



### OVERVIEW

- The Natural Health Product Regulations require that any Canadian site where natural health products (NHPs) are manufactured, packaged/labelled and/or imported must have a site licence to perform these activities.
- Licensable activities must be conducted in accordance with the requirements of the Canadian Good Manufacturing Practices (GMPs).
- The importer is responsible for ensuring each foreign site meets the Canadian GMP requirements.

See the *Site Licence Guidance Document* at:

[http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/slgd-drle\\_e.html](http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/slgd-drle_e.html)

### WHO DOES THIS APPLY TO

- Importers, packagers, labellers, manufacturers
- Site licences are not required for:
  - Facilities used for warehousing and storage purposes only – the site licence holder is required to list sites on the application and ensure that GMPs are maintained.
  - Pharmacists, health care practitioners and traditional healers that compound for sale to the individual patient only.
  - Businesses involved in growing, procuring or processing raw materials, but do not produce a product ready for consumption by the consumer.
  - Businesses that manufacture, package or label NHPs for the sole purpose of exporting outside of Canada.

### WHAT'S NEW

- Typical timelines for approval are now one to three months.

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## KEY POINTS

The site licence includes the following information:

- A declaration of the activities to be performed by the applicant (i.e., manufacturing, packaging, labelling or importing)
- The address of each facility to be used, including any applicable foreign site
- For importers, the address of each storage facility
- A statement if any of the products is sterile
- Evidence from a Quality Assurance person (e.g., Quality Assurance Report – QAR) that the buildings, equipment, practices and procedures used to conduct each activity are performed according to the Canadian requirements for GMPs for NHPs

Refer to the *Guide for Completing Site Licence Application (SLA) Form*:  
[http://www.hc-sc.gc.ca/dhp-mps/prodnatur/applications/licen-site-exploit/form/form\\_sla-guide-dle-eng.php](http://www.hc-sc.gc.ca/dhp-mps/prodnatur/applications/licen-site-exploit/form/form_sla-guide-dle-eng.php)

### The Quality Assurance Report (QAR)

- The Quality Assurance Report assesses and provides evidence of GMP compliance. It is prepared by either a quality assurance person or a third party auditor who has the training, experience and technical knowledge relating to the activity conducted and the requirements of the GMPs.
- Importers must submit a QAR (or equivalent – see below) for each foreign site. The QAR for a foreign site is valid for one year minus one day from the date of completion; it must be submitted for review with the site licence application or renewal.

Refer to the *Instructions for Completing the Quality Assurance Report Form – Site Licensing – Natural Health Products*:  
[http://www.hc-sc.gc.ca/dhp-mps/prodnatur/applications/licen-site-exploit/form/forms\\_qar\\_instructions-eng.php](http://www.hc-sc.gc.ca/dhp-mps/prodnatur/applications/licen-site-exploit/form/forms_qar_instructions-eng.php)

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### Alternatives to the QAR

- Establishment licence holders may submit a copy of their current establishment licence when activities performed for drugs and NHPs are aligned.
- A valid drug GMP inspection report from a Health Canada Inspection conducted within the last three years or an inspection following equivalent GMP guidelines (e.g., U.S. cGMP or PIC/S GMP).
- A corporate audit performed by a qualified person, covering all applicable sections of the GMPs. Include any corrective measures taken to address noted deficiencies and an assessment of these corrective measures by the auditor.

### Site Licence Renewals

- As of September 1, 2007, the NHPD has revised its site licence renewal cycle and will require only a completed QAR with the first application, in the fourth year, in the tenth year and every three years thereafter. For renewal applications between these dates, a completed Summary of Net Changes Form along with copies of recent samples of records (logs) will be considered sufficient evidence of compliance with Good Manufacturing Practices.

TABLE 1 – Site Licence Renewal Cycle

	Site Licence issued by the NHPD (Date of Issuance)	1 <sup>st</sup> Date of Renewal	2 <sup>nd</sup> Date of Renewal	3 <sup>rd</sup> Date of Renewal	4 <sup>th</sup> Date of Renewal*	5 <sup>th</sup> Date of Renewal	6 <sup>th</sup> Date of Renewal**	7 <sup>th</sup> Date of Renewal	8 <sup>th</sup> Date of Renewal
<b>Renewal Cycle</b>	Sept 25, 2008	Sept 25, 2009	Sept 25, 2010	Sept 25, 2011	Sept 25, 2013	Sept 25, 2015	Sept 25, 2017	Sept 25, 2020	Sept 25, 2023
<b>GMP Evidence Required</b>		Provide a Summary of Net Changes and records	Provide a Summary of Net Changes and records	Provide a completed QAR and records	Provide a Summary of Net Changes and records	Provide a Summary of Net Changes and records	Provide a completed QAR and records	Provide a completed QAR and records	Provide a completed QAR and records

*Licence renewed on anniversary date of being issued.*

*\*Licence renewed every two years between the 4<sup>th</sup> to the 6<sup>th</sup> renewal.*

*\*\* After the 6<sup>th</sup> renewal, all subsequent renewals occur every three years.*

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### Site Licence Amendments

A licence amendment is required for any of the following changes:

- Adding a new activity
- Adding a new building for operations or storage
- Changing from manufacturing, packaging, labelling or importing a non-sterile dosage form to a sterile dosage form
- Adding a new foreign site

### Site Licence Notifications

A site licence notification is required within 60 days of any of the following changes:

- A change in the name, mailing address, telephone number, facsimile number or e-mail address
- Any substantial change that alters any building, equipment, practice or procedure that was previously referred to in the Quality Assurance Report submitted

## FAQ

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

Yes. Any Canadian site where NHPs are manufactured, packaged, labelled and/or imported are required to have a site licence. Businesses can choose to have a single site licence for all operations on multiple sites or an individual licence for each site.

### 2. Can I use my FDA inspection as my QAR?

Yes. An FDA inspection of a drug facility within the last three years can be used for the QAR.

### 3. Will I be inspected?

Yes. Health Canada will be implementing a program of routine inspections of NHP site licence holders that may commence in 2009.

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#### 4. What is government enforcement like?

At the time of submission, site licence applications are carefully scrutinized to ensure that all required information is present and copies demonstrating compliance to GMPs are included. If necessary, additional information is requested before the licence is granted.

#### 5. Will Health Canada recognise a third-party service to act as a Quality Assurance Person for an NHP company?

Yes. The qualifications and responsibilities of the Quality Assurance Person are outlined in the GMPs. If these are followed, the activities can be performed by a suitable third-party service.

**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 [gmills@qualityandcompliance.com](mailto:gmills@qualityandcompliance.com).

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NHP Compliance QuickNote -- NHP Site Licensing

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