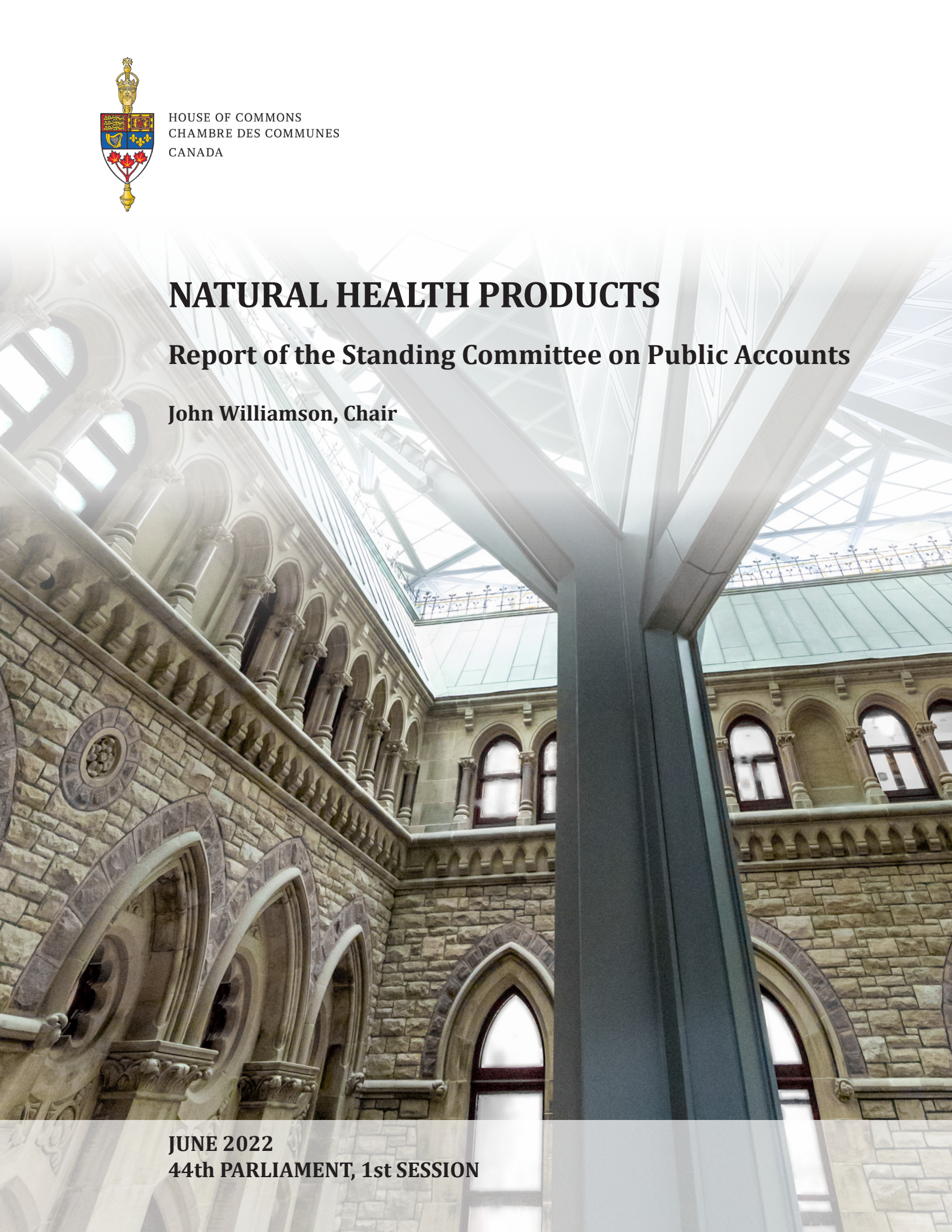

HOUSE OF COMMONS
CHAMBRE DES COMMUNES
CANADA

NATURAL HEALTH PRODUCTS

Report of the Standing Committee on Public Accounts

John Williamson, Chair

JUNE 2022
44th PARLIAMENT, 1st SESSION

NATURAL HEALTH PRODUCTS

Report of the Standing Committee on Public Accounts

John Williamson
Chair

JUNE 2022

44th PARLIAMENT, 1st SESSION

NOTICE TO READER

Reports from committees presented to the House of Commons

Presenting a report to the House is the way a committee makes public its findings and recommendations on a particular topic. Substantive reports on a subject-matter study usually contain a synopsis of the testimony heard, the recommendations made by the committee, as well as the reasons for those recommendations.

STANDING COMMITTEE ON PUBLIC ACCOUNTS

CHAIR

John Williamson

VICE-CHAIRS

Jean Yip

Nathalie Sinclair-Desgagné

MEMBERS

Valerie Bradford

Blake Desjarlais

Han Dong

Eric Duncan

Peter Fragiskatos

Philip Lawrence

Jeremy Patzer

Brenda Shanahan

OTHER MEMBERS OF PARLIAMENT WHO PARTICIPATED

Luc Desilets

Branden Hanley

Chris Lewis

Hon. Tim Uppal

CLERK OF THE COMMITTEE

Angela Crandall

LIBRARY OF PARLIAMENT

Parliamentary Information, Education and Research Services

André Léonard, Analyst

Dillan Theckedath, Analyst

THE STANDING COMMITTEE ON PUBLIC ACCOUNTS

has the honour to present its

EIGHTEENTH REPORT

Pursuant to its mandate under Standing Order 108(3)(g), the committee has studied Report 2, Natural Health Products — Health Canada, of the Commissioner of the Environment and Sustainable Development and has agreed to report the following:

