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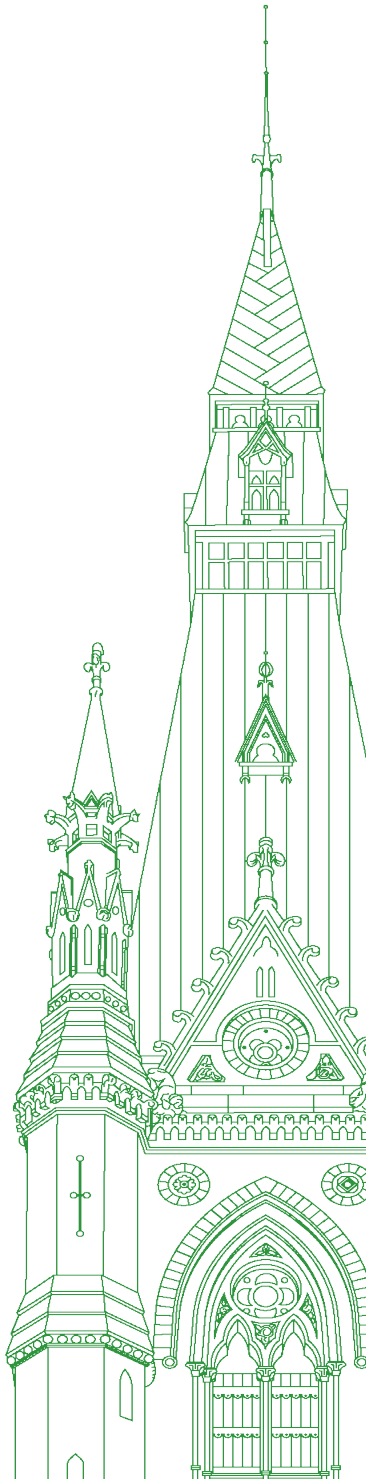

Chair: Mr. John Williamson

Standing Committee on Public Accounts

Thursday, March 24, 2022

● (1100)

[*English*]

The Chair (Mr. John Williamson (New Brunswick Southwest, CPC)): I call this meeting to order.

Welcome to meeting number 10 of the House of Commons Standing Committee on Public Accounts.

Pursuant to Standing Order 108(3)(g), the committee is meeting today to undertake a study on "Report 2: Natural Health Products—Health Canada".

[*Translation*]

Today's meeting is taking place in a hybrid format, in compliance with the House order of Thursday, November 25, 2021. Members can attend in person or remotely using the Zoom application.

The proceedings will be made available through the House of Commons website. So you are aware, the web broadcast will always show the person speaking rather than the entirety of the committee.

Given the current pandemic situation and in light of recommendations from public health authorities, as well as the Board of Internal Economy's directive of October 29, 2021, to remain healthy and safe, everyone attending the meeting in person must follow the health rules.

[*English*]

As the chair, I'll be enforcing these health measures for the duration of the meeting. I thank members in advance for their co-operation.

To ensure an orderly meeting, I would like to outline a few rules to follow.

[*Translation*]

Members and witnesses can speak in the official language of their choice. Interpretation services are available for this meeting. On the bottom of your screen, you have the floor, English and French as options. If you can no longer hear the interpretation, please let me know immediately, and we will ensure it is correctly re-established before we continue with our meeting.

Please use the raise hand feature, which is on the main toolbar, if you would like to speak or get the chair's attention.

[*English*]

For members participating in person, proceed as you usually would when the whole committee is meeting in person or in a committee room.

Before speaking, please wait until I recognize you by name. If you are on the video conference, please click on the microphone icon to unmute yourself. For those in the room, your microphones will be controlled as normal by the proceedings and verifications officer. When speaking, please speak slowly and clearly. When you're not speaking, your mike should be on mute.

[*Translation*]

I remind you that any comments from members and witnesses must be addressed through the chair.

[*English*]

With regard to a speaking list, the committee clerk and I will do the best we can to maintain a consolidated speaking order for all members, whether they are participating virtually or in person.

I'd now like to welcome our witnesses.

From the Office of the Auditor General, we have Jerry V. DeMarco, commissioner of the environment and sustainable development, and Heather Miller, Assistant Auditor General. From the Department of Health, we have Dr. Stephen Lucas, deputy minister; Pamela Aung-Thin, associate assistant deputy minister; and Linsey Hollett, director general, health product compliance.

Before I begin, I'd like to let members know that Dr. Lucas will have to leave the meeting at 12:15. This is due to a scheduling conflict that we agreed to respect. If you have questions for the good doctor, who is the deputy minister, I'd ask that you be aware of this limitation and focus your questions on him for the next hour and a bit.

Thank you for being here today.

Mr. DeMarco, you have the floor for five minutes. Please proceed.

● (1105)

[*Translation*]

Mr. Jerry V. DeMarco (Commissioner of the Environment and Sustainable Development, Office of the Auditor General): Thank you, Mr. Chair.

We are happy to appear before your committee today to discuss our report on natural health products, which was tabled in the House of Commons in April 2021.

I want to start by acknowledging that this hearing is taking place on the traditional unceded territory of the Algonquin Anishinaabeg People.

Joining me today is Heather Miller, the assistant auditor general responsible for this audit.

Canada began regulating natural health products in 2004. At that time, the federal government wanted to balance consumer safety with freedom of choice and access to traditional medicine. To be lawfully sold in Canada, natural health products must be licensed by Health Canada. This is to ensure that products are safe and effective. Health Canada considers a natural health product to be safe when the product's benefits outweigh the risks, so long as it is used as intended. The department considers a natural health product to be effective if the evidence supports that the product will provide the benefits described in the claims.

We focused our work on how Health Canada regulated the industry to make sure that the products were safe and effective. We looked at the licencing of manufacturers and the licencing of products. We further considered the monitoring of the marketplace once products were available for sale. Overall, we found weaknesses in Health Canada's oversight. We were concerned that too much reliance was placed on up front licencing approvals but that not enough was done to inspect manufacturing facilities. Inspections are meant to ensure that products are manufactured according to good manufacturing practices, for example using a sterile environment when appropriate.

[*English*]

With upwards of 91,000 natural health product licences in existence in Canada at the time of our audit, it is important to know where, how and when these products are being manufactured. Natural health product licence-holders are required to inform the department which licensed facilities manufactured their products before selling them. However, fewer than 5% did so. This makes it extremely difficult to adequately monitor the production of these products as a whole.

When Health Canada conducted site inspections, it found problems with product manufacturing and product quality. In nearly half of its inspections, the department took regulatory action in response to health risks.

Generally speaking, once products were on the market there was very little monitoring and it was largely complaints-driven. Health Canada's monitoring was insufficient to ensure that the label on products matched the product that was licensed for sale.

We found that 88% of the products we examined carried potentially misleading information, including health claims that were not authorized by Health Canada. These included claims that products relieved fatigue, enhanced endurance or burned fat, as well as having incorrect dosage information. We also found that the department did not do enough to prevent the sale of unlicensed products.

We were completing our examination work as the COVID-19 pandemic began. We expanded the scope of our audit to include the work the department was doing related to natural health products and COVID-19. While we found some issues with the process, Health Canada responded to the urgent needs for COVID-19 products such as alcohol-based hand sanitizers. The department temporarily waived compliance with the specific regulatory requirements to afford Canadian manufacturers some flexibility without increasing the risk of serious safety concerns. It also increased its oversight of the products marketed for COVID-19.

Health Canada has agreed with all five recommendations provided in our report.

This concludes my opening remarks. We would be pleased to answer any questions the committee might have.

Thank you.

● (1110)

The Chair: Thank you very much, Mr. DeMarco.

I now call on Dr. Lucas to make an opening statement.

You have the floor for five minutes.

Dr. Stephen Lucas (Deputy Minister, Department of Health): Thank you, Mr. Chair and committee members, for the opportunity to appear before you today.

Joining me today are Pam Aung-Thin, associate assistant deputy minister of the health products and food branch, which is responsible for product and site licensing, as well as monitoring of advertising; and Linsey Hollett, director general of health product compliance for the regulatory, operations and enforcement branch, which supports the compliance and enforcement of natural health products.

Natural health products are used by Canadians daily to care for themselves and their families. They include vitamin supplements, minerals, probiotics, herbal remedies, homeopathic products and traditional products, such as traditional Chinese medicines. Natural health products also include frequently used products such as toothpaste, mouthwash and sunscreen. Particularly relevant in the context of COVID-19, they also include alcohol-based hand sanitizers.

[*Translation*]

In Canada, these products are regulated under the Food and Drugs Act and the Natural Health Products Regulations. Through the natural health products program, Health Canada provides oversight to ensure that the natural health products available for sale in Canada are safe and effective.

[*English*]

Overall, the audit found both strengths and areas for improvement.

The audit found that Health Canada licensed products appropriately, based on evidence of safety and efficacy. The audit also found that, when an issue was brought to Health Canada's attention, immediate action was taken.

