HOUSE OF COMMONS
CHAMBRE DES COMMUNES
CANADA

Standing Committee on Health

HESA • NUMBER 036 • 1st SESSION • 41st PARLIAMENT

EVIDENCE

Tuesday, March 27, 2012

Chair

Mrs. Joy Smith

Standing Committee on Health

Tuesday, March 27, 2012

● (0850)

[*English*]

The Chair (Mrs. Joy Smith (Kildonan—St. Paul, CPC)): Good morning, ladies and gentlemen.

Thank you so much for being here today. I want to welcome you to the session this morning.

Because we have a very full agenda this morning, I'll quickly ask the committee to pass the budget, first off. The motion is that in relation to the study of the role of government and industry in determining drug supply in Canada, the proposed budget in the amount of $18,450 be adopted.

Can I have someone move that, please?

Ms. Block, thank you.

Does someone second it?

A voice: That's fine.

The Chair: Great.

Thank you very much.

So we have the budget passed. Also—

A voice: You have to call for the vote.

The Chair: All in favour of the motion?

(Motion agreed to)

The Chair: Thank you.

Sorry; I was rushing too fast. I knew you'd pass it.

I think now we can go directly into our....

We have a couple of other things to finish, but I see that we're missing some members, so I'll wait until the end for that. We'll just take five minutes at the end of committee.

We have a full agenda today. We'll start with the study of the role of government and industry in determining drug supply in Canada.

From the Canadian Generic Pharmaceutical Association, we have Mr. Keon, Dr. Desai, and Mr. Michel Robidoux, who's president of Sandoz Canada.

Welcome. We're very glad that you're here.

We also have, from Canada's Research-Based Pharmaceutical Companies, Mr. Russell Williams, president, and Mr. Mark Ferdinand, senior director.

Welcome. We're so glad you're here as well.

From the Canadian Association for Pharmacy Distribution Management, we have Mr. Johnston and Mr. Reynolds. Mr. Johnston is the president and chief executive officer, and Mr. Reynolds is the vice-president.

We're so glad you're here as well. Thank you.

Our fourth presentation is from HealthPRO Procurement Services. Ms. Kathleen Boyle is vice-president and Mr. Michael Blanchard is the clinical director.

Welcome. We're very glad you're here.

The presentations will be 10 minutes for each presenter.

I will start with the Canadian Generic Pharmaceutical Association.

Mr. Keon, I believe you will be presenting. Would you begin, sir.

Mr. Jim Keon (President, Canadian Generic Pharmaceutical Association): Thank you, Madam Chair, and good morning, honourable members.

We want to thank you for providing Canada's generic pharmaceutical industry with the opportunity to contribute to your study of the domestic drug supply system.

As the chair said, I am Jim Keon, president of the Canadian Generic Pharmaceutical Association, or CGPA. Our member companies research, develop, manufacture, and market generic drugs in Canada and internationally.

I am joined today by Dr. Jeremy Desai, the president and chief operating officer of Apotex. Apotex is a privately held Canadian company based in Toronto. Dr. Desai provides the experience of Canada's largest pharmaceutical R and D investor, manufacturer, and employer. He personally has extensive experience in working with Canadian, U.S., and foreign regulatory agencies.

I'm also joined by Monsieur Michel Robidoux, president of Sandoz Canada, a company that develops, produces, markets, and distributes a wide range of generic products. They are headquartered in Canada, in Boucherville, Quebec. Sandoz is the second-largest producer of generic drugs in the world.

CGPA member companies take the responsibility of providing high-quality, lower-cost generic drugs to Canadian patients very seriously. Millions of Canadians rely on these products daily to maintain or improve their quality of life. Generic drugs are dispensed to fill 60% of all prescriptions in Canada, and they provide significant value to Canadians. Retail generic drug prices are internationally competitive. Today, three to four generic prescriptions in Canada can be filled for the price of one patented brand-name prescription.

The generic pharmaceutical industry is devoted to working with all stakeholders to minimize the current shortages and to mitigate factors that could contribute to future shortages. We are aware of the distress caused to patients, families, and clinicians by disruptions in the drug supply, particularly with respect to drugs identified as medically necessary.

Most of the pharmaceutical manufacturing capacity that exists in Canada is operated by generic drug companies. We have two of the largest Canadian manufacturers here with us today, Sandoz in Quebec and Apotex in Ontario. Canada is fortunate to be home to an internationally significant cluster of generic manufacturers, which contributes positively to the Canadian drug supply.

In addition to supplying the domestic market with high-quality pharmaceuticals, we export about half of our domestic production to more than 115 countries around the globe, with the United States forming the single largest market for our products.

● (0855)

[*Translation*]

The generic drug industry is a highly competitive, low-margin industry that operates in a highly regulated environment.

Before bringing a new generic drug to the Canadian market, a company must carefully weigh several business considerations. These include the cost of development, the cost of production and market prospects. It also needs to navigate Canada's complex and costly legal environment, which creates a great deal of business uncertainty for a generic manufacturer seeking to make a new generic product available to Canadians.

It takes several years to bring a new generic product to market. Once Health Canada has reviewed and approved a new generic drug as being safe, efficacious and bioequivalent to a reference brand name drug, it can be sold anywhere in Canada. All pharmaceutical manufacturers are subject to ongoing reporting requirements and inspections aimed at ensuring the product meets current and evolving regulatory standards in Canada and other countries in which a Canadian-made product is sold.

To be reimbursed under the provincial drug programs and obtain significant sales volumes, the generic drug must be listed on provincial drug benefit plans. The manufacturer must submit a separate application to each province and await a response. It can take up to one full year to have the new generic listed in all provinces.

The generic manufacturer negotiates with pharmacy customers and other purchasers to sell its products. For the hospital market, group purchasing organizations conduct a tendering system where pricing is the main consideration. This has led to a number of sole-source contracts in the hospital market.

The generic manufacturer typically distributes the medicine to pharmacy customers through a wholesaler, although companies also have some in-house direct distribution to pharmacy.

[*English*]

Despite the best efforts of all parties in the pharmaceutical supply chain, shortages of prescription medicines can and do occur in Canada and other countries. There are various reasons why a brand or generic manufacturer cannot temporarily supply a drug. The specific reasons may vary and can be complex.

The most common causes for drug shortages are: issues around the active ingredient quality or the availability of the active ingredient; manufacturing issues; the evolving regulatory environment and, in the view of our members, an increasingly inflexible approach to enforcement by the U.S. Food and Drug agency; and marketplace issues.

When shortages of prescription medicines occur in Canada, generic pharmaceutical manufacturers aggressively pursue remedies, including finding alternative sources of products. Canada's generic pharmaceutical manufacturers recognize the importance of providing transparent information to help patients, health care professionals, and provinces and territories prepare and deal with current and anticipated shortages of prescription medicines.

CGPA has been a leader in the activities of the multi-stakeholder group on drug shortages, which includes representatives of several organizations that will appear before this committee, including Rx&D and CAPDM, which are here today, as well as the Canadian Pharmacists Association and the Canadian Medical Association, which you will hear from later this week. Health Canada has also participated in that multi-stakeholder group.

The work of the multi-stakeholder group led to an interim solution for the reporting of current and anticipated drug shortages on public websites operated by the University of Saskatchewan's Saskatchewan Drug Information Services and Sainte-Justine Hospital in Montreal. CGPA member companies have been reporting to these websites. The information has also been available on our own CGPA website. The availability of these websites has been promoted to health care professionals.

Recently, CGPA and Rx&D have been working very closely to accelerate the development of a national bilingual reporting website for Canadian drug supply stakeholders. Our associations have each committed up to $100,000 to accelerate the development of this website. Earlier this week, the website www.drugshortages.ca went live. The French website is available at www.penuriesdemedicaments.ca.

