



### OVERVIEW

- The Natural Health Product Regulations require that individuals obtain a product licence before they sell any NHP (natural health product) in Canada.
- The licence is obtained by submitting an application demonstrating the safety, quality and efficacy of the NHP when used according to the recommended conditions of use.
- All products on the market prior to January 1, 2004 must have a submission for a licence by January 1, 2010.

See an overview of the *Product Licensing Requirements and Process* at:  
[http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/license-licence\\_guide\\_tc-tm\\_e.html](http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/license-licence_guide_tc-tm_e.html)

### WHO DOES THIS APPLY TO

- These regulations apply to any individual intending to sell an NHP in Canada.

### WHAT'S NEW

- New multi-vitamin/mineral supplement monograph. (Nov 2007)
- A completely revised version of the *Guideline Document: Evidence for Quality of Finished Natural Health Product* for use with product licence applications. (Oct 2007)
- A new assessment stream for Licensing of Homeopathic Medicines with non-specific recommended uses or purposes. (Apr 2008)
- Numerous new and revised Product and Single Medicinal Ingredient monographs are being published regularly.
- The information provided in the Product Licence Application (PLA) and proposed label text must correspond in full to that which is outlined in the monograph or the PLA will be refused. Applications corresponding in full to the monograph will proceed directly to licensing.
- The transition period for all categories of natural health product already on the market in January 1, 2004 that were prioritized for submission has elapsed. All product licenses must be submitted by January 1, 2010.

15-6400 Millcreek Dr.,  
Suite 321  
Mississauga, Ontario  
L5N 3E7 Canada  
TOLL FREE: 1-877-877-5152  
PHONE: 905-363-1182  
FAX: 905-542-7981

info@qualityandcompliance.com  
www.qualityandcompliance.com  
www.validapharm.com  
www.nhpcompliance.com

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- The Food Directorate in collaboration with the Natural Health Products Directorate will review Product Licence Applications for natural health products in food formats (e.g., juices, yogurts and butters). Both the Natural Health Product Regulations and the interim *Guidance Document for Preparing Submission for Foods with Health Claims* will be used for the assessment.
- The Licensed Natural Health Products Database contains specific information on those natural health products that have been issued a product licence by Health Canada.

Refer to the user guide for the *Licensed Natural Health Products Database*:  
[http://www.hc-sc.gc.ca/dhp-mps/pubs/natur/lnhpd\\_guide\\_bdpsnh-eng.php](http://www.hc-sc.gc.ca/dhp-mps/pubs/natur/lnhpd_guide_bdpsnh-eng.php)

## KEY POINTS

### Types of Product Licence Applications (PLAs)

PLA	Description
Compendial (May have a traditional or non traditional claim)	Products that are in the <i>Compendium of Monographs</i> published by the NHPD for specific NHPs and NHP combinations.
TPD Category IV/Labelling Standard	These products are listed by Health Canada and contain low risk non-prescription drug products. They have been reclassified as drugs or NHPs.  They are transitioning into the <i>Compendium of Monographs</i> .
Traditional Claim	Products that have been used within a cultural belief system or paradigm for at least 50 years.
Non-Traditional Claim	Products that contain medicinal ingredients that are shown to be safe and effective that are not covered by the <i>Compendium of Monographs</i> or other categories due to strength, combination and identity.

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PLA	Description
Homeopathic	Products that are manufactured from or contain medicinal ingredients that are referenced in a recognised homeopathic pharmacopeia. (e.g., Homeopathic Pharmacopeia of the United States (HPUS), European Pharmacopeia (EP), Encyclopaedia of Homeopathic Pharmacopeia.)
Homeopathic DIN	Homeopathic medicines that have previously been issued a DIN.

Refer to the *Product Licensing Guidance Document*:  
[http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/license-licence\\_guide\\_tc-tm-eng.php](http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/license-licence_guide_tc-tm-eng.php)

Refer to the *Compendium of Monographs*:  
<http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/compendium-eng.php>

### Application Requirements

- The identity of the applicant or Canadian representative if the applicant is not Canadian
- Medicinal ingredients
- Non-medicinal ingredients
- Brand name\Recommended conditions of use
- Safety and efficacy information (if required)
- Finished product specifications
- Attestation that the product will be manufactured under GMP

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Refer to the following documents for more information:  
*Evidence of Safety and Efficacy of Finished NHPs:*  
<http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/efe-paie-eng.php>

*Evidence for Quality of Finished NHPs:*  
<http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/eq-paq-eng.php>

*Evidence for Homeopathic Medicines Guidance Document:*  
<http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/ehmg-nprh-eng.php>

*Clinical Trials for NHPs:*  
[http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/clin\\_trials-essais\\_nhp-psn-eng.php](http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/clin_trials-essais_nhp-psn-eng.php)

### Post Licensing Requirements

- Once an NHP has been granted a Natural Product Number (NPN or DIN-HM for Homeopathic medicines), it is expected that the product is manufactured in:
  - Accordance with the specifics filed in the Product Licence
  - A facility that has been granted a site licence, or is included in a site licence granted to an importer
  - Accordance with the Good Manufacturing Practice requirements for NHPs
- If there are any changes to the approved conditions in the application (e.g., change in recommended dose, duration of or recommended use, a change in the quantity or substitution of a medicinal ingredient, a change in the specifications), the licensee is required to amend the application or notify the NHPD dependant on the type of change under consideration.

Refer to *Post Licensing Guidance Document:*  
[http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/plgd\\_psdldr\\_1-eng.php](http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/plgd_psdldr_1-eng.php)

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## FAQ

### 1. Do I need a Product Licence?

Yes. Before any natural health product can be sold in Canada, it must first undergo a pre-market review where it will be assessed for safety, efficacy and quality. Evidence demonstrating this must be submitted to Health Canada by means a product licence application. Products which meet the criteria will be authorized for sale and issued a Natural Product Number (NPN) or Homeopathic Medicine Number (DIN-HM).

### 2. Does a submission number constitute an authorization for sale?

No. A submission number is proof of the receipt of a complete PLA by the NHPD and is not an authorization for sale. However, compliance efforts will be focussed on products that do not have a submission number or that pose an unacceptable risk to Canadians.

### 3. What is a product monograph?

A product monograph is a factual, scientific document that contains information on the active ingredient, source material, route of administration; dosage form; use or purpose; dose; duration of use; risk information; specifications; and non-medicinal Ingredients. It was developed as a tool to facilitate the review of the safety and efficiency of many commonly used NHPs.

### 4. If there are updates to the product monographs included in a submitted Product Licence Application, do the changes have to be made?

Yes. Applicants should note that any submissions in queue are assessed against new and updated monographs.

### 5. How long does it take to obtain a Product Licence once an Application has been submitted?

Compendial applications and transitional DIN products have a 60-day default cycle. Homeopathic medicines receive an expedited review but no performance standard has been stated. Remaining applications may take two to three years for approval.

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**Contact NHP Compliance**  
with your questions about Natural Health Products.  
Phone Graham Mills toll-free at 1-877-877-5152,  
extension 210, or email him at [g mills@qualityandcompliance.com](mailto:g mills@qualityandcompliance.com).

NHP Compliance QuickNote -- NHP Product Licensing

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