

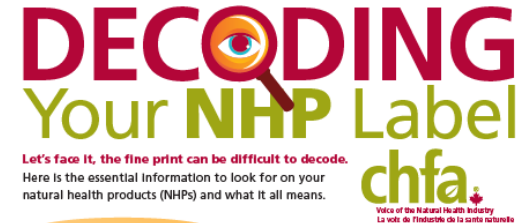
Health Canada Proposes New Rules to Regulate NHPs Like Drugs



Our Current System

NHPs are regulated under the *Natural Health Products Regulations*

- All products are licensed by Health Canada
 - All products carry an NPN
- Products carry diverse claims
 - Therapeutic claims
 - Structure function claims
 - Non-traditional claims
- Health Canada accepts appropriate evidence based on the product claims



What's Being Proposed

- Changes could fundamentally alter how NHPs are approved and marketed in Canada
- Self-Care Products Includes: Natural Health Products (NHPs), Non-Prescription Drugs and Cosmetics
- Proposes to regulate all self-care products similarly based on level of risk posed
- Health Canada will only review claims based on “scientific evidence”

Proposed 3-Tier Class System

Lower Risk Products:

- Go straight to market (no Health Canada approval = no NPN)
- Health claims about diagnosis/treatment/prevention/cure/reduction **not allowed**
- Products **must** carry:
 - Disclaimer i.e. “This product has not been reviewed for effectiveness by Health Canada”

Proposed 3-Tier Class System

For Medium and High Risk:

- Must be approved by Health Canada (will carry a licence number)
- Health claims about diagnosis/treatment/prevention/cure/reduction allowed
- Evidence to support products and claims must be 'scientific evidence'

What's Being Proposed – Low/Medium/High Risk

Low Risk	Medium Risk	High Risk
No Health Canada Review	Some Review by HC	Full Review by HC
HC to set Quality Standards	Products to be licensed	Products to be licensed
Only certain ingredients will be allowed	HC to Set Quality Standards	Companies to provide evidence to support Quality, Safety and Efficacy
Claims of diagnosis, treatment, prevention, mitigation not allowed	Health Canada Approves Claims	Health Canada approves claims
Other claims i.e. allowed but would not be reviewed by Health Canada	Claims subject of Monograph	
Claims subject to a disclaimer: HC has not reviewed for effectiveness		

Health Canada Examples of Product Classification

Low Risk	Medium Risk	High Risk
Cosmetics, many vitamin and mineral products , toothpaste, mouthwash, homeopathic products , diaper rash products.	Topical and oral pain relievers (such as acetaminophen and ibuprofen), cough and cold products , laxatives , allergy relief products .	Products that are switching from prescription to non-prescription status, products that contain new medicinal ingredients, products related to cardiovascular health

This Could Mean...

- Traditional Medicine like Traditional Chinese medicine, Herbal medicine, Homeopathy may not make claims like we see today:

NHP Ingredient	Claims Allowed Today	Under Self-Care Proposal
For example: Cranberry	(Traditionally) used in Herbal Medicine to help prevent (recurrent) urinary tract infections (UTIs)	Claims to UTI prevention will no longer be allowed

Some NHPs may no longer continue on the market if the new standard of evidence is similar to drugs

This Could Mean...

- NHP claims based on reasonable evidence, (any standard of evidence below gold-standard, double-blind, placebo controlled studies) may not be permitted under the self-care proposal

Examples Includes:

- Fish oil products: 'Helps to reduce serum triglycerides/triacylglycerols'
- Weight loss products: 'To be used with a program of reduced intake of dietary calories and increased physical activity (if possible) to help in weight management'

This Could Mean...

- Multiple-ingredient NHP formulas where the claim is based on the action of one ingredient may require:
 - Scientific evidence to demonstrate that the combination of all ingredients is effective
- This is a significant departure from our current practices and many companies may not be able to remain on the market under this proposal

Potential Impact

- Elements of the current system would be lost
- Some NHPs would be regulated like drugs and have to provide evidence
- Store Shelves:
 - some NHPs will have licence numbers
 - others carry disclaimers for products not reviewed by Health Canada
- Fewer products on the market
- Financial impacts on business

So what can you do?