● (0900)

We consider this an important milestone. We are now focused on continuing our communications efforts with the goal of providing robust, timely, and transparent information to all drug supply stakeholders.

Cooperation and joint action between the generic and brand-name industry is not particularly common in Canada or any other jurisdiction. The fact that we have set aside our differences and come together to combat drug shortages in Canada we believe demonstrates how critically important both sides of our industries view this issue and how committed we are to finding workable solutions.

While the reporting of backlogs and shortages to all drug supply stakeholders is important, reducing the potential for backlogs and shortages is a high priority for the generic pharmaceutical industry. To mitigate the potential for disruptions in our domestic drug supply, our member companies have invested more than $100 million over the next three years in new systems, personnel, equipment, and facilities. They have heavily allocated additional resources, both human and financial, to quality control and quality assurance operations to ensure continued compliance with the evolving regulatory environment. They have improved forecasting capability and prioritized production to better adapt to shifting market demand. They are working with Health Canada on an ongoing basis to prioritize product reviews and approvals based on shortages or potential shortages. They are implementing industry best practices guidelines for the prevention, notification, and management of drug shortages. A copy of the CGPA "Best Practices Guidelines for the Notification and Management of Drug Shortages" has been provided to committee members.

CGPA and its members remain committed to working with Health Canada and all our partners in the prescription drug supply chain to develop solutions to help mitigate the impact of prescription drug shortages in Canada.

Dr. Desai, Mr. Robidoux, and I would be pleased to answer any questions you may have. Thank you.

The Chair: Thank you so much. We will continue with the presentations and then have the questions following that.

We will now go to Rx&D. Mr. Williams, I believe you are going to make the presentation. Thank you.

Mr. Russell Williams (President, Canada's Research-Based Pharmaceutical Companies (Rx & D)): Merci beaucoup. Thank you, Madam Chair.

Thank you, committee members, for the opportunity to appear before you today.

As you mentioned, seated with me is Mark Ferdinand, our senior director of health and economic policy. He has been a key worker in terms of the working group that Jim Keon just mentioned. If there are other questions, he will certainly add to them.

Rx&D, as you know, is a national association that represents 50 companies that represent the innovative pharmaceutical industry.

[*Translation*]

Our members research, discover, develop and deliver life-saving and life-changing medicines and vaccines.

[*English*]

To start, let me state that patient access to the widest array of effective medicines and vaccines is of paramount importance to Rx&D and its members. Simply put, we are in the business of improving health outcomes. This is best achieved by maximizing the choice of therapies to which patients and physicians have immediate and consistent access.

I want to assure this committee that our members appreciate the anxiety and frustration that drug shortages cause Canadian patients, their families, and health care professionals.

[*Translation*]

Indeed, the drug shortages issue demands attention and collaboration from everyone—we as innovators, generics, governments, health care professionals, and all others who play a role in providing medicines to Canadians.

I believe that Canadians want and deserve answers to three very simple, specific and straightforward questions.

[*English*]

First, why do drug shortages sometimes occur? Second, what is our industry, along with others, doing to address this issue? Third, and most importantly, what can we do, using public policy tools and expertise of industry, to ensure that drug shortages do not occur in the future?

Turning to the first question of why and how shortages occur, let me provide some context. Each and every day, Rx&D members adhere to the highest standards of management and manufacturing practices. They are constantly refining their business continuity plans to supply, in a reliable fashion, Canadians with the medicines they need. These practices include: actively managing supply chains to ensure regional balance and access; securing backup suppliers for base components and raw materials and active ingredients; and monitoring stock throughout the wholesaler community. Nonetheless, it has long been recognized that shortages can occur, and no country is immune from this reality.

Reasons for the drug shortages, as Mr. Keon has just mentioned, can include a number of factors: unprecedented and unusual demand for product is one factor; unforeseen manufacturing, safety, and quality problems; procurement policies; interruptions in distribution networks or factors beyond anybody's control, such as accidents or natural disasters. These are all magnified due to the practice of single-source purchasing in the post-patent market.

Turning to question number two, Rx&D has worked with the pharmaceutical supply chain community, including wholesalers, distributors, physicians, pharmacists, chain drugstores, and Health Canada officials on this issue since last summer. In fact, last October Rx&D members created a public and bilingual web-based platform to inform Canadians of shortages. Our site includes key information, such as the name of the drug in shortage; strength and dosage form; its drug information number, DIN; name of the member company; the reason for the shortage; and expected duration and resupply date.

● (0905)

[*Translation*]

Three weeks ago, we expanded our site's capability and opened it so that any manufacturer in Canada—innovators, generics, Rx&D members or the Canadian Generic Pharmaceutical Association—could use our platform to report on shortages.

[*English*]

We strongly encourage them to do so, and many companies have accepted this offer. As suggested by the last speaker, this information can be found at www.drugshortages.ca

[*Translation*]

or www.penuriesdemedicaments.ca.

[*English*]

Two weeks ago, both Rx&D and the generic association came together to commit up to $100,000 each toward a comprehensive national and bilingual platform and plan that will do two important things: permit real-time reporting of drug shortages, and recommend potential solutions when medications are not available.

I am proud of our leadership on this joint initiative. However, while better reporting on shortages helps health care professionals deal with the immediate challenge, it does not address the root causes of drug shortages and will not mitigate by itself the risk of future drug shortages.

That brings me to the fundamental question posed at the outset of my remarks: what can we do, in terms of public policy, to better assure Canadians the medicines they need will be there for them, day in and day out? I will be unequivocal in the answer. The present Canadian policy environment does not favour better access to prescription medicines. If this environment does not change, based on what we have learned from the current situation, the potential for problems caused by future drug shortages will not diminish.

Federal, provincial, and territorial policy makers must clearly understand that procurement approaches, such as sole-source contracts or bulk purchasing of medicines in the generic, post-patented sphere, which limits competition and patient access to medicines, have real and lasting consequences, like the scarcity of supply to all Canadians.

Mike de Jong, the Minister of Health for British Columbia, recognized this fact last week when he said:

> If you become overly reliant on a single source for any product, there are risks. I have to say, one of the things we are discussing, amongst provincial health ministers, in our zest to drive the cost down on behalf of taxpayers...have we inadvertently created a condition where competition has been compromised?

That is a powerful statement.

Moreover, the unintended consequences of short-term, cost-containment strategies that compromise health outcomes have been witnessed over the past few years in areas such as surgical supplies and vaccines, and now we see it in medicines too.

To protect against future shortages we recommend that a system of competitive diversity for post-patented medicines must exist to ensure there are enough companies in the market that can increase production immediately if needed. We need to guard against procurement models that run afoul of the old adage, “Don't put all your eggs in one basket.” It's a simple concept, but one that I think we have to look back on.

Our members sincerely appreciate the very serious fiscal challenges facing all levels of government across this country. We are working with governments on what we call value-demonstrating initiatives—those projects that take health care challenges and, through an evidence-based approach, identify ways to improve patient outcomes and cost-effectiveness.

Yes, government has a responsibility to manage taxpayer dollars, but we have now seen only too clearly what can happen when Canadians rely on one supplier for the medicines they need. It is not in the best interests of patients, does not account for the essential role pharmaceuticals play in our health care today, and runs contrary to the values and intent of our health care system.

Our preference is for increased choice domestically, but we have also repeated at both the provincial and national levels that more work must be done to expedite Canadian approvals for medications from jurisdictions such as Europe and the United States. We've also encouraged better fast-tracking of alternate sources of supply when shortages occur. I know that is being worked on as we speak.

● (0910)

[*Translation*]

On behalf of Rx&D, you have my commitment that we will continue to work in partnership with governments and our supply chain partners to report on drug shortages on an ongoing basis.

[*English*]

We believe that our joint efforts on a joint reporting site with all the interveners of the chain is an important first step; however, we need all policy-makers to work with us towards a long-term solution to ensure that we have a system that can respond quickly when drug shortages do occur.

