



Health
Canada

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Subject: Upcoming NHP GMP Inspection Pilot Program – Part 3 of the *Natural Health Products Regulations*

Le français suit....

Dear Stakeholder,

Health Canada is announcing changes to its oversight of regulated activities pertaining to natural health products (NHPs) subject to Part 3 of the [Natural Health Products Regulations](#)¹ (NHPR) – Good Manufacturing Practices (GMPs). All references to NHPs include homeopathic medicine (HM).

Health Canada currently verifies the compliance of NHP companies through paper-based reviews during the licensing process, complaint-based compliance verifications and short term compliance monitoring projects. To complement this process, **Health Canada is implementing a pilot NHP GMP inspection program, which may transition to a permanent NHP GMP inspection program further to an evaluation of the pilot.**

The purpose of these changes is to:

1. Strengthen support for its mandate as a regulating authority, to ensure compliance of the NHP industry with regulatory requirements, and prevent non-compliance, and
2. Strengthen the protection of the health and safety of Canadians, by ensuring NHPs are safe, effective and of high quality.

In line with its ongoing commitment to [transparency](#)², Health Canada will post a summary report when the pilot is completed. As per previous practice with compliance monitoring projects Health Canada will make every effort to share the results of the pilot with the industry in advance of the publication. Health Canada intends to initiate the posting of individual inspection results on the [Drug and Health Products Inspections Database](#)³ for the permanent inspection program, if it is implemented.

Good Manufacturing Practices for NHPs

Part 3 of the NHPR sets out specific GMP requirements for NHPs ("NHP GMP") and has been in force since 2004 to help ensure the safety and quality of NHPs for sale in Canada. Refer to the [GMP Guidance Document on NHPs](#) and the [Quality of Natural Health Product Guide](#) for more information about NHP GMP requirements.

In order to manufacture, package, label and/or import an NHP for sale in Canada, a site licence (SL) is required. Health Canada currently issues a SL based on a paper-based review of evidence in support of its compliance with Part 3 of the NHPR (NHP GMP). Once licensed, a site is required to maintain its compliance with the NHPR.

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NHP GMP Compliance

In 2016, Health Canada published a report titled [Evaluation of the Natural Health Products \(NHPs\) Program 2010-2011 to 2014-2015](#)⁴, in which it recommended the use of proactive tools, such as inspections, to balance the paper-based licensing process.

As part of its proactive activities, Health Canada conducted two NHP GMP Compliance Monitoring Projects (CMPs) in [2017](#)⁵ and 2018/19 (report to be posted online shortly). The purpose of these CMPs was to verify compliance with specific aspects of the NHP GMP, such as the requirements for Specifications, Stability and Recall Reporting, and to gather information on the state of compliance of SL holders. This was accomplished through a partial on-site verification of 46 sites across Canada. During both CMPs, a range of GMP compliance issues were observed at all facilities. Though it is not uncommon to find non-compliances, the nature of the issues found at some sites meant that Compliance and enforcement actions, including stop sales and recalls, were initiated based on the risk posed by the GMP issues identified. In approximately half of the cases, the issues were significant enough for Health Canada to notify the site, through a regulatory letter, of either its intention to suspend or immediately suspend the site and/or product licences. Further details on these CMPs can be found [online](#)⁶.

NHP GMP Inspection Program

Inspections are a compliance and enforcement tool used by a number of programs within Health Canada, such as the Medical Devices Program, the Cannabis Program and Controlled Substances Program. This tool is used to proactively verify compliance and prevent non-compliance with applicable Acts and regulations.

In order to help ensure acceptable quality of NHPs for Canadians and in response to the compliance outcomes identified during the CMPs and to complement HC's current paper-based process, Health Canada is implementing a pilot NHP GMP inspection program. The purpose of this pilot is to continue the verification of the NHP industry's compliance with Part 3 of the NHPR, promote compliance to these regulations, and prevent non-compliance, through the inspection of a selection of site licence holders located across Canada. These inspections will include a more in-depth review of compliance with Part 3 of the NHPR. This work will allow Health Canada to gain additional knowledge of the NHP industry, which will be used to develop the framework for a potential permanent inspection program. NHP GMP inspections under the pilot program will start in 2021. At the conclusion of the pilot, results will be evaluated and implementation of the permanent inspection program may follow. **If the permanent program is implemented, it will mark the beginning of regular inspection of the NHP industry.**

The NHP GMP inspections will be conducted under the authority of Section 23 of the [Food and Drugs Act](#)⁷. The sites selected for an inspection will be given advance notice prior to Health Canada conducting the inspection. Due to current restrictions in place across Canada in response to the

COVID-19 pandemic, it is expected that some inspections conducted may be virtual through use of telecommunication.

Should a risk to health or non-compliance be identified during an inspection, Health Canada will take action(s) using the most appropriate level of intervention as per the [Compliance and Enforcement Policy \(POL-0001\)](#)⁸, which could include product recall or product/site licence suspension.

