



Pilot Natural Health Product (NHP) Good Manufacturing Practices (GMP) Inspection Program:

Questions and Answers for Regulated Parties Related to Implementation of the Pilot

1. When will the pilot and permanent program start?

Inspections as part of the pilot are anticipated to begin in February/March of 2021. Site Licence (SL) holders will be notified 4 weeks in advance and will be requested to provide specific information prior to the inspection. The NHP GMP inspections will be performed under the pilot program while a permanent inspection program is under development. A permanent program may be implemented at the end of the Pilot, but this will depend on Pilot progression and outcome.

2. How many inspections will be conducted during the pilot program?

Health Canada (HC) was planning to conduct a comparable number of inspections as were conducted during the previous two NHP GMP compliance monitoring projects (CMPs), but we are monitoring the COVID situation closely to determine final impact on the target number of inspections.

3. Why is Health Canada piloting a new inspection program now (during COVID-19)?

Health Canada's primary objective is to protect the health and safety of Canadians.

To protect the health and safety of Canadians, Health Canada remains committed to its mandate while balancing the unique demands during the COVID-19 pandemic. The work

was planned prior to the COVID-19 pandemic and overseeing NHPs is included in our mandate.

To help accommodate industry, due to the implemented government social distancing restrictions in Canada, virtual and on-site inspections may be conducted and will incorporate the use of approved technology for sharing sensitive business information.

4. Will these inspections be long term?

While this pilot inspection program is ongoing, HC will be developing a permanent inspection program. Health Canada may implement this permanent program upon completion and review of the pilot. If a permanent inspection program is implemented it will mark the beginning of regular inspection of the NHP industry.

5. Why are you choosing to implement inspections now?

In March 2016, the Office of Audit and Evaluation for Health Canada and the Public Health Agency of Canada released their report, [Evaluation of the Natural Health Products \(NHPs\) Program 2010-2011 to 2014-2015](#)¹. This report commented on the strong reliance on industry attesting to GMP requirements with no post market verification by HC. In response, HC conducted 2 NHP GMP CMPs and a quality audit, which partially verified NHP GMPs.

In response to the compliance outcomes identified as well as to complement HC's current paper-based process, HC is implementing a pilot NHP GMP inspection program starting in 2021, which may transition to a permanent NHP GMP inspection program. The pilot and permanent inspection program will cover more in-depth review of the NHP GMP requirements to strengthen compliance of the NHP industry with regulatory requirements, prevent non-compliance, and strengthen the protection of the health and safety of Canadians; by ensuring NHPs are safe, effective and of high quality. A permanent inspection program will be under development, which may be implemented upon completion and review of the pilot. If a permanent inspection program is implemented it will mark the beginning of regular inspection of the NHP industry.

6. Were the CMPs/quality audit conducted as pre-inspection projects?

The CMPs were conducted under HC's proactive activities, while the quality audit was conducted to complement the paper-based review. For both initiatives the goal was to gather information on potential gaps in our current knowledge of the state of compliance of SL holders given the current oversight of NHPs is paper-based. In

response to the compliance outcomes identified during the CMPs and quality audit, as well as to complement HC's current paper-based process, HC is implementing a pilot NHP GMP inspection program that will start in 2021 and may transition to a permanent NHP GMP inspection program.

- 7. How will sites be selected for the pilot and permanent inspection program?**
- 8. Will the companies visited during the CMPs be inspected during the pilot and/or permanent inspection program?**

All establishments licenced to manufacture or import NHPs, which are deemed as higher risk activities, will be considered for the pilot phase. For the pilot, similar criteria will be used as for the NHP GMP CMPs, meaning a combination of risk factors (e.g., regulated activities undertaken at the site and the relative impact of the activities on product safety and quality) and objective criteria (e.g., areas/products of concern) will be considered.

All sites across Canada (all regions) will be considered.

If the permanent inspection program is implemented, all establishments subject to part 3 of the NHPR will be considered for inspection (manufacturer, importer, labeller, packager, storage, test, distribution). Health Canada would establish a cyclic inspection schedule and site selection will take into consideration several factors in order to determine priority.

