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Chair

Mr. David Christopherson

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● (0850)

[*English*]

The Vice-Chair (Mr. Daryl Kramp (Prince Edward—Hastings, CPC)): Thank you, colleagues. I call meeting number 36 of the Standing Committee on Public Accounts to order.

Our chair is tied up on the little green bus at this particular moment. He'll be along shortly, so in the interim, out of courtesy and the opportunity to have some discussion with our witnesses, we will welcome them here and get the proceedings under way, so we'll have ample time in which to have an open conversation with them.

We have before us today Neil Maxwell, the assistant auditor general. We have Louise Dubé, a principal as well. We have, from the Department of Health, Glenda Yeates, the deputy minister; and of course, Paul Glover, the assistant deputy minister; and Marc Berthiaume, director.

Welcome to one and all.

I understand we have two opening statements, one by Mr. Maxwell and one by Glenda Yeates.

First, we will start with you, Mr. Maxwell, your opening statement, please.

Mr. Neil Maxwell (Assistant Auditor General, Office of the Auditor General of Canada): Thank you, Mr. Chair.

Thank you for this opportunity to present the results of our audit on regulating pharmaceutical drugs at Health Canada.

With me today, as you noted, is Louise Dubé, the principal responsible for audits in the health sector.

There are about 13,000 prescription and non-prescription drugs on the Canadian market. Pharmaceutical drugs play an important role in Canada's health care system and economy. Health Canada regulates the safety, efficacy, and quality of all pharmaceutical drugs in Canada before and after the products enter the Canadian marketplace.

The department does this through a combination of scientific review, monitoring, compliance, and enforcement activities. It aims to ensure that the public has timely access to safe and effective pharmaceutical drugs, and that those who need to know of safety concerns are informed.

For our 2011 fall report, we examined whether Health Canada fulfilled its key responsibilities for pharmaceutical drugs. These responsibilities involved timeliness, consistency, transparency, conflict of interest, and risk-based post-market activities.

[*Translation*]

We found that the department had not adequately fulfilled most of these key responsibilities related to clinical trials, submission reviews, and post-market activities.

In particular, we found that Health Canada had problems with the timelines and transparency of its activities.

Health Canada is not meeting its service standards for the timely review of most of the drug submissions it receives, thus delaying Canadians' access to the health benefits of new drugs. It is also delaying access to more affordable treatments.

Health Canada has established processes to identify potential safety issues for marketed drugs, but it is slow to act. It can take the department more than two years to complete an assessment of potential safety issues and to provide Canadians with new safety information.

In 2004, the House of Commons Standing Committee on Health recommended that this department create a public database to provide information on clinical trials in progress, abandoned and completed. Health Canada committed to enhancing public access to information about clinical trials. In the fall 2011 audit, we found that, despite this commitment, Health Canada had not taken action. This lack of information increases the risk that Canadians may be unaware of new treatment options or may unknowingly participated in an unauthorized trial.

The department is also not disclosing information on drugs that it rejects, drugs that the manufacturer withdraws from the review process, or drugs with conditions.

Health care providers have the discretion to prescribe a drug for conditions that the drug has not been authorized to treat. Therefore, it is important that health care providers be informed when the department rejects a marketed drug for a new use, so they understand the department's concerns.

● (0855)

[*English*]

We reported very similar findings in our June 2011 report on the regulation of medical devices about a lack of timeliness to review submissions related to those devices. We found that Health Canada was not making use of assessment work done in other jurisdictions, as part of its own assessments of the safety and efficacy of medical devices that could lead to program efficiencies. Health Canada has recently launched an initiative to make greater use of this information for medical devices and pharmaceuticals.

We are pleased that Health Canada has agreed with our recommendations from both reports and that it has developed action plans to address them.

The regulation of pharmaceutical drugs is important to Canadians. With an aging population, the role of pharmaceuticals is expected to grow as researchers come up with new therapies to replace earlier treatments or provide new options where no treatment existed before. The committee may wish to obtain the assurance and commitment from Health Canada to implement our recommendations in a timely manner.

Mr. Chair, that concludes my opening statement. We would be pleased to answer your committee's questions.

The Vice-Chair (Mr. Daryl Kramp): Thank you very much, Mr. Maxwell.

Please go ahead, Ms. Yeates.

Ms. Glenda Yeates (Deputy Minister, Department of Health): Thank you very much, Mr. Chair, and good morning to you and members of the committee.

Thank you for the opportunity to appear before the committee to discuss chapter 4 of the Auditor General's report dealing with the regulation of pharmaceutical drugs in Canada. I am joined here today, as was noted, by Paul Glover, assistant deputy minister of the health products and food branch, and Dr. Marc Berthiaume, director of the marketed health products directorate.

Canada has one of the safest and most rigorous drug safety systems in the world. At Health Canada, we take our regulatory role in support of the drug safety system very seriously and carry it out in a scientifically rigorous and independent manner. We know, however, that there is always room for improvement.

[*Translation*]

In this spirit, I would like to thank the Auditor General for his work. As the Auditor General noted, we need to improve the timeliness of our reviews; we can better document and accelerate the process of identifying potential safety issues; and we can increase the amount of information available to Canadians about our processes.

[*English*]

We do, Mr. Chair, as was noted, have a detailed action plan, which has been tabled with the committee. I can assure the committee of our commitment to carry out these actions as part of our ongoing process to improve how we protect the health and safety of Canadians.

I am pleased to report that as of April 1, 2011, we have significantly more resources available to fulfill our mandate as a result of our new cost-recovery program.

As was supported by the Auditor General in a previous audit, we have now increased fees that are charged to industry in support of drug applications, thereby returning us to a more historically balanced funding model. As a result, Canada is now much more in line with comparable international regulatory agencies such as the United States Food and Drug Administration and Europe's European Medicines Agency.

These fees are expected to generate, and in fact, are already generating significant new revenues. These incremental resources have already enabled us to hire 160 new staff, strengthen our capacity to improve our processes, and upgrade things like our computer systems.

Now I would like to briefly describe some of the specific actions that either have been taken or are under way to improve the safety, transparency, and timeliness of our systems.

At Health Canada, there is no higher priority than safety. The department reviews all drugs for safety, efficacy, and quality. Canadians can be confident that the drugs approved by Health Canada have undergone a rigorous assessment against these criteria.

The Auditor General recommended that Health Canada strengthen its risk-based approach to monitoring clinical trial sites and adverse drug reaction reports during clinical trials. This past September, we introduced a risk-based approach for monitoring and assessing clinical trial adverse drug reaction reports, and we have already completed and begun to implement an updated risk-based selection process for inspection of clinical trial sites.

Moving on to transparency, Mr. Chair, we recognize that the work we do is of great interest to Canadians, and that we have a duty to make information about the safety and effectiveness of drugs available to them. As I said, we take this duty very seriously.

The department is improving transparency with respect to marketed health products with the launch of phase II of the summary basis of decision project in June. These reports will provide information in a much clearer manner so that it can be understood by Canadians.

We are improving public access to information about clinical trials by publishing summary reports about clinical trial inspections. The first of these reports was published a few days ago.

We are also making important health information more easily accessible to doctors and patients. We are working with stakeholders to make labels more understandable to Canadians, and we are posting all authorized drug labels on Health Canada's online drug product database.

We will continue to take steps through policy guidance, and if necessary, regulatory proposals to improve transparency.

● (0900)

[*Translation*]

We are doing a number of things to improve timeliness in our core regulatory activities.

[*English*]

We believe that we are making significant progress in addressing the Auditor General's concerns about the pace of assessment of potential safety issues.

[*Translation*]

We are working with the United States and some European countries to streamline our drug-submission system and share information about inspections and adverse reactions. Moving forward, we plan to expand our cooperation with other countries.

With regard to evaluating drug submissions, I am pleased to report that we are making progress. The backlog for new drug submissions was eliminated in December 2011. We do still have a challenge in meeting our performance targets for generic drug reviews and we have devoted significant new resources to tackle this area.

[*English*]

In summary, the Auditor General's report has been helpful in guiding some of the changes that we need to make to continue to perform our regulatory responsibilities to protect the health and safety of Canadians. We have one of the most rigorous drug safety systems in the world, and Health Canada is consistently and constantly looking for ways to strengthen it, which is why we're taking the findings of the Auditor General very seriously.

Thank you.

My colleagues and I would be pleased to take your questions.

The Chair (Mr. David Christopherson (Hamilton Centre, NDP)): Thank you very much.

I assume everything that needs to be done to this point has been done, so all of the statements that are going to be made have been made.

Very good.

In that case, we will start with Mr. Saxton. You have the floor, sir.

Mr. Andrew Saxton (North Vancouver, CPC): Thank you, Mr. Chair, and my thanks to our witnesses for being here today to discuss the Auditor General's report on regulating pharmaceutical drugs.

I was pleased to note that the Auditor General examined many important areas of regulating pharmaceutical drugs, including transparency and timeliness in communicating information about clinical drug trials, conflicts of interest, timeliness of safety assessment recommendations for marketed drugs, and how Health Canada applies risk-based standard operating procedures. Along with Health Canada's other drug regulation activities, these are all important areas to Canadians and to Canadian drug manufacturers and suppliers.

In this context, could the deputy minister provide this committee with some additional details on how Health Canada regulates prescription drugs to ensure that it is putting the health and safety of Canadians first?

Ms. Glenda Yeates: This is a very important question for the committee to consider. We have a very safe and rigorous regulatory system. As was mentioned in the Auditor General's report and in the member's question, this is done in a variety of ways. It's done before the drugs ever come to market by looking at the clinical trials. It's done as the drugs are submitted for approval. It's done as we put them on the market and continue to have surveillance mechanisms to ensure that we understand all the possible consequences of these drugs.

We are the only drug regulator in the world that has established performance standards on the post-market side for completing safety assessments when a drug is already on the market. Our international partners are very interested in talking to us to see if they can adopt this practice. Most drug regulators have only timelines and benchmarks for the review of drugs.

We've strengthened the user fee proposal that was put through Parliament under the User Fees Act, which now supplies a substantially enhanced resource base to the department and rebalances the fees paid by industry in accordance with the support given by the public tax base, thus providing us with new resources. For example, we have virtually doubled the number of chemists who are able to work on the generic drug files. While we are up to date in meeting our performance standards and have eliminated the backlog for brand-name or new drugs, we are not yet meeting our performance standards for generic entities. That's why we've put these new resources in—to improve our performance in that area.