It also identified areas for improvement, such as the need for increased oversight on the quality of natural health products, greater monitoring of labels and advertising and improving labelling compliance and enforcement activities. The recommendations validated key gaps that the department had already identified and started working on to address prior to the audit.

The audit supports the direction Health Canada is taking to strengthen the oversight of these products.

[*Translation*]

To address the recommendation to improve quality oversight, Health Canada has taken steps to require site licence applicants to demonstrate compliance with good manufacturing practices, such as by requiring test results instead of relying on an attestation-based approach.

[*English*]

In March 2021, Health Canada launched the natural health products good manufacturing practices inspection pilot to promote and verify industry compliance with the regulatory requirements through inspections of licence-holders across Canada. Results of the pilot to date are demonstrating a high rate of non-compliance and a need to further industry education as well as ongoing, proactive, risk-based oversight. In this regard, Health Canada is on track to implement a permanent good manufacturing practices inspection program to increase oversight of NHPs and better protect Canadians.

The department is building on work that began during the pandemic to expand its oversight of online advertising of natural health products to ensure that advertisements are consistent with the product license.

Additionally, the department recently consulted on a regulatory proposal to improve product labelling with the objective of ensuring that labels are clear, consistent and legible for consumers to support the safe use of these products.

In response to the audit, Health Canada indicated its intent to propose new tools to strengthen the department's ability to deter and address non-compliance, notably the extension of powers under the Protecting Canadians from Unsafe Drugs Act to natural health products. Known as Vanessa's Law, which received royal assent in 2014, this law strengthened Health Canada's ability to collect information and take quick and appropriate action when a serious health risk is identified for therapeutic products and medical devices. However, these authorities do not exist for natural health products, and as a result, we lack the authority to force a recall or a label change of a product, even in the case of a serious health risk such as contamination.

In our departmental response to the audit findings, Health Canada reaffirmed the need for sustainable and predictable funding through fees charged to industry to support increased oversight of these products. Natural health products are the only line of health products for which all regulatory activities are funded by the public. Revenues from fees would support pre- and post-market regulatory activities, including inspections of the facilities that make them.

In closing, Health Canada's priority is the health and safety of Canadians. For many Canadians, natural health products are an important part of maintaining a healthy lifestyle. Health Canada welcomes the commissioner's recommendations and is committed to the continuous improvement of the NHP program to ensure that the products sold in Canada are safe and effective.

● (1115)

[*Translation*]

Again, I would like to thank the committee for inviting me.

I will be pleased to answer any questions you may have.

[*English*]

The Chair: Thank you very much to both our witnesses.

I now turn to the official opposition.

Mr. Lawrence, you have six minutes.

Mr. Philip Lawrence (Northumberland—Peterborough South, CPC): Thank you, Mr. Chair.

I'd just like to start with a brief statement, if I could. I want to start off by saying that, in the two years I've been on the public accounts committee, this is perhaps one of the most damning reports I've read. While, as a Conservative, I have some skepticism with respect to government intervention and regulations, this seems to have set up the worst of both worlds where we are peddling to the public a false sense of security.

On the first page of the report, it says that some products were found to cause "serious and unexpected adverse reactions", including "septic shock, jaundice, and disruption of liver function", to name some of them, some of which "required hospitalization".

Instead of providing Canadians with the assurance they deserve for these products, numbers of them were unsafe, mislabelled and otherwise misleading. We are peddling, underneath Health Canada's, a false sense of security to Canadians.

With that, I'd like to start with the deputy minister, if I could. Specifically, I'd like to talk about some of the issues with respect to the withdrawal or the recall of products. I believe there were 36 out of 40 that were successfully recalled and three that were just simply unable to be recalled. Even for the ones that were recalled, it took multiple months. On average, I believe it was three months. Do you not find this disturbing, and are there any products out there right now that are supposed to be recalled and are not?

Dr. Stephen Lucas: Thank you, Mr. Chair.

I will respond and, as well, in course of my response, turn to Linsey Hollett to provide further information.

We are committed at Health Canada to working to ensure products available to Canadians are safe and effective and, in that regard, as I've noted, have accepted the recommendations of the commissioner.

Indeed, we're acting prior to the report and during the course of the audit to address a number of these areas, including increasing our good manufacturing practices inspections to ensure the quality of the facilities producing the products, and we have taken steps, including in the context of [*Technical difficulty—Editor*] and in a pilot program to look specifically at advertising to ensure that issues are addressed, in particular for—

Mr. Philip Lawrence: [*Technical difficulty—Editor*] on that. My time is brief here.

I'm talking about specifically—and would just like the public to know—if there are any products you have recalled that haven't come off the shelves, because I think it's important for Canadians to know that.

Dr. Stephen Lucas: Okay. I will make one further point before passing this to Linsey Hollett on that point.

One of the recommendations in the audit and an area that Health Canada has been working to address is to strengthen our powers for mandatory recall, mandatory labelling changes and increased fines, for example. These were not included in Vanessa's Law, which was passed in 2014, as I noted, and we are working to have those included.

Linsey, can you speak specifically to the recall issue?

Ms. Linsey Hollett (Director General, Health Product Compliance, Department of Health): Yes. Thank you, Deputy.

As the deputy said, while we don't currently have a mandatory recall power for natural health products and we are pursuing that, what I can say is that our first step when an issue comes to our attention is to mitigate risk. That can look like many different things, including a stop sale, public communications.... While all recalls that we have requested may not have been followed [*Technical difficulty—Editor*] cases we've been able to take action to mitigate the risks to the health and safety of Canadians.

● (1120)

Mr. Philip Lawrence: Just on that, since Vanessa's Law was passed in 2014, Deputy Minister, how many times have you asked the government to change the laws? Has the government responded in the, I guess, eight years now since then? How many times have you asked, when did you first ask, and what has been the government's response and when will they give you these powers?

Dr. Stephen Lucas: This is an area where Health Canada has provided advice. We are looking for an opportunity to bring those legislative changes forward to strengthen the powers as outlined and as committed to in our response to the audit of the commissioner.

Mr. Philip Lawrence: With respect, I'd like to ask specific questions and I'd like some very specific answers. When was the first time your department asked for the strengthening of Vanessa's Law to include natural health products?

Dr. Stephen Lucas: I think it was initially advice provided in Bill C-51 in 2008. It was not included in Vanessa's Law, which received royal assent in 2014. The department has been working and continues to work to see that these authorities—

Mr. Philip Lawrence: While we have Canadians exposed to unsafe products, this government hasn't done anything in the past eight years to make sure that these products get off the shelves for Canadians.

Dr. Stephen Lucas: That—

The Chair: That was a statement, so I'm going to leave it right there, Doctor. There was no question mark there.

You're out of time.

Next I'll turn to MP Bradford, please.

You have six minutes.

Ms. Valerie Bradford (Kitchener South—Hespeler, Lib.): Thank you very much.

I do share the concerns stated by my colleague Mr. Lawrence.

When I read this report, I saw that a number of red flags that the Auditor General identified.

I just want to confirm the following. I'll address this to you, Mr. DeMarco. Are licences granted without inspections actually happening of the manufacturing facilities where the products are processed and manufactured?

Mr. Jerry V. DeMarco: Our audit found that the attestation process used by Health Canada for manufacturing facilities fell short because it didn't include, as you suggest, inspections. However, in terms of the work plan and the responses put forward from Health Canada, I believe that they are committed to taking a risk-based approach to inspections. One of the three witnesses from Health Canada can perhaps confirm that.

Ms. Valerie Bradford: Thank you.

Ms. Hollett, I was wondering if you could please explain what an attestation-based approach is. What does that entail? I presume it's supplied by the actual manufacturer.

Ms. Linsey Hollett: I will invite, in a second, my colleague from the health products food branch to jump in, as that is the organization that overseas the attestation process.

What I can say, however, as has been mentioned, including by the Auditor General, is that we are indeed in the active process, and have been since 2017, of ramping up our proactive inspection activity. In the attestation process that is administered, it does include the oversight and the assessment of information submitted by a company that speaks to their adherence to or compliance with good manufacturing practices.

I will pass to my colleague who overseas the attestation process itself.

Ms. Pamela Aung-Thin (Associate Assistant Deputy Minister, Department of Health): Thank you, Linsey, and thank you for the question, Chair.

As we stated earlier, natural health products are an important part of maintaining our healthy lifestyle. Through our regulatory role, we provide oversight for safety and efficacy and quality. Before products can be sold in Canada, they are assessed before a licence is provided. This includes a review of the types of ingredients, the dosage and health claims to determine which products can be safely used by consumers.

As you noted, while the audit identified areas for improvement, I'll also note that our approach to assessing the safety and efficacy of natural health products prior to licence was found to be appropriate. The audit also found that when an issue was brought to our attention, the department took action to mitigate the risks.

I'll stop there.

● (1125)

Ms. Valerie Bradford: Right, but you don't have the power to recall currently.

