

Reports of the Commissioner of the Environment and Sustainable Development to the Parliament of Canada

Report 2

Natural Health Products—Health Canada



Independent Auditor's Report | 2021



Office of the Auditor General of Canada

Bureau du vérificateur général du Canada



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Performance audit reports

This report presents the results of a performance audit conducted by the Office of the Auditor General of Canada (OAG) under the authority of the *Auditor General Act*.

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- report both positive and negative findings
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Cat. No. FA1-26/2021-1-2E-PDF

ISBN 978-0-660-38238-8

ISSN 2561-1801

Cover and title page photos: Life and Times/Shutterstock.com

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Introduction

Background

Natural health products

2.1 Natural health products are a type of self-care product made from naturally occurring ingredients and used for general health maintenance. Such products 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
- certain sunscreens, toothpastes, and shampoos with health claims

2.2 According to a 2010 public opinion poll on natural health products, about 70% of Canadians regularly used such products to maintain their health and prevent minor health problems. In a 2016 survey, more than half of the Canadian participants said they used vitamins and minerals weekly.

2.3 There is a perception that because natural health products are made from ingredients found in nature, they are safe. However, some products 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.

2.4 The regulation of natural health products in Canada began in 2004. The federal government wanted to balance consumer safety with consumers' freedom of choice and access to traditional medicines. To be sold in Canada, natural health products must be licensed by Health Canada to ensure that they are safe and effective. The department considers a natural health product to be safe if its benefit outweighs the risk when the product is used as intended and according to directions. The department considers a natural health product to be effective if evidence supports that the product will provide the benefits

described in the claims. Since 2004, Health Canada has issued more than 91,000 licences for natural health products.

2.5 Natural health products are regulated differently from over-the-counter drugs (manufactured drugs that can be sold without a prescription) and cosmetics (Exhibit 2.1). They sit side by side in pharmacies where Canadians most often buy them.

Exhibit 2.1 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

Roles and responsibilities

2.6 Health Canada is responsible for administering the *Natural Health Products Regulations*, which govern the safety and efficacy of natural health products. Before products go on the market, the department licenses products and the sites that manufacture them. The department is responsible for overseeing products and sites after the products appear on the market. However, the primary responsibility for the safety and efficacy of products and manufacturing sites rests with the industry.

2.7 Health Canada can enforce product and site-licence conditions for natural health products by, for example,

- suspending or cancelling licences
- directing a stop sale of products
- seizing products
- requesting voluntary product recalls
- issuing public alerts and advisories on the Health Canada website

2.8 Health Canada 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.

Focus of the audit

2.9 This audit focused on whether Health Canada ensured that natural health products available for sale in Canada are safe and accurately represented to consumers.

2.10 This audit is important because many Canadians use natural health products. They expect these products to be safe and effective, and they expect to be properly informed about them.

2.11 More details about the audit objective, scope, approach, and criteria are in **About the Audit** at the end of this report (see pages 20–23).

Findings, Recommendations, and Responses

Overall message

2.12 Overall, Health Canada’s oversight of natural health products available for sale in Canada fell short of ensuring that products were safe and effective. The department did approve products on the basis of evidence that they were safe and effective. However, gaps in the oversight of manufacturing sites and in the monitoring of products once on the market left consumers exposed to potential health and safety risks because products were not always manufactured or marketed according to licence conditions.

2.13 The absence of routine inspections did not allow Health Canada to ensure that manufacturing sites were following good manufacturing practices. The department also did not monitor product label information to ensure that products were as described on the label or licensed for

sale. When licence conditions are not followed, products may not deliver the promised health benefits or may cause adverse reactions ranging from mild to severe. Though Health Canada investigated products suspected of causing serious health risks, such as adverse reactions, and took immediate action to address such risks, the department's approach was reactive and not always successful in having all products pulled from the shelves.

2.14 During the **coronavirus disease (COVID-19)** pandemic, the department successfully modified its approach to licensing hand sanitizers. This helped to address market shortages of sanitizing products that curb the spread of the coronavirus. Health Canada also proactively monitored the advertising of natural health products making health claims related to COVID-19. It took action when it identified false claims, though we found that many licensed and unlicensed natural health products were still making unauthorized claims at the time of the audit.