We are doing a number of things to improve our performance. We're improving the access Canadians have to identify post-market issues. We've strengthened our MedEffect database and our Canada vigilance program to make sure that whether you're a physician or a consumer, if you have an adverse event, you will be able to submit these to us easily. We have strengthened our standard operating procedures for those programs. We've taken a number of steps—I've just mentioned a few—to strengthen the process of the drug regulatory program.

● (0905)

Mr. Andrew Saxton: It appears from your remarks and opening statement this morning that Heath Canada is treating the Auditor General's recommendation as a priority and taking his concerns seriously. It also appears that Health Canada is taking steps to address each of the 10 recommendations from the Auditor General's report. Could the deputy minister, or one of her officials, confirm that the department is going beyond the recommendations of the Auditor General in order to ensure the safety of Canadians?

Ms. Glenda Yeates: Thank you, again, for the question. It is quite important.

The Auditor General's recommendations are very helpful to us. We have accepted all of them. In fact some of them that were short term are already completed, and a number more are in the medium or long term. We have long-term strategies in place and systems that are being built to address them.

We are very actively working on all 10 of the recommendations, but we have not stopped there. We would never be satisfied, nor would the Auditor General, with ever thinking we were finished with improving our performance in this area that is so critical to Canadians. There are a number of areas where we are going beyond what the Auditor General has noted.

We are, as I said, expanding our capacities in a number of areas. We're focusing on the standard operating procedures to strengthen them in many areas. We've put out some regulatory and discussion documents for consultation to discuss how we might go further in areas of transparency and others.

Perhaps because of the detailed nature of the question, I will turn to my colleagues to ask them to give additional examples of where we've gone beyond the action plan to the Auditor General's recommendations.

The Chair: Very briefly, please.

Mr. Paul Glover (Assistant Deputy Minister, Health Products and Food Branch, Department of Health): If I may then, Mr. Chair, very quickly, as was pointed out on transparency, we're looking at what we can do to accelerate and go beyond the recommendations of the Auditor General.

We're looking at issues like the labels and how readable they are, plain language information for Canadians, and the product monographs, which are quite large and sometimes difficult for physicians to digest quickly—so easier and more accessible summaries.

We're taking a look at a range of things beyond what the Auditor General pointed out.

The Chair: Thank you, Mr. Saxton.

Moving along to Madame Blanchette-Lamothe.

You have the floor.

[*Translation*]

Ms. Lysane Blanchette-Lamothe (Pierrefonds—Dollard, NDP): Thank you very much.

The Auditor General's report indicates that the department has limited regulatory power when it comes to modifying the labelling of drugs after they have been authorized for sale.

I would like you to explain a little about why this power is limited, what that means exactly. Would it be better for the department to have more power in that respect?

● (0910)

Mr. Paul Glover: Mr. Chair, I thank the member for her question.

It's true that our powers are somewhat limited with respect to our ability to request a change on…

[*English*]

the monograph, the labels. We do have limited powers to demand or impose label updates on products as we see them. We end up working in collaboration with the companies in order to negotiate the sorts of changes we would like to see.

[*Translation*]

The process to obtain an update on instructions for a drug is now being negotiated with the industry.

[*English*]

We find that this works for us. Obviously we exert a fair amount of influence over industry to comply with our requests.

We have the power, if we feel that industry is not complying, to simply issue a warning saying we've asked the industry to do *x* and they've declined. Oftentimes that's enough to have industry come into compliance with our recommendations. We do have powers beyond just the negotiation.

In Bill C-51, a previous piece of legislation, there were some proposals that would have allowed us to go beyond simply working in a collaborative nature with industry, to one that would be imposing our direction upon them. Given what happened with that piece of legislation, we are taking a look at what other steps we can take to ensure the regulatory framework we have allows us to move as quickly as possible.

The one problem I would acknowledge with the current process is that it does take a bit of time in terms of negotiating rather than simply directing.

The Chair: Thank you. Could you keep the answers brief, please?

[*Translation*]

Ms. Lysane Blanchette-Lamothe: Thank you.

Let's talk about the response time once a drug is on the market. We've been told that it can sometimes take more than two years before a safety issue with a drug is identified.

Fairly briefly, if you can, could you explain why it can take so long. Would it be important for improvements to be made to these timelines?

Dr. Marc Berthiaume (Director, Marketed Pharmaceuticals and Medical Devices Bureau, Marketed Health Products Directorate, Health Products and Food Branch, Department of Health): We need to take into account an important factor. We must not forget that we always deal with the most urgent things first. Health Canada's priority remains the safety of Canadians. We will grant priority to the various issues related to drugs. Some of them may take longer because of that prioritization.

It is important to understand that, when we identify an issue with a product that is on the market, we have to investigate that issue, which can take some time. We generally start by gathering information on the product itself, on how it is used in Canada. Then, we talk to our international colleagues to see what information they can provide. Sometimes, we get information from the industry…

Ms. Lysane Blanchette-Lamothe: I'm sorry for interrupting you, but I understand why this may take so long: it's a complicated process.

Would it be better for the process to be quicker? Would it be beneficial for the safety of Canadians to have a quicker safety issue assessment process?

Dr. Marc Berthiaume: Actually, what's important is dealt with as a priority. Of course, we always want to do things as quickly as possible. However, when there is a significant risk for Canadians, we act as quickly as we can.

Ms. Lysane Blanchette-Lamothe: I'm not trying to corner you, but I would like you to tell me whether, in your opinion, it would be relevant to be more efficient when it comes to identifying safety issues.

Dr. Marc Berthiaume: I think that, in the past few years, the department has made considerable progress with respect to its ability to tackle the drug safety issues that arise. The department has increased its ability to respond; it has improved its response time; it has increased the number of issues that are analyzed. There are more resources. Everything has been done to be more and more efficient with respect to the department's response time to health issues that emerge when products are put on the market.

Ms. Lysane Blanchette-Lamothe: I'll ask my question one last time. Please answer with a "yes" or a "no".

I fully understand that there have been improvements, but would it be relevant to increase the efficiency with respect to identifying safety issues?

● (0915)

Dr. Marc Berthiaume: As I just said, all of our actions show our commitment…

Ms. Lysane Blanchette-Lamothe: I'm not questioning your commitment.

Answer "yes" or "no": would it be relevant to increase this efficiency?

Perhaps the answer is "no", since you are saying that anything urgent is already made a priority. I want to know whether or not it would be relevant to increase the efficiency.

Dr. Marc Berthiaume: I think all of our actions indicate that this is what we're currently doing.

[*English*]

The Chair: Thank you.

Mr. Kramp, you have the floor, sir.

Mr. Daryl Kramp: Thank you, Chair.

Certainly, welcome to our witnesses.

Obviously, there's a recognition that the Auditor General had some concerns, and that the department has been reacting, and quite frankly, I'm pleased to see in a very favourable manner.

The one point I would make right off the bat is that I'm absolutely encouraged. Generally, this committee takes its responsibility very seriously and asks for a definitive action plan based upon the testimony of the witnesses, and of course, the response to the Auditor General. I'm very pleased to see that we have one before we've asked for one. I think that's a great step forward. Obviously, we're going to have to have some time to digest it, and quite frankly, see whether or not we find it satisfactory to this committee, but at least it's a marvellous step forward. So thank you very much for providing to the committee a response to some of the concerns that have already been registered. It shows that you're just not sitting on your fanny waiting for the committee's recommendation to move forward, and you do take these concerns seriously. So thank you very much.

My question in this is this. In moving forward, I unfortunately haven't digested this thing, but I'm concerned. What I don't want to see are abstract words like we're thinking about this, we have a desire to do this, we have a willingness to do that. I want to see absolute, concrete, definitive action. Now in this action plan here, rather than go through the whole thing with definitive action, could you at least pull out a couple of measures in the action plan that would demonstrate a concrete move forward—moves that are addressing real problems identified by the Auditor General?

Ms. Yeates.

Ms. Glenda Yeates: Again, thank you very much for the question.

We agree, and I share the committee's interest in seeing concrete actions because it is an enormously complex area and we actually want to see steps. Beneath this action plan, I can assure the committee that there are many substeps. So when you have a chance to digest the plan, you may say, why is something not showing a date until, for example, March 2013? That will be, I can assure the members, because we've said, “Okay, what are the steps? How do you build this computer system to make that happen?”.

For example, on the question of timeliness, of notifying clinical trial sites of compliance ratings, the Auditor General pointed out that we did not have a standard operating procedure. We would inspect the clinical trial and we didn't actually have a benchmark for when that would occur. Now we are establishing those timeframes very specifically, so that our inspectors know that if they find something in a clinical trial site, there is a benchmark by which they are to have notified that shortfall back to the company specifically. So it's those kinds of operating procedures.

The Auditor General made a number of findings, where they said, “You tell us you're doing this according to a risk base. We don't see the absolute problems...but we don't see the documentation that can show us.” For example, on timeliness, in number 2 of our action plan, we are specifically doing that.

In terms of timeliness, the actual recommendation is that we meet our service standards. As I mentioned, we have improved our monitoring of the service standards. We now have a database. We look at them monthly at our executive committee table. As I mentioned, we can see that in most of our areas, such as new drugs, we've eliminated the backlog and we can monitor them very specifically. We have adapted the new resources and have devoted new resources to, very specifically, moving forward on the generic drugs.

I note here that there was a comment made about conflict of interest. We took immediate action. Actually, the Auditor General said that we had not documented our general conflict of interest policies. Our forms were in keeping with the policies, but we had, perhaps, to go above and beyond in an area as sensitive as drugs. So last November we actually took every person in the branch, addressed that conflict of interest very specifically, and we have those now back from the vast majority of employees in the branch. We have also hired an outside resource to advise us as to whether, more specifically, there are best practices worldwide that should take us beyond that.

So there are a number of things here. We have built quite specifically on the post-marketing side as well.

● (0920)

Mr. Daryl Kramp: That gives us an indication, obviously, of some solid, concrete action. All I would ask is this. I wouldn't be complacent about the fact that you have an action plan in place, though, because I can assure you that this committee will probably ask for an update and/or consistent updates on the progress along the way to ensure that the recommendations are being followed. We do appreciate your cooperation in this matter.

Thank you very kindly.

The Chair: I'm sorry, your time has expired. I know it goes fast when you're having fun.