HOUSE OF COMMONS
CHAMBRE DES COMMUNES
CANADA

NATURAL HEALTH PRODUCTS

KEY FINDINGS OF THE COMMISSIONER OF THE ENVIRONMENT AND SUSTAINABLE DEVELOPMENT

- Health Canada did not always verify that manufacturing facilities followed good manufacturing practices before natural health products were marketed for sale in Canada.
- Health Canada left natural health products unchecked after they entered the market and was not always successful in responding to serious problems.
- Health Canada did not sufficiently monitor whether product label information and advertisements met the product-licence conditions.
- Health Canada responded effectively to natural health products related to COVID-19.[1]

SUMMARY OF THE COMMITTEE'S RECOMMENDATIONS AND TIMELINES

Recommendation	Recommended Measure	Timeline
Recommendation 1	Health Canada should provide the House of Commons Standing Committee on Public Accounts with a report about A) improving how it verifies that licensed sites follow good manufacturing practices before products are released on the market; and B) obtaining information about which natural health products are available on the market.	31 December 2022 and 31 December 2023

1 Commissioner of the Environment and Sustainable Development (CESD), Natural Health Products—Health Canada, 2021 Reports 1 and 2 of the Commissioner of the Environment and Sustainable Development, At a glance, Our findings.

Recommendation	Recommended Measure	Timeline
Recommendation 2	Health Canada should provide the Committee with a report about implementing a risk-based approach to regulating licensed natural health products on the market, including those available to Canadians through the Internet, to A) ensure that product labels are readable; and B) monitor product label and advertisement information to ensure that they contain accurate and complete product information, consistent with their licence conditions.	31 December 2022 and 31 December 2023
Recommendation 3	Health Canada should provide the Committee with a report about implementing a risk-based monitoring and inspection program that establishes the scope and frequency of inspections and that considers risks related to natural health products, sites, and problems raised from its follow-up activities, including for natural health products intended for vulnerable populations living with specific health problems or for which there has been a history of ingredients being substituted.	31 December 2022 and 31 December 2023

Recommendation	Recommended Measure	Timeline
Recommendation 4	Health Canada should provide the Committee with a progress report about implementing a risk-based monitoring program to A) identify unlicensed natural health products and take appropriate action so that they are not available for sale to consumers in Canada; and B) identify unauthorized activities and take appropriate action so that labelling and advertisements meet product-licence conditions.	31 August 2022
Recommendation 5	Health Canada should provide the Committee with a report about obtaining the information it needs to ensure that natural health products suspected of causing serious health risk are not available for sale to consumers in Canada.	31 December 2022 and 31 December 2023
Recommendation 6	Health Canada should ensure that its process to amend current legislation regarding natural health products includes an analysis and a possible increase of the current maximum fine for violation of the law of $5,000.	N/A

INTRODUCTION

According to the Commissioner of the Environment and Sustainable Development (the Commissioner), natural health products are self-care products made from naturally occurring ingredients and used for general health maintenance. They include:

- Vitamins, minerals, and probiotics;
- Homeopathic medicines;

- Traditional medicines like Chinese and Ayurvedic (East Indian) medicines that are based on the theories, beliefs, and experiences of different cultures and used in the ancient practice of medicine for the maintenance of health;

- Non-traditional products making health claims, such as claims about managing weight or aiding sleep;

- Alcohol-based hand sanitizers; and

- Certain sunscreens, toothpastes, and shampoos with health claims.[2]

Research from a 2010 public opinion poll shows that "70% of Canadians regularly used such products to maintain their health and prevent minor health problems" and that more than half of the Canadian participants in a 2016 survey reported taking vitamins and mineral supplements every week.[3]

Although natural health products (NHPs) are made from ingredients found in nature, some of them "can cause negative effects when combined with other medications or when not used as directed. There have been cases of people experiencing serious and unexpected adverse reactions to authorized and unauthorized natural health products. Such reactions have included septic shock, jaundice, and disruption of liver function; some adverse reactions required hospitalization."[4]

In 2004, the regulation of NHPs began in Canada with the Government of Canada aiming to balance consumer safety with freedom of choice and access to traditional medicines. As such, to be sold in Canada, NHPs must be licensed by Health Canada to ensure they are safe and effective. (It considers an NHP to be safe if its benefit outweighs the risk when the product is used as intended and according to directions.) The department also considers an NHP to be effective if it provides the benefits described in the claims, as supported by evidence. To that end, it has issued more than 91,000 licences for NHPs.[5]

In Canada, NHPs are regulated differently from over-the-counter medicines (i.e., manufactured drugs that can be sold without a prescription) and cosmetics,

2 Ibid., para. 2.1.

3 Ibid., para. 2.2.

4 Ibid., para. 2.3.

5 Ibid., para. 2.4.

although they are placed alongside each other in pharmacies where Canadians most often buy them. Table 1 explains some of these differences.[6]

Table 1—How natural health products are regulated compared with over-the-counter drugs and cosmetics

	Natural health products	Over-the-counter drugs	Cosmetics
Accepted ingredients	Naturally occurring ingredients, their extracts, and synthetic duplicates	Synthetic ingredients only	Natural or synthetic ingredients
Health claims permitted by Health Canada	Pain and symptom relief, treatment of certain diseases	Pain and symptom relief, treatment of certain diseases	None
Evidence required to show safety and efficacy	Scientific evidence and evidence from traditional use or homeopathic practices	Scientific evidence	Evidence may be requested
Health Canada is notified when a product enters the market	No	Yes	Yes
Health Canada can force a recall	No	Yes	No
Health Canada charges product application fees	No	Yes: between $1,616 and $400,288	No
Fine issued for violations of law	Maximum $5,000	Maximum $5,000,000	Maximum $5,000

Source: Prepared with information from Commissioner of the Environment and Sustainable Development, Natural Health Products—Health Canada, 2021 Reports 1 and 2 of the Commissioner of the Environment and Sustainable Development, Exhibit 2.1.