- 9. Will foreign sites be subject to inspection as part of the pilot?**

Inspections conducted during the pilot phase will be limited to domestic sites.

- 10. Will the Self Care Framework have any impact on inspections during the pilot inspection program?**

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.

Health Canada will use 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.

11. What will inspectors examine during an inspection?

Inspectors will conduct an in depth review of the systems and processes that are in place at the establishment, which are intended to ensure the safety and quality of NHPs as per Part 3 of the Natural Health Products Regulations (NHPR). There is useful information on HC's website, which may be helpful to industry and are listed here:

- [A Guide to Health Canada Inspections²](#)
- [*Good Manufacturing Practices Guidance Document³*](#)
- [Finished Product Specification Form User Guide⁴](#), appendix 2
- [NNHPD's Compendium of Monographs⁵](#)

12. How will the inspections be conducted?

Due to the global pandemic of COVID-19, and implemented government social distancing restrictions in Canada, virtual and on-site inspections may be conducted and will incorporate the use of approved technology for sharing sensitive business information.

13. What happens at the end of the inspection?

As part of the pilot, Compliant (C) or Non-Compliant (NC) ratings will not be assigned to establishments and a summary report outlining the observations will be provided to the company. A response with corrective and preventive actions (CAPAs) to address the

issues identified during the inspection will be required in a prescribed timeframe. The inspection observations and CAPAs will also be assessed to determine whether further actions on the site licence or product licences, such as a suspension, are necessary.

A summary report of all findings will be made available at the completion of the pilot (referenced below).

If a permanent program is implemented, C and NC ratings will be assigned to each inspection. With the implementation of a permanent inspection program, HC would initiate the posting of individual inspection results on the [Drug and Health Products Inspections Database \(DHPID\)](#)⁶

14. What will be included in the pilot summary report that will be posted online?

15. What will HC do with the results of this pilot project?

HC will use the information collected as part of this project to identify areas that could benefit from additional compliance promotion and inform the development of a permanent inspection program. HC will take steps to ensure that any identified risks to health and site compliance issues are addressed following the inspection. The actions Health Canada takes are based on the [Compliance and Enforcement Policy \(POL-0001\)](#)⁷. HC will make every effort to share the results of the pilot with the industry in advance of the publication.

16. Will companies need to be inspected to obtain a SL and/or for renewal during the permanent inspection program?

HC will use the information collected as part of this project to identify areas that could benefit from additional compliance promotion and inform the development of a permanent inspection program.

17. Can companies opt-out of the pilot or the permanent inspection program?

Every person that conducts an activity subject to the Food and Drugs Act (FDA) or the NHPR is expected to comply with the FDA and its Regulations. Through the inspection, inspectors confirm whether establishments are following NHP GMPs. The powers of inspectors are outlined in [Section 23 of the FDA](#)⁸. [Section 24 of the FDA](#)⁹ stipulates that obstruction or providing false information to an inspector is an offence. Co-operation between regulated parties and HC helps an inspection run more smoothly.

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- ¹ <https://www.canada.ca/en/health-canada/corporate/transparency/corporate-management-reporting/evaluation/2010-2011-2014-2015-natural-health-products-program.html>
- ² <https://www.canada.ca/en/health-canada/corporate/mandate/regulatory-role/what-health-canada-does-as-regulator/guide-inspections.html>
- ³ <https://www.canada.ca/en/health-canada/services/drugs-health-products/natural-non-prescription/legislation-guidelines/guidance-documents/good-manufacturing-practices.html>
- ⁴ <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>
- ⁵ <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>
- ⁶ <https://www.canada.ca/en/health-canada/services/inspecting-monitoring-drug-health-products/drug-health-product-inspections.html>
- ⁷ <https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/good-manufacturing-practices/policies-standards/compliance-enforcement-policy-0001.html>
- ⁸ <https://laws-lois.justice.gc.ca/eng/acts/F-27/page-5.html#docCont>
- ⁹ <https://laws-lois.justice.gc.ca/eng/acts/F-27/page-6.html#docCont>