Monsieur Dubé, you have the floor, sir.

[*Translation*]

Mr. Matthew Dubé (Chambly—Borduas, NDP): Thank you, Mr. Chair.

I'd like to thank our guests for being here today.

Drug safety is obviously an important issue for Canadians. When I think about drug safety, one aspect in particular concerns me, and that's the Sandoz matter. Sandoz is a company in Boucherville, Quebec, near my riding. This matter was raised by the mayors of the municipalities in my constituency when I had the opportunity to meet with them recently. After speaking with them and with the people of the region, I am very concerned with this matter.

I use that example because, both in the Auditor General's report and in your statements, you are asking for better language on the labels. But I have a lot of difficulty with that because, for example, a hospital in Toronto found drugs that have been improperly labelled. I have difficulty understanding that we can think about the language on labels when the drugs are not properly labelled to begin with.

What do you think about that? Is that among the improvements that you are going to undertake in applying the Auditor General's recommendations?

Ms. Glenda Yeates: Thank you. There is an important point I would like to share with the committee.

There are two sides to the word "label", and it's a bit confusing. I myself was confused occasionally in the beginning.

[*English*]

The word “label” we often think of as the label on the bottle, which is the issue you referred to in terms of Sandoz. But the label we are talking about is a much more complex document, which is often posted on the web. It is the longer piece.

When we talk about simplifying the label, it's because we actually think physicians and Canadians need simpler language in the description of how to take the medication, what the contraindications are, what signs to look for, and the possible side effects. That is considered the label, and we think it's very important. That's why we're putting a great deal of emphasis on simplifying that information.

The actual issue we had with Sandoz—with one shipment having mislabelled vials in it—was very specific. It was a problem that was caught. There was a very significant effort, working with the company, to ensure that this was not something that actually reached Canadians or caused them any difficulty.

I would want to reassure the committee and the members that the label simplification we are talking about is so that consumers and practitioners have better information. It should not be linked in any way to the mislabelling problem that occurred at Sandoz.

[*Translation*]

Mr. Matthew Dubé: I appreciate the clarification. I wasn't aware of that distinction but, in my opinion, when we are talking about drugs, one mistake is one mistake too many. Even though we aren't talking about the same type of label, as you just explained so well, there were safety and regulatory problems in that case. The report deals with that.

In your action plan and in the steps you are taking, is that type of situation generally taken into account in finding long-term safety and regulatory solutions?

Ms. Glenda Yeates: Yes, it is very important that this entire multi-step process is applied as part of the work of our investigators.

● (0925)

[*English*]

The work they do in compliance and enforcement is very important as part of this. I think it is very helpful to appreciate, as the member has noted, that it is simply not enough for us to make sure that we put the drug out into the market as safe, and then wait for the reports to come back. We actually have regular inspectors who inspect plants. They inspect for good manufacturing practices. We have, in fact, improved our ability to target those resources. We've added new resources with the new user-fee money, so we have new inspectors. We actually are able to inspect plants on a regular basis, and they inspect the ones we are a bit more worried about more frequently. For the ones that have a very strong track record, we don't have to be there as often. Those are the kinds of inspections that pick up these labelling or other issues.

We look at those on an ongoing basis.

[*Translation*]

Mr. Matthew Dubé: I'm going to have to interrupt you because I only have a little bit of time left and there is one other topic I want to bring up. My question is for the representatives from the Office of the Auditor General.

One of the beauties of the Canadian health care system is that it is public and that we are not at the mercy of large insurance companies. Could you give us more information about the issue of conflicts of interest and tell us if this concerns you, given that the role of our system is to serve the population and not the interests of large pharmaceutical companies?

Mr. Neil Maxwell: Mr. Chair, thank you for the question.

At Health Canada, we have looked at a few aspects of conflicts of interest.

[*English*]

Our main concern was really the fact that we thought the department hadn't really assessed where the risks lie in terms of managing conflict of interest for its reviewers of drug submissions. And really, its processes were meeting Treasury Board requirements, but nothing more.

The Chair: Thank you very much. Merci.

Now Mr. Shipley, you have the floor, sir.

Mr. Bev Shipley (Lambton—Kent—Middlesex, CPC): Thank you, Mr. Chair.

Welcome to the witnesses.

First of all, I do want to say that I appreciate the fact that an action plan has been put forward, and it does see concrete movement.

But let me go back to the Auditor General's comments, and I am actually pretty concerned about this point. In number eight, Mr. Maxwell, you said that in 2004, the House of Commons committee on health recommended that the department create a public database to provide...whatever. You went on, but my time is short.

You also said that in the fall 2011 audit, you found that, despite this commitment of Health Canada, actions had not been taken.

First of all, I'll ask Madame Yeates, was there a commitment through the recommendation of the House of Commons committee on health? Was there a commitment by the department to get back to the committee with a timeline of recommendations?

Second, as my colleague has said, we can almost assure you that there will be timelines coming for a request from this committee. When I look at the report here, as of March 23, there are four completed recommendations, and 17 that are on target. Most of those seem to have started recently, not in 2004. Could you help me understand a little bit why it has taken so long?

Ms. Glenda Yeates: Thank you for the question.

My understanding is that in 2004 there was a recommendation from the committee, and in fact, the department took a number of steps at that time. It had some expert witnesses, I understand. It looked into the question of what was feasible, and what was reasonable in terms of clinical trials.

As was noted, for example, there was a bill that was introduced at that point, Bill C-51, which addressed some of that, so a lot of energy went into understanding whether we should do things as part of the legislation. When that legislation did not go forward, the department made a number of changes. It increased the transparency by focusing.... It actually encouraged, as we write a letter to a clinical trial site, that we ask them to put their posting on one of the WHO international sites. So we have a number of clinical trials that are now doing that.

Mr. Bev Shipley: Okay. I apologize for interrupting, but we only have a few minutes.

I'm wondering could you, for this committee, give some summary of actions that had some concrete movement in terms of the concerns that the Auditor General had. I think that would help this committee in terms of our final report, if you could do that.

● (0930)

Ms. Glenda Yeates: Certainly.

Mr. Bev Shipley: Secondly, you talked in your presentation about the international connections and communications that you have. It seems that some countries seem to be able to act more quickly in terms of pulling products, and we may have a product on here that—it was mentioned—takes two years to assess, and you talked about having a priority.

I'm just wondering, do you communicate with them on the approval process, the effects, and then the withdrawal of a product? Say in the United States there's a significant pharmaceutical product that has been withdrawn from the market. There's not much difference between a person living in Ontario and in Michigan, so does it automatically come back, and do we pull that product?

Ms. Glenda Yeates: I'll maybe ask my colleagues to speak to the specifics, but I would say that, in fact, we have ongoing and regular connections with our international regulatory partners. While there are some examples that are listed where we were behind the U.S. in doing something, there are times when we are, in fact, ahead of the USFDA in terms of moving. But there is very constant dialogue.

I'll ask my colleagues to speak more specifically.

Mr. Paul Glover: Thank you.

Very briefly, the first is on the actual submission and approval of a product before it hits the market. We are in close collaboration with our international colleagues. There are some complexities with that where the drug companies don't always submit at the same time to different jurisdictions. So it may be in Canada before the U.S., it may be in the U.S. before Canada, and there can actually be differences between the submissions from country to country, which the companies do for their own specific reasons.

However, once that's said, when we can, we definitely do collaborate. We look at where they're the same and where they're different. Once the product is on the market, absolutely, we are collaborating on signal detection, so adverse events are shared globally to find out if there are issues. When there are problems, they are shared internationally.

As the deputy pointed out, there are numerous examples where we have gone before the U.S., where our review might actually say—to your point—the problem that the FDA found was already on the label in Canada, and there was no need to adjust the product in Canada. We have examples where we were 10 years ahead of the U. S. in terms of what our label had on it compared to what they did, and vice versa. So there are instances where we pull product, and they don't; we issue label updates, and they don't.

The Chair: Very good. Thank you. Sorry, time has expired, Mr. Shipley.

Over to Mr. Byrne; you have the floor, sir.

Hon. Gerry Byrne (Humber—St. Barbe—Baie Verte, Lib.): Thank you, Mr. Chair.

Health Canada has a minimum of eight years of understanding exactly what the appetite of Parliament is in terms of this issue. It has had much longer than eight years to understand the appetite of the pharmaceutical industry to want to limit disclosure and transparency. It has had much more than eight years of understanding the Canadian public's appetite to want to expand transparency.

I would like to have this included in our report, as to whether or not Health Canada's meeting what the broad objectives were originally within the Health Canada study of increased transparency.

Would you be able to explain to us or provide and maybe table to this committee not just that you have an action plan and are committed to it, but spell out to us exactly what is in the action plan? When will disclosure occur, not only for clinical trials but for marketed drugs? What information will be disclosed? How often will that information be disclosed? Can you tell us, how is it disclosed, and quite frankly, whether or not it is done in a routine and regular basis, and how inclusive it is—whether or not all drugs are being summarized or being posted or published on a regular basis, and not just whether or not intermittent inspections are being published?

Would you commit to being able to table to the committee that comprehensive form of information, providing us with exact, full details—full disclosure—of how Health Canada is going to approach this in the future?

Ms. Glenda Yeates: Yes, thank you very much. We share the desire of the committee for greater transparency. In fact, as we've gone forward with our strategic thinking in terms of how we tackle this with the new resources that I've mentioned.... We have to focus first on timeliness, because we know that we had some issues. We need to focus on some of the regularization of some of the processes and making sure that we strengthen that. Transparency is very much part of our agenda. We would be pleased to give a sense to the committee of what our plan is, what we post, the progress we've made, and the progress we foresee making in the next years.

● (0935)

Hon. Gerry Byrne: I want to be very clear. I appreciate, Deputy Minister, your forthrightness on this. I'm not looking for a sense. I'm looking for hard timelines and inclusiveness. We, as a committee, don't want a sense of what you're about to do. We need and want to know what you are going to do. What level of detail is going to be provided? When is it going to be provided? Will the public have genuine access to it or not? We will be very rigorous in assessing that to determine whether or not you are meeting the spirit and the test of what is expected of Health Canada by Canadians and by Parliament.

I'll now go into another question. I'll take that as a yes that you'll have that full disclosure. Would that be correct?

