Natural Health Products Labelling and the Question of Cannabidiol: A Canadian Perspective

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Disclaimer

- The statements, conclusions and views expressed are those of the presenter and do not represent the view of affiliated/associated institutions;
- I work as a consultant with a number of organisations in the not-for-profit, governmental and private sectors.

Acknowledgement of Country

I would like to acknowledge the Gadigal of the Eora Nation, the traditional custodians of this land and pay my respects to the Elders both past and present.”

Land Acknowledgement

I would like to acknowledge that the land on which I live and work, in Stratford, Ontario is the traditional territory of the Anishnabek, Haudenosaunee (Iroquois), Ojibway/Chippewa peoples. This territory is covered by the Upper Canada Treaties. I make this acknowledgement to reaffirm my commitment and responsibility in improving relationships between nations and to improving our own understanding of local Indigenous peoples and their cultures.

Outline

- Overview of the Canadian Regulation of Natural Health Products
- New regulations for Natural Health Products labelling (July 2022)
- Regulation of Cannabidiol as a health product
- Final Thoughts

Canadian Regulation of Natural Health Products

Laws are like sausages, it is better not to see them being made.

Otto von Bismarck

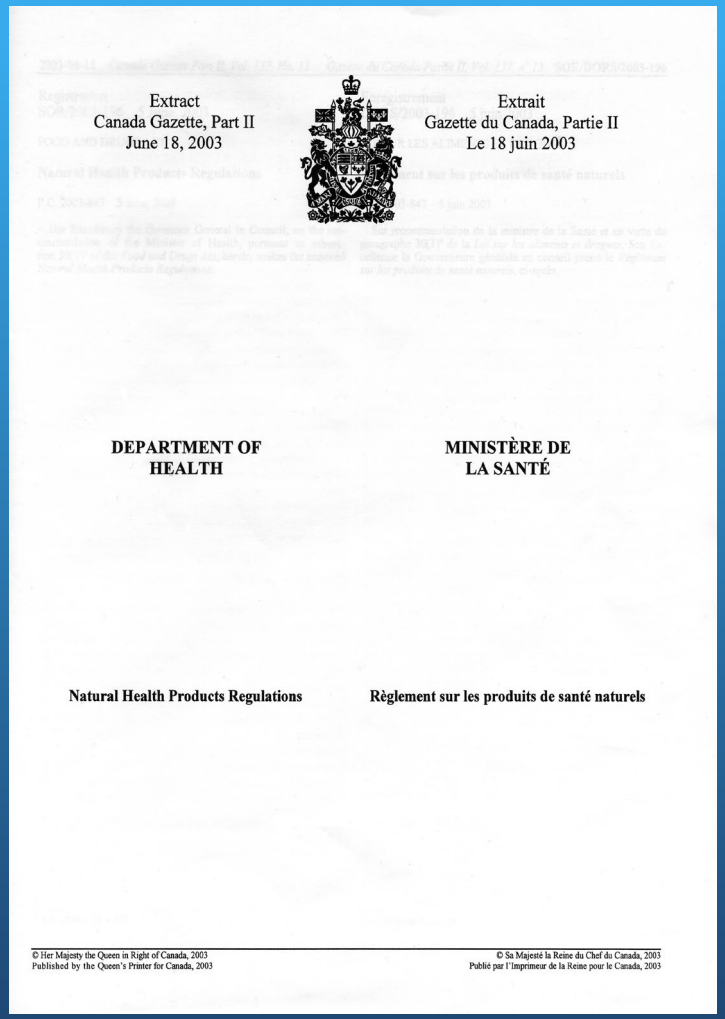
“If you’re in the dietary supplement business, you’re in politics.”

