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Proposal to Change the Regulatory Process Used to Assign Prescription Drug Status (Repeal of Schedule F)

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Canada

Federal Budget 2012: Bill C-38

Announced in the federal Budget plan of 2012:

- Government is taking action to remove the requirement for regulatory amendments to Schedule F to assign prescription status for drugs, or switch their status from prescription to non-prescription.

Followed by targeted amendments to the *Food and Drugs Act (FDA)* under the *Jobs, Growth and Long-term Prosperity Act* (Bill C-38):

- Replace the current regulatory process with an improved and transparent posting of each new prescription drug on HC's website.

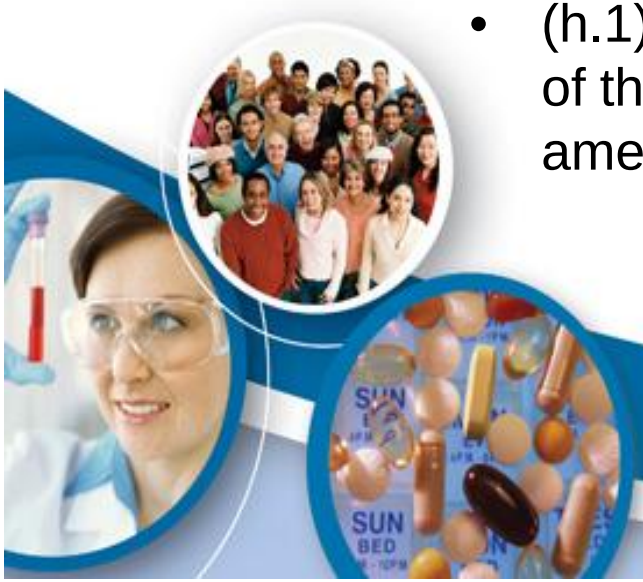
Royal Assent – June 29, 2012

Food and Drugs Act Amendments

- 29.1 (1) **Subject to the regulations**, the Minister may establish a list that sets out prescription drugs, classes of prescription drugs or both

The Governor in Council has been given a new regulation making authority :

- (h.1) **respecting the establishment** by the Minister of the list referred to in subsection 29.1(1), including amendments to it



What will change

- The **process** of assigning prescription status will become more efficient by replacing the requirement for a regulatory amendment to Schedule F with a web-based list of prescription drugs.

What will NOT change

- The sale, advertising restrictions, or importation of prescription drugs will remain the same.
- Science. All drug submissions to Health Canada will continue to be subject to rigorous safety, efficacy and quality assessments prior to approval, including the designation of prescription or switch to non-prescription status.
- Notification and public consultation will remain.

Realizing efficiencies from Bill C-38

- Amendments to the *Food and Drug Regulations* are needed to realize the efficiencies from Bill C-38.

- During the summer of 2012, Health Canada obtained **feedback on criteria** used to determine prescription status with the aim to propose regulatory amendments in CGI.

- The concept of developing *overarching scientific criteria* that will support the *existing Schedule F factors in guidance* was generally **well supported by stakeholders**.

Parallel Publication of:

Regulations

- **Proposed regulatory amendments** in *Canada Gazette I.*

Guidances

- **Draft guidance document** along with details in **Q&As document**.

Implementation

- Concurrent publication of **draft Prescription Drug List.**

(Published on December 22, 2012)

Proposed Regulatory Amendments

New provisions would be introduced to Part C, Division 1, of the *Food and Drug Regulations* to do the following:

a) Define prescription drug

- This would ensure that the prohibitions relating to the sale, import, and advertising of prescription drugs continue to apply to drugs with prescription status.
- Previously such drugs would have been subject to those prohibitions because they contained substances listed on Schedule F.

Proposed Regulatory Amendments

b) Define the Prescription Drug List

- This would be a Web-based list of drugs that the Minister is able to establish under the new section 29.1 of the Act.
- The PDL would include drugs or classes of drugs that have to be sold pursuant to a prescription from a licensed practitioner.
- This list would reproduce the list of drugs that are currently in Schedule F, with some minor modification for reasons of clarity.

Proposed Regulatory Amendments

c) *Establish scientific basis for listing*

- Three scientific criteria would be set out to determine whether a drug or class of drug should be sold pursuant to a prescription.
- These criteria would support the existing and publicly available Schedule F factors that would be re-stipulated in a guidance document.
- To add to the PDL, the Minister of Health shall consider whether any of the scientific criteria apply to a drug.
- To remove a drug or class from the PDL, the Minister shall consider the criteria and must determine that none of them apply to the drug or class.