Ms. Glenda Yeates: Yes. The only thing I would comment to the committee is that in some cases we are in consultations. If we're actually talking to the public, consumers, and experts, we may not be in a position to pre-empt those discussions and say precisely the outcome of those consultations. We can certainly outline, for the committee, the process we are going through and when we expect to be through that process. With that understanding, I'm happy to commit.

Hon. Gerry Byrne: You are also talking to Parliament, which is providing some pretty specific instructions. I'll ask you this. You indicated that you felt there were some restrictions as to how far you could go with public disclosure because of privacy rights and legislation. Could you detail for us what specific privacy rights, and what other specific legislation beyond the Privacy Act may be inhibiting your ability to properly inform, in a transparent and lawful way, on what is expected? You sense the spirit of what is expected.

Inform us so that we as parliamentarians can be aware of this and we can potentially consider changes to those legislative mechanisms that may restrict your ability to be transparent. Would you be able to provide us with that information?

Ms. Glenda Yeates: Yes. Certainly, as I say, one of the things that is part of our consultation is to understand where it is we want to head. I mentioned in my opening remarks that we were looking at guidance and possibly regulatory changes if that is required to enable us to do this. I would say those are things the department—

Hon. Gerry Byrne: I appreciate that, but what you said in direct response to the Auditor General's report is that you will develop policies on enhancing public access to information on authorized clinical trials that respect privacy rights and legislation. It implies that you have already identified what those privacy rights are and what those statutory and regulatory limitations are that you have. Otherwise, you would not have replied to the Auditor General in the way that you did. Would you table to our committee your findings or your concerns—your list, as it were—of specific privacy legislation concerns and other legislative statutory concerns that restrict your ability to comply with what is being asked of you, with a view that we can potentially change those laws?

Ms. Glenda Yeates: I appreciate the sentiment very much, and we will give you the sense of where we are. In some cases, we are still in the process of having our legal people work through those, so when we put the language there, it's not because we have identified the precise nature in all cases. In some cases we have identified whether the law allow us to do this, or is there a way to actually do this.

We are in the process of working that through, so we will be as specific as we can be with the knowledge we have at this time.

The Chair: Thank you. Sorry, your time has expired.

We're moving on. Mr. Aspin, you have the floor, sir.

Mr. Jay Aspin (Nipissing—Timiskaming, CPC): Thank you, Chair, and welcome, witnesses, to our meeting.

I'd like to focus on conflict of interest. As we all know, it's essential that our federal regulatory system be as objective and impartial as possible. Drug approval decisions should be based on what's safe for Canadians, not on any private interest, and I'm sure you're aware of the Values and Ethics Code for the Public Sector, which requires all departments to establish measures to manage conflicts of interest.

The Auditor General's report found that Health Canada's code of conduct and conflict of interest guidelines are consistent with the government's Values and Ethics Code for the Public Sector, but did note that improvements needed to be made. In his report, the Auditor General recommends that Health Canada do a better job in assessing the risks of conflicts of interest in the drug review process.

Ms. Yeates, you alluded to this in your earlier remarks. I'd like to focus on what Health Canada is doing to ensure that drug reviewers are not using confidential information about drug approvals for personal gain.

● (0940)

Ms. Glenda Yeates: I appreciate the question. I think it's a very important issue, as the Auditor General pointed out.

The department was in keeping with Treasury Board policy, but I think raised a very valid question about whether that is sufficient in this very sensitive area. We did have a mechanism in place. All employees, when they sign on, sign a conflict of interest declaration. We deal with that. We do have a code of conduct. We do have a values and ethics code we reinforce periodically with employees, but I think the answer to the question of whether we can do a better job is yes.

I think this was the Auditor General's point, and we agree. We are very confident. We have very strong professional employees in this area, so I want to reaffirm that the Auditor General did not find any situation of actual conflict of interest, nor do we want to undermine our confidence in our employees in any way. That doesn't mean that as an employer we don't think that perhaps there is a best practice here that we should reinforce and perhaps we should have some systems in place that go beyond what we do for the general department.

That's why we've undertaken, as of last November, to have all our health products and food branch employees actively reconfirm that they've looked back at the code and that they abide by it. That's why we have an outside party doing a review for us right now, to say that given the particular nature of this kind of work, certainly understanding the professionalism of our staff, what would be a best practice? Are there things we should be doing routinely to strengthen this area?

So I think it was a very helpful observation, and we agree that despite abiding by the overall code, and again, a new one will be coming out next week and that gives us a chance for the department as a whole to reinforce this for all public servants, but we want to have the best advice. Should we be doing more in this particular area? We've already gone one step beyond, but there may be other practices that we should put in place in the future. That's what we're doing in this area.

Mr. Jay Aspin: Has there been a conflict of interest case?

Ms. Glenda Yeates: No. The Auditor General did not find one, although as they point out, that wasn't the focus of their audit, but certainly they did not identify anything. As we've gone through this process of having our staff reconfirm their commitment, we have not discovered anything in that process either.

So I think the professionalism of our staff is working very well, but I think at the same time that's not to say that we cannot strengthen our processes. So I'm very pleased to say to the committee that this is not a situation where we've had a problem and are addressing it after the fact. This is, in a sense, a preventive situation where we want to be out in front of a possible problem.

Mr. Jay Aspin: In your pursuit of improving or doing better, you've alluded to developing best practices. What do you use as a source for that? Are there other health organizations in other parts of the world, or are there other health organizations in other provinces that you're looking to? What do you use as a guideline?

Ms. Glenda Yeates: I was a former provincial deputy minister and this is not an area wherein the provinces, although we do look to them on many other fronts, would necessarily have that kind of expertise, although they may in some regulatory areas. We certainly would look to them in many cases, but here I think it's the other international regulators. The USFDA is obviously a very well-known, well-respected institution and there's the European Medicines Agency. We have partnership agreements with a number of regulatory bodies in Australia, the U.K., and others, so that we can actually take from those who are dealing with a very similar set of challenges.

As Paul mentioned, we in fact have an ongoing regulatory dialogue with those other parties because this is a very complex and rapidly evolving world, and we want to make sure that we're learning from other regulators across the spectrum, including in this area.

● (0945)

The Chair: Thank you very, Mr. Aspin.

We go over to Mr. Allen.

Sir, you have the floor.

Mr. Malcolm Allen (Welland, NDP): Thank you, Chair.

Thank you, folks, for being with us.

Madam Yeates, you had a discussion with Mr. Aspin about transparency and conflict of interest. I think we are all in agreement, but let me ask a two-part question on the piece on conflict of interest.

In your response to the recommendation, you said that beyond the piece that you've talked about now, which quite frankly MPs have to do every year, the decision to do something—other than Treasury Board Secretariat rules and your conduct code—you said you'd have it done by March 31, 2012, which actually is Saturday.

The first question, obviously, is how far along are you?

The second piece of that is if you're far enough along, can you actually give us a sense of what it is you're hearing you ought to be doing? I would expect that you've already received the report. The deadline to receive the report is Saturday, but I don't think it's coming to you in the mail on Saturday, so it's either coming tomorrow or you already have it. Could you respond, please?

Ms. Glenda Yeates: I guess I will just say there are two things and I'll turn it over to my colleague to speak to the consultant's or the external report.

I would say that the first part that we did immediately was actually to do the—

Mr. Malcolm Allen: I understand. I'm clear on that. I think you've been clear on that. I had my earpiece on and I heard.

Mr. Glover.

Mr. Paul Glover: Thank you.

Briefly, we will receive the report tomorrow. We have not yet received it. We will carefully consider that report, its recommendations, the feasibility of implementing those recommendations—

Mr. Malcolm Allen: I have that, thanks.

We only get.... You see how tough this guy is over here, he cuts us off real fast.

Let me get to the point.

Mr. Paul Glover: September is when we'll have a plan.

Mr. Malcolm Allen: What you're saying is that a report is coming tomorrow, and by September you'll have some sort of plan.

My request is that you table the report with us after you receive it, since you're going to get it tomorrow, and then you say your implementation plan is for September. I would expect to see also that you table the implementation plan of what you intend to do with that report at the same time, so that we know what you intend to do with that particular report. We don't want to see it collect dust. Clearly this is a huge issue for all of us. You can see on both sides of the divide here, both groups are very interested in what exactly we're going to do with this.

The Auditor General was very clear about you needing to do something. You were very clear in your response that, yes, you would. So now we are very clear about making sure you actually have an action plan and get it done. We'd appreciate you tabling that.

Let me move to the assessment and response to safety issues, on pages 22 and 23 of the Auditor General's report. It goes back to 2009 and 2010, which isn't that far removed from now. There were 99 assessments of potential safety issues, but what I would draw to your attention is that of those particular issues, 54 weren't identified by Health Canada.

Let me break down the chart for you: 25 of them came from actions by foreign regulators; 15 came from scientific literature, not yours; 9 were from adverse drug reaction reports from previous Health Canada assessments; and 5 were from safety information provided by manufacturers—so you had 54. The vast majority of them Health Canada never saw. Someone else saw them and gave them to you. That's one statement about what's happening or not happening, in my view.

The second chart, exhibit 4.5, gives a performance of how you did and whether you met your requirements or not. If it was a high rating—there were none, so you didn't have any to look at in 80 days. The medium-potential safety issues, you have 130 working days. Of the 54, you assessed 29 of them. Sixteen you managed to get done within the timeframe, and 13 you didn't. That's a significant number.

When it came to low-potential, where you had 200 working days to get it done, you had 25 assessments reviewed. You got 18 done, and 7 you missed.

Can you tell me how you're going to do better than that? Quite frankly, with those marks in school, you would fail. You wouldn't have graduated high school with those marks.

So can you tell me how you intend to make sure that, as we head to 2012, 2013, and 2014, we're not going to see this as parliamentarians, and more importantly, that Canadians aren't going to be with this sort of a standard that, quite frankly, is below standard? It's not an acceptable level—it's not even close.

Besides the fact that you have more resources and you hired 130 or 160 more folks, can you tell me what the action plan is, so that when you set a standard for yourself, when you say 29 need to be done in 180 days, you're going to get 28 done and you're going to have a reason why you didn't get the 29th done.

● (0950)

Ms. Glenda Yeates: I'll ask my colleagues to speak to the specific latter part of the question.

But I want to reassure the committee on the point that we have learned of some of these issues from elsewhere. I actually think that is a mark of the system working well. I'll just say that although we may hear of them from a foreign regulator, what we understand as a smaller country with fewer people on any given medication—some of which as my colleagues said, may have been introduced in other countries before they were actually on the market in Canada—is that we as regulators want to pool the signals. We want to pool the circumstances—

Mr. Malcolm Allen: I hate to cut you off, Madam Yeates, but I'm going to have to because he is going to run me out of time.