-- Sen. Tom Harkin

Events, dear boy, events

Harold McMillan
(British Prime Minister 1950s)

NHP Regulations



Extract
Canada Gazette, Part II
June 18, 2003

Extrait
Gazette du Canada, Partie II
Le 18 juin 2003

DEPARTMENT OF HEALTH

MINISTÈRE DE LA SANTÉ

Natural Health Products Regulations

Règlement sur les produits de santé naturels

- Definitions
- Part 1 – Product Licences
- Part 2 – Site Licences
- Part 3 – GMPs
- Part 4 – Clinical Trials
- Part 5 – Packaging and Labelling
- Part 6 –Transitional Provisions
- Including, of interest:
  - Adverse Reaction Reporting
  - Standards of Evidence

NHP Definition: Substances

- Finished health products with these medicinal ingredients (mainly schedule 1):
  - Traditional medicines, e.g Chinese, Ayurvedic;
  - Homeopathic medicines;
  - Plant, algal, fungal, bacterial, non-human animal materials, their extracts and purified isolates;
  - Vitamins and minerals;
  - Amino acid and fatty acid supplements;
  - Synthetic duplicates of the above substances;
  - Probiotics.
- Except when under separate federal regulations (mainly schedule 2):
  - Radiopharmaceuticals, biologics (e.g vaccines), antibiotics, prescription medications, controlled substances, conventional non-prescription drugs of synthetic origin, drugs to be injected, tobacco except in medicinal products.
- Not when under provincial/territorial regulations:
  - Place of sale, practice of medicine/regulation of health professionals, compounding

Self Care Initiative

- In 2016, Health Canada announced a self care framework applying oversight proportional to risk for regulatory oversight of self care products – non-prescription medicines, natural health products and cosmetics
- For the coming years, Health Canada has a very aggressive timeline for implementing these changes.
- Since the original announcement this initiative has undergone a number of changes, but key elements are:
  - Risk based post marketing oversight
  - Consideration of evidence as it relates to claims
  - Supporting informed choice
  - Cost recovery and modern business systems

Supplemented Food Regulations

July 20, 2022 | Ottawa, ON | Health Canada

"Today, Health Canada announced new regulations for supplemented foods. The new regulations will continue to protect the health and safety of Canadians, while providing people in Canada the information they need to make informed choices about these foods. The new rules will also allow industry to bring new and innovative products to consumers.

Supplemented foods are pre-packaged foods containing one or more added ingredients, such as vitamins, mineral nutrients, amino acids, caffeine or herbal extracts. Examples of supplemented foods include beverages with added minerals, caffeinated energy drinks, and snack bars with added vitamins."

www.canada.ca/en/health-canada/news/2022/07/health-canada-announces-new-regulations-for-supplemented-foods.html

Audit of the NHP program

- In 2021, the Commissioner of the Environment and Sustainability Development (CESD) within the Office of the Auditor General published a report on Health Canada's management of the NHP program

- While the general finding was that while the current approval process of products for both safety and efficacy was based on evidence, there were serious failings in a number of areas
  - Health Canada did not directly verify that facilities followed good manufacturing practices before products arrived on the market. The audit identified that Health Canada depended largely on manufacturers' attestation that they were following guidelines rather than actually inspecting sites
  - Health Canada did not check natural health products after they entered the market and was not always successful in responding to:
  - Health Canada responded effectively to natural products related to COVID-19 in that it exercised due diligence implementing a risk-based approach for the manufacturing/sale of hand sanitizers and identifying/acting on companies making false claims.