Proposed Regulatory Amendments

Three overarching scientific principles anchor upon:

- Supervision by a practitioner is necessary
- The level of uncertainty respecting the drug, its use or its effects justifies supervision by a practitioner
- Use of the drug can cause harm to human or animal health or a risk to public health and the harm or the risk can be mitigated by a practitioner's supervision

Proposed Regulatory Amendments

d) Allow for public consultation

- The Minister would be required to consult the public on any proposal to remove a drug from the PDL for a period of time sufficient to allow comments from external stakeholders.
- This would also meet international obligations under the World Trade Organization's Agreement on Technical Barriers to Trade (TBT).

Current Format - *Schedule F*:

- **Part I** lists medicinal ingredients that, when found in a drug, require a prescription for human use and for veterinary use;

- **Part II** lists medicinal ingredients that, when found in a drug, require a prescription for human and veterinary use, except those drugs labelled for veterinary use only or in a form unsuitable for human use.

New Format - Prescription Drug List:

- a list of medicinal ingredients that, when found in a drug, require a **prescription for human use**; and

- a list of medicinal ingredients that, when found in a drug, require a **prescription for veterinary use**.

Adding or Removing an Ingredient from PDL

Decision-Making and Transparency:

- The Minister of Health delegates the authority to a senior official within the Health Products and Food Branch of Health Canada, who makes a decision following a recommendation from a Health Canada committee of scientific experts.

- Each time a medicinal ingredient is added or removed from the Prescription Drug List, the rationale for the change would be provided.

Adding an ingredient to PDL

- **Typically**, the *addition* of a medicinal ingredient to the Prescription Drug List is triggered by a company submitting an application to Health Canada for a drug that is new to the Canadian market.

- **In unique circumstances,** Health Canada may add a medicinal ingredient regulated as a non-prescription drug to the Prescription Drug List. This type of addition is triggered by new information that comes to the Department's attention through post-market activities or a drug submission.

Removal of ingredients from the PDL

- Switches from prescription to non-prescription status are initiated by a request from a company in the form of a drug submission.

- Drug submissions contain information and data regarding the drug's safety, quality and efficacy. After reviewing this data, Health Canada may determine that the drug should be available by prescription only, or that non-prescription sale is appropriate.

Process for Removal

Steps for Removals:

- Notice posted to the Health Canada website regarding the Minister's intent to remove a medicinal ingredient from the Prescription Drug List, including:
  - Notification that Health Canada will undertake a consultation.
  - Rationale for proposed removal.

- 75 day consultation

Process for Removals from PDL

- Following the comment period, a notice would be posted to Health Canada website and include:
  - a summary of comments received and Health Canada's response.
  - the Minister's decision to remove the medicinal ingredient.
- Removal comes into effect **6 months later.**

WTO TBT Notification Obligation

- The proposed regulatory changes will not modify or have impact on Health Canada's obligation to notify internationally under the Technical Barriers to Trade (TBT) agreement set out under the World Trade Organization.

- The notification process will remain the same.

- Impact from Clove Cigarette Dispute Settlement for Article 2.12 of TBT: obligation to allow reasonable interval between publication and entry into force of technical regulations, a minimum of **6 months**.

  (Indonesia and US – Clove Cigarettes)

Transitions

- Regulatory amendments to add certain medicinal ingredients that were proposed for addition to Schedule F of the *Food and Drug Regulations* are proceeding - these particular amendments can be completed prior to Schedule F being removed.

- Other medicinal ingredients that were proposed for addition to Schedule F will follow the process to add medicinal ingredients to the Prescription Drug List - manufacturers will be advised of these ingredients shortly.

Next Steps

- Consultation on all three streams will be open for 75 day comment period. The comment period ends on **March 7, 2013.**

- Health Canada will review the comments received during the CGI consultation period and consider any concerns before publishing in CGII.

- Health Canada will continue to work with stakeholders to develop details of an efficient implementation framework.

Information Links

- Link to Proposed Amendment to Food and Drugs Regulation in Canada Gazette

  http://gazette.gc.ca/rp-pr/p1/2012/2012-120-22/html/reg2-eng.html

- Link to Draft guidance: *Determining Prescription Status for Human and Veterinary Drugs*

  http://www.hc-sc.gc.ca/dhp-mps/consultation/drug-medic/pdl_gd_draft_ord_ld_ebauche-eng.php

- Link to Q&A for the Prescription Drug List:

  http://www.hc-sc.gc.ca/dhp-mps/consultation/drug-medic/pdl_qa_ldo_qr-eng.php