The Chair: I'm sorry, I am. You are out of time.

I'll allow you to continue, Madam Yeates.

Ms. Glenda Yeates: I will ask my colleague, but I would say the fact that the foreign regulators are sharing information—and much bigger populations may see more signals earlier. We may have one or two cases. They may have 20 or 30. That, in fact, is the system working well.

The fact that we're looking at the scientific literature constantly, picking up signals in the scientific literature worldwide, and then using that as the signal, I think, frankly, is the system that gives Canadians the most comfort. In fact, this is not us relying on whatever resources we will ever have in Health Canada, but this is us tapping the worldwide network and making sure that we are looking for the signals and the signs across the world. Because that way, we'll catch things much more quickly and much more effectively for Canadians.

But I'll turn to my colleague to speak to the specific—

The Chair: No. I'm sorry. We're a minute and a half over. I've been as generous as I can be. So thank you very much. We must move along.

Madam Bateman, you have the floor.

Ms. Joyce Bateman (Winnipeg South Centre, CPC): Thank you very much, Mr. Chair.

I want to speak to Madam Yeates and I'm going to be focusing on transparency. First I want to clarify a few things with Mr. Maxwell.

When a department heartily agrees with all of the recommendations, this is what makes Canada wonderful. This is what makes our bureaucracy a model for the world. We listen and we work in partnership to make things better for all Canadians. I compliment the work of the Auditor General, always.

Was this your first review, Mr. Maxwell, of the responsibilities for pharmaceutical drugs in regard to transparency and consistency?

Mr. Neil Maxwell: We have audited almost everything in the federal government. This particular area, the regulation of pharmaceutical drugs, was something we hadn't looked at for about a decade. In my opening statement, I mentioned that we had done a similar audit of the medical devices regulation with quite similar findings. Yes, it's the first in some time.

Ms. Joyce Bateman: We should be comfortable knowing that you will be following up on this audit.

Mr. Neil Maxwell: We haven't made any specific decisions about which audits we will follow up on and whether this will be one or not. We certainly see this as quite an important audit. We see that there were a number of concerns raised by it. Yes, we are considering it.

Ms. Joyce Bateman: That's the magic. Nobody knows which ones you're going to follow up on. It's all good. We all have to behave.

Madam Yeates, I want to focus on the transparency issue. You've heard the passion on all sides of this committee. As parliamentarians we understand the importance of sharing information with the public. When it comes to authorized drug trials, there are a few aspects that I want your view on.

It's important for those in the trials to have access to the information. This is also important for people who end up on those drugs. I would suggest it's very important for Canadians who are making a decision about taking that drug. We are now seeing more and more that people's physicians will say to take a drug, and people will say, wait a second, and they're going to the Internet and they're verifying it. Certainly, parents do that for their children all the time. Obviously, the Auditor General focused in on your risk-based approach with regard to the inspection of clinical trials. There were a number of cases of non-compliance that you had also determined.

What actions are you taking, as a department, to disclose the information related to the clinical trial inspections in those three parts: the participants, the prospective users, and the users?

● (0955)

Ms. Glenda Yeates: There are five actions that I would bring to the committee's attention. First, if someone gets an approval from us in a clinical trial, we encourage them to register the clinical trial at a publicly available registry endorsed by the WHO. As the business becomes increasingly international, we think this is helpful for patients.

Secondly, we require that the product monographs be posted. Individual consumers are looking for drugs that are on the market to understand if they might be interested in taking them. Those are in a searchable database that Health Canada has. We are working to make, as my colleague mentioned, the labels easier to read, because sometimes the monographs can be—

Ms. Joyce Bateman: How are you making it easier for a mother, or a person who has an older parent.... How are you making it easier for that Canadian to access this information?

Ms. Glenda Yeates: There is a searchable database where Canadians can see individual drugs.

Ms. Joyce Bateman: So as members of Parliament on all sides of this table, would we be able to provide that information and that link to our constituents?

Ms. Glenda Yeates: Maybe I'll ask my colleagues to speak to this, but yes.

Ms. Joyce Bateman: That would be helpful.

Thank you.

[*Translation*]

I would like to specify that I think the Auditor General is really an added value.

[*English*]

Mr. Paul Glover: Just very briefly, Mr. Chair, in response to the member's question, I would be happy to provide the link to the various parts of our database.

We have a newsletter that people can subscribe to for adverse events, so that they don't have to go searching. If they're worried about adverse events in a range of drugs and want product updates, that is sent to them directly, automatically.

So we have a newsletter, and we have automatic feeds—

Ms. Joyce Bateman: So you have a link that we could all access and we could all share with our constituents. How many hits do you get on this, normally?

Because I'm willing to bet you that if we all shared it, it would be....

Mr. Paul Glover: I apologize; I don't have that number off the top of my head. But it is growing significantly each and every year.

Ms. Joyce Bateman: Through the chair, may we respectfully request that we all receive this information so that we can share it with all of our constituents?

The Chair: Yes, and that will conclude your time.

Ms. Joyce Bateman: Okay.

Thank you very much, all of you.

I knew I would be cut off.

The Chair: Yes, well, I could show you that you did get your share of the generosity, I assure you.

Moving on, Mr. Byrne, you have the floor, sir.

Hon. Gerry Byrne: Thank you, Mr. Chair.

I think it would be fair to say the committee, and the House of Commons generally, is seized not with the existence of an action plan, but the content of the action plan and exactly what information will indeed be disclosed over the course of time, and sooner rather than later.

Deputy Minister, you mentioned that just a few days ago you published summary reports about clinical trial inspections. How were they published?

Ms. Glenda Yeates: It's an aggregate report that has been published. It's the first one we've done of that type.

Perhaps I'll ask my colleague to speak more to that.

Hon. Gerry Byrne: How was it distributed? That's the better question.

Mr. Paul Glover: It's been posted on our website, so it's available to all Canadians for them to query.

Hon. Gerry Byrne: And it's not an infringement of privacy to do so.

Mr. Paul Glover: This is an aggregate report. This is the first in a series of steps we'll be taking to improve transparency in clinical trials. These are all trials: the types of issues we've seen, the types of trials being run, etc.

Hon. Gerry Byrne: Okay. So it doesn't actually provide any information if....

If someone were considering participating in a clinical trial for psoriasis, for a particular psoriasis drug, this doesn't actually provide them with any specific information as to whether or not that trial is being managed effectively.

Mr. Paul Glover: It does provide information on trial management, the types of issues—

Hon. Gerry Byrne: But it an aggregate way.

Mr. Paul Glover: —the types of problems, the documentation, things to look for, the most common adverse events we see, safety issues to look for.

There is a wealth of information at an aggregate level—from our consultations, both participants and sponsors were looking for this—about trials, how they operate, what works, and what doesn't. It's to inform them.

● (1000)

Hon. Gerry Byrne: But see, the problem here is that people don't take aggregate drugs, they take individual drugs. They take specific drugs. That, I think, is the appetite of the public, and I think that's the safety issue that the public has raised—i.e., I don't take an aggregate drug, I take a specific drug, and I want to know the specific details of that drug and what has been found of that drug.

I'll ask you this. Health Canada has moved to an industry user-fee model, which actually increases.... Can I actually get, or can I request, the amount of money that a particular firm or company has paid in user fees related to their clinical trials or their necessary Health Canada approvals? Can I get that information?

It would be kind of an interesting metric as to how much scrutiny has gone into the oversight of that particular drug.

Mr. Paul Glover: Mr. Chair, in response to the member's question, first and foremost, there is specific information on all of the drugs we've approved, and through MedEffect and CARN, any adverse events that are being reported to us.

While we acknowledge that people take individual drugs, we provide information on that individual drug and the types of adverse events, updates, and warnings to both health professionals and to the general public. That information is, and will continue to be, made available.

On clinical trials, we're looking to expand it, as well, in the early stages of the product development.

With respect to user fees, we are at this point posting aggregate information, but we could, obviously, provide detailed information.

I would have to pause on my answer there and just confirm exactly what level of detail our accounting system and others would be able to put forward, but we can commit to transparency on both the fees we're collecting and the performance standards we're using to meet those.

Hon. Gerry Byrne: I appreciate it. I think Canadians want to audit Parliament in the next short while as to exactly whether or not we are helping you to be transparent and to allow full disclosure. That's why I'm really looking forward to your detailed summary of specific concerns or specific limitations that you have identified, or that the industry has identified and that they use to demand that you not disclose information. You obviously have that information as well, that feedback from the industry, saying you can't disclose this information because they have a right to have that information protected.

Perhaps you could forward to the committee all of that information about what restrictions you have in terms of not only the Privacy Act but also the other legislation that you've identified.

Mr. Maxwell or Ms. Dubé, I would ask you that same question: did you identify anything during the course of your audit that specifically restricted Health Canada's ability to disclose information through statute or regulation?

Mr. Neil Maxwell: Thank you.

It was really up to the department to identify those constraints. Certainly nothing came to our attention, other than the general and obvious point the member has made, which is that there are general laws of application about privacy and such in play here.

Hon. Gerry Byrne: Mr. Chair, with that, I'll just repeat again my very strong desire to receive specific items from Health Canada in terms of further scoping down and defining. We're not getting a sense of defining the action plan. When are things going to occur? What exactly is going to be disclosed? How inclusive will it be? Will it be all-inclusive? Will it be intermittent or an occasional reporting, depending on when an inspection occurs? It's things like whether or not inspections are set over a period of time or if they're intermediate.

This is the information, I'll just suggest to you, that we're going to be looking for in our report so that we can actually gauge...so that we don't have to be eight years out, still trying to get a sense of where this is going.

Mr. Chair, I'll just leave it at that.

The Chair: Yes, you will.

Thank you so very much.

Mr. Hayes, you have the floor, sir.

Mr. Bryan Hayes (Sault Ste. Marie, CPC): Thank you, Mr. Chair.

First off, I'd like to commend the assistant auditor general and staff. This is a really comprehensive audit and I learned an awful lot going through this. As members of this committee, we certainly can't know everything about every department. And I'm significantly more intelligent now about the process than I was.