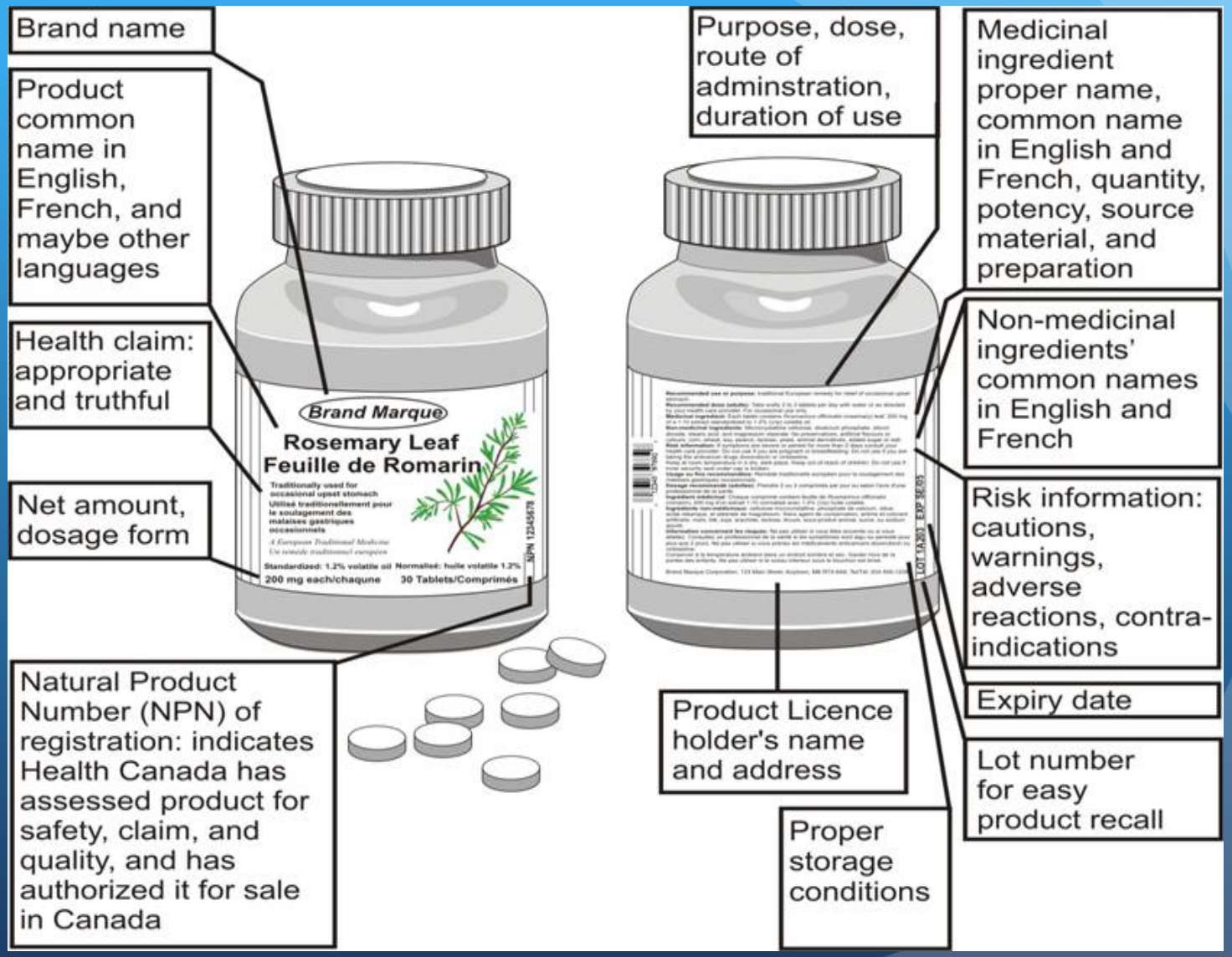
- The CESD also identified a number of challenges with the current regulations and policies that, as noted in the report, hindered the regulations from being effectively implemented and enforced. These included:
  - absence of mandatory on-site inspection of manufacturing facilities,
  - lack of mandatory recall provisions for NHPs together with low financial penalties for infringement as compared to other health products,
  - lack of financial resources needed to effectively manage the regulatory framework due in part to the last of a cost recovery system,
  - significant workload caused by the sheer number of product licences submitted for review especially when many were for products not brought to market by the sponsor.

- Health Canada accepted all the recommendations and have committed to moving forward with improvements to address them

- More information at www.oag-bvg.gc.ca/internet/English/parl_cesd_202104_02_e_43806.html

New Labelling Requirements for Natural Health Products

Original NHP Labelling Requirements



New NHP Regulations for Labelling (1)