Thank you very much, Madam Chair and committee members, for your attention. I look forward to your questions and a discussion following the other presentations.

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

Now we'll go to the Canadian Association for Pharmacy Distribution Management.

Mr. David Johnston, I believe you're going to give the presentation. Thank you.

Mr. David Johnston (President and Chief Executive Officer, Canadian Association for Pharmacy Distribution Management): Good morning. As mentioned, I'm David Johnston, president and CEO of the Canadian Association for Pharmacy Distribution Management, or CAPDM, as we are known.

On behalf of CAPDM, I thank the members of the House of Commons Standing Committee on Health for the opportunity to outline the role of the pharmaceutical wholesalers with respect to drug shortages. This is an issue that our industry is very concerned about and is working closely to address with other health care organizations in Canada, including those organizations presenting this morning.

First, I would like to offer you a brief overview of CAPDM so you see how we fit into the health care system generally and the drug shortages situation specifically.

Established in 1964, CAPDM is the voice of the Canadian pharmacy supply chain. Members consist of pharmaceutical wholesalers, self-distributing pharmacy chains, prescription and non-prescription drug manufacturers, both brand and generic, as well as goods and services providers to the pharmacy supply chain sector. We are a significant contributor to the efficiency of the Canadian health care system. Over 95% of pharmaceuticals across Canada are distributed to community and hospital pharmacies as well as long-term and specialized facilities by pharmaceutical wholesalers and self-distributing chains, with an order accuracy greater than 99%. Distribution of pharmaceutical products by pharmaceutical wholesalers is the system of choice for pharmacies and manufacturers.

By offering same day and next day delivery five days a week to all parts of Canada, through thousands of employees working in distribution centres in nearly every province, pharmaceutical wholesalers help to ensure timely patient access to vital pharmaceuticals and over-the-counter medicines. CAPDM pharmaceutical wholesalers, working with Health Canada regulators, are proud to be part of a pharmaceutical supply chain that has come to be admired at home and abroad as one of the best systems in the world.

The role of pharmaceutical wholesalers is to obtain available products from pharmaceutical manufacturers and distribute them under highly regulated pricing regimes in a safe, secure, timely, and economical manner to pharmacies. On the surface this may seem like a simple process. However, behind the scenes there are highly complex skills and technologies used by wholesalers to consolidate shipments from hundreds of manufacturers and deliver them to thousands of pharmacies.

This is crucial in sustaining the safety and viability of Canada's pharmaceutical distribution system, which in turn means the viability of the health care system itself. In today's world of growing demands and service, just-in-time storage and delivery are crucial to pharmacies, wholesalers, and manufacturers alike.

Before I describe our role when a product shortage occurs, I'd like to quickly define what the notion of shortage means to our industry. Shortage represents a reduced availability of one or several products from one or several manufacturers. Typically when a manufacturer experiences a supply issue, it will create an allocation for the impacted product or products to ensure fair distribution of available inventory to the market. This allocation may be at the geographic level or wholesaler distribution level, or even at the customer level, based on historical trends.

Pharmaceutical wholesalers do not cause drug shortages, nor do they have the information to predict a shortage. They do not determine the adjusted supply levels to each customer in the event of a shortage.

In times of shortage, the role of the pharmaceutical wholesaler is to support the allocation process by fulfilling and delivering orders according to the defined allocation instructions and stock replenishment received from the manufacturer. With their available inventory, pharmaceutical wholesalers will then implement order limits to ensure that as many customers as possible have access to the product experiencing a shortage and that no one region or organization will have a disproportionate amount of product.

CAPDM recognizes that drug shortages are a major issue, and we have developed a committee that is actively participating in a cross-industry initiative with Health Canada, known as the drug shortage working group, along with other health stakeholders, on proactively reporting on shortages. There's still much to be done by all stakeholders, and we look forward to continuing the progress made to date in creating a system to help Canadians better manage their medication needs within shortage situations.

In summary, during times of drug shortages, pharmaceutical wholesalers will continue their essential role of distributing all available products through the safe, secure, and efficient system they have developed.

● (0915)

Pharmaceutical wholesalers do not influence the cause of drug shortages but do manage the flow of available products in the market during shortages, and they are working with manufacturers, health care providers, and government to help find a solution to this situation. We look forward to continuing this important collaborative initiative.

Thank you for your time and attention. We'd be delighted to answer any questions.

The Chair: Thank you. There will be time to do that following the last presentation.

Ms. Boyle.

Ms. Kathleen Boyle (Vice-President, Services, HealthPRO Procurement Services Inc.): Thank you for inviting HealthPRO Procurement Services to present at today's meeting. My name is Kathy Boyle, vice-president of pharmacy services at HealthPRO. I would like to introduce my colleague, Michael Blanchard, clinical director at HealthPRO.

HealthPRO is Canada's national group purchasing organization for health care, representing the purchasing interests of hospitals, provincial health authorities, and shared services organizations from coast to coast. We recognize the critical impact that drug shortages can have on delivering quality patient care. We are doing everything possible to help our members find alternative solutions to drugs that are in short supply, and we are actively collaborating with industry stakeholders to find solutions. To that end, we are pleased to be invited to participate in today's important event.

Although the problem is not new, the number of drug shortages has significantly increased in the last few years. This is a complex problem, with no easy solutions. It is important to first understand the following key factors that contribute to the global problem. It is also important to consider that every situation is different, and that each product on back order and each shortage is driven by unique contributing factors.

The global supply chain is complex. A trend by manufacturers to outsource active pharmaceutical ingredients and raw materials has created intricate and increasingly less stable global supply chains. Manufacturers are susceptible to shortages or delays at any of their global facilities.

The move to consolidate production overseas warrants consideration. The health care sector's ability to respond to Canadian shortages is further hampered by suppliers' attempts to consolidate production overseas, generally in one plant, which increases vulnerability to production interruptions.

There is increased demand without increased production. As the need for medications grows, manufacturers are struggling to keep up with demand. Contributing factors can include rigid regulatory control over manufacturers' active pharmaceutical ingredients, raw material shortages, and delays caused by line production increases of drugs in greatest demand.

We now have stricter drug regulations and improved quality. In response to several tainted drug and food incidents over the past several years and the increasing challenge of counterfeit drug production, the U.S. Food and Drug Administration has increased the frequency and intensity of audits with a focus on complete traceability of all compounds. In several cases, strict FDA audits have impeded production of high-demand drugs at manufacturing facilities, contributing to temporary shortages.

Public policy directives on health care costs have affected drug supplies. The drive to control health care costs in Canada has led to a leaner supply chain and tighter hospital, distributor, and manufacturer inventory across the country. Shrinking margins for manufacturers and distributors affects inventory and product availability. Shrinking margins can also negatively reshape the market, leading manufacturers to focus on the most profitable products.

Canada's market share is limited. Canada represents 3% of the global drug market. Of that 3%, Canadian hospitals represent just 10%, a small business market opportunity for global manufacturers.

There is no stakeholder in the Canadian supply chain that has not contributed to, or been complicit in, the problem of drug shortages, including global parent companies, local manufacturers and distributors, Health Canada, provincial authorities, group purchasing associations, and hospitals. Nevertheless, there is room for each of these key stakeholders to consider how they might contribute to a solution.

● (0920)

We have the following suggestions related to each of the stakeholders.

Health Canada may consider guarding against standards of other countries overriding the high-quality standards in Canada, ensuring there are multiple suppliers of medically necessary drugs in Canada, mandating early warnings of anticipated supply disruptions, mandating early warnings of manufacturers' plans to exit the market, regulating the exit of the market for medically necessary drugs, easing the process for access of secondary suppliers of single-source critical drugs not already in Canada, and overseeing the establishment and sustained funding of a national drug shortage reporting system.