This question would also follow along the review, because I understand you're in charge of supervising the claims in the labelling, etc., right? Is that correct? Okay.

Do the labels of these natural health care products currently list the ingredients?

Ms. Pamela Aung-Thin: 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.

Ms. Valerie Bradford: Okay, thank you.

Back to you, Ms. Hollett.

Getting back to the supervision of the manufacturing facilities and inspections, you've done a pilot that showed there's a high rate of non-compliance, so you're going to implement a permanent good manufacturing practices inspection program. I see from the timeline this is not expected to be in place until November 2024. Given there's such concern that there are no real regular inspections right now but instead have a process of attestation, I wonder if Ms. Hollett could address why it's taking such a long time to get regular inspections in place to ensure that these products are being manufactured in clean facilities with no contamination. I say this given that many of these products are ingested: they're vitamins, supplements, etc.

Ms. Linsey Hollett: As has been said, since March 2021 we have been and are now in the middle of a successful project piloting proactive inspections. I will mention, however, as I stated a couple of minutes ago, that we have actually been ramping up activity in the proactive inspection area since 2017. It is correct that in our commitment to the management response action plan, there is a window during which we will assess the results of the pilot, consult the stakeholders, and then determine our path forward with respect to a permanent inspection program.

However, in the interim, with the one-year pilot that we are soon concluding, between that pilot's ending and our assessing the output and consulting with stakeholders, that does not mean that inspection activity will stop. Inspections will continue. We will continue with the momentum that we built up over the last number of years, so there will not be a period—

[*Translation*]

The Chair: Thank you very much.

Ms. Sinclair-Desgagné, you have the floor for six minutes.

Ms. Nathalie Sinclair-Desgagné (Terrebonne, BQ): Thank you, Mr. Chair.

First, I would like to thank all the witnesses with us today, particularly Mr. DeMarco. He and his team did a tremendous job in producing the report.

I also want to emphasize that I totally agree with my colleague, Mr. Lawrence. He pointed out that this report reveals the erosion of our trust in the institutions that are supposed to protect us.

What I understand from the recent testimony and recent responses is that there has already been progress. I am very pleased to see it, but this needs to continue. What the report shows is that there is still a lot of work to do.

The false sense of confidence is very serious, especially at a time when science is being valued less and less. We need our institutions to be exemplary, especially Health Canada.

I'll give an example, a personal one. When I was pregnant, there was very little information about the potential effects of hand sanitizers that contained alcohol. Some people said I should not use it because it could harm my baby. Others ignored it. There was very little information on this. To be honest, I have to say that this was at a time when there was already a lot of uncertainty. The situation was far from ideal. I would have liked to have more information before buying a product. I especially would have liked to know that the product had been inspected and that manufacturing standards had been met.

What I learned from the report is that this was not necessarily the case. The impact may not be felt now, but it could be felt over the next few months or years. I hope that won't be the case.

Mr. DeMarco, can you tell us about the differences between regulations for verifying good manufacturing practices for health products and regulations pertaining to good manufacturing practices for medication?

Can you tell us more about the impact of this regulatory difference on society and on consumers?

● (1130)

Mr. Jerry V. DeMarco: Thank you for the question.

Exhibit 2.1 of our report compares three types of products: over-the-counter drugs, natural health products and cosmetics. You're right, there are differences between the three. Drugs and natural health products may have similar benefits and purposes, but they are regulated differently.

I understand that the different regulations are an issue, but I can't explain the rationale behind them. Health Canada officials should explain it to you.

Ms. Nathalie Sinclair-Desgagné: Thank you.

What would happen if natural health products were regulated in the same way as drugs? Could there be an upside to that?

Mr. Jerry V. DeMarco: I'm sure Health Canada can answer that.

It's not that the department failed to approve the recommendations. In this case, the department agrees with the recommendations. Health Canada's report and research show that issues have come up, and the department is aware of them.

The deputy minister himself stated that Health Canada was working on amendments to the legislation that will modernize the program.

The Chair: You have 30 seconds left.

Ms. Nathalie Sinclair-Desgagné: I will go ahead and ask my question even though Health Canada officials will not have enough time to answer in the 30 seconds I have left. This will give them some time to think about why the regulations are so different.

I know that a pilot project is currently under way, but why haven't the regulations been implemented yet?

The Chair: Thank you very much.

● (1135)

[*English*]

MP Desjarlais, you have six minutes, please.

Mr. Blake Desjarlais (Edmonton Griesbach, NDP): Thank you very much, Mr. Chair.

I want to thank the members of the committee who've already spoken. I think they've addressed some good points. I know that our colleague Mr. Lawrence—he's not here—mentioned his advocacy for the quality of the report here and how damning it truly is. I think it's of serious concern to this committee to know that these reports in fact can reveal devastating facts about our public service and the areas that need to be improved.

Right from the audit period from February 2017 to December 2019, there was also an extension, I understand, for two months to look at new products and site licences approved between April and May o 2020.

I'd be remiss, as a member of the New Democratic Party, if I didn't mention my concern with the fact that the Office of the Auditor General has workers on strike outside of our office, outside of this meeting. I'm growing more and more concerned about the impact of keeping those workers locked out of the Office of the Auditor General and the relationship it has to the quality of these reports, especially as it relates to the comments by my colleague Nathalie on trust in institutions. We need to be able to trust the Office of the Auditor General and these reports.

Although I do believe this report to be of good quality, I'm growing more and more concerned about the fact that we have over 100 employees of the Office of the Auditor General outside our office right now who can't do the quality of work that we expect this committee to do. I'm concerned about that. I think it's a very legitimate concern.

Many, many people are concerned about our work here. They're concerned about the potential impact of not being able to have the credible reports that this committee needs in order to do the work that this country has done for over 150 years. These reports, I believe, have everything to do with how we understand our role at public accounts. The trust of this institution is so important. The work we do at this committee is some of the most important work this country can do on behalf of Canadians.

I admire and respect every single member of our team, not just my colleagues around this table but also my colleagues who also work in the Office of the Auditor General. I respect that work. I just need to know, as a member of this committee, whether or not any future reports coming to this committee, including this one, especially during the period between April and May 2020, are impacted by the workers being locked out right now. Can we expect delays to the quality of our reports moving forward if all of this continues?

Mr. Jerry V. DeMarco: Thank you for the question, and also for the endorsement of the important work of this committee as well as our office. We have a great team at the Office of the Auditor General. As commissioner, I'm an integral part of the Office of the Auditor General.

We are looking forward to a new mandate regarding the labour negotiations from Treasury Board next week. The labour disruption has proceeded for a long time, and we do foresee delays in our work, including delays for upcoming publications of audits. We will not be issuing substandard work, though. If there's an impact on our work, it would be to delay the release of reports rather than to issue reports on time that are not up to audit standards.

So there is a disruption to our work, but it will not result in our publishing or tabling with Parliament substandard work. I can assure you of that.

Mr. Blake Desjarlais: I want to thank the commissioner for that answer.

I think it's very important that this committee understands what the commissioner said. There will be an impact and delay to our work, to a committee as critical and important as this, because of the fact that we're not respecting workers.

I do want to really thank the Office of the Auditor General for the work it's doing and for the advocacy to ensure that Treasury Board does its part. I do believe the Office of the Auditor General, from speaking to members there, has done the best it can to ensure that a fair deal is reached. It's very critical, to the point that the commissioner mentioned, that the Treasury Board does its job too so that we can restore confidence in this committee and restore our schedule.

As was mentioned by the commissioner, there will be a delay. We need to get on top of this. This should be a non-partisan issue. We need to protect our institutions. We need to protect the people who work at the Office of the Auditor General. We need to make sure that we have a report in a timely fashion so that all Canadians can ensure that this institution continues.

I want to thank you, Commissioner, for your honest answer and for your support in ensuring that we come to a swift and good conclusion on behalf of everyone at the Office of the Auditor General and we no longer incur the delays that you have cited.

I have one minute left, so maybe I'll just mention this quickly for an answer in the next round. I want to touch on the idea of traditional medicine and how important traditional medicine is for indigenous people. The regulation of it is something of concern. Regulating traditional medicines and how medicines can be sold or even put on the market is concerning to indigenous people. I'll elaborate more later.

Thanks so much to the commissioner.

● (1140)

The Chair: You still have 45 seconds.

Mr. Blake Desjarlais: Well, in that case, I'll continue my question on traditional medicines.

When traditional medicine is considered for the purposes of ensuring that indigenous people have access to these products, there's also the fear that these health products could be appropriated by non-indigenous people to exploit our traditional understanding and our way of using these medicines in a sacred and reciprocal way.

There are huge concerns with the regulation of how we post these on the public market. Indigenous people do not want to see non-indigenous people harvesting these and then creating exclusive zones, where these products can be put on the market for purchase.

Indigenous traditional medicine needs to continue to be excepted, and needs to continue to be unregulated in the sense that indigenous people have been regulating it in a way that is traditional to our own understanding and ways moving forward.