6 Ibid., para. 2.5.

HEALTH CANADA'S RESPONSIBILITY

Health Canada is responsible for administering the *Natural Health Products Regulations*, which govern the safety and efficacy of NHPs. Before products go on the market, the department licenses such products and the sites that manufacture them; it also oversees products and sites after the products appear on the market. However, the primary responsibility for the safety and effectiveness of NHPs and their manufacturing sites rests with the industry.[7]

Additionally, the department can enforce product and site-licence conditions for NHPs by the following:

- Suspending or cancelling licences;
- Directing a stop sale of products;
- Seizing products;
- Requesting voluntary product recalls; and
- Issuing public alerts and advisories on the Health Canada website.[8]

Notably, the department "does not have the authority to order a change to a label or force a mandatory recall of a natural health product for any reason, including when a product presents a serious or imminent risk of injury to health."[9]

In 2021, the Commissioner released an audit that aimed to determine whether "Health Canada ensured that natural health products available for sale in Canada are safe and accurately represented to consumers."[10]

On 24 March 2022, the House of Commons Standing Committee on Public Accounts (the Committee) held a hearing on this audit with the following in attendance:

7 Ibid., para. 2.6.

8 Ibid., para. 2.7.

9 Ibid., para. 2.8.

10 Ibid., para. 2.9.

- Office of the Auditor General of Canada—Jerry V. DeMarco, Commissioner of the Environment and Sustainable Development, and Heather Miller, Assistant Auditor General.

- Health Canada—Dr. Stephen Lucas, Deputy Minister; Pamela Aung-Thin, Associate Assistant Deputy Minister; and Linsey Hollett, Director General, Health Product Compliance.[11]

Table 2 explains some of the key definitions used in this report.

Table 2—Key Definitions

Term	Definition
Coronavirus disease (COVID-19)	The disease caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)
Unlicensed product	A natural health product that is available for sale but does not have a product licence from Health Canada
Unauthorized activity	A labelling or advertising activity for a licensed natural health product from Health Canada that does not meet regulatory

Source: Prepared with information from Commissioner of the Environment and Sustainable Development, Natural Health Products—Health Canada, 2021 Reports 1 and 2 of the Commissioner of the Environment and Sustainable Development, Definitions.

FINDINGS AND RECOMMENDATIONS

Verifying Manufacturing Facilities and Market Availability

Health Canada requests that site-licence applicants provide a written attestation that they follow good manufacturing practices. The Commissioner found that the department relied on NHP manufacturers' attestations that their facilities followed these practices and had not conducted an inspection before the products went on the market. It also noted that the department takes a different approach with drug manufacturers—that is, it does an initial inspection before those products arrive on the market. Good manufacturing practices are key controls to ensure that NHPs:

11 House of Commons Standing Committee on Public Accounts, *Evidence*, 1st Session, 44th Parliament, 24 March 2022, Meeting No. 10.

- Include the right medicinal ingredients at the right dosage;
- Are free from microbial and chemical contamination;
- Remain active and stable until their expiry date; and
- Are processed by qualified personnel, using equipment in facilities that follow good sanitation practices.[12]

In 13 of the 25 sites sampled by the Commissioner, the department relied on inspections performed by domestic and regulatory authorities from other countries when licensing these sites. However, CESD found that the department did not have assurance that 10 of these 13 sites followed good manufacturing practices because it did not have evidence that these inspections included the NHP lines.[13]

Of the remaining 12 sites that were sampled, the department obtained some site information before issuing a licence; however, it did not verify one or more of the following key types of evidence:

- The facility's quality assurance official having the necessary qualifications;
- Adequate standard operating procedures for product testing, sanitation, quality assurance, premise and equipment maintenance; and
- Test results showing that product specifications were met.[14]

Health Canada is unable to verify certain good manufacturing practices, such as product testing, until after production has started. Furthermore, it is not told when NHPs will be released on the market, unlike for drugs, for which the department is notified about when products are sold. Therefore, it could not verify that NHPs sold to Canadian consumers were manufactured in sites that complied with good manufacturing practices before they went on the market.[15]

Consequently, the Commissioner recommended that Health Canada should obtain:

---

12 CESD, Natural Health Products—Health Canada, 2021 Reports 1 and 2 of the Commissioner of the Environment and Sustainable Development, para. 2.21.

13 Ibid., para. 2.23.

14 Ibid., para. 2.24.

15 Ibid., para. 2.25.

- Sufficient evidence to verify that licensed sites follow good manufacturing practices before products are released on the market; and

- Information about which NHPs are available on the market.[16]

In its Management Response and Action Plan, Health Canada acknowledged "its limited regulatory authorities to compel companies to provide information on quality as part of the product license submission process" and in response to this recommendation it will:

- Establish fully costed options for a risk-based approach to quality oversight prior to the issuance or renewal of licenses and determine the full regulatory and operational implications of these options;

- Explore mechanisms to obtain information about which products are available on the market; and

- Take steps to propose user fees to NHPs to offset the costs of licensing and post-market activities.[17]

Additionally, the department provided the following milestones:

1) Within the existing framework:

- Assess the capacity and tools required in the pre-market functions associated with quality review to effectively deliver mandated program activities, identify gaps, and develop an options analysis report with recommendations, which are expected to include proposed regulatory amendments (January 2022).

- Develop a multi-year implementation plan, based on the approved recommendation(s), to improve the pre-market oversight of the quality of NHPs (September 2022).

- Signal to industry the department's intention to implement fees for NHPs to provide stable funding for key regulatory activities and develop a fee proposal for consultation (October 2021).

16 Ibid., para. 2.26.

17 Health Canada, Management Response and Action Plan, p. 1.

- Consult on a cost recovery proposal (April 2022).

- Amend the Fees Order to include NHPs (October 2023).