Safety and efficacy of natural health products

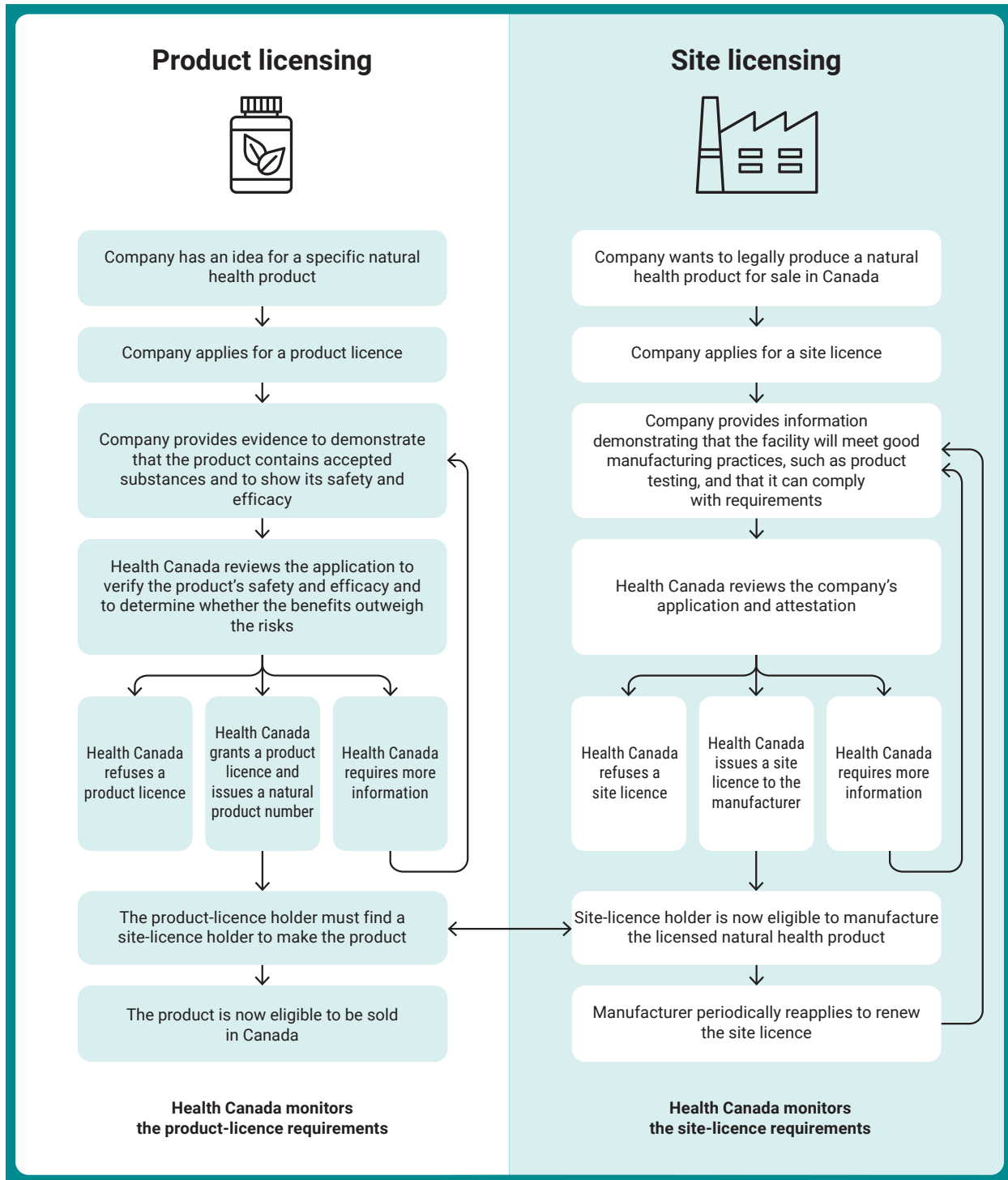
Context

2.15 Natural health products are a subset of drugs under the *Food and Drugs Act*. They are regulated by the *Natural Health Products Regulations*, which govern their manufacturing, packaging, labelling, importation, distribution, storage, and sale. Every natural health product sold in or imported to Canada must have a product licence from Health Canada and be manufactured in a facility with a site licence from the department.

2.16 Exhibit 2.2 summarizes how Health Canada's system is designed to issue a natural health product licence and a site licence for manufacturing natural health products.

Coronavirus disease (COVID-19)—The disease caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).

Exhibit 2.2 The natural health product-licensing and site-licensing processes



Health Canada did not verify that facilities followed good manufacturing practices before products arrived on the market

What we found

2.17 We found that Health Canada did not always verify that manufacturing facilities followed good manufacturing practices before natural health products were marketed for sale in Canada. The department relied on manufacturers' attestations that their facilities followed good manufacturing practices.

2.18 The analysis supporting this finding discusses the following topic:

- Reliance on manufacturers' attestations

Why this finding matters

2.19 This finding matters because Health Canada is responsible for verifying that natural health products are made in facilities that follow good manufacturing practices. These practices help ensure that products are safe and effective as described.

Recommendation

2.20 Our recommendation in this area of examination appears at paragraph 2.26.

Analysis to support this finding

Reliance on manufacturers' attestations

2.21 Health Canada requests that site-licence applicants attest, by means of written declaration, that they follow good manufacturing practices. We found that the department relied on natural health product manufacturers' attestations that their facilities followed these practices and had not conducted an inspection before the products went on the market. We 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 natural health products

- include the right medicinal ingredients at the right dosage
- are free from microbial and chemical contamination
- remain active and stable until their expiry date
- are processed by qualified personnel, using equipment in facilities that follow good sanitation practices

2.22 We reviewed a sample of 25 (out of 250) active site licences for Canadian manufacturing sites and foreign sites of Canadian importers

that Health Canada approved between 2017 and 2019, along with their first licence renewal. We examined whether, before products went on the market, Health Canada had verified that these sites followed good manufacturing practices.