I would like to have some clarity. I know we probably won't have enough time here, but how can we protect that, and how is this law, that we're debating in relation to the principle of 2014, related to this?

The Chair: Thank you.

Again, just to remind everyone, this will be Dr. Lucas' last round. There will be a quick question after this round for Dr. Lucas. I don't want to interfere, but it's coming from the analyst, so it's worth raising.

MP Patzer, you have the floor, for five minutes.

Mr. Jeremy Patzer (Cypress Hills—Grasslands, CPC): Thank you.

I'm wondering if there's about a 30-second answer to the last statement that was made by my colleague from the NDP just to finish that point. Is there anything that you guys want to comment on about traditional medicines?

Ms. Pamela Aung-Thin: I will speak briefly to it, and then I'm happy to come back to it.

In terms of non-traditional medicines, including indigenous medicines, homeopathic products, and others, how a retailer chooses to group the products is outside of the purview of Health Canada. We recognize that there is an abundance of choice, when it comes to what we call “self-care products”. Knowing which product to purchase for oneself and one's family can be challenging.

In an effort to provide better support, we are proposing the changes to improve natural health product labels so that they're clear and legible. I can come back with more detail on that, and more specifically on indigenous traditional medicine, when we have more time.

Mr. Jeremy Patzer: Thank you.

Go ahead, Dr. Lucas.

Dr. Stephen Lucas: I'm going to indicate that the regulations pertain to products that are sought for sale. For products, such as traditional medicine, where a community or indigenous group harvests and uses them and are not for sale, they would not be subject to regulation.

Mr. Jeremy Patzer: Thank you for that.

I guess this question is more for Health Canada. Over 70% of Canadians are regularly using natural health products. Why aren't the penalties higher on those manufacturers who fail to meet Health Canada's standards? Both you and the report have mentioned that you cannot force a recall of a product, and you are not notified when a new product enters the market. The maximum fine for violating the law is only $5,000. It just seems like it's not a large enough deterrent to stop the bad actors from violating the rules that have been imposed.

What are your thoughts on that?

Dr. Stephen Lucas: As I indicated, and as is outlined in the report, Health Canada does believe and will seek the opportunity to include in Vanessa's Law natural health products, such that those increased fines and other powers, such as product recall, can be granted.

In regard to information on when products are brought to market and requirements for site license information for quality review, we are taking steps now and have been taking steps to strengthen that, as my colleagues have noted. We'll be making modifications to the regulations to build in those requirements. On the side of notification and the site licence information, those would be regulatory changes, but we are taking steps in advance of that at this time.

● (1145)

Mr. Jeremy Patzer: You say that you will be asking for that. Are there any timelines for when that's actually going to happen? This report has identified many flaws, but one for sure is, how do you deter people from taking advantage of Canadians?

You said you will, but when is that going to happen? Is there a timeline in place for when that's going to happen? What assurances do we have that this is actually going to take place?

Dr. Stephen Lucas: I think the department's commitment, as outlined in the response to the audit report and our management response in our testimony today, clearly commits us to seek the legislative change needed to add natural health products to Vanessa's Law and we will seek the earliest possible opportunity to do that in consultation with central agencies and others to enable that legislation to move forward as quickly as possible.

Mr. Jeremy Patzer: Okay. For lots of regulations, there's a mandatory review time frame. Is there one in place for Vanessa's Law, or is this something that is basically just left up to your department to do whenever it sees fit?

Dr. Stephen Lucas: Mr. Chair, I'm not aware of a mandatory review time for Vanessa's Law specifically, but as I indicated, we are committed to having that legislative change made as quickly as possible. The decision was made at the time to not include natural health products, and we want to see that change made at the earliest possible opportunity.

The Chair: Thank you, Mr. Patzer.

MP Dong, you have the floor for five minutes.

Mr. Han Dong (Don Valley North, Lib.): Thank you very much, Chair.

I want to thank all the witnesses for coming today.

The way I look at this study is the same way I look at most government regulations: On one end, you have the consumer benefits, so the safety of consumers. On the other hand, you have a thriving market that includes the producers, importers and retailers. I think somewhere in the middle would represent consumer choice, alternative medicine, affordability and the thriving market.

I do want to say that I was in Japan and Hong Kong. I know this industry has been thriving in Korea and Taiwan for many, many years. Mainland China is picking it up as well. I see signals in Canadian markets. Especially in big urban centres like Toronto, these shops are opening up. Obviously that's a sign that there's a market for it. If you go into Loblaws or Metro or these franchise chains, you will see this product on the shelf, so it is actually very important for us to get ahead of this and to take a look at the licensing and inspection.

I have questions on licensing. Just help me to understand the process here. First of all there is a lot being talked about manufacturing domestic products. What's the requirement for import products when it comes to licensing?

Maybe the deputy minister can start.

Dr. Stephen Lucas: Certainly. I'll provide an initial response and then turn to my colleague Pam Aung-Thin for further information.

Product licensing requirements are requirements for all products that are intended for sale in Canada whether they're manufactured in Canada imported. Those include requirements in terms of the safety, efficacy and quality of those products. In regard to the findings of the audited areas in which Health Canada has been taking and will continue to take action and strengthen our work, we are strengthening the information required that is associated with the quality of products as part of that pre-market or pre-licensing review. That includes moving from an attestation system in which that product site licence meets specifications to one in which we are seeking test results in terms of product quality and further notification. We will be building that into our regulations, but it's a practice that we're implementing now, as my colleagues have outlined.

● (1150)

Mr. Han Dong: Thank you.

It sounds to me as though it's a bit easier to understand when it comes to domestic products because you have a manufacturer you can go to and a supply chain you can trace. However, when it comes to import products, do you just depend on the ingredients, the information the importer provides, or is there actually a requirement for a Canadian institution to test them to see the actual ingredients or proper labelling? Can you shed a light on that and tell us how long that period usually takes?

Dr. Stephen Lucas: I'll turn to Pam with regard to the free market review, and Linsey on the site inspection, where we do some on-site visits and work with other regulators internationally where we have trusted relationships to use their reviews.

Pam, please start.

Ms. Pamela Aung-Thin: Thank you, Deputy Minister; and thank you for the question.

For imported products, companies require a site licence to import those products. This is to ensure that the products meet the standards set out in regulations. The importer also needs to provide evidence that any foreign manufacturer meets good manufacturing practices.

In terms of the regulations we've put in place, they respect the range of cultural and philosophical diversity that underlie the broad range of products. You named a number of products in this space. Our regulations were informed by recommendations of the Standing Committee on Health.

For the second part of that question, I'll pass it on to my colleague Linsey.

Mr. Han Dong: Okay. Go ahead.

The Chair: Could you just keep it very short, please?

Ms. Linsey Hollett: Thank you. It will be very short.

I will add that, for many of the reasons you mentioned, importers are actually a huge focus of ours in the inspection pilot and will continue to be. As we move towards a more permanent program, half if not more of those we are inspecting for compliance with regulations are importers.

Mr. Han Dong: How long does the licensing period take?

The Chair: I'm going to have to ask you to come back on that question.

Mr. Han Dong: Okay. I'll ask it later. Thank you.

[*Translation*]

The Chair: Ms. Sinclair-Desgagné, you have the floor for two and a half minutes.

Ms. Nathalie Sinclair-Desgagné: Thank you, Mr. Chair.

Mr. Lucas, further to my last question, what would be the impact of any potential negligence in auditing and inspecting sites prior to their operation?

Dr. Stephen Lucas: I'll start by saying that Health Canada takes its responsibility to respond to all complaints and consider all available information very seriously. Our approach is to be reactive to information.

Ms. Hollett can provide further details, but I can say that we're working on a more proactive inspection system to target very high-risk products, like those claiming to treat cancer.

Ms. Hollett, I'll turn it over to you.

[*English*]

Ms. Linsey Hollett: Thank you.

We've had quite a robust for-cause inspection activity or program for some time now. That has always been very risk-based, and as the deputy minister shared, moving forward on all our proactive activity will also be risk based. We look at a fair number and a consistent set of criteria, including at the top, of course, imminent risk to public health and safety. We have a robust triage system that ensures that where we put our focus, but also where we put our highest service standards such as time to first action, is risk-based, ensuring again that we deal with the highest risk situations in a timely and immediate fashion in most cases.

● (1155)

[*Translation*]

The Chair: I'm sorry, but you're already out of time.

[*English*]

MP Desjarlais, you have two and a half minutes.

Go ahead, please.

Mr. Blake Desjarlais: Thank you very much, Chair.

I want to thank my colleague from Cypress Hills—Grasslands for helping to answer my last question related to traditional medicines. I appreciate the answer that was given related to the specific differentiation between indigenous people harvesting the medicine and sharing that medicine among the nation, and having the ability and support from the government to do that effectively and efficiently. I want to thank you for that very clear answer.