Site Selection for Inspection:

All establishments licenced to manufacture or import NHPs, which are deemed as higher risk activities, will be considered for the NHP GMP Inspection Pilot. A combination of other factors will also be considered, similar to those used for the NHP GMP CMPs, including, but not limited to:

- Regulated activities undertaken at the site and the relative impact of the activities on product safety and quality,
- Objective criteria such as areas and products of concern and history of compliance issues, and
- Location in Canada, to ensure an equal distribution of inspections from East to West.

Self Care Framework

Through its Self-Care Framework (SCF) initiative, Health Canada is looking to update its current approach to regulating NHPs, with the objective to modernize the oversight for NHPs in a manner that respects the values established in 2004 when the NHPRs came into law, while continuing to allow for a wide range of products to be available for Canadian consumers, and better supporting consumers' ability to make informed choices. This had always included the implementation of GMP inspections, which is now realized with the NHP GMP Inspection Pilot Program.

The principles established through the SCF will be considered within the NHP GMP inspection pilot, but will also take into account the history of compliance issues and the need to know who is actively manufacturing what products at which sites.

To this end, Health Canada is using the NHP GMP inspection pilot to establish a baseline to assess:

- Knowledge of GMPs
- What products are being made at which sites
- Complexity of manufacturing activities.

This will be used to better inform both the future inspections under a permanent NHP GMP inspection program, which will take into consideration all of the principles of the SCF and can be

used in the future to determine frequency and type of inspection that would be applied in future instances for low-risk products.

For more information contact hc.nnhpd.consultation-dpsnso.sc@canada.ca.

Next Steps:

Prior to initiating NHP GMP Inspections under the pilot program, Health Canada plans to host two webinars early in the New Year, which will provide information to stakeholders regarding:

1. Inspection as a Compliance and Enforcement Tool
2. Application of Part 3 of the NHPR (NHP GMP)

Review the attached “Save the date” communication for more information.

Additional Information:

For additional information on NHP GMPs and inspections please refer to the following Health Canada guidance:

1. A Guide to Health Canada Inspections: <https://www.canada.ca/en/health-canada/corporate/mandate/regulatory-role/what-health-canada-does-as-regulator/guide-inspections.html>⁹
2. [GMP Guidance Document on NHPs](#)¹⁰
3. [Quality of Natural Health Product Guide](#)¹¹
4. [Finished Product Specification Form User Guide](#)¹², appendix 2
5. [NNHPD’s Compendium of Monographs](#)¹³

Attachments:

1. Save the date – Webinars: (1) Orientation to Compliance and Enforcement and (2) Part 3 of the Natural Health Products Regulations (Good Manufacturing Practices for Natural Health Products).

Health Canada would like to take this opportunity to remind the industry that it is their responsibility to ensure that all health products they sell in Canada and all the activities they undertake in regards to these health products comply with the requirements set out in the FDA and its associated Regulations.

¹ <https://laws-lois.justice.gc.ca/eng/regulations/sor-2003-196/>

² <https://www.canada.ca/en/health-canada/corporate/transparency/regulatory-transparency-and-openness.html>

³ <https://www.canada.ca/en/health-canada/services/inspecting-monitoring-drug-health-products/drug-health-product-inspections.html>

⁴ <https://www.canada.ca/en/health-canada/corporate/transparency/corporate-management-reporting/evaluation/2010-2011-2014-2015-natural-health-products-program.html>

⁵ <https://www.canada.ca/en/health-canada/services/inspecting-monitoring-drug-health-products/compliance-monitoring-reports/2017-reporting-compliance-monitoring-natural-health-products.html>

⁶ <https://www.canada.ca/en/health-canada/services/inspecting-monitoring-drug-health-products/compliance-monitoring-reports.html>

⁷ <https://laws-lois.justice.gc.ca/eng/acts/f-27/>

⁸ <https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/good-manufacturing-practices/policies-standards/compliance-enforcement-policy-0001.html>

⁹ <https://www.canada.ca/en/health-canada/corporate/mandate/regulatory-role/what-health-canada-does-as-regulator/guide-inspections.html>

¹⁰ <https://www.canada.ca/en/health-canada/services/drugs-health-products/natural-non-prescription/legislation-guidelines/guidance-documents/good-manufacturing-practices.html>

¹¹ <https://www.canada.ca/en/health-canada/services/drugs-health-products/natural-non-prescription/legislation-guidelines/guidance-documents/quality-guide.html>

¹² <https://www.canada.ca/en/health-canada/services/drugs-health-products/natural-non-prescription/legislation-guidelines/guidance-documents/finished-product-specifications-form-user-guide.html>

¹³ <http://webprod.hc-sc.gc.ca/nhpid-bdipsn/monosReq.do?lang=eng>