Global drug manufacturers must shoulder greater moral accountability for health care in Canada. A licence to make profits on Canadian health care should go hand in hand with a commitment to patient care in the form of a stable supply. We must ensure that any required remediation plans do not negatively affect to a significant degree the production of supply available in Canada.

Manufacturers and distributors must be more transparent with respect to potential supply disruptions and take responsibility for ensuring there is fair share distribution in place to prevent product hoarding, and have appropriate technology in place to handle an allotment approach effectively.

Provincial authorities should establish and monitor a fair share mandate and ensure that hospitals do not stockpile supplies of drugs and continue sharing information regarding clinical alternatives with their fellow provinces.

Group purchasing organizations must take a national perspective that ensures that everyone is not relying on a single supplier, create multi-award contracts that improve the security of supply for medically necessary products, and try to create a more attractive business environment to encourage multiple suppliers in Canada to stay in Canada and to encourage new suppliers to enter Canada.

HealthPRO noted the increasing instances of shortages and supply disruptions and a year ago proactively began working on a revised contracting strategy to better protect HealthPRO's pharmacy members. Our revitalized strategy was developed with direct input from suppliers and HealthPRO members, and it addresses many of the concerns being discussed here today.

The new contracting strategy strives to strike the right balance between competition, purchasing power, and a more reliable supply chain, while ensuring full compliance with regulatory requirements and contracting guidelines. It aims to fortify relationships with suppliers to better manage emerging shortages.

As part of the new strategy, HealthPRO has set more specific guidelines, and HealthPRO suppliers will now be contractually accountable for providing notification about critical inventory levels for hospital-specific items, notifications and action plans for anticipated drug shortages, correction plans for drug shortages lasting more than 60 days for hospital-specific items, and notification regarding an intention to discontinue drugs.

In addition, HealthPRO fully supports the establishment of a national drug reporting system. We have been providing just that service to our members for the last 10 years. Now more than ever it is imperative that we work together to improve transparency and communications surrounding drug shortages. We, as Canada's health care GPO, must adjust our procurement strategies to encourage additional and stable sources of supply. Security of supply is as important as safety, efficacy, and value to the health care of Canadians. We at HealthPRO are committed to making this happen.

Thank you.

● (0925)

The Chair: Thank you very much. I hope you got everything in that you wanted.

We'll now go to our Qs and As, and we'll begin with Ms. Davies.

Ms. Libby Davies (Vancouver East, NDP): Thank you very much, Chairperson.

Thank you to the witnesses for coming here today.

This is obviously a very urgent and important issue we're discussing today. It's an issue that has concerned many Canadians across the country. As you know, we had an emergency debate in Parliament on March 14, which is not a regular thing. It's not easy to get an emergency debate. That was followed by a motion that was passed unanimously by the House, which I'm sure you're aware of, on March 14. It called for a number of things, which I'll go into.

It's interesting to hear your presentations today. I think all of you have said, from varying perspectives, that this is a very complex situation. In fact, you've all gone to great lengths to describe what you believe are some of the factors involved in the drug shortages. What I take from that is that yes, there are complexities, but it's something that actually requires an intervention.

I don't know how anybody could argue that the status quo is acceptable and that these shortages will be kind of up and down and ongoing, on and off. To me, the immediate response is that there has to be a much stronger intervention in the public interest. I just want to put that out there. The motion we passed on March 14 clearly outlines that we need a national strategy that anticipates, identifies, and manages this drug shortage question—this is what was passed through the House of Commons—and ensures that there's required reporting.

In trying to sort through all these causes of the shortages, I noticed that it was only Mr. Keon, from the Generic Pharmaceutical Association, who, when you listed the most common causes, used the phrase “marketplace issues”. I'd like to know what those are.

I don't know if you're aware that the Canadian Medical Association surveyed their members—basically the doctors who are facing these shortages. One doctor put it very bluntly:

> I find it interesting that the ones I have trouble accessing are always the lowest cost alternative and always need a more expensive substitution. It fuels my paranoid suspicions about Big Pharma only wanting to produce drugs with a higher profit margin.

I'm very curious to know what these marketplace issues are in terms of mergers and in terms of pricing. Apparently, many of the shortages apply to the generics, which may be taken off the market. Suddenly they're not available. It does cause enormous suspicion. I think this whole issue of marketplace issues is very important for us to pursue.

Second, I know that in New Zealand, smaller buyers come together. They have a contractual arrangement whereby the suppliers themselves must develop other sources. It's part of the contract, and there are heavy penalties if they don't follow that.

I'd like to ask HealthPRO, specifically, if that's something they've considered here in Canada. There's a way to actually ensure in the contract that there are alternatives, which the suppliers themselves follow through on.

I'll ask those two questions.

● (0930)

The Chair: Who wants to begin?

Mr. Keon can begin.

Mr. Jim Keon: With regard to marketplace issues, I think we were referring to marketplace issues in Canada and internationally. Some of the speakers have mentioned that for some of these older products, there's a diminishing number of suppliers, and that is true. There has been rationalization internationally, and the reality is as—

Ms. Libby Davies: Excuse me. What do you mean by rationalization internationally?

Mr. Jim Keon: There are fewer.

Ms. Libby Davies: Could you just answer us sort of straightforwardly?

Mr. Jim Keon: Prices have been going down worldwide for some of these products, and therefore there are fewer companies that can commercially exist making those products.

Ms. Libby Davies: Is there a change, then, into production of higher-priced products, and how much has that happened?

Mr. Jim Keon: The reality is that if prices go down too low, and we're relying on suppliers internationally and they go out of business, we will have fewer suppliers available to us. That has been happening. Canadian prices have been declining. Prices have been declining in the U.S. and Europe. Around the world, generic drug prices have gone down, and that has caused supply issues internationally. It has led to shortages. It was mentioned by HealthPRO. This is not a brand-new issue. There have been some shortages over the past couple of years. So that is a factor.

We rely on international sources for our active pharmaceutical ingredients. There is some manufacturing of that in Canada. Apotex does that. But by and large we are reliant on an international supply, and that has been increasingly difficult to source.

The Chair: Ms. Boyle, do you want to make a comment?

Ms. Kathleen Boyle: Yes.

Part of our new strategy—and we are putting this strategy in place in the contracts we are going to award in September 2012—is to take a multi-supplier award and not a single-supplier award for what we call hospital-specific items, which are primarily injectable products used mostly in hospitals. So wherever possible we will be looking at awarding contracts to more than one supplier, and where there is only one supplier we will be actively pursuing other suppliers to bring a product into market.

The Chair: Thank you.

Ms. Block.

Mrs. Kelly Block (Saskatoon—Rosetown—Biggar, CPC): Thank you very much, Madam Chair.

I want to welcome all of our guests here today. This is certainly a very timely study, and I really appreciated all of your presentations.

I want to echo Mr. Williams' opening remarks, where he stated that their members certainly appreciate the anxiety and frustration that drug shortages cause Canadian patients, their families, and health care professionals. I think that could be said of all of us around the table here today.

We also recognize that drug shortages are a global problem, with multiple roles and responsibilities on the part of industry, provinces and territories, and Health Canada. That is why on March 11, 2011, the Minister of Health wrote to several industry associations asking that they establish a plan to share information on drug shortages with health professionals. After that, it's my understanding that the associations joined together to form a working group that plans to update Health Canada on its progress.

The minister also wrote, in April 2011, stating that this plan must include an agreed-to standard for notification of drug shortages to health professionals that is timely, accurate, and comprehensive. If the proposed plan falls short, the minister wrote that her department will be prepared to proceed with legislation that will force companies to disclose this information.

Today I will focus on asking questions of the representatives here from Sandoz.