I'd also like to commend the deputy minister of health and her department for their ongoing efforts to ensure that drugs sold in this country are safe. I'm a consumer of many. I've had a few problems along the way and I've never had an adverse reaction. As a matter of fact, last week I went to get a prescription and the pharmacist, who knew what other drugs I was on, advised me as to, “No, this isn't really a good mix. You need to not do this one if you're going to do this one.” So I have great confidence in the system.

My question is specifically going to focus on user fees. As the witnesses know, manufacturers of prescription drugs benefit from the regulatory services and oversight provided by Health Canada. They also benefit when consumers know that Health Canada has approved a product. We also understand the importance of cost recovery, particularly when trying to eliminate the deficit while also maintaining low taxes for individuals and businesses.

My question is this. Could the deputy explain what is meant by “increased user fees”? Obviously, at one point there were user fees, and now they have been increased. I'm trying to get a little sense of dollar value. I'm also trying to get a sense of how those increased fees have led to improved performance. You did allude to increased staffing, but I do really want a sense that you have the confidence in your human resource staffing component and their ability to fulfill your obligations that have been determined by the assistant auditor general and his staff.

● (1005)

Ms. Glenda Yeates: Thank you very much, Mr. Chair.

It's a pleasure to be able to speak to the user fee initiatives. In some ways I think it was a huge undertaking for the department and I think it is very important.

I know the user fees were set in the mid-nineties, and at that point they were about roughly half, 50%, of the cost of doing the work. In some ways that reflects the sense that there's a public interest in having drugs reviewed and an industry interest as well, and that they should bear some of the responsibility and cost for doing this work.

Over time, as the costs have increased and as the complexity and volume of submissions have increased, the fees haven't kept pace. As a result they have fallen to about 25% of the cost, in rough figures, of doing the reviews. We had fallen behind our international partners. The USFDA, for example, is at about 50% Europe, depending on the country, will be 60% to 70%. So Canada was really out of line.

With the requirements of the User Fees Act, Parliament has very clearly set out the requirements for a department that wishes to go forward with a user fee proposal. There's a great deal of due diligence that must go into a user fee proposal. We did all of that economic work, took it through the parliamentary process, and Parliament in its wisdom gave us the ability to actually increase those fees. As of April of 2011, we have been seeing a significant increase in fees.

The member asked about the magnitude. We now collect about $70 million in user fees, and that's an increase of about $34 million —not all of that is in the drug area. The assistant auditor general mentioned medical devices. It's also in the medical device area. It's across the spectrum, but a significant portion obviously is in the prescription drug area.

We think that's a significant move forward. There are a number of things we've been putting these resources to. In some cases it has allowed us to significantly increase our scientific expertise, so we've been hiring new people. We've in fact been able to hire them in different markets. We've expanded in our Toronto area to take advantage of the expertise in that labour market as well.

We've been able to hire significant new scientific experts. As I mentioned, we have new inspectors. It's across the board. We've been able to strengthen the computer system in some ways. What the Auditor General points out is that sometimes you can get a lot of these adverse reports, but you actually need to be able to prioritize, search them, go through them, so we've been able to augment our IT, information technology, capacity as well.

It's been a big time of gearing up for the department. We are not yet through all of it.

When you get new reviewers, the interesting thing is that it takes some time to train them. In the short term it actually can take some of your existing skilled reviewers, seasoned reviewers, off the files to train the new folks. It's not an immediate solution, but we are seeing now that we are getting new people on board and getting them trained up. We feel this will serve us in very good stead going forward.

● (1010)

The Chair: Thank you.

Sorry, Mr. Hayes, time has expired.

Monsieur Dubé, you have the floor, sir.

[*Translation*]

Mr. Matthew Dubé: Thank you, Mr. Chair.

I want to come back to the question I started to ask at the end of my last turn, about the conflict of interest. I cannot reiterate enough just how important the issue is. As I said, the beauty of our health care system is that it serves the public and not other interests. That's why conflicts of interest can be problematic.

I understand that there aren't any conflicts of interest, but you spoke about risks. Mr. Allen spoke about the proposed solution, of the report that will be tabled, and that's great. However, to fully understand the solution, it's just as important to understand the problem.

So I would like to give the representatives of the Office of the Auditor General the opportunity to speak about what is meant by the risks. Are we to understand that there may be interests other than the interest of the public or the health of Canadians?

Mr. Neil Maxwell: Thank you for the question.

Perhaps I could talk about two types of risk in this kind of situation.

[*English*]

The first is, and it's been mentioned before, that there is the potential for financial gain. The second kind of risk is probably less obvious. Having looked at certain cases over and over again from some of the same companies, there can be what we call in audit land "familiarity risk".

There are those two types of risks. I do emphasize that we didn't go looking for cases and we didn't find a case. Our concern was that those controls have to be strengthened to ensure there was no shadow of a doubt cast over any of the employees doing this important work.

[*Translation*]

Mr. Matthew Dubé: Thank you very much. I appreciate your answer.

Correct me if I'm wrong, but I thought I understood a little earlier that this wasn't the main objective of the report. That's fine; it's not a problem.

Having said that, given the importance of the issue for the reasons I mentioned—and it seems to me that I have the agreement of the people present—would you be willing to say that it's an issue that Parliament should look into, whether through an audit done by your office, a study of the legislation or a study by the Standing Committee on Health?

Do you have an opinion on that?

Mr. Neil Maxwell: Thank you for your question.

The Treasury Board has taken a few steps to improve the requirements relating to conflicts of interest.

[*English*]

Potentially, the committee might wish to focus there next, which is to understand the issue more globally. We're talking about conflict of interest in one particular department, but there is a broader story here about how conflict of interest is being managed across the government. That, I might suggest, might be one place to focus.

[*Translation*]

Mr. Matthew Dubé: So it would be important for Parliament to follow this important issue in the next few months, and even over the next few years.

I would like to come back very quickly to another issue. I am very pleased to learn that there is good cooperation between Health Canada and your international colleagues. We were just talking earlier about the Sandoz issue. In that case, we saw that the FDA was the first to identify the problem.

Let's go back to what Mr. Allen said earlier, with respect to the number of times where the report points out that the problems were detected by international agencies. I am very pleased to learn that you are able to work with those agencies.

However, we need to think about our "medical sovereignty", if you'll pardon the somewhat ridiculous term. Don't you think it's important for Health Canada to be able to identify the problems on its own, without being taken hostage by other authorities in Europe or the United States?

[*English*]

Mr. Paul Glover: Thank you very much, Mr. Chair.

I'd like to begin by just underlining that Health Canada was inspecting Sandoz. We did do an inspection. We found a number of areas. We made some observations in our report to them and we're following up with them.

We made, as we do in any inspection, observations and asked for further follow-up. The FDA in their inspection of Sandoz, which includes two plants in the U.S. and one in Canada, found a particular issue. Their approach was to issue a warning letter. It was Sandoz who made a business decision about how to respond to that warning letter. So Health Canada had and continues to be inspecting the plants in Boucherville, Quebec.

We had found areas that we had already written to the company on, asking for them to take corrective action. The FDA and the product in question was a product not sold into the Canadian market. Their approach was a warning letter, and it was Sandoz that made a business decision about how to respond, not just in the Boucherville plant but the two other plants in the United States. That is important to know.

● (1015)

The Chair: Sorry, the time has expired. Thank you.

Our last speaker in the full rotation is Mr. Dreeshen and you have the floor, sir.

Mr. Earl Dreeshen (Red Deer, CPC): Thank you very much, Mr. Chair, and thanks to our guests for being here today.

I have a bit of a health care background, at least in management. I've been a hospital board chairman for a number of years in Alberta. With regard to some of the types of things that happen, there has to be an acute awareness of health and safety needs. So I guess the things that I want to focus on are transparency and timeliness. I guess when you're taking a look at the information about health and safety that's stemming from authorized clinical trials, it's important that people are participating in these trials and that they get information back about what has taken place.

With this in mind, I would appreciate it if the deputy minister could advise the committee on how Canadians can be assured that Health Canada has taken the necessary steps to improve the amount of information that is being shared with the public?

Ms. Glenda Yeates: Thank you very much, Mr. Chair, and I'll begin, and then turn it over to my colleagues on the specifics of clinical trials.

But it does strike me that there are two components in the question. One is what do the people who are in the clinical trials—and again one of the things that we look to as we inspect clinical trial sites will be things like informed consent and ensuring that there are the right mechanisms between the participants in the trial and the trial site, for example. So those are things that the individual patients in the trials can be assured of. Those are things that are part of our oversight requirements at clinical trials.

Then, with regard to the question about what citizens generally can know about clinical trials, as was mentioned, we've been encouraging all of the companies who have clinical trial sites in Canada to post them on international WHO-recognized websites, so that individuals can learn of those trials. That's one of the ways that people can understand it. Again, from our consultations, this summary document that we mentioned, people said this will be very helpful to understand, and we are continuing down the path of giving more information on specific trials as well.

Maybe now I'll turn it over to my colleagues.

Mr. Paul Glover: Thank you very much, Mr. Chair, for the member's question.

With respect to safety, first and foremost, the design of all clinical trials is subject to a review and approval by the department to ensure that the trial both achieves its objective in its design and that the patient's safety isn't compromised throughout that.

As the Auditor General pointed out, we needed a better process to identify risks in those trials and figure out which ones to inspect. We have done that. We have instituted standard operating procedures. We have mandatory reporting of adverse events from all clinical trials. We now have a system to prioritize those adverse events so that we can figure out what the significant signals are indicating that we might have to go in to follow up with the sponsor about the design of the trial, or to inform participants or ask the sponsor to inform participants about particular health and safety issues.

We've also developed standard operating procedures that we're in the process of implementing to make sure that we inspect the right clinical trial sites to make sure that they are correctly following their own processes, as per their submission to us. We didn't have that clearly documented; it is now documented. We have a risk-based process for doing this, to identify those we think are of greatest risk, and have trained and are in the process of implementing that procedure.

So we have taken a significant number of steps to protect the health and safety of the participants in the trials and to improve reporting to us. As was noted, we started to make transparent aggregate results of clinical trials, and we won't stop there. We'll continue; that's just the first step.

Mr. Earl Dreeshen: I'd like to go back.

Madam Yeates, in your presentation you spoke about the backlog for new drug submissions and about how it had been eliminated in 2011, but you talked about the challenge in meeting performance targets for generic drug reviews.