2) Outside existing framework:

- Seek regulatory amendments to improve the oversight of the quality of NHPs, dependent on the approved recommendation(s), with timelines based on the implementation plan.[18]

At the hearing, Dr. Stephen Lucas, Deputy Minister, Health Canada, explained the department's process for regulatory amendments of this nature:

> [The] department develops a policy proposal. In general, we will consult stakeholders on it prior to seeking the authority of Treasury Board to publish it for formal consultation in Canada Gazette, Part I. Indeed, in the case of the labelling regulations, we had for several years consulted a range of stakeholders on changes to the labelling regulations. Those were then brought forward into a proposal and approved by the Treasury Board in the spring of 2021 and gazetted in June 2021 on the basis of feedback from those stakeholders.
>
> As I've indicated, we are finalizing the proposal on those natural health product labelling regulations to propose it again to Treasury Board for consideration of its final form this spring.[19]

In response to a question about why Canada has such deficiencies with regard to site inspection for NHP manufacturing, Pamela Aung-Thin, Associate Assistant Deputy Minister, provided the following:

> [We] recognize that there is a gap. We are already taking steps to address this, including updating our product licence application forms, which include information to collect site information as part of the application. At the same time, we're working on longer-term solutions to incorporate this requirement in the regulations.[20]

Therefore, the Committee recommends:

---

18 Ibid.

19 House of Commons Standing Committee on Public Accounts, *Evidence*, 1st Session, 44th Parliament, 24 March 2022, Meeting No. 10, 1210.

20 Ibid., 1245.

Recommendation 1—Obtaining and verifying information

That Health Canada provide the House of Commons Standing Committee on Public Accounts with a report about A) improving how it verifies that licensed sites follow good manufacturing practices before products are released on the market; and B) obtaining information about which natural health products are available on the market. An interim progress report should be provided by 31 December 2022 and a final report by 31 December 2023.

Product Labelling and Advertising

Health Canada did not sufficiently monitor whether product label information and advertisements met the product-licence conditions. The Commissioner found that the department monitored product labels and advertisements in response to complaints instead of monitoring the market using a risk-based approach.[21]

To gain an understanding of the market, the audit examined a sample of 75 licensed products for sale on Canadian websites and found that 88% of these products were advertised with misleading product information. Moreover, 56% of the products examined were marketed with misleading label information, including one of more of the following problems:

- Health claims not authorized by Health Canada because they might not have been proven, such as claims to relieve fatigue, enhance endurance, or burn fat;
- An erroneous statement that the product was recommended for children of ages 3 and older when it was authorized only for adolescents and adults;
- An incomplete list of risks and authorized ingredients;
- The wrong dosage of medicinal ingredients; and

21 CESD, Natural Health Products—Health Canada, 2021 Reports 1 and 2 of the Commissioner of the Environment and Sustainable Development, para 2.32.

- Product label information in very small print (e.g., safety warnings in 4-point font).[22]

(It should be noted that in response to these findings, the department began to follow up on some of the advertisements and product labels that contained misleading information.[23])

Additionally, over 25% of the 75 licensed products the Commissioner examined did not show if they had a natural product number issued by Health Canada. Consumers can get information on NHPs from Health Canada's online Licensed Natural Health Products Database. However, the Commissioner found that the database included all safety information from the product licences it examined, except for the source of medicinal ingredients and the recommended duration of use.[24]

Consequently, the Commissioner recommended that Health Canada should, for licensed NHPs on the market, including on the Internet, take a risk-based approach to:

- Ensure that product labels are readable; and

- Monitor product label and advertisement information to ensure that they contain accurate and complete product information, consistent with their licence conditions.[25]

In its action plan, Health Canada stated its agreement with the recommendation and that it "has started to take steps through extensive stakeholder engagement and the development of a regulatory proposal to improve the labelling of NHPs, to make them easier to read, understand and compare with other similar products" and that it will:

- Continue to pursue regulatory and policy changes to improve labelling of NHPs;

- Explore options to require licence holders to display a Canadian label, including a Natural Product Number (NPN), in advertisements targeted to Canadians; and

---

22 Ibid. According to Health Canada, poor readability of the printed label information contributes to incorrect product use. Font sizes under 8 points are difficult to read without magnification.

23 Ibid.

24 Ibid., paras. 2.33 and 2.34.

25 Ibid., para. 2.35.

- Take steps to implement a comprehensive proactive monitoring strategy to ensure that labels and advertising of NHPs are consistent with the product licence.[26]

Additionally, the department provided the following milestones:

1) Within the existing framework:

- Pilot an approach, analyze the pilot and develop a multi-year implementation plan to expand proactive monitoring of advertising to NHPs, including full costing and the identification of Artificial Intelligence tools needed for the expanded approach (February 2022).

- Conduct a feasibility study to expand proactive monitoring oversight to online monitoring of NHP labels (June 2022).

- Begin implementation of the approved approach for the expansion of proactive monitoring of advertising of NHPs (October 2022).

- Complete an analysis on the display format of a Canadian label online, including presentation of the NPN, to identify recommended options and a critical path forward (December 2022).

- Evaluate lessons learned to determine feasibility of expanded proactive monitoring of NHPs and make necessary modifications as per an internal proactive monitoring process review (September 2023).