- Formal Consultations started in 2016 and consisted of initial draft proposal, analysis of comments to initial proposal, technical briefings with key groups, cross country 'road trip' of consultations, Canada Gazette I publication of draft regulations
- On June 6th 2022, the final regulations were published in Canada Gazette II
- The proposed labelling changes fall into four basic areas:
  - *"A Product Facts table*: Important product information is required in the format of a standardized facts table. Certain exemptions are provided to accommodate products in very small packages, products that are relatively low-risk, products that are to be used within one day or less (as per the directions on the label), and products with package(s) that contain, at most, three dosage units.
  - *Labelling of food allergens, gluten, added sulphites and aspartame*: If a product contains a priority food allergen (i.e., one that is likely to lead to anaphylaxis in affected communities), gluten or added sulphites, a food allergen source, gluten source and added sulphites statement is required on the label. If a product contains aspartame, a statement to this effect is required on the product's label.
  - *Clearly and prominently displayed label text*: Regulatory text on the label, including within the Product Facts table, is subject to improved legibility requirements, including a minimum type size, font types, and contrast. Utilizing a risk-based approach, exemptions from these requirements are provided for certain label information (e.g. the product number and marketing information), as well as for products with very small packages, products that are to be used within one day or less (as per the directions on the label), and products with package(s) that contain, at most, three dosage units.
  - *Modernized contact information:* A manufacturer or importer is required to display an e-mail address, telephone number, or website address within an NHP's Product Facts table (or elsewhere on the label if the NHP is exempt from the facts table requirement), instead of a postal address of the manufacturer and the importer (if there is one), as is currently required"

New NHP Regulations for Labelling (2)

- Recognising that these changes could require extensive changes to NHP labels, there will be an implementation period of 3 years for new products with an additional 3 years for existing NHPs.
- "Health Canada recognised that in some cases there could be practical challenges and have added additional flexibilities to those indicated in the original proposal". These include products with
  - small labels,
  - short/limited duration of use,
  - containers that contain three or fewer dosage units, and
  - NHPs that have a localised effect such as topical aromatherapy.
- The definition of a small package size has increased from 75cm^2 proposed in CGI to 90cm^2 which includes more products notably those from traditional forms of medicine.
- Regarding monographs, commitment made by Health Canada (in Regulatory Impact Analysis Statement – RIAS- not the regulations) "will undertake a review of the compendium of monographs in order to help product licence holders accommodate a product facts table on their label" and to remove unnecessary warning statements from the monographs as well as amending them to make the language more "concise and understandable"
- Draft guidance documents have also been published

Concerns and Questions – New NHP Labelling Regulations

- While the new regulations contain a number of positive changes notably regarding labelling of allergens and ingredients causing sensitives, many concerns and questions exist. Key amongst them are:
  - Reason for choosing the regulatory route;
  - Incomplete consultation process;
  - Lack of link to government's published priorities;
  - Practicalities of implementing these changes especially given current environment;
  - Inaccurate and incomplete international analysis of regulations for comparators will hinder Canada's competitiveness globally;
  - Failure to learn from lessons re: implementation of similar framework for non-prescription drugs especially regarding costs and access to products;
  - Environmental impact; and
  - Failure to recognize changing role of printed labels as compared to electronic resources.

"Though intuitively it may be hypothesised that improved labeling will result in a reduction of harm, no independent, quality evidence is provided to support this assumption. Indeed, a recent review of the literature has come to the conclusion that changes in labeling of NHPs has little impact on the behaviour of consumers. The lack of scientific support for the proposed labeling changes therefore limits the ability to develop science- and evidence-based health policy and regulations"

Response from Board of Directors of the Natural Health Products Research Society of Canada to Publication of new NHP regulations for labelling in Canada Gazette I September 24th 2021

"Given the limited resources available, focusing on improving NHP labels could detract attention from other areas which have a higher potential of harm supported by a more robust evidence base. Some notable examples include evidence standards, product quality, and inadequate compliance and enforcement of the NHP regulations"

Response from Board of Directors of the Natural Health Products Research Society of Canada to Publication of new NHP regulations for labelling in Canada Gazette I September 24th 2021

Regulation: One size does not fit all

Regulatory Oversight of Cannabidiol

A Canadian Example – Cannabidiol (CBD)

- In July 2018, Canada passed the *Cannabis Act* and became the second country to legalise recreational cannabis including CBD - https://www.canada.ca/en/health-canada/services/drugs-medication/cannabis/laws-regulations.html

- At that time, changes were made that excludes CBD from the NHP and health products regulations:
  - Modification to the updated Industrial Hemp Regulations
  - Addition of synthetic, concentrated and extracted phytocannabinoids (including CBD) to schedule II of the NHP regulations
  - Addition or synthetic, concentrated or extracted phytocannabinoids (including CBD) to the Prescription Drugs List

- These steps went against recommendation of a Government of Canada expert committee (2016) created to advise on the recreational cannabis regulations which identified the NHP regulations as a potential option for bringing CBD to market as an NHP

- Recognising the many outstanding scientific questions about health products containing cannabis, Health Canada decided to convene a *Scientific Advisory Committee on health products containing cannabis*. A call for nominations was made in 2019 with committee members announced in late 2020.