Is there anything specific to a generic review that has caused a delay in meeting these performance targets? Or does it simply happen to be one of those situations in which you were dealing with one part and hadn't gotten around to the other?

● (1020)

Ms. Glenda Yeates: Thank you. It's a very important question in terms of the generic reviews.

We have established the targets precisely so that we can monitor to see where we're falling short, as we are in generics.

We've seen a significant increase in the volume. In some cases we've seen an increase—I think in the last year a 33% increase is the number that sticks in my mind—in the number of submissions coming in. Even as we're gearing up—as I mentioned, doubling some of the capacity in some specific areas—the increases in volume mean that we have not yet reached our targets.

We're also doing a pilot, and we'll be evaluating it, to see whether we can better integrate our reviews and collaborate with other reviewers worldwide. If there is information that we can share back and forth to make sure that a broader pool of science expertise is looking at these questions, that may speed this up for all of us. We're piloting a number of methodologies in this area, and we'll be looking to see whether that gives us some ongoing process improvements.

But we acknowledge that this is an area that still requires work, and I can reassure the committee that this is why we've put these extra resources there, and have tried to build the systems and look for the process changes that would aid those resources to move more quickly.

The Chair: Very good.

I'm sorry, Mr. Dreeshen, that concludes your time, sir. Thank you very much.

Colleagues, we have a little more time, and I'm in the hands of the committee. We can continue—going back to the beginning of the rotation, if you wish—and go to the exhaustion of the meeting, or we can conclude matters here. I'm in your hands.

Mr. Byrne.

Hon. Gerry Byrne: We could start with a new rotation, but maybe condense the time a little for each questioner.

The Chair: What do you think?

Hon. Gerry Byrne: Will that be okay? Will we be able to get in a full—?

The Chair: You won't get a whole round, if you do five, no. You would get a minute each, if you're going to do the whole thing.

I'll throw this out, colleagues. If we were to cut it at the end of Mr. Byrne's normal rotation, that would have given the government two more questions, the official opposition two more questions, and Mr. Byrne would still get his chance to have the floor.

Are you open to that? We'll truncate the time. We'll make it, say, three minutes. That would mean there would be six more speakers.

Mr. Andrew Saxton: Why don't we say it's four more speakers, two from the government and one from each of the opposition parties—four more questions? Maybe we'll finish early.

The Chair: Let's not be kids in the parking lot and spend more time on the rules than playing the game.

Mr. Malcolm Allen: I think Mr. Byrne wants an opportunity to speak. As the official opposition, I'm happy to accept Mr. Saxton's suggestion.

The Chair: Do you mean one each?

Mr. Malcolm Allen: Yes, that's one each.

The Chair: Are you saying one each for the whole time, five minutes?

Mr. Malcolm Allen: It would be ten, five, and five.

The Chair: Okay, so it would be five minutes each, and I reserve the right to make a couple of comments at the end.

You have the floor.

Mr. Andrew Saxton: Thank you, Mr. Chair.

Health Canada has the duty and legal responsibility to ensure the safety of pharmaceutical drugs on the Canadian market, and we know that rigorous tests are done before a drug is approved for use in Canada. But the responsibility does not end there. There is also a need to continue monitoring drugs once they are on the market. Indeed, should safety concerns be identified once a drug is available to the public, the need for a quick response is essential to ensure that as few people as possible are exposed to health or safety risks.

Can you explain what steps are being taken to ensure the safety of Canadians in this regard?

Ms. Glenda Yeates: Yes. Thank you to the member for his question.

I'll begin and then very quickly—I'm thoughtful of the time—hand it to my colleagues, who in fact are the experts doing this day to day.

It is very much the case that we work to make sure, right through the clinical trial approval stage, through the drug approval stage, and then in the post-market stage, that we are looking at safety at every step. We post, as my colleague mentioned, the product information on the web so that individual practitioners and Canadians can see it. We post advisories, wherever we have concerns. We have mechanisms to determine which signals might be ones we should be prioritizing.

I'll turn to my colleagues for a more complete answer.

Mr. Paul Glover: Once a product is on the market, adverse events are the most important signal for us. We follow those up very actively. To provide the committee with some specific numbers, there were over 30,000 domestic adverse events reported to Health Canada in the last year—that is in addition to more than 300,000 international adverse events. We pool that together, we look for common safety signals, and we investigate those.

Out of those several hundred thousand safety signals and events that were reported to us, we narrow the focus down. In the last year, it was about 1,600 particular investigations that we did. That further narrows down to about 125 specific events that we felt were really worthy of further investigation.

Of those, there were between 60 and 90 risk communications, and that could be a label update, it could be a warning to the public, or it could be a withdrawal of a drug. There's a range of things in those activities. It's a case of constantly going from large volumes of data down to something very specific.

Just to respond to one of the questions earlier, for which we ran out of time, we would acknowledge that in those areas of the report card, which was mentioned by one of the members, we were not meeting performance targets. With the new fees, with the new changes in processes, we're pleased to report that we are meeting our performance targets on post-market surveillance and safety. The signals are being assessed in the timeframes that we have, they're being assigned, and the investigations are concluding.

We're very pleased that not only have we set those performance standards, but we are now able to meet them and to deal with sifting through those large amounts of data.

● (1025)

Mr. Andrew Saxton: Most of that information comes from the drug companies themselves. They supply you with that information. Is that right?

Mr. Paul Glover: The drug companies supply us with adverse events from other jurisdictions. They also supply us with adverse events reported to them. We also take adverse events from physicians directly—there is a form that they fill out—and from individual patients themselves.

So we get it from the health community, from those receiving the drugs, the drug companies, and international colleagues. We try to make sure that we get adverse event reports from as many sources as possible.

Mr. Andrew Saxton: Thank you.

The Chair: Thank you.

Ms. Joyce Bateman: Does he have one tiny second left of his time?

The Chair: He has more than a tiny second. You're welcome to it, if you'd like.

Mr. Andrew Saxton: I'd be happy to share it with my colleague.

The Chair: I think that was her inference.

The clock is going. Talk.

Ms. Joyce Bateman: This is so silly. We're in the parking lot again.

Are all of those adverse reports that we were talking about earlier put on the website?

Mr. Paul Glover: That goes back to the MedEffect and the Canadian adverse event reporting newsletter. We have several thousand people who subscribe to it.

Ms. Joyce Bateman: So it could go on your website. It doesn't—

Mr. Paul Glover: It is on it.

Ms. Joyce Bateman: Oh, it is on your website.

So that link that we're all going to get has that information? Joe Q. Public can access that information?

Mr. Paul Glover: Yes. We don't post those hundreds of thousands of adverse events. We sift through that information to what the real events are—what the things are that we've followed up on.

Ms. Joyce Bateman: Why don't you post the hundreds of thousands of adverse events? If I were putting my child on medication and I knew that there were hundreds of thousands of adverse events, I would want you posting them.

Mr. Paul Glover: What we post is the specific summaries of those, as we've investigated them. Otherwise, you're swimming in a sea of data, with hundreds of thousands year after year.

Ms. Joyce Bateman: Fair enough; but you utilize all this information.

Mr. Paul Glover: Yes, and that is what is summarized in the adverse event newsletters, warnings to health professionals, etc.

Ms. Joyce Bateman: Is your newsletter available by a link as well?

Mr. Paul Glover: Yes.

Ms. Joyce Bateman: From this link that we're going to get, we could get not only the summary piece, but the newsletter as well?

Mr. Paul Glover: We'll provide several links. We'll provide a link to all of the drugs that are available for sale in Canada. We'll also provide a link to our adverse events, the MedEffect, and Canadian adverse reaction newsletter. So you will have both those, all drugs and all adverse events, and health and safety updates.

Ms. Joyce Bateman: And we can share this with the public?

Mr. Paul Glover: It is already shared with the public.

Ms. Joyce Bateman: Excellent.

Thank you so much.

The Chair: There you go.

You're very welcome.

Moving on over to Madam Blanchette-Lamothe. You have the floor.

[*Translation*]

Ms. Lysane Blanchette-Lamothe: Thank you very much.

I have a question for Ms. Yeates, because I would like a clearer answer.

The report states that Health Canada sometimes takes more than two years to identify safety-related issues. I would like to know if you think that it would be relevant to increase the efficiency of the process even further, to reduce the time frames for identifying safety-related issues.

[*English*]

Ms. Glenda Yeates: Thank you.

It's a very important question. What we would try to reassure the committee and to communicate to the committee is that when we are trying to assess the time between getting some piece of information and putting out a communication.... If we assess this to be a real and serious signal that affects the health of Canadians, obviously two years will be far too long. We don't wait. Those are prioritized and those are done immediately.

There are some signals where we would say more information needs to be gathered. We would take the time to make sure that we are confident the advice we would be giving to Canadians is, in fact, the right advice. We would say that the standard operating procedures—the clarification, which the Auditor General suggested, that we are very clear about how we prioritize that work, and set ourselves timelines.... We are meeting those timelines, as my colleague mentioned, and these signals are so unlike each other that one timeline in a sense wouldn't be appropriate for all of them. What's important is that they are done in the priority that reflects their seriousness. So for some, 24 hours would be the right timeline, and for others much longer, and different mechanisms and tools would be used.

We are comfortable that we are addressing those in a timely way, and that's, I think, the prioritization that my colleague was flagging. We always want to be making sure that we are doing a better job, though, and that's why we look to these system improvements, these process improvements, and these procedures to help us ensure that we are always catching the important ones early and that we are, in fact, setting timelines for all of them. I think that's the spirit of the way in which we're looking at this.

● (1030)

[*Translation*]

Ms. Lysane Blanchette-Lamothe: Thank you, Ms. Yeates.

I have another question for you.

You still have a lot of challenges to overcome. I am aware that you are doing everything you can to improve your services, with the resources available to you. Could other resources be made available to you to help you respond to all these challenges you will face in the coming months?

[*English*]

Ms. Glenda Yeates: I think we are at the moment. Because of the significant increase in resources that's come to us at this time through the user fee proposal, we are busily staffing up, in a sense, to those levels. So at this time I think we're feeling that we are simply trying to work through that process of getting the new reviewers and the new inspectors, getting everyone trained up, getting our computer systems updated in some cases. We are working with that, and at this point, managing the complexity of this change is really the focus of our efforts.

[*Translation*]

Ms. Lysane Blanchette-Lamothe: Thank you.