2) Outside the existing framework:

- Publish proposed amendments to the Natural Health Products Regulations (NHPR) in Canada Gazette Part I to improve the labelling of NHPs with a product facts table and minimum font size, for formal consultation (targeting June 2021)

- Dependent on the above, publish final regulatory amendments to the NHPR in Canada Gazette Part II to improve the labelling of NHPs (targeting June 2022).[27]

---

26 Health Canada, Management Response and Action Plan, p. 2.

27 Ibid.

At the hearing, when questioned about labelling requirements, Pamela Aung-Thin responded as follows:

> Yes, labels currently list the ingredients, but as noted in the report, we had started and continue to take measures to improve labelling of these products to make them more visible, more readable, with more evidence for consumers when they're purchasing these products.[28]

When pressed further on how and when the department plans to implement this strategy, especially given that fewer than 5% of product licence holders have provided Health Canada information on the source of their products, Ms. Aung-Thin provided the following:

> The department has already begun to take action to address the deficiency … that is in the report. We're updating an application to verify this information. It's a strategy that will allow you to find information on the websites of natural products about where they come from. For example, it will include those that will be targeted by application.
>
> We are also working on long-term solutions to address this gap.
>
> […]
>
> [There] is already a labelling measure under way. A notice was published in the Canada Gazette Part I last spring, and the process will continue. We intend to publish a notice in the Canada Gazette Part II this spring.[29]

Therefore, the Committee recommends:

Recommendation 2—Product labelling and information

That Health Canada provide the House of Commons Standing Committee on Public Accounts with a report about implementing a risk-based approach to regulating licensed natural health products on the market, including those available to Canadians through the Internet, to A) ensure that product labels are readable; and B) monitor product label and advertisement information to ensure that they contain accurate and complete product information, consistent with their licence conditions. An interim progress report should be provided by 31 December 2022 and a final report by 31 December 2023.

---

28 House of Commons Standing Committee on Public Accounts, *Evidence*, 1st Session, 44th Parliament, 24 March 2022, Meeting No. 10, 1125.

29 Ibid., 1250.

Monitoring of Products and Manufacturers

Health Canada did not have a program to conduct routine on-site inspections of manufacturing sites for NHPs on an established cycle. In contrast, the Commissioner noted that health regulatory agencies in Australia and Europe have a cycle for conducting routine inspections of manufacturing sites over a four-year period.[30]

Although the department did identify sites it considered high risk, it was limited to those that manufactured sterile products, such as eye care products. It did not identify which licensed sites were making other types of high-risk NHPs, such as:

- Products for vulnerable populations, such as children and pregnant or breastfeeding women;
- Products making claims for specific health conditions, such as diabetes; and
- Products with a compliance history of having substituted ingredients, such as those targeting weight loss and sexual enhancement.[31]

According to the Commissioner, Health Canada faced challenges in monitoring licensed products in part because of the large number of licensed products (e.g., since 2004, the department has licensed 91,000 NHPs), "yet by its own estimates, only half of them went to the Canadian market."[32] Moreover, the number of applications for NHPs was 10 times higher than those for over-the-counter drugs, with many applications being redundant. This happens because companies are able to submit multiple applications for hypothetical products that have not been developed and they are not required to pay a fee to apply for a product licence or a site licence, unlike for all other health products regulated by Health Canada.[33]

The Commissioner also found that Health Canada:

- Did not know where all licensed products were manufactured;

30 CESD, Natural Health Products—Health Canada, 2021 Reports 1 and 2 of the Commissioner of the Environment and Sustainable Development, para. 2.36.

31 Ibid., para. 2.37.

32 Ibid., para. 2.38.

33 Ibid.

- Conducted limited monitoring of licensed manufacturers and could not identify and inspect all high-risk sites;

- Found that when it did conduct inspections, there were high levels of industry non-compliance related to manufacturing practices and product quality;

- Renewed five site licences without verifying that the companies met other important good manufacturing practices, such as confirming the absence of chemical contaminants; and

- Did not verify that all sites followed good manufacturing practices and thus could not be sure that products were safe and effective.[34]

In light of these discoveries, the Commissioner concluded that "Health Canada's findings illustrate the risks of the department relying on manufacturers to attest that their sites follow good manufacturing practices when it approves site licences. Some of the department's findings could have been avoided if the department had performed more verification of good manufacturing practices when it issued and renewed site licences."[35]

Consequently, the Commissioner recommended that the department "should develop a risk-based monitoring and inspection program that establishes the scope and frequency of inspections and that considers risks related to products, sites, and problems raised from its follow-up activities."[36]

In its action plan, Health Canada stated its agreement with this recommendation and recognized that "NHPs are the only line of health products for which there is no ability to mandate a recall or to impose terms and conditions to mitigate safety risks associated with these products."[37] The department has completed several "compliance monitoring projects to gather information on quality oversight of NHPs and recognizes the need to expand its activities into a more robust inspection program" and will also:

- Implement a pilot NHP Good Manufacturing Practices (GMP) inspection program to promote and verify compliance of the NHP industry through

34 Ibid., paras. 2.39 to 2.41, 2.43.

35 Ibid., para. 2.46.

36 Ibid., para. 2.47.

37 Health Canada, Management Response and Action Plan, pp. 2–3.

inspections of licence holders across Canada, and take further actions based on the outcome of this pilot;

- Take steps to propose new tools to strengthen the department's ability to deter and address non-compliance which include moving forward with a proposal to extend the use of the *Protecting Canadians from Unsafe Drugs Act (Vanessa's Law)* powers to NHPs;

- Establish fully costed options for a risk-based approach to inspections; and

- Take steps to propose the expansion of user fees to NHPs to offset the costs of post-market activities.[38]

Additionally, the department provided the following milestones:

1) Within the existing framework:

- Launch a pilot NHP GMP inspection program (March 2021).

- Assess the results of the pilot and identify options for a risk-based NHP inspection program, which includes full costing (April 2022).

- Complete consultations with stakeholders on recommendations for a future risk-based NHP inspection program (August 2022).

- Determine next steps to implement an effective risk-based approach to monitoring compliance and inspections based on the approved recommendations and existing resources (April 2023).

2) Outside the existing framework:

- Seek authority to introduce legislative amendments to the *Food and Drugs Act* with a view to expand the Vanessa's Law powers to NHPs (October 2021).

- Dependent on obtaining authority, consult stakeholders on the policy and implementation to extend the use of Vanessa's Law powers to NHPs (January 2022).