The sale of indigenous medicines—to put it more clearly, the sale of indigenous medicines by non-indigenous persons—would amount to appropriation in many ways and, in some sense, an abuse of the use of these sacred medicines. How do we find ways to warn people or create an environment where those who are seeking indigenous medicine go to indigenous people, rather than to Walmart or some big box store, where they're going to buy a whole package of sweetgrass and then never learn the importance and value of this medicine? It allows for the disenfranchisement of indigenous peoples and the understanding of how we use and apply those medicines in a good way.

It's akin, in some sense, to the abuse of over-the-counter prescription drugs. When you have those prescription drugs for the purposes of very specific things and ailments in western culture—let's say sleep medication—it's abused, oftentimes, for other purposes.

How do we make sure that the indigenous medicines that are for sale and that may be for sale by non-indigenous people are being regulated?

Dr. Stephen Lucas: I'll provide some brief comments and turn to Pam for any further comment.

The member raises an important point [*Technical difficulty—Editor*] indicating the importance of a broader, more holistic approach that not only includes those specific requirements in the regulations to ensure the safety, quality and efficacy of products—both before they get on the market and while they're on the market, as we've been discussing—and clarity in labelling, such as our labelling regulations, which were published in June 2021 and will be finalized this coming spring. It's also important in terms of advertising and awareness.

There is a public education dimension to this, which we think is an important part of the program. We want to continue to work with partners, including indigenous partners, in that regard.

Pam, I will turn to you on these important considerations.

The Chair: Pardon me. I'm going to have to come back to you, Ms. Aung-Thin. I'm afraid we're out of time. If the question pops up again, hopefully, we'll hear from you.

We're turning again to MP Patzer. You have the floor for five minutes.

Mr. Jeremy Patzer: Thank you very much, Mr. Chair.

Commissioner, I'll get your response on this first, and then if Health Canada wants to respond, as well, you guys are free to do that.

One thing I find really interesting is a bit of a theme throughout the report as follows. The end of paragraph 2.6 reads:

> However, the primary responsibility for the safety and efficacy of products and manufacturing sites rests with the industry.

We start seeing other stats and information, like in paragraph 2.32, which reads:

> ...88% of these products were advertised with misleading product information. Also, 56% of the products we examined were marketed with misleading label information...

A lot of these products must have a Health Canada stamp of approval on them. Am I correct in saying that?

To see that there's such a discrepancy between their advertised uses and what they actually accomplish despite having a Health Canada stamp of approval on them.... Are there any concerns from the department and from the commissioner on that?

If the commissioner wants, he can go first.

Mr. Jerry V. DeMarco: We definitely have concerns about the accuracy of the label and whether the contents of the package match what's been licensed. It's all the more challenging with consumer choice now being carried out in the Internet marketplace, as well as on store shelves. There are some challenges.

It's impossible, with 91,000 product licences out there, and who knows how many of those are actually marketed.... There's no comprehensive list of how many of those licences have come to market. With that amount of products, Canadians can't rely on the *caveat emptor* approach to this. We need Health Canada to guarantee the safety of these products. That is its mandate with respect to natural health products.

The report revealed our concerns with regard to that. The response, as well as the work plan of Health Canada, I think will go at least partway to addressing some of those concerns. They're not wholly within its control, though, because some of the responses signal the need for a legislative change.

● (1200)

Mr. Jeremy Patzer: Then, Health Canada, what are your thoughts on seeing that 88% of products advertised have misleading product information, yet had the Health Canada stamp on them? What do you think of that?

Dr. Stephen Lucas: Mr. Chair, in response, this is an area where we were taking action prior to the report, and have done so subsequently. We think it is critically important that the products are not only reviewed by Health Canada's commissioner...tested in a report, and that the pre-market review of safety and efficacy is done well and appropriately, but also that while they're on the market, it be ensured that Canadians accessing them can feel comfortable that they are safe, effective and of high quality.

We have gazetted, in the spring of 2021, labelling regulations to improve the quality and readability of information required, including dosage and warning information. Those will be finalized this spring. We have moved to proactive monitoring of advertising, including online, both for COVID products and, as I'd mentioned, for NHPs with cancer-related claims. We are going to be broadening this. We're taking steps to strengthen our ability to do this as well through increased resources by bringing in cost recovery from manufacturers and licence-holders for natural health products to strengthen our ability to provide this post-market oversight.

Mr. Jeremy Patzer: Okay. Thanks for that.

To Health Canada as well, paragraph 2.23 of the report refers to trusting or working with inspections “performed by domestic and regulatory authorities from other countries when licensing these sites.” What assurances do Canadians have that the standards of these other countries are the same as Canada's? What work has been done to ensure that that level is there.

The question for the commissioner is this: What needs to be done to ensure that those standards are met? Perhaps Health Canada wants to start with that one.

Dr. Stephen Lucas: Mr. Chair, I'll start with that and turn to Linsey. We have a rigorous system of developing mutual recognition agreements with other regulators so that we have assurance that the standards they're inspecting to and their inspections methods conform with and are equivalent to those of Health Canada. Linsey can give you the practical experience of how we effect that.

The Chair: I'm afraid we're going to have hold off on that.

I'm moving through in a timely way here, so that we will have time for the fourth round, everyone. You'll be able to have the time to come back to these important questions.

I turn now to Ms. Yip. You have the floor for five minutes, please.

Ms. Jean Yip (Scarborough—Agincourt, Lib.): Thank you.

I would like to commend Health Canada for responding so quickly and flexibly on products like hand sanitizers to help limit the spread of COVID. I do believe it did help educate the wider public and also to give them some comfort.

My first question is for Health Canada. If claims to cure and treat cancer are forbidden under the Food and Drugs Act, why would some claims of products preventing cancer be allowed? I think that's dangerous and misleading to the public?

What types of preventable natural health products are allowed?

Dr. Stephen Lucas: Thank you. Perhaps I'll turn to Linsey in responding to that.

Ms. Linsey Hollett: With respect to the first part of that question, I can say that from a compliance and enforcement standpoint, when we look at issues, including labelling issues, what we find is that lots of companies are in non-compliance, or in contravention, with their market authorization. As the member says, it is something that's not allowed under our legislation, nor would their market authorization allow them to make a claim, but in some cases, you still find the claim. Then, they are in direct contravention with the Food and Drugs Act and the regulations, and that is where our compliance enforcement would come in, including such tools as stopping sales, seizing product, and public communications. That would be in contravention of a market authorization, the act and the regulations.

Deputy, I think I will ask Pam if she would like to add anything.

● (1205)

Ms. Pamela Aung-Thin: Thank you, Linsey.

I will just respond by saying that examples of natural health products to treat cancer are certainly very rare. That being said, there is a wide category of products. One example is sunscreen, which is used in conjunction with other prevention activities for the prevention of skin cancer.

Ms. Jean Yip: Thank you.

During the pandemic, Canadians turned more to online purchases. More than one quarter of 75 licensed products did not show they had a natural product number. Also, it's something that I think the public really relies on: If they see this natural product number, it will help give them some sort of confidence in a product. However, there isn't such a requirement for this number to appear online. Can you clarify if there will be a requirement on how online products will be regulated with this number?

Dr. Stephen Lucas: I'll turn to Pam to speak to our labelling regulations and this question specifically.

Ms. Pamela Aung-Thin: 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 tool. There is work that is under way.

Ms. Jean Yip: Could you give further examples of some of the AI tools being used?

Ms. Pamela Aung-Thin: I don't have the specific name of the actual AI tool, but we've been testing and piloting different ones that are available to do that online monitoring so that we can move from a complaints-based response to a more risk-based response moving forward.

The Chair: Thank you.

Just at the chair's discretion, I have questions from our analysts here.

Dr. Lucas, could you or someone on your team help us with two questions? On page 1 of your management response and action plan, it states, “Dependent on the approved recommendation(s), seek regulatory amendments”. That quote then continued.

Our two questions are as follow. First, which recommendations are you referring to? Second, what is the process to seek regulatory amendments?

Thank you.

Dr. Stephen Lucas: Mr. Chair, I'll speak to the second question, and then, after I've done that, one of my colleagues—perhaps Pam—can speak to the specific part of the management response.

In terms of the process to seek regulatory amendments, 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.

Pam, in regard to the specific point the chair raised about the management response, I'll turn to you.

● (1210)

Ms. Pamela Aung-Thin: Yes. Thank you for the question.

We are assessing the tools that are required for the pre-market to strengthen our oversight. When we were developing the MRAP, we expected that they would include changes that require regulatory amendments. We're finalizing those recommendations now and we'll be working towards bringing forward a regulatory proposal. However, just to reiterate the deputy minister's response, we are certainly continuing to move forward our regulatory proposal specific to label changes.

The Chair: Thank you very much to the two of you. I'm getting a thumbs-up from our team here, so I appreciate it.

Dr. Lucas, I know you might well sign off any moment now, so I do want to thank you for appearing today. I know we're in good hands with your two associates.

I'm now going to turn to our third round. To kick it off for the Conservatives is MP Patzer, please.

You have five minutes.