Mr. Maxwell, I'll give you the opportunity to wrap up. Based on what you have heard today and the action plans that are being implemented, would you like to add anything with respect to your audit and your positions?

Mr. Neil Maxwell: Yes, thank you. You read my mind.

[*English*]

I was hoping someone might ask that question. I have maybe three quick points, being conscious of time. I'll speak in English, since I can speak more quickly.

Concerning the two years it has taken, I listened with interest and I'm encouraged by the fact that the department is now meeting its timelines. But I would emphasize that it is a multi-step process, and there are timelines only for certain parts. So that's improvement, but we found—and it was a large number—almost 50% of the cases took more than two years, when they had to go from evaluation through to the actual communication to the medical professionals and Canadians. We found things such as breakdowns in communication between the different sections, between the people dealing with brand name and generic.

We found as well that quite often there were delays because it was easier to batch a number of label changes, if there were a number of different generics. So I think there are more structural things that will also need to be looked at with regard to that.

I have two other quick points. There's been a lot of discussion on clinical trials today, and a lot of encouraging action. Auditors always reserve judgment until they can go back and re-audit, but encouraging indeed.

The one thing that I think remains the largest gap is the question of the availability of information on specific clinical trials. As we sit here now, you could find many of those clinical trials by going to the FDA site or the European Medicines Agency. So I'm encouraged by the actions that Health Canada's taking, but a gap still exists today in terms of the information Canadians have.

Maybe I'll stop there.

The Chair: That's fine, and that exhausts our time.

Thank you very much, Madame and Monsieur.

We'll now go to Mr. Byrne.

An hon. member: No. Chair....

The final thing I said was one from each. One, two, three.

Some hon. members: No. Two and two....

You're both going to go with two then? That's not what I said, but if that's your understanding, that's more important. So go ahead then....

That's fine. I stand corrected.

Mr. Kramp, then over to Mr. Byrne.

Mr. Daryl Kramp: Thank you, Chair.

Mr. Glover, you made a statement, and maybe I didn't hear it right. I'd like a little clarification, if you would. It was with regard to your comment on Sandoz. You mentioned they have three plants, two in Canada and one in the U.S. Yet the problem that surfaced came from the U.S. plant, if I heard you right.

So if that is the situation, why are we having a problem with availability of their product here in Canada?

● (1035)

Mr. Paul Glover: Mr. Chair, I'll try to be as clear as I possibly can, perhaps it was my miscommunication.

Sandoz has a plant in Boucherville, Quebec, and two in the U.S. The FDA inspected all of those. The FDA was concerned with what it saw in the Boucherville plant in Quebec, with respect to a product that they make there that is not sold in Canada. It is sold into the U.S. That was what the FDA found. They issued a warning letter to Sandoz saying they had this concern, and Sandoz had 30 days to respond with a plan to address that concern.

We also inspect Sandoz and its plants, just as we inspect all plants that provide product to the Canadian market, or we work with international partners to make sure they all get inspected. In the particular case of the Boucherville plant, we had been in and continue to be in it. We were in just last Friday, given the packaging mix-up. Our inspection found a number of problems, and we noted those problems and asked them to follow up with how they would respond to those observations. They were still compliant. We didn't feel the plant needed to be shut down. It could still continue operating, but we wanted to see further improvements in their operations, and that is fairly standard in terms of all our inspections.

Mr. Daryl Kramp: Okay, but there's no restriction on their product coming out to Canada?

Mr. Paul Glover: No. We were monitoring and watching that.

The ultimate issue, if I may, was a business decision by Sandoz, in terms of responding and how they chose to respond, that has resulted in this. They could have responded to both the FDA warning letter and to our reports differently than they have chosen to.

Mr. Daryl Kramp: Okay. Thank you very much.

I have three quick questions for Ms. Yeates, if I have an opportunity to get them in.

Just for common knowledge, I was talking to the minister of revenue the other day, and 42,000 people work for Revenue Canada. How many people work for Health Canada?

Ms. Glenda Yeates: In rough figures, I'd say 10,000.

Mr. Daryl Kramp: What's your yearly budget?

Ms. Glenda Yeates: It's in the neighbourhood of $3.7 billion.

Mr. Daryl Kramp: Thank you very much. Are you currently involved in any litigation?

Ms. Glenda Yeates: Yes.

Mr. Daryl Kramp: You're in several litigations? Thank you.

Can you just quantify, one, two, three, five hundred. Give us an approximate—

Ms. Glenda Yeates: I wouldn't have that number with me. I'll just give an example the committee might be aware of. We are often the third party in a significant number of tobacco litigations, but there would be a number of others.

Mr. Daryl Kramp: Fine, thank you very kindly.

That's enough, Chair.

The Chair: Thank you.

Now we'll go to Mr. Byrne.

Hon. Gerry Byrne: Thanks, Mr. Chair.

I just want to follow up on Mr. Maxwell's comments. In 2004, the Standing Committee on Health recommended that the department, Health Canada, create a public database on clinical trials. That was in 2004. Are you committed to establishing a Canadian, Health Canada-administered database on clinical trials?

Ms. Glenda Yeates: We are very committed to making clinical trial information more transparent, and we are currently in consultation about the best way of doing that. As the clinical trial sites become multinational, the question of whether we should build a Canadian-only site, or whether we should require companies to put their clinical trial information on international WHO-sanctioned sites, which we have been encouraging companies to do, is a question that is still outstanding.

Canadians, I think, are interested. Some of these clinical trials are with patients who have very specific conditions. You'll be interested, as a parent or as a family member, in knowing what is happening in the sites in Canada and also whether those drugs are being tested internationally.

Hon. Gerry Byrne: Would it be fair to say that the answer to the question is no, until convinced otherwise?

Ms. Glenda Yeates: When I mentioned that we are doing consultations and are exploring this, that is precisely the kind of thing we are exploring. We want to build something here. We want to go down the path that is the most useful to Canadians.

Hon. Gerry Byrne: Not to be too critical, but it has been eight years. I'll just leave it at that.

I have a question about drugs the department rejects and drugs the manufacturer withdraws from the review process. You're not disclosing any information. What specifically do you intend to do to rectify that?

Ms. Glenda Yeates: We are, in fact, moving in that direction. That will be when we come back with our commitment here. We have been—

● (1040)

Hon. Gerry Byrne: I'm sorry, what was that?

Ms. Glenda Yeates: We do intend to take that step to make sure. Right now we have a plan, and as the committee has requested, we will be even more specific about the steps in this plan. But we will broaden our information so that Canadians have information on conditions and rejections, for example.

Hon. Gerry Byrne: Does the department do any foreign inspections of plants, like the USFDA did to Sandoz in Quebec? Do we do foreign inspections?

Ms. Glenda Yeates: Yes, we do, but I'll ask my colleague to speak to the specifics.

Mr. Paul Glover: We do a number of foreign inspections, and we also have what we call mutual recognition agreements, where we have gone through confidence-building and rather than constantly going all around the world, we work with our international partners and exchange information. For those that we have mutual recognition agreements, we collaborate and coordinate, and for those that we don't, we do foreign inspections.

Hon. Gerry Byrne: Could you provide a list, for the last two years, of which plants you have done foreign inspections of? That would be extremely helpful information.

I'll leave time for you, Mr. Maxwell or Ms. Dubé, if you have any further parting comments you would like to make.

Mr. Neil Maxwell: No, other than that I would say, I'm very pleased to see the committee focus on action plans. Different members had mentioned that, and that is music to an auditor's ears. Thank you for that.

The Chair: Are you good, Mr. Byrne?

Hon. Gerry Byrne: Yes, thanks.

The Chair: Very good. Thanks.

I just want to make a couple of comments, and then we'll be on time to adjourn.

I want to underscore the importance, obviously, that everybody takes to this issue, and you can understand why. I think it's good that the action plan is giving Mr. Maxwell and his shop some comfort that you're on the right track.

It was good that you tabled this with us prior to coming here today. That is our rule, our policy. Not everybody is following it, but let it be known now that we'll be cracking down on that. You won't need to be on that list because you did meet the timeline, and it is appreciated.

I do want to underscore, and I think this is important, that this was not a good report. I think Mr. Allen commented that overall you didn't get a passing mark on something that is very close to every one of us here because of our constituents.

I will end on a positive note, but first I want to underscore that in the remarks from Mr. Maxwell this morning, he mentioned the 2011 fall report....

Now, people who have been on this committee for a while will know that nothing enrages me more than when things have been audited or looked at in the past, with recommendations made, recommendations accepted, and they go off with “Yes, sir, we'll do it”, but then, when they're brought back a couple of years later, it's not done. I have been on this committee, and Mr. Kramp too, where there have been four and five previous audits. Yours isn't quite that bad, but it's not good.

Mr. Maxwell said in his comments:

> For our 2011 fall report, we examined whether Health Canada fulfilled its key responsibilities for pharmaceutical drugs....
>
> We found that the department had not adequately fulfilled most of these key responsibilities....

Further:

> We found that Health Canada had problems with the timeliness and transparency of its activities.
>
> Health Canada is not meeting its service standards....

In paragraph 7, “but it is slow to act”, and I'll come back later to the 2004 example.

> The Department is also not disclosing information....

There is a list of those, and we've talked about those.

> We found that Health Canada was not making use of assessment work done in other jurisdictions....

Then there's the issue of the database back in 2004, which has been referred to by a number of members. In 2011 there was an audit where you were rapped on the knuckles for not having met your commitments in 2004, and here we are in 2012 and it's still not done.

So this is very serious. I said I'd end positive, and I will.

The action plan, I agree with Mr. Maxwell, looks very comprehensive. I think it gives us a good sense that you're on the right track.

But I do want to underscore to you, Deputy, that it will not be a pleasant day if your department returns, upon follow-up by Mr. Maxwell, and these things are not addressed. Given the assurances you're giving us—and my sense is that the committee is prepared to accept those assurances at face value—please do not come back here, upon a further review, and still have failed in all the commitments that you've made previous and made today. Please don't let that day happen. It won't be a pleasant one. Okay?

But we're feeling good. That was a good discussion. The answers were fulsome. Let's hope that going forward we can focus on being far more positive than any of the negatives, because I know you want to do the best you can for Parliament and for Canadians.

With that, I will thank you all very much. Thank you to the assistant auditor for being here today, and all of our other witnesses.

Colleagues, is there any other last-minute business to come before the committee?

Hearing none, this committee meeting now stands adjourned. Thank you.

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