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La voix des Producteurs de la santé naturelle

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Natural Health Products

are **NOT** Drugs

Help us show Health Canada that **NHP Regulations work.**

Trade Shows and Conferences

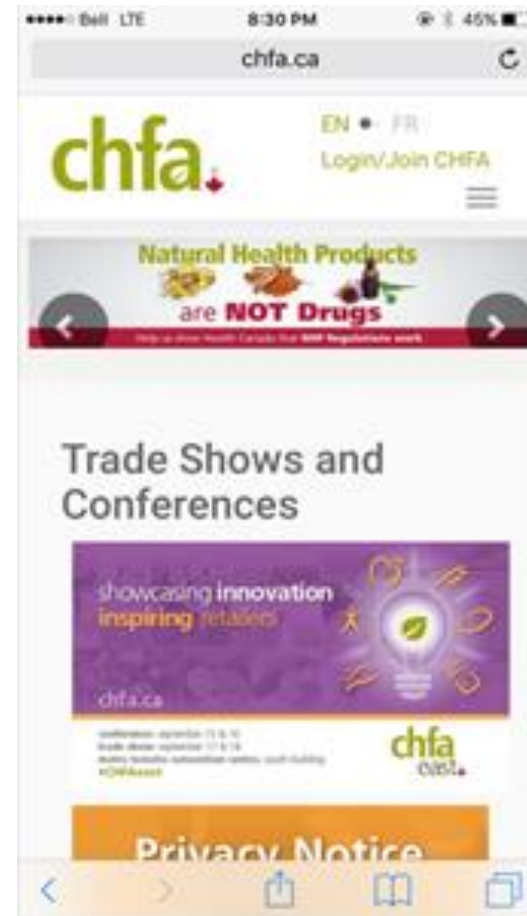
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Click the
Natural Health
Products are
NOT Drugs
image.



NHPs Are Not Drugs

Health Canada has recently launched the *Consulting Canadians on the Regulation of Self-Care Products in Canada* document. Previously referred to as the *Consumer Health Product Framework*, this document has changed dramatically since its original inception, and proposes that, in the future, many natural health products (NHPs) be regulated using the same rules as drugs.

We want to make one thing clear: natural health products are NOT drugs.

Changing the entire regulatory system based on a single public opinion poll and six weeks of consultation is irresponsible.

This hasty consultation is in stark contrast to the previous consultation on the regulation of NHPs, carried out by the Standing Committee on Health (SCOH).

The SCOH met with hundreds of witnesses, including consumer groups, Health Canada, the Canadian Food Inspection Agency, international regulators, and received hundreds of submissions over a half year review period. It set out a robust and thoughtful framework for the regulation of NHPs that resulted in the passage of the NHP Regulation and the establishment of the NHPD (now NNHPD).

Canada is already a global leader in the regulations of NHPs, let's move forward instead of back

Our current pre-market approval system respects traditional values from many different cultures and allows Canadians freedom of choice and access to these important products. Changing the current NHP Regulations is trying to fix a system that is not broken.

Natural health products shouldn't be regulated like drugs. Natural health products are different in nature from drugs and must be treated differently.

Please click the button below to send a letter to your local Member of Parliament, urging them to make your views known to the Minister of Health.

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NHPS ARE NOT DRUGS

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There is a brief overview of what's going on. Click the Send Letter icon.



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La voix de l'industrie de la santé naturelle

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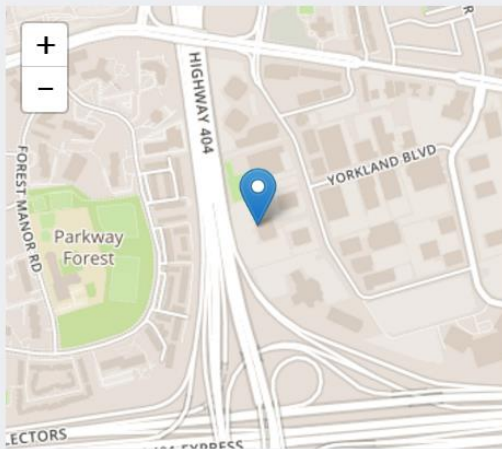
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LIBERAL MP



Geng Tan



Don Valley North

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Helen Long
235 Yorkland Blvd
Suite 302
Ontario
Toronto, Ontario
M2J 4Y8

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RE: Concern about Health Canada's treatment of Natural Health Products^x

Mr. Geng Tan, M.P.
House of Commons
Parliament Buildings
Ottawa, Ontario
K1A 0A6

Sep 14, 2016

Dear Mr. Tan,

As a constituent in your riding I was shocked to learn of a proposal from bureaucrats at Health Canada to take away consumer choice in natural health products. Our natural health products are just that - natural! They are not drugs and shouldn't be regulated the same way as drugs.

Natural health products are safe and effective, and the current regulatory framework protects consumers and consumer choice. The proposal by bureaucrats throws out a world-class Canadian system brought in by Liberal Health Minister Allan Rock with all party support and a full year of parliamentary committee study.

As someone from your community, I am asking that you oppose this proposal and make my views known to the Minister of Health.

I look forward to your response.

Thank you.

Helen Long
235 Yorkland Blvd
Suite 302
Ontario
Toronto, Ontario
M2J 4Y8

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