2.23 In 13 of the 25 sites in our sample, Health Canada relied on inspections, such as drug inspections, performed by domestic and regulatory authorities from other countries when licensing these sites. However, we found that the department did not have assurance that 10 of these 13 sites followed good manufacturing practices because the department did not have evidence that these inspections included the natural health product lines.

2.24 For the remaining 12 sites in our sample, Health Canada obtained some site information before issuing a licence. However, it did not verify one or more of the following key types of evidence demonstrating that the sites followed good manufacturing practices:

- evidence that the facility's quality assurance official had the necessary qualifications
- adequate standard operating procedures for product testing, sanitation, quality assurance, premises, and equipment
- product testing results showing that the product specifications were met

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

2.26 **Recommendation.** Health Canada should obtain

- sufficient evidence to verify that licensed sites follow good manufacturing practices before products are released on the market
- information about which natural health products are available on the market

The department's response. Agreed. Health Canada notes its limited regulatory authorities to compel companies to provide information on quality as part of the product-licence submission process. Applicants are required to provide only an attestation that their product will meet the prescribed quality requirements. To improve its pre-market quality oversight of natural health products, the department has been using information gathered through 2 compliance monitoring projects and a paper-based audit of good manufacturing practices at a number of manufacturing sites. The department also acknowledges that natural

health products are the only line of health products for which all regulatory activities are funded by the public. The absence of a stable funding framework combined with the limited regulatory authorities for quality has placed significant pressure on the department to perform its regulatory activities and efficiently respond to the increasingly high number and scientific complexity of product submissions. In response to this recommendation, the department will

- *establish fully costed options for a risk-based approach to quality oversight prior to the issuance or renewal of licences and determine the full regulatory and operational implications of these options*
- *explore mechanisms to obtain information about which products are available on the market*
- *take steps to propose user fees to natural health products to offset the costs of licensing and post-market activities*

Health Canada left natural health products unchecked after they entered the market and was not always successful in responding to serious problems

What we found

2.27 We found that Health Canada did little to prevent poor information from being given to consumers about licensed natural health products. It did limited monitoring of licensed products and manufacturers and of unlicensed products, such as checking whether product labels and advertising contained misleading information. The department's monitoring of products focused on reacting to complaints brought to its attention. When it did take action after finding problems with natural health products, Health Canada's response was not always successful in resolving the problems.

2.28 The analysis supporting this finding discusses the following topics:

- Poor information for consumers on licensed products
- Limited monitoring of licensed products and manufacturers
- Limited monitoring of unlicensed products and unauthorized activities
- Partial success in resolving serious problems with products

Why this finding matters

2.29 This finding matters because products should not be on the market unless they are safe and the information provided to consumers is accurate and complete.

Recommendations

2.30 Our recommendations in this area of examination appear at paragraphs 2.35, 2.47, 2.51, and 2.56.

Analysis to support this finding

Poor information for consumers on licensed products

2.31 We examined whether, before approving natural health products, Health Canada ensured that there was appropriate evidence to demonstrate the products' safety and efficacy. We found that the department did approve natural health products according to appropriate safety evidence. The *Natural Health Products Regulations* require that this product safety and efficacy information be disclosed on the product label to help consumers make informed choices. The specific product safety and efficacy information that must be disclosed to consumers is part of the product's licence conditions.

2.32 We found that Health Canada did not sufficiently monitor whether product label information and advertisements met the product-licence conditions. We found that the department monitored product labels and advertisements in response to complaints instead of monitoring the market using a risk-based approach. To gain an understanding of the market, we examined a sample of 75 licensed products for sale on Canadian websites. We found that 88% of these products were advertised with misleading product information. Also, 56% of the products we examined were marketed with misleading label information—label information that included one or 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
- product label information, such as safety warnings, printed very small (that is, in a 4-point font); on paper, font sizes under 8 points are difficult to read without magnification; according to Health Canada, poor readability of the printed label information contributes to incorrect product use

In response to our findings, during our audit, Health Canada initiated follow-up on some of the advertisements and product labels that contained misleading information.

2.33 We also found that more than one quarter of the 75 licensed products that we examined did not show if they had a natural product number issued by Health Canada. This finding is important because the department recommends that consumers buy only products with this number on the label, because it means that the department has assessed these products for safety and efficacy. Although the regulations require that the natural product number appear on product labels or packaging, there is no such requirement for the number to appear in online information.

2.34 Consumers can get information on natural health products from Health Canada's online Licensed Natural Health Products Database. We found that the database included all safety information from the product licences we examined, except for the source of medicinal ingredients and the recommended duration of use. This safety information is important for consumers to make sure that they use the products as recommended.