38 Ibid.

- Dependent on obtaining authority, start to develop regulations to extend the full suite of Vanessa's Law authorities to NHPs (November 2022).[39]

At the hearing, when questioned about how the department defines "risk-based approach," Linsey Howlett, Director General, Health Canada, provided the following explanation:

> The term "risk-based" is something that, in the regulatory space especially, confines enforcement. You will hear us speak to it often. It directs much of our decision-making.
>
> What we mean when we say "risk-based" is that when we are looking at a situation to determine the level of risk, we apply a fairly lengthy but consistent set of criteria. We look at the nature of the non-compliance, although all are important. We look at whether it is a labelling issue versus contamination, the type of non-compliance and what risk that represents. We then look at the target population of a product.
>
> […]
>
> What we do to ensure it is risk-based is to consistently apply those criteria. That dictates what action we take and how quickly.[40]

Additionally, the officials reiterated the department's commitment to seeking amendments to Vanessa's Law for improved authority regarding NHPs.[41]

Therefore, the Committee recommends:

Recommendation 3—Monitoring and inspection

That Health Canada provide the House of Commons Standing Committee on Public Accounts with a report about implementing a risk-based monitoring and inspection program that establishes the scope and frequency of inspections and that considers risks related to natural health products, sites, and problems raised from its follow-up activities. It should also include natural health products intended for vulnerable populations living with specific health problems for which there has been a history of ingredients being substituted. An interim progress report should be provided by 31 December 2022 and a final report by 31 December 2023.

---

39 Ibid.

40 House of Commons Standing Committee on Public Accounts, *Evidence*, 1st Session, 44th Parliament, 24 March 2022, Meeting No. 10, 1220.

41 Ibid., 1110.

Unlicensed Products and Unauthorized Activities

Health Canada monitored alerts from other international regulators and opened cases when it became aware of serious issues with a non-compliant product (i.e., either an unlicensed product or licensed product involved in an unauthorized activity). However, the Commissioner found that the department did not actively monitor high-risk unlicensed products on the market. In fact, it conducted little monitoring of non-compliant products despite a growing number of such products for sale in Canada, particularly online.[42]

Additionally, the Commissioner examined whether "Health Canada monitored high-risk products identified by organizations in Canada and other countries that specialize in testing and label reviews of natural health products. These products were suspected of containing substituted ingredients or substances such as stimulants and other toxic substances that could pose serious health risks."[43] It found that the department did not follow up to determine if any such products were available for sale in Canada with the same substances (e.g., in a sample of 61 suspected high-risk products, 38 of them were sold online in Canada without a product licence).[44]

In Canada, claims to cure and treat cancer are forbidden under the *Food and Drugs Act*. In contrast, certain claims of a product preventing cancer are permitted under the *Natural Health Products Regulations*, subject to a product's licence conditions. The Commissioner reviewed advertisements for 48 products online that made cancer claims and found that none of these claims were authorized by Health Canada and that four of these products were not licensed.[45]

Consequently, the Commissioner recommended that Health Canada should develop a risk-based monitoring program to

- Identify unlicensed products and take appropriate action so that they are not available for sale to consumers in Canada; and

42 CESD, Natural Health Products—Health Canada, 2021 Reports 1 and 2 of the Commissioner of the Environment and Sustainable Development, para. 2.48.

43 Ibid., para. 2.49.

44 Ibid.

45 Ibid., para. 2.50.

- Identify unauthorized activities and take appropriate action so that labelling and advertisements meet product-licence conditions.[46]

In its action plan, Health Canada stated its agreement with the recommendation and that although it maintains a complaint-based program for regulatory advertising compliance oversight, it recognizes that an additional risk-based approach is required to ensure unauthorized activities are prevented and/or stopped.[47] Going forward, the department will:

- Implement a risk-based approach to monitoring of advertising; and
- Take steps to propose new tools to strengthen its ability to deter and address non-compliance, which include moving forward with a proposal to extend the use of Vanessa's Law powers to NHPs.[48]

Additionally, the department provided the following milestones:

- Develop and launch a risk-based approach for monitoring NHP advertising incidents, via a tool which will classify advertising incidents based on level of risk (January 2022).
- Assess the feasibility of partnering with other government departments to address non-compliance in NHP advertising – this will also include the development of costing assumptions (January 2022).
- Subject to approval, implement a collaboration approach jointly with other departments to allow them to use existing enforcement powers for serious non- compliance incidents in advertising of NHPs (April 2022).[49]

At the hearing, when questioned about these concerns (given that Canadians are increasing the scope of their online purchases, especially during the COVID-19 pandemic), Pamela Aung-Thin provided the following:

46 Ibid., para. 2.51.

47 Health Canada, Management Response and Action Plan, p. 4.

48 Ibid.

49 Ibid., pp. 3–4.

> We are definitely looking into this. Our recommendations for online products are definitely in development. You're right in that it's not currently required, but we are working on a proposal.
>
> I'll just take the time as well to mention that one recommendation was around monitoring. It was around developing a risk-based monitoring program to identify unlicensed products and to take appropriate action. The department has been working on exploring various tools, including artificial intelligence web scraping, to proactively support monitoring under the program, including unlabelled products. Those next steps will include determining the feasibility of linking terms of the market authorization database with an external AI [Artificial Intelligence] tool. There is work that is under way.[50]

Therefore, the Committee recommends:

Recommendation 4—Risk-based monitoring system of unlicensed products and unauthorized activities

That, by 31 August 2022, Health Canada provide the House of Commons Standing Committee on Public Accounts with a progress report about implementing a risk-based monitoring program to A) identify unlicensed natural health products and take appropriate action so that they are not available for sale to consumers in Canada; and B) identify unauthorized activities and take appropriate action so that labelling and advertisements meet product-licence conditions.