Mr. Jeremy Patzer: Thank you very much, Mr. Chair.

My question is to Health Canada. How many people have you fined $5,000?

Dr. Stephen Lucas: Mr. Chair, I'll pass that question to Linsey Hollett.

With the chair's recognition of my schedule, I will sign off at this point and thank the committee very much for the opportunity to appear on this topic. We're certainly committed to keeping the committee updated as needed on our progress in addressing these important findings and recommendations.

Linsey.

Ms. Linsey Hollett: Thank you, Deputy Minister; and thank you, Chair, for the question.

As to the exact number since the inception of the program in 2004, I will have to commit to getting that information back to the committee. What I can say is that in deciding which cases would go that route, and by that, I mean prosecution, and if successful, in fines, is something we administer very closely with the Public Prosecution Service of Canada. It is not a space in which we act alone. They are the ultimate decision-makers.

However, with respect to the member's question, I can commit to getting the exact number post-meeting, if that is acceptable.

The Chair: It is. Thank you.

Mr. Jeremy Patzer: Yes, we would definitely like that number, because the report points to it. You guys have acknowledged that changes are needed. We've had no assurances of when those changes are going to happen and we don't have any kind of sense of urgency on when this is going to happen.

Again, when we're seeing things such as, literally, every single site had issues but it's only a $5,000 deterrent for having contaminants in your product, what is the level of the sense of urgency to actually get some real, strong deterrents and actual teeth that are going to prevent bad actors from taking advantage of Canadians, who quite frankly are having negative experiences?

There are people who are taking products out that they're thinking are going to help them with cancer but in some cases aren't. What are you guys going to do and what is the level of urgency to make sure that we actually get real teeth to prevent these bad actors from taking advantage of vulnerable Canadians?

Ms. Pamela Aung-Thin: Thank you for the question. I can start off and perhaps my colleague Linsey can add in anything she wishes.

As we outlined earlier, there are a number of recommendations in the report and we have agreed with all five of them. I'll also add that leading up to the report there already had been work started, and that was clearly under way to tackle some of the gaps that came out later in the report.

I think the deputy minister covered fairly extensively earlier that we continue to pursue legislation through Vanessa's Law to provide additional protections for consumers, and that follow-up continues fairly vigorously as we work with our colleagues not only internally but with central agencies to move that forward.

Linsey.

● (1215)

Ms. Linsey Hollett: Thank you, Pam.

With respect to a sense of urgency, I will just point out—and hopefully it will be helpful to the committee—that we really come at regulated parties and issues of non-compliance on two fronts. First and foremost, always, is mitigating risk to safety. Once that is done, we look at punitive measures, and that's where we come in with prosecutions and fines.

As was said, in all respects, we are looking to bolster our tools and our authorities, but certainly in that first instance of assessing risk proactively to Canadians, we do feel a sense of urgency. That is why you see the inspection pilot program. That is why we will continue inspection activity while we are assessing the pilot to keep momentum going, because we do agree with the member that there is a need to do more in this space.

Mr. Jeremy Patzer: Really quickly to the commissioner, from your findings, is $5,000 enough of a fine or should it be higher?

Mr. Jerry V. DeMarco: 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.

The Chair: Thank you very much.

We're turning now to MP Fragiskatos.

You have the floor for five minutes. Go ahead, please.

Mr. Peter Fragiskatos (London North Centre, Lib.): Thank you very much, Chair.

I'm just looking at the report. I just want to get clarification where it says—and I'm quoting now—"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." Why is that?

If you go into the substance of the report, it does say that, "Health Canada can enforce product and site-licence conditions for natural health products", and it gives examples, "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." Those are substantive, but why is there no authority to change a label, or force, say, a mandatory recall? Is that a legislative gap? What does that relate to?

Ms. Pamela Aung-Thin: Thank you for the question. I can start, and certainly turn to my colleague Linsey if she has anything to add.

Certainly that was well documented in the report and is something that we are very conscious of and that we are responding to. In one response we indicated that we would be seeking Vanessa's Law powers for natural health products, which will allow us additional authorities, some of which you have outlined.

In terms of some of what we call post-market activities, perhaps I'll turn to Linsey.

Ms. Linsey Hollett: Thank you, Pam.

Thank you, Chair, for the question.

As the member suggests—and I will speak specifically to recalls—that is, as Pam says, a legislative issue that we are looking to fill. From the list that the member read out, one thing you may have noted was requesting voluntary recalls. Because that is there specifically, that is all we can do.

However, I will say, having now run the program for close to 18 years, that although it says "voluntary recalls", we in many cases have great success in working with a company when making a voluntary request. In the small number of circumstances in which that is not successful, we are able to use one of the harder-hitting tools that you've heard mentioned a couple of times this morning.

● (1220)

Mr. Peter Fragiskatos: Thank you very much.

There are a number of recommendations, but one of the most important reads as follows, “Health Canada should, for licensed natural health products on the market, including on the Internet, take a risk-based approach.” I understand what the Auditor General has said there, but how does Health Canada define “risk-based approach” in relation to this recommendation? Where is the progress on this particular recommendation, as well? That's for whoever wishes to take it.

Ms. Linsey Hollett: Maybe I can start, Pam.

Thank you, Chair, for the question.

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. Perhaps it's a vulnerable sub-population or something of that nature. We will look at the compliance history of the party we're dealing with.

What we do to ensure it is risk-based is to consistently apply those criteria. That dictates what action we take and how quickly. It really directs all of our decision-making.

Pam, do you have anything to add?

Ms. Pamela Aung-Thin: Yes. Thank you, Linsey.

I will add a little bit more to that, because there was also a component in the report that talked about a risk-based monitoring program to identify unlicensed products and take appropriate action. This is a recommendation that we agreed with.

We maintain a complaint-based program for regulatory advertising compliance oversight. We also recognize that an additional risk-based approach is required so that we ensure unauthorized activities are prevented or stopped. We are implementing this risk-based approach to monitor advertising, and we are taking steps to propose new tools that will strengthen our ability to do so.

I mentioned some of those earlier. We ran a pilot—

The Chair: I'm going to stop you right there. Thank you.

We have the transcript, so we can refer to that. Thank you very much. I apologize.

[*Translation*]

Ms. Sinclair-Desgagné, you have the floor for two and a half minutes.

Ms. Nathalie Sinclair-Desgagné: Thank you, Mr. Chair.

I'd like to follow up on my colleague Mr. Fragiskatos's very good question. The risk mitigation approach is excellent, especially given the serious health risks. That's the most important factor.

I understand that other factors come into play, as our witnesses have clearly outlined. However, the medium- and long-term effects of certain products are to a large extent unclear, especially for more vulnerable groups like pregnant women. Very little information is available on the medium- and long-term effects that natural health products could have on pregnant women.

Is a risk mitigation strategy sufficient? Shouldn't a preventive strategy be developed instead?

That is still not the case, it seems. The products and manufacturing sites are not being inspected. No strategy has been put in place to prevent risk rather than trying to mitigate risk based on complaints. We need to ensure that all, or at least a reasonable sample, of the products that come to market in Quebec and in Canada are inspected to protect the health of Quebeckers and Canadians.

What guarantees do we have?

The question is for Health Canada officials.

Ms. Pamela Aung-Thin: Thank you for the excellent question.

We subject all natural health products that are on the market to some kind of oversight to ensure they are safe to use. If any risks are identified, we make sure that warnings are issued to the public, and we work very closely with the companies to ensure that labels are updated to reflect those risks.

Ms. Hollett, do you have anything to add?

● (1225)

[*English*]

Ms. Linsey Hollett: Thank you, Pam.

I would agree with the member, in that in our world, it is often much easier to identify and assess the immediate risk. Medium-term and longer-term are more in-depth processes.

However, in what you see in our management response action plan, I think there is a theme that goes throughout. There are multiple actions to gather more information so that we at Health Canada have more information about the products on the Canadian market.

That will have multiple benefits and uses, but certainly one of them is to inform a medium- and longer-term picture of the risks, as the member mentioned.

The Chair: Thank you very much.

We will turn now to Mr. Desjarlais.

[*Translation*]

Mr. Desjarlais, you have the floor for two and a half minutes.

[*English*]

Mr. Blake Desjarlais: Thank you very much, Mr. Chair.

I want to, again, thank the witnesses for their very important discussion on how we make sure that these products continue to be regulated in a safe and effective way. There's room to ensure that we have a fair understanding, as a committee, as to how we can continue to do this better. It's very clear here that there's much improvement that's required to the system.

I understand, just from our discussion today, that it partly has to do with the lack of legislation. It has to do with a lack of authority in particular areas of jurisdiction that your department would like to see in order to empower itself to make these things more credible. I hear that point.

In terms of when we look at licensing and labelling, I was part of a process in Montreal that looked at the intellectual property of indigenous artists. That's also a very unregulated field. We have seen a huge abuse of indigenous people by non-indigenous people copying, creating fakes, or pretending to create art and selling that art across the country, particularly in Quebec, at enormous prices.