2.35 **Recommendation.** Health Canada should, for licensed natural health products on the market, including on the Internet, take a risk-based approach to

- ensure that product labels are readable
- monitor product label and advertisement information to ensure that they contain accurate and complete product information, consistent with their licence conditions

The department's response. Agreed. Health Canada has started to take steps through extensive stakeholder engagement and the development of a regulatory proposal to improve the labelling of natural health products, to make them easier to read, understand, and compare with other similar products. The department will

- continue to pursue regulatory and policy changes to improve labelling of natural health products
- explore options to require licence holders to display a Canadian label, including a natural product number, in advertisements targeted to Canadians
- take steps to implement a comprehensive proactive monitoring strategy to ensure that advertising of natural health products is consistent with the product licence

Limited monitoring of licensed products and manufacturers

2.36 We found that Health Canada did not have a program to conduct routine on-site inspections of manufacturing sites for

natural health products on an established cycle. We noted that health regulatory agencies in Australia and Europe, for example, have a cycle for conducting routine inspections of manufacturing sites over a 4-year period.

2.37 We found that Health Canada did identify sites it considered high risk, but it identified only those that manufactured sterile products, such as eye care products. It did not identify which licensed sites were making other types of high-risk natural health products, such as:

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

2.38 We found that Health Canada faced challenges in monitoring licensed products in part because of the large number of licensed products. Since 2004, the department has licensed 91,000 natural health products, yet by its own estimates, only half of them went to the Canadian market. In addition, the number of applications for natural health products was 10 times higher than the number for over-the-counter drugs, and many applications were redundant. Factors that contributed to the large number of natural health product-licence applications included the following:

- Companies have been able to submit multiple applications for hypothetical products that have not been developed.
- Applicants have not been 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.

2.39 We found that Health Canada did not know where all licensed products were manufactured. Natural health product-licence holders are required to tell the department which licensed facilities manufactured their products before selling them. However, fewer than 5% of all active product-licence holders did so. The department did not enforce that requirement or contact product-licence holders to get the information. In addition, the department was not required to be notified when licensed products entered and exited the Canadian market. This made it challenging to identify high-risk manufacturing sites in order to focus its monitoring resources.

2.40 We found that Health Canada did limited monitoring of licensed manufacturers. In 2016, the department piloted on-site inspections to determine whether the sites followed good manufacturing practices. Between 2017 and 2019, it inspected around 6% of the 766 active

licensed companies. The department chose domestic sites either randomly or because they had poor compliance history. It also chose all sites that manufactured sterile products because they were considered the highest-risk products. Although Health Canada had information about the type of manufacturing processes at the sites, it did not have information about the products made at all sites. Therefore, it could not identify and inspect all high-risk sites.

2.41 When Health Canada did inspections, there was a high level of industry non-compliance with product manufacturing and product quality. On-site inspections found product quality problems at all sites. In nearly half of the 46 sites it inspected between 2017 and 2019, the department took regulatory action because it identified significant health risks. Such regulatory actions included cancelling 7 site licences and suspending or cancelling 5 product licences.

2.42 We examined the files for 7 of the 46 site inspections to determine whether Health Canada verified that the companies had corrected the problems it identified before renewing their site licences. For 2 of the sites, the department determined that the companies did not have an acceptable action plan and refused to renew their licences. However, we found that 1 of these companies was still selling its products online without a licence in October 2020.

2.43 In the 5 other site-inspection files, we found that Health Canada verified information supporting the product expiry date and certain product testing results. However, we found that it renewed these 5 site licences without verifying that the companies met other important good manufacturing practices, such as confirming the absence of chemical contaminants.

2.44 We also examined a sample of 25 initial site-licence renewals approved by Health Canada after products were on the market. We found that in 22 of the 25 samples, the department did not verify that all sites followed good manufacturing practices. Without always verifying that product testing results meet specifications or that key documented procedures comply with good manufacturing practices, the department cannot be sure that products were safe and effective. We found that even after their first site-licence renewal, most companies still had not demonstrated full compliance with good manufacturing practices. For example, we found the following:

- Nine companies had one or more incomplete standard operating procedures for product testing, sanitation, quality assurance, premises, or equipment.
- Seventeen companies did not provide product testing results that confirmed the identity and quantity of medicinal ingredients, the product expiry date, and the absence of chemicals and microbial contaminants.

- Seven companies did not provide evidence that their quality assurance official had the necessary qualifications.

2.45 Health Canada conducted other activities to gather compliance information, which also exposed quality problems with certain manufacturers. For example, in 2019, the department reviewed 35 companies' testing results for 2 products that each company had recently released for sale. The department found problems at all sites, including the use of expired raw materials, unacceptable amounts of contaminants, and product tests that did not confirm the product expiry date. For half of the 35 companies, Health Canada took regulatory action, such as issuing a notice of intent to suspend the site licence, because the problems were serious.

2.46 In our opinion, 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.

2.47 **Recommendation.** Health Canada 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.