- The Scientific Advisory Committee on Health Products Containing Cannabis published its final report in July 2022 and Health Canada is now considering how to proceed

Scientific Advisory Committee on Cannabis in Health Products (1)

- Important to recognize that the role of the committee was to provide scientific advice and they did not have any regulatory authority
- Decision was made by the committee to focus on CBD
- Committee had a subcommittee dealing with veterinary panel dealing with products for animals
- Committee was made up of nine external experts. While all members were eminent in their field, with the notable exception of one member, there was limited expertise regarding a self care context.

Scientific Advisory Committee on Cannabis in Health Products (2)

- Regarding use of CBD in humans, committee made 6 recommendations (in brief):
  - CBD is safe and tolerable for short term use (max of 30 days) at doses from 20mg/day to 200mg/day orally in consultation with pharmacist related to other medications;
  - Labels contain information regarding drug interactions and that products should not be taken in pregnancy, lactating, those considering pregnancy or allergic to cannabis
  - Packaging should contain clear information regarding dosing and warning of potential adverse effects
  - Labels should contain warning that though CBD is not habit forming, cannabis products should not be used for withdrawal from opioids or alcohol
  - Consumers should be encouraged to report adverse events and pathways should be used/developed to facilitate this
  - Early evidence supports the short-term use of CBD to treat mild symptoms associated with stress and nervousness. Insufficient evidence to either support or refute use CBD products to promote sleep or relieve pain.

CBD as a self care health product in Canada?

- Growing evidence from many respected sources that CBD is not habit forming and is relatively safe;
- As a distinct substance, CBD has no history of use within traditional and indigenous forms of health and healing
- Limited but growing evidence supporting CBD may be useful in some self-limiting conditions such as stress and nervousness
- Scientific expert panel committee suggested the NHP regulations as a valid option to be explored
- Limited information regarding what dosage is appropriate within a self care setting
- Significant economic potential in allowing to be sold as a health product.

Regulation: Access and Informed Choice

“We all see only that which we are trained to see”.

Robert Anton Wilson

Tell me what you want, what you really, really want.

The Spice Girls

Final Thoughts

The trouble with normal is it always gets worse

Bruce Cockburn

The original concept of Evidence Based Medicine is based on three basic premises – individual clinical expertise, the best external evidence and patients' values and expectations. The challenge faced by the regulator is to ensure that these are in play and to support consumers in making informed choices that are often made in a self-care setting.

Dwyer JT, Coates PM, Smith MJ. Dietary Supplements: Regulatory and Research Resources. Nutrients. 2018. Jane 4: 10(1)

In the long history of humankind, those who learned to collaborate and improvise most effectively have prevailed

Charles Darwin

Australia is well placed

For complementary medicines, Australia is in an enviable situation of having a:

- Robust complementary medicines industry
- Specific regulatory framework and policies for complementary medicines
- World class research and academic community with significant capacity in complementary medicines
- Mature marketplace with an increasingly informed consumer base

Useful Resources

- Self-care Initiative
  - https://www.canada.ca/en/health-canada/topics/self-care-products.html
- Canadian NHP Regulations
  - https://www.canada.ca/en/health-canada/services/drugs-health-products/natural-non-prescription.html
- New NHP labelling regulations
  - https://canadagazette.gc.ca/rp-pr/p2/2022/2022-07-06/html/sor-dors146-eng.html
- Guidance document NHP Labelling
  - https://www.canada.ca/en/health-canada/services/drugs-health-products/natural-non-prescription/legislation-guidelines/guidance-documents/labelling.html
- Scientific Advisory Committee on Health Products Containing Cannabis
  - https://www.canada.ca/en/health-canada/corporate/about-health-canada/public-engagement/external-advisory-bodies/health-products-containing-cannabis.html#a5

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Southern Cross University

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Thank you /Miigwetch/
Niá:wen /
Merci beaucoup