Drugs, which contains examples of drug facts tables for various active ingredients. The examples are intended to show the application of the specific formatting requirements for drug facts tables as set out in the Guidance Document: Good Label and Package Practices Guide for Non-prescription Drugs and Natural Health Products (**GLPPG**).

As part of the Plain Language Labelling Initiative, Health Canada will require that any new drug identification number (**DIN**) applications or supplemental new drug submissions submitted on and after June 13, 2017, comply with the drug facts table requirements set out in the GLPPG. In addition, currently marketed products must comply with the drug facts table requirements at the production level by June 20, 2019, and at the retail level by June 30, 2021.

The Plain Language Labelling Initiative imposes significant new obligations on industry. Interested stakeholders should consider whether the Draft Guidance – Drug Facts Table for Non-Prescription Drugs appropriately addresses the formatting requirements as set out in the GLPPG.

Link:

Draft Guidance Document: Drug Facts Table for Non-prescription Drugs

For more information, please contact your IP/Life sciences or healthcare practice professional at Norton Rose Fulbright Canada LLP.

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