50 House of Commons Standing Committee on Public Accounts, *Evidence*, 1st Session, 44th Parliament, 24 March 2022, Meeting No. 10, 1205. For additional information on Artificial Intelligence and some of its applications, refer to Dillan Theckedath, *Understanding Artificial Intelligence—Canadian Perspectives*, HillNotes, Library of Parliament, 20 June 2018.

ADDITIONAL FINDING

The Commissioner noted that Health Canada employed "a risk-based approach to speed up the licensing of the applications it received in spring 2020 for products to help limit the spread of COVID-19." It implemented "effective temporary measures to meet the urgent need for products facing shortages, such as alcohol-based hand sanitizers" and "provided flexibility to Canadian manufacturers by temporarily waiving compliance with specific regulatory requirements without increasing the risk of serious safety concerns." Additionally, the department increased its oversight of products marketed for COVID-19.

Consequently, the Commissioner made no recommendations in this area.

Source: Commissioner of the Environment and Sustainable Development, Natural Health Products—Health Canada, 2021 Reports 1 and 2 of the Commissioner of the Environment and Sustainable Development, para. 2.61.

Resolving Serious Problems

The Commissioner acknowledged that when Health Canada discovered serious problems, such as product- or site-quality issues or adverse reactions involving hospitalization, it initiated immediate action to address serious health risks. For example, it communicated these concerns with the public and where necessary, took enforcement actions such as directing a "stop sale" of products and requesting a voluntary product recall. In fact, the department's actions successfully removed affected products off the market in 36 of the 40 total cases of serious health risks. However, it took close to three months (on average) for it to verify that they were no longer marketed for sale. And for voluntary recalls, it took around six months to verify that product recalls were completed.[51]

In contrast, for the remaining four cases examined by the Commissioner, the department's actions were not successful in getting them off the market for one of the following reasons:

- The company did not comply with the department's notice of seizure;

51 CESD, Natural Health Products—Health Canada, 2021 Reports 1 and 2 of the Commissioner of the Environment and Sustainable Development, para. 2.53.

- The department did not receive sufficient information to demonstrate that the recalled products had been recovered, destroyed, or removed from the market;

- The department did not receive sufficient information to demonstrate that the company had stopped the sale and import of the products and had disposed of all products from its inventory; and

- The Internet domain hosting the advertising did not comply with the department's request to remove the advertising for the unlicensed product.[52]

ADDITIONAL FINDING

Of the products in the 36 cases that Health Canada successfully got off the market between2017 and 2019, the products in seven of these cases had re-entered the market.

Source: Commissioner of the Environment and Sustainable Development, Natural Health Products—Health Canada, 2021 Reports 1 and 2 of the Commissioner of the Environment and Sustainable Development, para. 2.54.

Consequently, the Commissioner recommended that "Health Canada should, in cases of products suspected of causing serious health risk, obtain the information it needs to verify and ensure that these products are not available for sale to consumers in Canada."[53]

In its action plan, Health Canada stated its agreement with this recommendation and committed to taking steps to propose:

- New tools to strengthen its ability to deter and address non-compliance, which include moving forward with a proposal to extend the use of Vanessa's Law powers to NHPs; and

- The expansion of user fees to NHPs to offset the costs of licensing and post-market activities.[54]

52 Ibid., para. 2.54.

53 Ibid., para. 2.56.

54 Health Canada, Management Response and Action Plan, p. 5.

At the hearing, when questioned about these matters, Pamela Aung-Thin responded as follows:

> [In] regard to the report, one of the findings was around our approach in following up on serious health risks once they're identified. We are proposing several tools to help strengthen our ability to both deter these risks and make the information available when we're addressing non-compliance.one of the findings was around our approach in following up on serious health risks once they're identified. We are proposing several tools to help strengthen our ability to both deter these and make the information available when we're addressing non-compliance.[55]

Therefore, the Committee recommends:

Recommendation 5—Ensuring non-compliant products are not available for sale

That Health Canada provide the House of Commons Standing Committee on Public Accounts with a report about obtaining the information it needs to ensure that natural health products suspected of causing serious health risk are not available for sale to consumers in Canada. An interim progress report should be provided by 31 December 2022 and a final report by 31 December 2023.

Non-Compliance and Deterrence

On the issue of enforcement and non-compliance, when questioned about whether the current maximum monetary penalty of $5,000 was suitable (compared to the maximum penalty of $5,000,000 for non-compliance of over-the-counter drugs), Jerry V. DeMarco, Commissioner of the Environment and Sustainable Development, provided the following:

> The difference between the two columns in [Exhibit] 2.1, $5,000 and $5 million, is disproportionate to the levels of risk. There's no indication that the risks from natural health products are 1/1000th as important as the risks from over-the-counter medications. There does need to be a revisiting of that. The signal that it sends to potential bad actors is that this is not important when you have a maximum fine of only $5,000.[56]

Therefore, the Committee recommends:

55 House of Commons Standing Committee on Public Accounts, *Evidence*, 1st Session, 44th Parliament, 24 March 2022, Meeting No. 10, 1245.

56 Ibid., 1215.

Recommendation 6—Monetary penalties

That Health Canada ensure that its process to amend current legislation regarding natural health products includes an analysis and a possible increase of the current maximum fine for violation of the law of $5,000.

CONCLUSION

The Committee concludes that Health Canada was deficient in its oversight of natural health products available to the Canadian market. Although the department approved products on the basis of evidence that they were safe and effective, its oversight of manufacturing sites and monitoring of products once on the market left consumers exposed to potential health and safety risks. Moreover, though it investigated products that were suspected of causing serious health risks and took immediate action to address such risks, Health Canada's approach was reactive and not always successful in having them removed from the market.

To that end, the Committee has made six recommendations in this report to help Health Canada improve its administration and oversight of NHPs.

The Committee would also like to acknowledge that during the early stages of the COVID-19 pandemic, Health Canada acted quickly to license alcohol-based hand sanitizers to help address market shortages and that it proactively monitored NHPs that had claims related to COVID-19 and took action when it identified false claims.