Early last fall the Minister of Health received a commitment from several professional and industry associations for a voluntary plan to provide timely, accurate, and comprehensive information about drug shortages. I understand that you are a member of the Canadian Generic Pharmaceutical Association, which contributed to the development of this plan. However, you did not make available clear and timely information regarding the supply disruptions, which is contrary to the spirit and principles of the pledge made to the minister. Why didn't your company wait to ensure your customers were able to secure alternatives before making your business decision after the FDA's findings?

● (0935)

Mr. Michel Robidoux (President, Sandoz Canada, Canadian Generic Pharmaceutical Association): Chair, committee members, this is an opportunity for us to reaffirm our commitment to patients and to reaffirm our commitment to quality products.

With regard to your question, I might want to go back in time a little bit to November. This is when we received the warning letter.

A warning letter is very important. It is very serious. At Sandoz, we are a health care company operating in a highly regulated environment. It is our responsibility to comply with all regulations. Definitely, it is very important for us to meet the expectations of the regulators.

At that time, there were no shortages. At that time, Sandoz had undertaken a process called “quality transformation” within Sandoz to constantly improve the quality system and to constantly improve internally our manufacturing plant and our quality operation.

The warning letter really put us in a situation where we had to accelerate the remediation activities. It is important we comply with the regulations, so it is important that we improve our quality standards, our quality system. Because of that, we had to consider managing a reduced production. We are still in the December period. When we realized our production was going to be reduced, we decided to clearly make some key decisions.

Number one, in January, our company informed the marketplace and our customers that we would be stopping production of ointments, suppositories, and ophthalmics. In light of the situation, these were less medically necessary products.

In late January, we recognized that we would need to focus all remaining production on medically necessary products. At Sandoz, we have a long list of products. We have over 225 presentations. There are 140 different molecules with a different presentation, for a total of 235. As an example, morphine is one of our products, but we provide morphine in 15 different presentations.

Going back, in late January we worked with HealthPRO, key hospitals, and key pharmacists to identify what would be the most important medically necessary products to produce. At that time, there were no shortages. At that time, we made a decision to suspend from our production, because of our reduced capacity, 74 products. It's not because you suspend 74 products that you're in back order immediately. As a matter of fact, for the majority of those 74 products, we had one month, two months, five months, up to 12 months of supply. So at that time, there were no shortages.

When we went to the market on February 15 to announce there were going to be shortages, we had previously worked with the members of CAPDM to create an allocation system in order to ensure that we would spread the distribution of our products equally to the marketplace. As of February 15, we clearly posted on our website all of the back orders and prospective back orders. After the additional request of Minister Aglukkaq, we voluntarily posted on the two sanctioned Health Canada websites all of our current and perspective back orders.

Thank you.

● (0940)

The Chair: Thank you.

We'll now go to Mr. Hsu.

Mr. Ted Hsu (Kingston and the Islands, Lib.): Thank you, Chair.

I would like to follow up with Mr. Robidoux on that last point. Are you saying that the ministry of health was not aware of any potential shortages before February 15 and was not made aware by Sandoz before that date of any potential shortages?

Mr. Michel Robidoux: We have been very clear, and it is our internal rule, that whenever we have an inspection and whenever we have exchanges of correspondence regarding our manufacturing plant in Boucherville, whether it's with the Canadian or the U.S. authorities, we share and exchange....

So when we received the warning letter, we were very clear and transparent with Health Canada that we had received a warning letter. At that time, a warning letter would not immediately create a reduced production output.

The way the warning letter works...we had three weeks to respond to the warning letter, which we did. Thereafter, we realized that the production output was going to be reduced. We took this situation seriously, and at all times our decision was based on minimizing patient disruption. That's why we worked on the most medically necessary products.

Mr. Ted Hsu: What did you tell the ministry of health during this January period, when there was some reduced production but there were still stockpiles, and you reduced production of, let's call it, less critical medications? What did Sandoz tell the ministry of health at that time?

Mr. Michel Robidoux: It was very clear to us in January. We informed them that we would see our production reduced. The first decision we wanted to make was to remove from our production schedule less medically necessary products, like ointments, ophthalmics, suppositories. Thereafter, it was very important for us to focus all available production on medically necessary products.

Just to reassure people, because I know many things have been said in the newspapers about the current supply, we are currently supplying and meeting over 80% of the Canadian demand on our products.

If I take the top six most medically necessary products as identified by the key hospitals and Health Canada, and I'd like to name them if I can—morphine, midazolam, fentanyl, hydromorphone, naloxone, and dexamethasone—these are very critical products for hospitals, and today we are meeting over 95% of the demand.

When you look at managing a warning letter, mitigating the risk to patients, we've taken very seriously working with all the various stakeholders—hospital members, distributors—to create an allocation system that would minimize the shortage.

We understand it's a very difficult situation, but in light of all of this, I think we're working tirelessly to ensure a safe supply.

● (0945)

Mr. Ted Hsu: I want to go quickly to the new websites that have been set up that were mentioned in the CGPA and Rx&D presentations. But my question is actually to HealthPRO and to Mr. Johnston.

Have you looked at these websites, and are you satisfied with the quality of these websites? Do you agree with their definitions of potential shortages? Are you happy with those websites, or do they reflect accurately what you're seeing?

Ms. Kathleen Boyle: I haven't actually seen the new version of the website, if there was a version just launched.

We do know the principles under which the intention to form the website was founded, and we in fact put in a proposal to offer to provide the website for people because of our many years of experience in pharmacy, particularly in hospital pharmacy and knowing what members want. They need the information to be reliable and accurate, but more than anything they need to have it in advance, because being in the middle of a shortage is not enough, now, to fix it. You have to know ahead of time so you can start to mitigate the risk and put other options in place.

Mr. Ted Hsu: Mr. Johnston, are you happy with what you're seeing on the website, and with the accuracy?

Mr. David Johnston: I think the accuracy is correct. But what you have is the first iteration. The industry has come together through the drug shortage working group, and in response to the minister's requests has come up with a solution on how to proactively and accurately report any shortages. That's the process that's going on right now, but it's not finished yet. It's the first iteration, and we're looking forward to that working group continuing to work and continuing to improve those websites so they become progressively more accurate.

Are we happy with what we've achieved at this point? Yes. Is it the end point? No.

Mr. Ted Hsu: For Mr. Keon and Mr. Williams, do you have plans to fund these websites on a continuing basis going forward in the future? Do you have plans to check with, say, pharmacists, people on the ground, to make sure that what they're seeing is the same as what your website is saying?

Mr. Mark Ferdinand (Senior Director, Health and Economic Policy, Canada's Research-Based Pharmaceutical Companies (Rx & D)): Just with regard to the health care professionals, we started this work last year following surveys done by the Canadian Medical Association, the Canadian Society of Hospital Pharmacists, and the Canadian Pharmacists Association. We've heard directly from health care professionals as to what they need.

I think Mr. Williams outlined what our site reports on, and those were the elements or fields of information that folks said they wanted.

To Mr. Johnston's point, the work is not yet done. We need to also provide alternatives for drugs that are in shortages, and that's the next step of work that we're working on with the working group.

Mr. Ted Hsu: Will you be soliciting feedback from pharmacists? That is my question.

Mr. Mark Ferdinand: We're planning a multi-stakeholder workshop that we're looking to hold within the near term, precisely with people in the group that we've been working with over the last year. So the feedback from pharmacists, doctors, hospital pharmacists, manufacturers, and distributors are all essential ingredients to the type of site we want to build, as is that of Health Canada.

Mr. Ted Hsu: Is there a commitment in terms of ongoing funding?

The Chair: I'm sorry, Mr. Hsu, our time is up. Thank you.

We'll now go to Dr. Leitch.

Ms. Kellie Leitch (Simcoe—Grey, CPC): Good morning. Thank you very much, everyone, for presenting.