The department's response. *Agreed. Health Canada recognizes that natural health products 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. The department has completed a number of compliance monitoring projects to gather information on quality oversight of natural health products and recognizes the need to expand its activities into a more robust inspection program. The department will*

- *implement a pilot program for inspecting the good manufacturing practices of natural health products to promote and verify compliance of the natural health product industry through inspections of licence holders across Canada and take further actions on the basis of 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 to natural health products the use of powers under the Protecting Canadians from Unsafe Drugs Act (Vanessa's Law)*
- *establish fully costed options for a risk-based approach to inspections*
- *take steps to propose the expansion of user fees to natural health products to offset the costs of post-market activities*

Limited monitoring of unlicensed products and unauthorized activities

2.48 We found that Health Canada monitored alerts from other international regulators and opened cases when it became aware of serious issues with a non-compliant product. A non-compliant product is either an **unlicensed product** or a licensed product involved in an **unauthorized activity**. We found that Health Canada did not have a program to actively monitor high-risk unlicensed products on the market. Despite a growing number of such products for sale in Canada, particularly online, the department did little monitoring of non-compliant products.

2.49 We 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. We found that Health Canada did not follow up to determine if any such products were available for sale in Canada with the same substances. In our review of 61 suspected high-risk products, we found that 38 of them were sold online in Canada without a product licence.

2.50 Claims to cure and treat cancer are forbidden under the *Food and Drugs Act*. Some claims of a product preventing cancer are allowed under the *Natural Health Products Regulations*, subject to a product's licence conditions. We reviewed advertisements for 48 products online that made cancer claims. We found that none of these claims were authorized by Health Canada and that 4 of these products were not licensed.

2.51 **Recommendation.** 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
- identify unauthorized activities and take appropriate action so that labelling and advertisements meet product-licence conditions

The department's response. *Agreed. Health Canada does maintain a complaint-based program for regulatory advertising compliance oversight but recognizes that an additional risk-based approach is required to ensure unauthorized activities are prevented or stopped. The department will*

- *implement a risk-based approach to monitoring advertising*

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 requirements.

- *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 to natural health products the use of powers under the Protecting Canadians from Unsafe Drugs Act (Vanessa’s Law)*

Partial success in resolving serious problems with products

2.52 Natural health product-licence holders are required to report serious adverse reactions to Health Canada under the *Natural Health Products Regulations*. Other groups—such as hospitals and the public—can file a complaint when a licensed or unlicensed product is suspected of causing an adverse reaction, such as a serious health effect or disability. In response to these reports, the department will open a case to investigate products suspected of posing a serious health risk. Between 2017 and 2019, the department opened a total of 40 cases—each case involved one or more products.

2.53 In most of the cases that we reviewed, when Health Canada found serious problems, such as product- or site-quality issues or adverse reactions involving hospitalization, we found that it initiated immediate action to address serious health risks. The department responded by communicating with the public, for example, and where necessary, by taking enforcement actions. These enforcement actions included directing a stop sale of products and requesting a voluntary product recall. Health Canada’s actions successfully got the products off the market in 36 of the 40 total cases of serious health risks. However, on average, it took close to 3 months for the department to verify that these products were no longer marketed for sale. For voluntary recalls, it took around 6 months to verify that product recalls were completed.

2.54 For the other 4 cases of products with serious health risks, 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. (Exhibit 2.3 details the department’s actions in this case.)
- 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.
- The Internet domain hosting the advertising did not comply with the department’s request to remove the advertising for the unlicensed product.

Exhibit 2.3 Health Canada was not able to have a natural health product containing pharmaceutical ingredients removed from the market

The following is the timeline of Health Canada’s response to a reported health problem in 1 case involving 3 related products that were sold by 1 importer.

Period	Action taken by Health Canada or by the importer
April 2017	Adverse reaction report —Health Canada received an adverse reaction report involving hospitalization of a person who took 1 or more of these 3 products. The report included testing results from a poison centre that found that the products contained pharmaceutical ingredients that could cause miscarriages.
May 2017	Product seizure —The department placed the 3 products under seizure from the Canadian facility where they were stored.
August 2017	Product testing —After in-depth product testing, the department found that 1 of the 3 products (“product A”) contained pharmaceutical ingredients that could cause miscarriages and birth defects.
October 2017	Voluntary recall request —The department requested that the importer recall product A.
November 2017	Border alert and public advisory —The department issued a border alert to prevent the importation of product A. It also issued a public advisory.
December 2017	Unannounced on-site visit —The department did an unannounced visit to the facility. It found that some quantities of the products under seizure had been removed from the facility. The department immediately suspended the 3 product licences.
January 2018	Importer’s acknowledgement of possible product contamination —The importer acknowledged the possibility that these products had been contaminated with pharmaceutical ingredients that could cause miscarriages and birth defects.
June 2018	Cancellation and lifting of suspension of licences —Health Canada cancelled the product licence for product A and lifted the suspension of the other 2 product licences.
October 2020	Continued marketing of product online —Product A was still marketed for sale on the company’s Canadian website despite the product being unlicensed.

2.55 As of October 2020, we found that products in 2 of these 4 cases involving serious health risks were still marketed for sale online by the same retailer. In addition, of the products in the 36 cases that Health Canada successfully got off the market between 2017 and 2019, the products in 7 of these cases had re-entered the market.