APPENDIX A
LIST OF WITNESSES

The following table lists the witnesses who appeared before the committee at its meetings related to this report. Transcripts of all public meetings related to this report are available on the committee's webpage for this study.

Organizations and Individuals	Date	Meeting
Department of Health	2022/03/24	10
Pamela Aung-Thin, Associate Assistant Deputy Minister		
Linsey Hollett, Director General, Health Product Compliance		
Dr. Stephen Lucas, Deputy Minister		
Office of the Auditor General	2022/03/24	10
Jerry V. DeMarco, Commissioner of the Environment and Sustainable Development		
Heather Miller, Assistant Auditor General		

APPENDIX B
HEALTH CANADA RESPONSE TO A QUESTION ABOUT LICENSE APPLICATION PROCESSING TIMES

In response to a question at the hearing regarding time frames for processing a license application for natural health products, Health Canada provided the following information in a letter to the Committee:

All natural health products (NHPs) sold in Canada require a product licence in order to be sold and marketed in Canada. In addition, all manufacturers, packagers, labellers, and importers require a site license. The licensing requirements and timelines do not differ between domestically or foreign produced products

Timelines for product licensing:

Class	Definition	Timelines
Class I	Based on a single monograph	60 calendar days
Class II	Based on multiple monographs	90 calendar days
Class III	Outside of monograph process. Require a full assessment	210 calendar days

Timelines for site licensing:

Stream	Definition	Timelines
Stream I	Supported entirely by pre-cleared Good Manufacturing Practices (GMP) evidence (e.g., inspection by a recognized agency)	35 business days
Stream II	Supported by GMP evidence that is not pre-cleared, with up to 9 sites	65 business days
Stream III	Supported by GMP evidence that is not pre-cleared, with more than 9 sites	95 business days

APPENDIX C
HEALTH CANADA RESPONSE TO A QUESTION ABOUT FINES FOR NON-COMPLIANCE

In response to a question at the hearing regarding the number of fines issued for non-compliance, Health Canada provided the following information in a letter to the Committee:

Fines are one of a range of compliance and enforcement options that are available to Health Canada to correct non-compliance or mitigate a risk to Canadians including, for example, inspections, written warnings, recalls, licence suspensions/cancellations, public communications, and product seizures. Health Canada may also refer a recommendation of charges under the Food and Drugs Act (FDA) to the Public Prosecution Service of Canada (PPSC) for potential prosecution. The courts have the sole discretion to impose fines. The primary objective of Health Canada's compliance and enforcement approach is to manage the risks to Canadians using the most appropriate level of intervention.

Since 2004, Health Canada has recommended charges to the PPSC against four persons (companies or individuals) for violations specifically concerning natural health products, those persons were also charged with other non-NHP drug violations. PPSC proceeded with the laying of charges in those cases. During the court proceedings, all charges related to natural health products were withdrawn during plea negotiations and instead charges related to other drugs with higher fine amounts were imposed under the FDA and Controlled Drugs and Substances Act.

APPENDIX D
HEALTH CANADA RESPONSE TO A QUESTION ABOUT INSPECTIONS AND SUSPENSIONS BETWEEN 2020 AND 2022

In response to a question at the hearing regarding the number of inspections that were performed in 2020, 2021 and the first three months of 2022, and the number of suspensions that may have resulted from them, Health Canada provided the following information in a letter to the Committee:

2020

No inspections were conducted in 2020 as the pilot had not yet launched. However, as part of Compliance Monitoring Projects in 2019-2020, site visits were conducted at five companies previously visited in 2017 to verify compliance and follow-up on implementation of corrective actions related to specific GMP requirements of the Natural Health Products Regulations. Of these companies, one had its license suspended due to regulatory deficiencies—related to finished product specifications, operations, personnel, quality assurance and product stability—that persisted after the company was notified of these issues. The company provided additional information, which after review allowed the licences to be reinstated.

2021-2022

Inspections Conducted

In 2021, as part of our continued proactive and risk-based approach, and to complement our paper-based licensing process and complaint-based compliance verification process, we developed and implemented the pilot NHP GMP Inspection Program.

As part of the pilot, inspectors conducted inspections of 27 companies (18 importers and 9 manufacturers) in 2021, and 9 more inspections at manufacturers from January to March 2022. This represents about 4% of all companies with active NHP site licences in Canada.

Findings

To date, the results of 33 of the 36 inspections are identified. The most common regulatory deficiencies were related to quality assurance, product stability, and finished product specifications. Inspectors identified serious regulatory deficiencies at 13 of the 33 companies with completed inspections, which led to compliance and enforcement actions being taken with their site and/or product licence(s).

Compliance & Enforcement Actions taken:

- 7 companies received a notice of an intent to suspend their site licence and product licence(s).
- 4 companies received a notice of an intent to suspend their site licence.
- 2 companies received a notice of immediate suspension of their site licence and notice of intent to suspend their product licences.

Corrective Actions

- In six of the 13 cases where compliance action was taken, the companies proposed adequate corrective actions for the identified regulatory deficiencies, which allowed for closure of the intent to suspend and/or re-instatement of licence(s).
- In one case, the company's proposed corrective actions were not adequate, which led to suspension and then cancellation of their product licences. Further action was not taken on their site licence as they allowed their site licence to expire while addressing the deficiencies noted at the time of inspection.
- In another case, the proposed corrective actions are currently under review by the inspector.

In the remaining five cases, the corrective actions are pending from the companies.

REQUEST FOR GOVERNMENT RESPONSE

Pursuant to Standing Order 109, the committee requests that the government table a comprehensive response to this Report.

A copy of the relevant *Minutes of Proceedings* (Meetings Nos. 10 and 21) is tabled.

Respectfully submitted,

John Williamson, M.P.
Chair