My questions are for the representative from Sandoz. I have to say, to start off with, that I do take issue with your comment that 80% and go for patients and parents is acceptable. I think every Canadian parent who takes a child to a hospital, every Canadian patient who goes to a hospital, expects results, and that's incumbent upon all of us who are health care professionals, but also upon you as a provider.

So that being the starting premise, you then changed to 95%. I'm not sure what the number is, 80% or 95%. Maybe it's 85%.

I've worked in this world. We do our anticipation out of what we're going to do—at least with my patients—in 90 days, but usually 180 days, or maybe in 360 days I'll know about a procedure.

Recently you agreed to a 90-day notice on drug shortages to the public on two particular websites. We've heard that not great information is provided on those websites, that there isn't information that patients find acceptable on those websites. What are you doing to ensure this commitment is met, since you are already saying you're at 80% and go, or 95%? Are you going to be at 100%?

Mr. Michel Robidoux: Thank you for your comment.

First, I want to be clear. I didn't say I think that 80% is acceptable. I just wanted to state the facts that today, despite the challenges that exist at Sandoz, we are providing and we are meeting over 80% of the demand. One piece of information that is very important for us is that for the last several weeks, health care professionals have had access on our website to a very comprehensive status report on all of our 235 molecules and presentation.

On the sandoz.ca website, health care professionals have complete visibility on the production status of our products, the current allocation, the prospective allocation, the current back order, and the prospective back order. We have been working—

● (0950)

Ms. Kellie Leitch: Available 90 days ago.

Mr. Michel Robidoux: Sorry?

Ms. Kellie Leitch: When was that made available?

Mr. Michel Robidoux: This has been made available for the last four weeks.

Ms. Kellie Leitch: So not 90 days, let's be clear. Twenty-eight days?

Mr. Michel Robidoux: You're talking about the report?

Ms. Kellie Leitch: Yes.

Mr. Michel Robidoux: We have posted current and prospective back orders on our website since February 15. We did that for two weeks and then we realized we needed more transparency in working with the provinces, the hospitals, and the pharmacies. Our report has evolved significantly, and today it's one of the best, most comprehensive status reports we can provide to health care professionals. It enables them to see which format is discontinued or suspended and to use the report to plan the way to manage patients as best as possible.

Ms. Kellie Leitch: But you've only done that in the last 28 days.

Mr. Michel Robidoux: We announced the shortages on February 15—

Ms. Kellie Leitch: That's fine.

Mr. Michel Robidoux: —and I think if I go back two weeks later, we had this comprehensive report.

Ms. Kellie Leitch: On another issue, your company recently recalled drugs sent to hospitals because of a packaging error. So there is yet another place where transparency with the public may be a challenge. This resulted in important drugs also not being available. Patients arriving in hospital were not able to receive what they needed. A parent arriving with a child, maybe at the Hospital for Sick Children, was being sent home because of your drug not being available because of a packaging error.

Do you take responsibility for that?

Mr. Michel Robidoux: I thank you for raising the issue with regard to morphine. This is an issue we have dealt with.

Ms. Kellie Leitch: And could you tell me, please, and the committee how the mistake took place? How did that happen within your company, and what are you doing to make sure that this doesn't occur again? It contributed to shortages, but also, quite frankly, to the concern of the Canadian public.

Mr. Michel Robidoux: Yes. First, let me say we were very unhappy about this one product that had correctly labelled ampoules put in the wrong box. When we were made aware of the situation by one hospital in Ontario, we immediately quarantined all our current product. I have to say that this happened on the morphine 2 milligram per ml, which is one of the 13 presentations of morphine available on the market—one of the 13.

We worked rapidly with Health Canada to ensure patient safety, and at the same time to ensure supply.

Ms. Kellie Leitch: I don't want to know what you did after. How did the mistake happen?

Mr. Michel Robidoux: We're currently running an internal investigation about this situation. We're unhappy about it. We have found this one box out of a lot of 16,000 boxes, and clearly—

Ms. Kellie Leitch: I recognize you're unhappy.

Mr. Michel Robidoux: I recognize we're unhappy.

Ms. Kellie Leitch: How did the mistake happen, and what are you doing to fix it for the future? I would like to know what specific things you're going to do in your company to make sure that Canadian patients are safe.

Mr. Michel Robidoux: To address your previous question about supply, you affirmed that there was a shortage—

Ms. Kellie Leitch: I'd like you to answer the question I posed to you: what happened, how did it occur, and what do you plan to do to make sure it doesn't happen in the future—the specifics? I want to make sure that Canadian patients are safe.

Mr. Michel Robidoux: I'm not going to go into the specifics of that particular situation.

The Chair: Excuse me. At the committee, sir, you were asked a question. I will ask you to answer it specifically.

Mr. Michel Robidoux: We are currently running an internal investigation to strengthen our quality process in regard to packaging. That situation occurred in the packaging area of our site. We're currently reviewing this specific lot and ensuring that all of our processes are going to be strictly followed moving forward.

● (0955)

Ms. Kellie Leitch: I think my time is up.

The Chair: You have about another minute.

Ms. Kellie Leitch: I have one last question.

On March 12, Sandoz sent a note to the minister in which you stated specifically that you had adopted a comprehensive action plan to “help secure continued supply of critical injectable medications”.

What are the component parts of that comprehensive action plan? Could you please outline them to the committee? Again, I would like specifics, not generalities.

Mr. Michel Robidoux: From the get-go we worked to identify the key most important medically necessary products.

Ms. Kellie Leitch: In the last 14 days—you say from the get-go, so March 12 would be your get-go—who are the specific individuals you have worked with, and what are the specifics on them?

Mr. Michel Robidoux: We worked with HealthPRO to help identify which of the 235 different presentations were going to be the most important for us to keep in our production schedule. At the same time, we rapidly identified additional sources of supply around the world.

We were pleased to announce three weeks ago that we filed with Health Canada 15 new submissions on current products that are being manufactured in Boucherville that we will be able to bring to Canada from an alternate source.

Upon receiving our notice of compliance from Health Canada, we will be able to bring an additional supply that will truly help us in our product mix to ensure that additional supplies are being distributed to hospitals.

The Chair: I am sorry, but our time is up now.

Thank you, Mr. Robidoux.

We'll now go into our five-minute Q and A. We'll begin with Madame Quach.

[*Translation*]

Ms. Anne Minh-Thu Quach (Beauharnois—Salaberry, NDP): Thank you.

I would like to thank all of the witnesses who have come here today to provide us with information, advice, solutions and explanations regarding the reasons for the shortages, in particular. This is a topical issue. As many stakeholders have stated, this problem is becoming more and more serious as the years go by. I feel it is therefore somewhat unfortunate that people are trying to point a finger at some stakeholders in particular. I believe that this problem involves the entire system, and as several people have already said, all stakeholders, the various government levels and industry need to cooperate so that we can put the interests and needs of patients foremost. This is extremely important.

We have been told that the reporting requirements were problematic, but we also heard that certain suppliers had a monopoly and that there was a need to diversify sources of supply. Have you got any models or examples from other countries? Sweden comes to mind, where the government has a public supplier that provides 2% of the system's essential drugs.

Could the federal government offer incentives to encourage new secondary manufacturers, so that we do not have to rely on one provider of essential drugs? Should Health Canada and the Minister of Health be giving greater consideration to this alternative?

Moreover, we have seen that the voluntary reporting system currently in effect does not work very well. I have spoken to several local stakeholders, in Quebec. They told me that they did not really consult this site. In your opinion, is this because the system is not sufficiently effective, is it because people do not know about it, or is it because the information provided is neither relevant nor timely?

In mid-March, we unanimously adopted a motion calling upon the federal government to take initiatives in consultation with the provinces. What more can we do? Clearly, we need to take action at the federal level. But in terms of concrete action, what can we do to help people and patients feel secure about their medication?