2.56 **Recommendation.** 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.

The department's response. *Agreed. In addition to the immediate steps Health Canada already takes to protect the health and safety of Canadians when a serious risk to health is identified, the department will*

- *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 to natural health products the use of powers under the Protecting Canadians from Unsafe Drugs Act (Vanessa's Law)*
- *take steps to propose the expansion of user fees to natural health products to offset the costs of licensing and post-market activities*

Health Canada responded effectively to natural health products related to COVID-19

What we found

2.57 We found that Health Canada used 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. The department put in place effective temporary measures to meet the urgent need for products facing shortages, such as alcohol-based hand sanitizers. The department provided flexibility to Canadian manufacturers by temporarily waiving compliance with specific regulatory requirements without increasing the risk of serious safety concerns. The department also increased its oversight of the products marketed for COVID-19.

2.58 The analysis supporting this finding discusses the following topics:

- Successful approach for licensing hand sanitizers
- Proactive monitoring of COVID-19 product advertising

Why this finding matters

2.59 This finding matters because Health Canada needed to address an urgent need in the market for COVID-19 products while ensuring consumer safety.

Recommendations

2.60 We made no recommendations in this area of examination.

Analysis to support this finding

Successful approach for licensing hand sanitizers

2.61 In spring 2020, the COVID-19 pandemic created shortages of products in Canada, such as alcohol-based hand sanitizers to curb the spread of the virus. To meet the urgent need for these products, some

of which are considered natural health products, Health Canada made temporary regulatory and policy changes to speed up their licensing. The interim measures gave flexibility to Canadian manufacturers by waiving compliance with a few regulatory requirements during a short period of time while maintaining due care for safety.

2.62 We found that Health Canada exercised due diligence in implementing a risk-based approach for licensing new sites, which helped to deliver on the increased demand for hand sanitizers. Although the department's approach was practical in the circumstances, in our view the Minister of Health should have made an interim order under section 30.1 of the *Food and Drugs Act* and tabled it in Parliament. Such an interim order would have been the proper way to proceed for temporarily waiving and changing mandatory regulatory requirements. We noted that the department made such interim orders for regulatory changes for other health products used during the COVID-19 pandemic, but not for natural health products.

2.63 During April and May 2020, Health Canada approved more than 2,500 natural health product licences for hand sanitizers. On 13 July 2020, the department cancelled some of the interim measures and resumed its normal licensing process because it had evidence that manufacturers had the capacity to meet the demand for the upcoming year.

Proactive monitoring of COVID-19 product advertising

2.64 During April and May 2020, Health Canada proactively monitored the advertising of many types of natural health products to ensure they did not claim to mitigate, prevent, treat, diagnose, or cure COVID-19. The department found a total of 80 such instances, including false claims that some mushrooms would prevent COVID-19 and boost the immune system and that oil of oregano stopped the growth of multiple bacteria. Health Canada resolved many of these instances by contacting the companies and working with them to remove the advertising. We looked at a sample of 25 of these advertisements and found that 3 of them were still online at the time of the audit despite Health Canada's efforts.

2.65 At the same time that Health Canada was monitoring the online market, we also searched Canadian websites to determine whether products were making claims to prevent COVID-19 or protect against it or were making unauthorized antiviral claims. We examined 30 websites that advertised such products and found that 25 of them made unauthorized claims. Although the department actively monitored the COVID-19 market, we found that many licensed and unlicensed natural health products were still making unauthorized claims at the time of the audit. In a pandemic, it is even more important that consumers use only products that have been licensed by Health Canada. As we stated in our recommendation in paragraph 2.51, a risk-based monitoring program to

identify unauthorized activities and take appropriate action would ensure that misleading information is not marketed to consumers in Canada.

Conclusion

2.66 We concluded that Health Canada did not ensure that natural health products offered to Canadians were safe, effective, and accurately represented on the basis of appropriate evidence. The department approved products on the basis of evidence that they were safe and effective. However, its oversight of manufacturing sites and monitoring of products once on the market left consumers exposed to potential health and safety risks because products were not always manufactured or marketed according to licence conditions. Although Health Canada investigated products that were suspected of causing serious health risks and took immediate action to address such risks, the department's approach was reactive and not always successful in having the products pulled from the shelves.

2.67 During the early stages of the COVID-19 pandemic, Health Canada acted quickly to license alcohol-based hand sanitizers to help address market shortages. The department proactively monitored natural health products that had claims related to COVID-19 and took action when it identified false claims. Despite the department's proactive monitoring, natural health products were still making unauthorized claims at the time of the audit.

About the Audit

This independent assurance report was prepared by the Office of the Auditor General of Canada on natural health products. Our responsibility was to provide objective information, advice, and assurance to assist Parliament in its scrutiny of the government's management of resources and programs, and to conclude on whether Health Canada's oversight of natural health products complied in all significant respects with the applicable criteria.