The Inuit community, of course, in collaboration with the Government of Canada came to an agreement that helped to enforce justice for the Inuit community, making this better by instituting a label that was a qualifiable label of Inuit quality. It was a quality stamp.

When I think of this process and best practices, and the fact the government has this procedure for art, can it employ procedures like this for labelling to make sure that indigenous people and others who want to enjoy indigenous products understand that these have been ethically sourced, understood, and handled in a good way? Is that something the department has ever thought of doing, in collaboration with indigenous people, in labelling protection?

Ms. Pamela Aung-Thin: I can perhaps take that one. It's a very important issue. I commend the work that's being done in the intellectual property space.

For natural health products, and in particular for products that are more traditional in nature, including indigenous traditional medicines, as I mentioned earlier, we only label those that are for sale in outlets that require labels.

Our realm of authority is limited to health and safety and to claims that are made on those products. It doesn't, unfortunately, extend to some of the broader issues that you are mentioning. We certainly hear your concern. We'll continue our work in terms of the actual [*Inaudible—Editor*] recommendations in ensuring the health and safety of Canadians through these various programs.

The Chair: Thank you very much.

I'm turning again to the official opposition.

Mr. Lawrence, you have five minutes.

Mr. Philip Lawrence: Thank you, Mr. Chair.

My first questions will go to the commissioner. I bring to your attention paragraph 2.45 on page 13 of your report. It states that "The department found problems at all sites,"—there were 35, as mentioned in the previous sentence—"including the use of expired raw materials, unacceptable amounts of contaminants, and product tests that did not confirm the product expiry date."

I have a simple question for you, Commissioner. Is that concerning?

● (1230)

Mr. Jerry V. DeMarco: Yes, it is concerning. That was just a sample of 35 companies. If that situation holds true for many of the others that aren't inspected, then it implies that the situation is of a larger concern than mentioned in the sample. Yes, it is a concern. Health Canada can speak to how it is going to respond to those findings, and recommendation 2.47.

Member Desjarlais raised an issue a few times, and I don't think it's been addressed. I want to point him to the Nagoya Protocol on access and Benefit-Sharing under the UN Convention on Biodiversity. There's a huge international debate about the issues of biopiracy, bioprospecting, scientific imperialism, and so on. It's very important in the Canadian context. That's just so it doesn't appear that this issue has been left unaddressed.

Mr. Philip Lawrence: Thank you.

Mr. Chair, I assume I'll get some of Blake's time for that answer. I'm just kidding.

The Chair: You still have some time.

Mr. Philip Lawrence: Thank you for that response.

To the health department, when will this issue be resolved and could you also explain, if you could, what expired raw materials and contaminants were found by these inspections of 35 manufacturing plants?

Ms. Linsey Hollett: Maybe I can take that one.

I would like to say, to use the member's terms and to support what the Auditor General said, that we do find those concerning. It is not at all unusual to make observations during any kind of inspection. In fact, in the vast majority of inspections, there would be observations. However, when they are of the nature of the sample that the member cited, then that is when, from a compliance and enforcement perspective, you are at the top level of addressing that—at the top level of response in terms of time, in terms of the tools we use and the severity of the actions we take to mitigate risk to health and safety.

As for when that issue will be addressed, I'm assuming that the issue we're talking about is addressing the most serious observations that were cited during inspections. I can say that observations cited in inspections that are included in the scope of that report have been addressed with the companies. Again, I know I've mentioned it before—

Mr. Philip Lawrence: I have a question on that. My apologies for cutting you off, but my time is short. Of those 35 companies, how many had their manufacturing licences suspended?

Ms. Linsey Hollett: I will get the exact number for the committee. We have numbers of actual suspensions but also intentions to suspend. I would want to give accurate information so we can commit to get that for you.

Mr. Philip Lawrence: And just for clarity, it does say in here that there was a notice of intent, I believe, for half. It does say that, but I was just wondering how many were actually suspended just for clarity.

The other question I have for you—and if you don't know, I would appreciate a written response—would be how many inspections were performed in 2020, 2021 and the first three months of 2022? On that, how many suspensions were there?

Ms. Linsey Hollett: Again, I can give you the number of inspections. In terms of licence suspensions, I will commit to get that information quite quickly after the meeting.

In 2020, we had not yet launched our pilot, but we did do what would be a "precursor" or a mini inspection program, if you like. They are cited in the report and are called "compliance monitoring projects". There was one in 2020. That would have been 17 inspections, I believe, 17 to 18. In 2021, we would have launched our pilot, which carried over into the first three months of 2022. That included 36 inspections, the last couple of which we are in the process of wrapping up before March 31st.

● (1235)

The Chair: Thank you. The committee looks forward to receiving the information that was requested.

We turn now to Ms. Shanahan.

You have the floor for five minutes, please.

Mrs. Brenda Shanahan (Châteauguay—Lacolle, Lib.): Chair, I am giving my spot to Mr. Dong. .

Mr. Han Dong: Thank you, MP Shanahan, and thank you, Chair.

I'm going to go back to my last question on the time frame for processing a licence application. How long does it take? I'm talking about for domestic products and for imports as well. I recognize there might be a difference. If you don't have this information, can you send it to the committee afterwards? Okay. That would be great.

I have a very small question about labelling. Is there an emphasis put on ingredients that might potentially be allergens? Allergy is a very risky thing. Both of my kids have severe allergies. Is there attention paid to that?

Ms. Pamela Aung-Thin: Yes, absolutely. Allergens—yes.

Mr. Han Dong: Okay.

In terms of inspection, I think we really should differentiate between inspecting the manufacturing facilities and inspecting the retail facilities. I just want to talk about the retail facilities. Can you explain to me how these inspections are carried out? Is it carried out by an actual officer showing up at the door and looking through the product, or is it in written form?

Ms. Linsey Hollett: I can take that question.

Just to clarify, when we do inspections, they are focused on entities that conduct an activity for which you need a Health Canada licence. Right now, inspection programs—the one being piloted for natural health products but also more mature inspection programs we have—including for drugs, do not include retail inspections.

Especially during the pandemic, we have worked quite closely with the retail community—for example, on the hand sanitizer file—so there is a relationship there, but the inspection program I've been speaking of this morning and the pilot do not include retail inspections.

Maybe the last thing I can add is that for those that we do inspect, what that looks like is an announced, planned inspection on a date that is agreed to with the regulated party. We do unannounced inspections, but that is more on the reactive side—inspections for cause.

Mr. Han Dong: Okay. I just want this to be on the record. I've heard positive feedback from the retail sector on dealing with Health Canada inspectors. They've been very sensitive and accommodating in trying to be the least intrusive and to cause the least interruption to their business. I just want to pass that on and encourage you to continue doing that.

On the licensing and inspection, have you looked at what countries around the world are doing for those best practices? I say this because I think that in Japan or Hong Kong they have different classifications—like level one and level two—and they require different licensing and inspections. Have we looked at them?

Ms. Pamela Aung-Thin: Yes. Certainly on the licensing side, we do look at international regulators for best practices and to get that information to inform our own policies and information.

Mr. Han Dong: How much time do I have, Mr. Chair?

The Chair: You have just about a minute and a half.

Mr. Han Dong: That's good. I want to focus on TCM.

I want to say that I didn't believe in TCM, although I'm a Chinese Canadian, until 2005. My father actually went through rounds of chemo and was advised to use a TCM product: a traditional Chinese medicine product. These are in powder form. It was amazing. He didn't suffer any side effects of the chemo rounds. I know that this is very anecdotal evidence. My wife also recently benefited from TCM.

We have two provinces, B.C. and Ontario, that have regulated colleges for TCM and acupuncture. Can I have a commitment from Health Canada going forward, when you're tying up or fine-tuning your licensing and labelling, that you will consult with the provinces and, in MP Desjarlais' case, territorial governments, when it comes to labelling and licensing of traditional health products?

Is that a yes?

● (1240)

Ms. Pamela Aung-Thin: That is a yes. I'll just elaborate by saying that we do engage with a range of stakeholders, and that includes provincial regulators.

Mr. Han Dong: That's excellent.

The Chair: Thank you. That's your time.

Mr. Dong, I'm glad you clarified that “TCM” is traditional Chinese medicine. I thought it might be a cannabis product.

Voices: Oh, oh!

The Chair: Thank you for that.

We now are entering our fourth and final round and returning to the official opposition.

Mr. Lawrence, you have the floor for five minutes, please.

Mr. Philip Lawrence: I'm just going to ask a quick question and then I'll pass it on to my colleague Mr. Patzer.

I was asking earlier about the inspections of facilities and there were 35—17 and 35 or something like that. How many facilities or manufacturers are there in Canada that should be inspected? What's the denominator?

Ms. Linsey Hollett: Thank you for the question, Chair.

Maybe I can take this opportunity just to let the member know that I did misspeak earlier. In 2020, the number would have been 23 inspections.