● (1000)

[*English*]

The Chair: Who would like to take that?

Mr. Williams.

[*Translation*]

Mr. Russell Williams: I can at least begin. Thank you for asking this very complex question. You are quite right in saying that the solution...

[*English*]

The Chair: Just to let you know, when you start with a complex question, you have two minutes to try to compress your answer. I want you to get in everything you want to say, so we'll begin again.

Thank you.

[*Translation*]

Mr. Russell Williams: Thank you.

With respect to your question about diversifying sources of supply, this morning I heard that HealthPRO was going to make a suggestion. Perhaps this may be a model that we could use. At the federal level, we have worked on the vaccination file in the past. That may offer a solution. There is not only one winner, only one supplier. We can share. I am convinced that we need more than one supplier. Considering everything that we will be posting on our site, we will perhaps be informed earlier about upcoming problems, but if we do not consider a solution offering various choices, I think that the problem will persist. That is my initial reaction.

Moreover, we are starting to see some useful information on our site—for example, the name of the products, the related problems, the dates, etc.—and I think that is effective. The task force is in the process of doing this. If there is another way of improving access, so that the site is more user-friendly and used, that would be good. We are prepared to make changes. Regardless of what the case may be, I think that the first solution must be to have a bilingual site throughout Canada and, as far as that is concerned, we are on the right path. I think to that we will have to come up with other solutions and find other suppliers so that we can resolve problems that occur in the future faster.

Mr. Michael Blanchard (Clinical Director, Pharmacy Services, HealthPRO Procurement Services Inc.): The site is new to pharmacists and doctors. It is being developed. We are working primarily on information required by doctors, particularly with respect to treatments and available choices. This aspect needs further development.

Ms. Anne Minh-Thu Quach: What can the federal government do?

[*English*]

The Chair: I'm sorry, we've gone over time.

Mr. Gill.

Mr. Parm Gill (Brampton—Springdale, CPC): Thank you, Madam Chair, and my thanks to the witnesses for coming here today and for the presentations.

My question is for the Canadian Generic Pharmaceutical Association. The official opposition, the NDP, have been insisting that we act in what are traditionally provincial and territorial jurisdictions. The NDP wants to control the cost of generics. My understanding is that Health Canada sets the price ceilings for patent drugs, not generic drugs.

Could you describe how the prices of generic drugs are determined?

Mr. Jim Keon: There are two different systems: one for the retail pharmacy pricing and the other for the hospital pricing. With hospital pricing, prices are determined essentially by a tendering system and negotiations with the large buyers and other health care suppliers such as HealthPRO. That is a true marketplace price as a result of that bidding, and we've had several comments about whether there are several suppliers or whether it's just winner take all. So in the hospital market, it's a tendering system.

In the retail market, generic drug prices are subject to provincial regulation. For example, the government in Ontario has changed the regulation on generic pricing twice in the last five years. Starting in April, if you want to be listed on the Ontario formulary, you can charge no more than 25% of the equivalent brand-name product. They have some rules for exceptions if costs are higher. Pricing is set by provincial regulation. Ontario tends to be the leader. Quebec has a rule they call “the best available price rule”. Quebec will not pay any more than any other province. Then you go across the country with various pricing systems.

For the manufacturers who are trying to sell nationally, it tends to be a complicated system. It's like dealing with 10 different countries. But generic drug prices are regulated provincially.

● (1005)

Mr. Parm Gill: Can I ask why you did not give advance warning about these drug shortages? Would your organization be willing to give an advance warning, say, of six months for these drug shortages in the future?

Mr. Jim Keon: We have been working with the multi-stakeholder group—which includes doctors, pharmacists, hospital groups, manufacturers, and wholesalers—to put in place the most useful reporting system. We have developed information. Our members are all participating in it. They are all supplying the information. We recognize that there have been two websites: one in Saskatchewan and one in Quebec. That's why we've worked with Rx&D and others to put together one national website. It includes current and anticipated shortages. Our companies are all participating in this and providing information, and it's now available to everyone.

Mr. Parm Gill: This industry is worth billions of dollars, and I have a difficult time understanding how we were not able to foresee what was coming with regard to these shortages. What with the billions of dollars that are spent in this industry, you would think that your organization and the companies would be able to use their market research to forecast future needs. Honestly, I'm very disappointed that no one was able to see this coming.

Mr. Jim Keon: I think you heard from Sandoz about the history of their situation.

In regard to some of the shortages, I think I might ask Dr. Desai to respond.

The Chair: I am sorry, our time....

I've been waiting to hear the answer to Mr. Gill's question: would you be willing to put in a six-month warning for people? I didn't have that answer. Yes or no, sir?

Mr. Jim Keon: Our companies are providing anticipated shortages. If they know six months in advance, they would do so. Often, unfortunately, they do not know that.

The Chair: Thank you.

Dr. Morin.

[*Translation*]

Mr. Dany Morin (Chicoutimi—Le Fjord, NDP): Thank you very much, Madam Chair.

First of all, I must tell you that I am really pleased with what you said earlier about the fact that witnesses must answer questions, and, accordingly, the support you gave to Ms. Leitch, who interrupted Mr. Robidoux several times.

I recall that the Minister of Health came here twice. At that time, the opposition parties wanted to obtain answers to their questions and you prevented us from responding. We recall very clearly what happened: you told us to give her time to respond and as a result, she used up all of our five minutes.

So I am therefore expecting you to use the same procedure the next time that the Minister of Health comes here before the committee.

[*English*]

The Chair: Do you have a question, Dr. Morin?

[*Translation*]

Mr. Dany Morin: Yes.

My question is for Mr. Williams. You talked about the price of medication. As you said, and as we know, the price of medication goes down as a result of the price of generics. Large corporations have merged and only the most profitable remain.

Moreover, I would like to raise an interesting point regarding the price of medication for consumers. Since the early years of 2000, the average expenditure on medications per person was $329. Nine years later, this figure had more than doubled and the average was $736.

Despite the fact that drugs may be generating less profit, the demand is, nevertheless, growing throughout the country and particularly in Quebec. Quebeckers and Canadians are therefore spending more of their income on medication. I had cited the figure of $736 for 2009. This is an increase of 5.4% compared to 2008. Once again, we can see that the pharmaceutical sector is doing very well financially.

I am going to discuss some more specific numbers from 2009. On average, an individual taking Lipitor to reduce blood cholesterol levels will pay $800 per year. That amount represents a sizable amount of his income. In the case of Remicade, used to treat rheumatoid arthritis, the cost is $32,000; Effexor, used to treat depression, costs $450; and Nexium, used to prevent ulcers, costs $800 per year. So these patients have to pay large amounts of money.

There is another issue that worries me and also concerns consumers. We know that the hospitals pay a fixed price. However, when people go through their private insurance companies to pay for their medication, there is a large discrepancy in the price. The magazine *Protégez-Vous*, which you are no doubt familiar with, did an investigation in 2010 on the various prices charged by pharmacies for the same drug.

● (1010)

[*English*]

The Chair: Dr. Morin, you're speaking too quickly for the interpreters.

[*Translation*]

Mr. Dany Morin: Thank you for correcting me.

[*English*]

The Chair: Can you slow down just a little bit?

[*Translation*]

Mr. Dany Morin: Yes. I want to make the most use out of the five minutes that I am given.

As I was saying, the magazine *Protégez-Vous*, which you no doubt are familiar with, did a study on the price differences between pharmacies for the same medication.

Alesse 28, which is a birth control pill, was selling for $22.15 per box in Gatineau and $17.50 in Quebec city. So there is quite a difference in the price. Nexium, which I referred to earlier, was selling for $70 in Gaspé and $89 in Montreal. So this would represent a difference of $230 per year for two patients living in two cities in Quebec. Synthroid cost $5.21 in Chicoutimi and $11.34 in Gatineau.