All work in this audit was performed to a reasonable level of assurance in accordance with the Canadian Standard on Assurance Engagements (CSAE) 3001—Direct Engagements, set out by the Chartered Professional Accountants of Canada (CPA Canada) in the CPA Canada Handbook—Assurance.

The Office of the Auditor General of Canada applies the Canadian Standard on Quality Control 1 and, accordingly, maintains a comprehensive system of quality control, including documented policies and procedures regarding compliance with ethical requirements, professional standards, and applicable legal and regulatory requirements.

In conducting the audit work, we complied with the independence and other ethical requirements of the relevant rules of professional conduct applicable to the practice of public accounting in Canada, which are founded on fundamental principles of integrity, objectivity, professional competence and due care, confidentiality, and professional behaviour.

In accordance with our regular audit process, we obtained the following from entity management:

- confirmation of management's responsibility for the subject under audit
- acknowledgement of the suitability of the criteria used in the audit
- confirmation that all known information that has been requested, or that could affect the findings or audit conclusion, has been provided
- confirmation that the audit report is factually accurate

Audit objective

The objective of this audit was to determine whether Health Canada ensured that natural health products offered to Canadians are safe and accurately represented on the basis of appropriate evidence.

Scope and approach

We examined Health Canada's pre-market licensing for approving the sale of natural health products and post-market activities for monitoring industry compliance and product risks and issues. When the COVID-19 pandemic started, we expanded our audit scope to cover the department's licensing and product monitoring targeted to COVID-19.

In pre-market licensing, we examined product and site licensing to determine whether Health Canada obtained adequate evidence that natural health products are safe, accurately represented, and of quality before they enter the market. In post-market monitoring, we examined whether

Health Canada’s oversight was sufficient to determine industry compliance with the *Natural Health Products Regulations* and whether the department took actions to mitigate higher health risks and problems.

The following areas were excluded from the audit:

- compounding of natural health products by health care professionals
- other health care products, such as supplemented food, consumer products, cosmetics, and pharmaceutical drugs
- classification of self-care products
- the Self-Care Framework
- substances in Schedule 2 of the *Natural Health Products Regulations*

We examined a sample of product licences approved in 2018 and 2019 and site licences approved between 2017 and 2019, along with their first licence renewals, and health risks and problems with natural health products that were raised during that period. We also examined the department’s modified approach to licensing new products and sites for hand sanitizers in April and May 2020 and Health Canada’s monitoring of the market during that period.

Criteria

Criteria	Sources
We used the following criteria to determine whether Health Canada ensured that natural health products offered to Canadians are safe and accurately represented on the basis of appropriate evidence:	
Health Canada approves natural health products that are safe and free from false or misleading information, on the basis of appropriate evidence.	<ul style="list-style-type: none"> • <i>Food and Drugs Act</i> • <i>Natural Health Products Regulations</i> • Compendium of Monographs, Health Canada, 2013 • Pathway for Licensing Natural Health Products Used as Traditional Medicines, Health Canada, 2012 • Pathway for Licensing Natural Health Products Making Modern Health Claims, Health Canada, 2012 • Evidence for Homeopathic Medicines, Health Canada, 2015 • Natural Health Products Management of Applications Policy, Health Canada, 2019
Health Canada assesses that manufacturers and foreign sites of importers comply with key good manufacturing practices before the natural health product enters the Canadian market.	<ul style="list-style-type: none"> • <i>Natural Health Products Regulations</i> • Good Manufacturing Practices Guidance Document, Health Canada, 2015 • Quality of Natural Health Products Guide, Health Canada, 2015

Criteria	Sources
<p>We used the following criteria to determine whether Health Canada ensured that natural health products offered to Canadians are safe and accurately represented on the basis of appropriate evidence:</p>	
<p>Health Canada's level of oversight is sufficient to conclude on industry compliance with the <i>Natural Health Products Regulations</i> to fulfill its regulatory responsibilities.</p>	<ul style="list-style-type: none"> • <i>Natural Health Products Regulations</i> • Site Licensing Guidance Document, Health Canada, 2015 • Compliance and Enforcement Policy for Health Products, Health Canada, 2005 and 2018 • OECD Best Practice Principles for Regulatory Policy: Regulatory Enforcement and Inspections, Organisation for Economic Co-operation and Development, 2014 • Manufacturer Inspections: A Risk-Based Approach to Frequency, Department of Health, Therapeutic Goods Administration, Australian Government, 2016 • Guideline on Good Pharmacovigilance Practices, Module III—Pharmacovigilance inspections, European Medicines Agency and Heads of Medicines Agencies, 2014
<p>Health Canada monitors Canadian markets to identify unauthorized natural health products and false or misleading advertisements or product labels, or both.</p>	<ul style="list-style-type: none"> • <i>Food and Drugs Act</i> • <i>Natural Health Products Regulations</i>
<p>Health Canada takes timely actions in response to unauthorized natural health products and licensed products that contain false or misleading product labels or pose health risks to consumers.</p>	<ul style="list-style-type: none"> • <i>Food and Drugs Act</i> • <i>Natural Health Products Regulations</i> • Compliance and Enforcement Policy for Health Products, Health Canada, 2005 and 2018

Period covered by the audit

The audit covered the period from February 2017 to December 2019 for all of the audit criteria. This is the period to which the audit conclusion applies. However, to gain a more complete understanding of the effects of the COVID-19 pandemic on natural health products, we also examined new product and site licences approved in April and May 2020 and the online marketing of natural health products during those 2 months.