Maybe I can turn to Pam on the number of site licence-holders. That is who would fall within the scope of an inspection program.

Ms. Pamela Aung-Thin: I'm madly searching for my numbers, but it is approximately 800 site licence-holders.

Mr. Philip Lawrence: I'll turn it over to Mr. Patzer, but I'll make a quick comment that at 30 or so per year, we wouldn't circle through all of them in many decades. That might be an area of concern that I would point out to the Health officials.

The Chair: Thank you.

Mr. Patzer, you have three and a half minutes.

Mr. Jeremy Patzer: Thank you.

I want to pick up on a theme I was working on earlier with regard to standardized regulations, because paragraph 2.23 references:

> 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.

Going along with the theme of trying to make sure we have equal regulations and processes in place, Health Canada doesn't have a program to conduct routine on-site inspections for manufacturing sites, yet Australia and Europe do. Why is there a gap there, especially when we're relying on other countries?

If we're trying to streamline and standardize these regulations, there appear to be some existing gaps. I wonder if there are some comments there.

Ms. Linsey Hollett: There are two parts to that question.

In terms of a standardized set of regulations, what I would use as the comparator—which is almost a gold standard in the drug world—are the good manufacturing practices we have. There is a large community of countries in the world that follow the same standard practice, and that has allowed us to rely on mutual recognition quite heavily.

In the natural health product space, although there is progress in this area, with all countries you would think of that may usually collaborate and co-operate, there are still some differences in the regulatory framework, such as how natural health products are regulated and even what they're called. As the member points out, however, there are jurisdictions—and I would put us, with our plans for an inspection program, in that group—that are leading the work to get to the point on NHPs that we are at with drugs and to fill the gap that member mentions.

The ideal outcome would be that we get to a place, including with a pro-active inspection program, that lets us make use at some point in the future of mutual recognition agreements that also include NHPs.

Mr. Jeremy Patzer: I have one more question that I really want to get in, regarding confidence in the products. We've identified risks, and it's going to take time to address those risks, but it doesn't change the fact that Canadians are buying those products today.

The report also shows in paragraph 2.39 that “Health Canada did not know where all licensed products were manufactured.” It goes on to say that fewer than 5% of all active product licence-holders told the department “which licensed facilities manufactured their products before selling them.”

Again, there seem to be some issues. How do we make sure Canadians are confident in the products they're buying, when there are so many holes, gaps and issues, whether they be contaminated products, expired products or not even knowing where these products are manufactured or where they're coming from?

● (1245)

Ms. Pamela Aung-Thin: Perhaps I can start.

In terms of what you've noted in paragraph 2.39, 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.

The Chair: Thank you very much. That is the time for you for today.

We're turning now to MP Dong. I understand you'll be sharing part of your time with our NDP colleague.

It's over to you.

Mr. Han Dong: Yes, Chair. Thank you very much.

Although the questions to the officials from Health Canada have been pretty tough, I still want to stress the point that we need to strike a balance on this. I think the report says over 70% of Canadians are using a range of the products we're talking about today. At the same time, there's a thriving market. Therefore, your role is very important to strike that balance. We don't want too heavy-handed government intervention, because that would drive the market into the black market, especially when it comes to health products. I just want to make sure that point gets across.

In a perfect world, we have the consumers understanding what kind of licences they're looking for, what kind of product needs licensing. For importers, they'll have the same information, and when they apply for a licence, the processing time is reasonable, so there is encouragement for them to go through that channel.

What kind of public education program or campaign are you doing or planning to do?

After you respond, I'll give the rest of my time to my NDP colleague.

Thank you.

Ms. Pamela Aung-Thin: Thank you for the question. They are all very good points. I'll just particularly emphasize your point in taking a balanced approach. As I had mentioned earlier, we certainly do consult broadly with stakeholders. I mentioned provinces and territories, but we consult with all stakeholders to make sure that we take that balanced approach.

In terms of education, that is also a very important part in making sure that information is readily available. As I had mentioned specifically 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.

We are also focused—

Mr. Han Dong: I'm sorry, but I want to make sure my colleague has time. I just want you to commit to at least considering a public education campaign so the broader public understands the risks and the benefits.

Thank you.

Ms. Pamela Aung-Thin: Yes, absolutely. Thank you.

The Chair: Mr. Desjarlais, we'll go over to you.

Mr. Blake Desjarlais: Thank you very much, Mr. Chair.

I thank my colleague Han Dong for allowing me to spend additional time to really continue a discussion that was actually started by my colleague Nathalie Sinclair-Desgagné, related to products that have affected, in her instance, pregnant women. I think women in particular, or gender-diverse people, have a disproportionate impact when it comes to health products, because they're looking for products in many ways that are unique not just to their gender, but maybe even to their success in fulfilling their own identity. I think of the trans community or the two-spirit community in particular, and I think of gender-affirming surgeries for that fact.

An immense amount of products have been coming into Canada in the last 24 months related to persons who are transitioning, and we're often seeing doctors referring to non-prescription drugs in some instances to help them in their recovery. There's no labelling for this and there's no information.

I've talked to youth in GSAs across Alberta and they're scared about this fact that they don't know what they're taking and they don't understand how some of this relates to their healing process. They're really concerned mostly with hormone therapy. I know hormone therapy is something that is regulated by Health Canada, but there are other supplementary drugs that exist on the market that have to do with understanding hormones other than testosterone, for example, or estrogen.

How do we protect those groups, particularly given the gender-based analysis that Health Canada has committed to, in understanding product labelling? Is there room to ensure that there's a gender-based analysis for that labelling for particularly women in the trans community?

● (1250)

Ms. Pamela Aung-Thin: Thank you for the question.

I think you've really captured well some of the complexities in this area. What I will just mention is, yes, we are committed to looking at all that we do through the SGBA+ lens in how we regulate all our health products, not just natural health products but across the spectrum of products that we regulate for health and safety.

Mr. Blake Desjarlais: Thanks so much.

I would also like to yield the remainder of my time to my colleague from the Bloc. We're sharing a bit of time here, so Nathalie, I'd like to share some time.

[*Translation*]

The Chair: Okay.

Ms. Sinclair-Desgagné, you have five minutes.

Ms. Nathalie Sinclair-Desgagné: I'd like to thank my dear colleagues.

I want to go back to my question about a prevention strategy versus a reaction strategy. What I understand from the report is that there have been a lot of complaints, which have been addressed.

In addition, several topics were discussed, including labelling and the control of products found on shelves and in online advertisements.

For all of these topics, will we actually establish a prevention dynamic, rather than a reaction dynamic?

Ms. Pamela Aung-Thin: Thank you for the question.

I think the answer is yes. All the responses we've received to the report and all the actions we're going to take are supposed to be harmonized.

We have put in place a decision-making framework that allows people to take care of their own health. It's for people who use natural health products because they're looking for different products. With this framework, many of the products in question and the responses we've received will be aligned to better protect the health of Canadians, including vulnerable people.

Ms. Nathalie Sinclair-Desgagné: How do you plan to adopt this strategy?

The report states that less than 5% of product licence holders have provided Health Canada information on the source of their products.

Ms. Pamela Aung-Thin: Thank you for the question.

The department has already begun to take action to address the deficiency you mentioned and 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 this application.

We are also working on long-term solutions to address this gap.

Ms. Nathalie Sinclair-Desgagné: When will this system be put in place?

Ms. Pamela Aung-Thin: Thank you for the question.

As noted in the report, in the senior management response and in our action plan, several measures have been announced.

First, 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.

● (1255)

Ms. Nathalie Sinclair-Desgagné: By this spring, do you mean now, because it's spring, or are you talking about next year?

Ms. Pamela Aung-Thin: I mean this spring.

Ms. Nathalie Sinclair-Desgagné: In other words, now.

Ms. Pamela Aung-Thin: Yes.

Ms. Nathalie Sinclair-Desgagné: That's great.

I'd like to get more clarification on the issue of products coming in from abroad. My colleague mentioned traditional Chinese medicine products.

How do you monitor the quality of these products, the manufacturing processes and the truthfulness of the information on the label, especially if the source isn't known?

Ms. Pamela Aung-Thin: Thank you for the question.

For products that come from other countries, we have the same requirements for good manufacturing practices, which must be met before they are exported to Canada. This ensures the quality of the products.

For traditional products, we use a number of prevention methods to better protect Canadians. We have proposed ways to change the labelling so that the information on the label is very clear, legible and easy to understand. This could help Canadians make better choices when buying these products.

[*English*]

The Chair: Thank you.

I wish to thank all of the witnesses for appearing today. I'm pleased that we managed to make it through all the rounds of questions, as well as the question I was able to ask.

To wrap up here, I remind members that we will be reviewing follow-up responses from the government to recommendations that the committee has previously made. A document prepared by the analyst was distributed Tuesday afternoon. This follow-up is a very important aspect of the committee's work. This is when we look at responses that we receive from the government to requests we've made to ensure they are fulsome responses that we are satisfied with.

The meeting is adjourned.