Date of the report

We obtained sufficient and appropriate audit evidence on which to base our conclusion on 3 December 2020, in Ottawa, Canada.

Audit team

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List of Recommendations

The following table lists the recommendations and responses found in this report. The paragraph number preceding the recommendation indicates the location of the recommendation in the report, and the numbers in parentheses indicate the location of the related discussion.

Recommendation	Response
<p>Safety and efficacy of natural health products</p> <p>2.26 Health Canada should obtain</p> <ul style="list-style-type: none"> • sufficient evidence to verify that licensed sites follow good manufacturing practices before products are released on the market • information about which natural health products are available on the market <p>(2.21–2.25)</p>	<p>The department’s response. Agreed. Health Canada notes its limited regulatory authorities to compel companies to provide information on quality as part of the product-licence submission process. Applicants are required to provide only an attestation that their product will meet the prescribed quality requirements. To improve its pre-market quality oversight of natural health products, the department has been using information gathered through 2 compliance monitoring projects and a paper-based audit of good manufacturing practices at a number of manufacturing sites. The department also acknowledges that natural health products are the only line of health products for which all regulatory activities are funded by the public. The absence of a stable funding framework combined with the limited regulatory authorities for quality has placed significant pressure on the department to perform its regulatory activities and efficiently respond to the increasingly high number and scientific complexity of product submissions. In response to this recommendation, the department will</p> <ul style="list-style-type: none"> • establish fully costed options for a risk-based approach to quality oversight prior to the issuance or renewal of licences and determine the full regulatory and operational implications of these options • explore mechanisms to obtain information about which products are available on the market • take steps to propose user fees to natural health products to offset the costs of licensing and post-market activities

Recommendation	Response
<p>2.35 Health Canada should, for licensed natural health products on the market, including on the Internet, take a risk-based approach to</p> <ul style="list-style-type: none"> • ensure that product labels are readable • monitor product label and advertisement information to ensure that they contain accurate and complete product information, consistent with their licence conditions <p>(2.31–2.34)</p>	<p>The department’s response. Agreed. Health Canada has started to take steps through extensive stakeholder engagement and the development of a regulatory proposal to improve the labelling of natural health products, to make them easier to read, understand, and compare with other similar products. The department will</p> <ul style="list-style-type: none"> • continue to pursue regulatory and policy changes to improve labelling of natural health products • explore options to require licence holders to display a Canadian label, including a natural product number, in advertisements targeted to Canadians • take steps to implement a comprehensive proactive monitoring strategy to ensure that advertising of natural health products is consistent with the product licence
<p>2.47 Health Canada 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.</p> <p>(2.36–2.46)</p>	<p>The department’s response. Agreed. Health Canada recognizes that natural health products 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. The department has completed a number of compliance monitoring projects to gather information on quality oversight of natural health products and recognizes the need to expand its activities into a more robust inspection program. The department will</p> <ul style="list-style-type: none"> • implement a pilot program for inspecting the good manufacturing practices of natural health products to promote and verify compliance of the natural health product industry through inspections of licence holders across Canada and take further actions on the basis of 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 to natural health products the use of powers under the <i>Protecting Canadians from Unsafe Drugs Act (Vanessa’s Law)</i> • establish fully costed options for a risk-based approach to inspections • take steps to propose the expansion of user fees to natural health products to offset the costs of post-market activities

Recommendation	Response
<p>2.51 Health Canada should develop a risk-based monitoring program to</p> <ul style="list-style-type: none"> • identify unlicensed products and take appropriate action so that they are not available for sale to consumers in Canada • identify unauthorized activities and take appropriate action so that labelling and advertisements meet product-licence conditions <p>(2.48–2.50)</p>	<p>The department’s response. Agreed. Health Canada does maintain a complaint-based program for regulatory advertising compliance oversight but recognizes that an additional risk-based approach is required to ensure unauthorized activities are prevented or stopped. The department will</p> <ul style="list-style-type: none"> • implement a risk-based approach to monitoring advertising • 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 to natural health products the use of powers under the <i>Protecting Canadians from Unsafe Drugs Act (Vanessa’s Law)</i>
<p>2.56 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.</p> <p>(2.52–2.55)</p>	<p>The department’s response. Agreed. In addition to the immediate steps Health Canada already takes to protect the health and safety of Canadians when a serious risk to health is identified, the department will</p> <ul style="list-style-type: none"> • 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 to natural health products the use of powers under the <i>Protecting Canadians from Unsafe Drugs Act (Vanessa’s Law)</i> • take steps to propose the expansion of user fees to natural health products to offset the costs of licensing and post-market activities