As the price of medication is always rising, the middle class winds up footing the bill.

[*English*]

Ms. Kellie Leitch: Can I have a point of order, please?

The Chair: Dr. Leitch.

Ms. Kellie Leitch: I apologize, but I thought the intent behind our committee discussion today was about drug shortages. The conversation you seem to be having, albeit we haven't made it to a question, is all about drug pricing. I wanted to make sure that we were staying on point.

This is a very important issue to me—drug shortages, that is—as is drug pricing, but they are separate—

Ms. Libby Davies: Excuse me, the agenda says “drug supply”. It's not up to you to determine—

Ms. Kellie Leitch: No, I'm just asking a question. That's why I raised a point of order.

Ms. Libby Davies: Well, look under the standing order.

[*Translation*]

Mr. Dany Morin: On a point of order.

[*English*]

Ms. Kellie Leitch: I did. Thank you.

The Chair: Can I just remind you of the relevance, and go ahead with your question.

[*Translation*]

Mr. Dany Morin: I would like to make a point of order. All of the witnesses said that the price of medication is going down. As I mentioned in my preamble, the price of medication is going down, which leads to a drop in profits, a consolidation in the pharmaceutical sector and a decrease in production. That therefore responds to a point that was raised.

Before I let you respond to everything I have said, I would conclude by saying that it is the middle class that winds up paying the bill. As I said with respect to the increase in percentages, year after year, the middle class is paying more. Since the insurance company claims increase every year, these companies have to increase insurance premiums. It is truly the middle class that has to pay the price.

Given everything I have just said, could you comment on the shortage resulting from this reality.

Mr. Russell Williams: Thank you very much. I may have to meet you after this meeting in order to answer all of your questions.

The cost of medication...

[*English*]

The Chair: Unfortunately, you only have 30 seconds left, but I'm going to stretch that out. We stopped the clock during the other discussion.

If you could answer as best you can....

[*Translation*]

Mr. Russell Williams: You have given me quite a challenge, but thank you all the same.

The PMPRB, the national body that monitors the price of medicine, has shown that the price of brand name drugs has decreased over the past two years whereas the cost of generics has gone up, and this is because of the use we make of these drugs. That is a simple fact.

Moreover, if you really want research to happen, you have to take other risks and invest more than $1 billion in order to discover new medication. You have to be able to recover this money in order to reinvest yet again in research.

[*English*]

The Chair: Thank you, Mr. Williams.

We will now go to Mr. Lizon.

Mr. Wladyslaw Lizon (Mississauga East—Cooksville, CPC): Thank you very much, Madam Chair.

I would like to thank the witnesses for coming here this morning.

I would like to direct my question to HealthPRO. Once a drug product is approved by Health Canada, manufacturers and purchasers are free to enter into a commercial contract for supply, including establishing the terms of these contracts. You are uniquely situated in a drug supply chain to communicate with both the drug makers and the customers, such as provinces and territories, in drug supply.

Can you explain why it is that drug purchasers and distributors have come to rely on a single source of suppliers of medically necessary drugs?

● (1015)

Ms. Kathleen Boyle: Within our contracting process we follow the rules of agreement on internal trade. We follow any provincial rules that govern competitive bidding. Certainly, in the past, I think it was quoted by the minister in B.C. that pricing has been a very big part of the focus of going to market and using competitive bidding to get pricing for hospitals that is fair, competitive, and within the rules and regulations. We have been using this process for years. It has only been recently, when we noticed an awful lot of shortages two to three years ago, that we recognized this traditional process with the full focus on price was no longer satisfactory.

In our contracting process we are obliged to post what we call our weighting criteria, which is what's important to us and how decisions are made. In this round of contracts we introduced a new section in our weighting criteria, which was assurance of supply. We reduced the importance of price. We reduced the importance of product quality and safety. We introduced, which is up to a 20% factor, a focus on drug shortage and a supplier's ability to supply the product in the marketplace. We did change our focus away from just price and quality to include this other significant aspect, which is actually getting the drug to the patient. It doesn't matter how safe, efficacious, and cheap it is; if the patient can't access it, it's of very little value.

Mr. Wladyslaw Lizon: Can you, or if you haven't, why didn't you, recommend a backup plan for other suppliers?

Ms. Kathleen Boyle: Within our contracting process on backup supply, a supplier who is under contract, who is committed to supply, is responsible for any differential in cost that a participating hospital might incur if that supplier cannot provide a product. If it comes to a single-source supplier, so only one supplier is available in the market, those are not things that we have control over in our contracting process.

The decision for a supplier to discontinue and to exit the Canadian market is not something that has been within our control.

Mr. Wladyslaw Lizon: To go further, who has control over that? As we heard from several presentations, there may be an occurrence, like a natural disaster, that would cause a great disruption in the production of medically necessary drugs. You're saying you have no control over it, and on the other hand there are no safeguards in existing contracts to protect patients and the Canadian public. What are your recommendations? Who has the power to do it? If you have no control over it, who has control over it?

The Chair: Just 30 seconds, I'm sorry.

Ms. Kathleen Boyle: The control we have is that going forward we will be awarding to more than one supplier where there is more than one supplier available in the market. Further than that, I believe it's the role of government if there needs to be regulation to control the exiting of suppliers from the marketplace.

Mr. Wladyslaw Lizon: Isn't your—

The Chair: I'm sorry, Mr. Lizon, your time is up.

Dr. Sellah.

[*Translation*]

Mrs. Djaouida Sellah (Saint-Bruno—Saint-Hubert, NDP): Thank you, Madam Chair.

Thank you to all the witnesses who are here.

In my eyes, as a doctor, it is clear that we have a very significant problem. I have two questions and the witnesses should feel free to respond to them.

First of all, why was it the FDA that raised the alarm bells regarding these facilities that don't meet health criteria? Are American standards more exacting, stricter than Canadian standards?

Secondly, let's look at the situation in other countries. We know that the United States has a law, referred to as the Preserving Access to Life-Saving Medications Act, which compels drug manufacturers to inform, without delay, the FDA of any incidents that could cause a drug shortage, once the decision has been made to cap or halt the production of drugs. In New Zealand, pharmaceutical manufacturers have a contractual obligation to inform the Pharmaceutical Management Agency of New Zealand, which is an independent crown corporation reporting to the Department of Health, when stocks fall below the two-month supply level or they become aware of a possible shortage.

Do you believe that Canada should intervene in a similar fashion? What would be the impact of such a law on our system? Instead of having a voluntary reporting system, do you not think that we should have a mandatory reporting system here in Canada?

Thank you.

● (1020)

[*English*]

The Chair: Who's going to take that one?

Mr. Desai.

Dr. Jeremy Desai (President and Chief Operating Officer, Apotex Inc., Canadian Generic Pharmaceutical Association): Good morning, Madam Chair and honourable members.

I'll answer the first question regarding the FDA. I think it's important to understand that there are no differing standards amongst what I would call the tier 1 regulators, whether it's the FDA, Health Canada, the European Union, or Australia, to name some of those.

What really happened, what triggered FDA's increased enforceability, and I think it may have been mentioned earlier on, resulted from the heparin contamination from a Chinese source that resulted in several deaths in the U.S., and very rapidly there was contaminated melamine in milk that also came from China. That coincided with the appointment of a new commissioner of the FDA, Dr. Margaret Hamburg. One of her first public speeches talked about increased enforceability to drug manufacturers, both branded manufacturers and generic manufacturers. That increased enforceability has really resulted in either mandated action imposed by the FDA as a result of warning letters and other instruments that are available to them, or voluntary action taken by the manufacturers to ensure that the products they are putting on the marketplace will meet the stricter enforceability compliance guidelines that the FDA imposed and other regulatory agencies followed thereafter. The standard did not change.

The Chair: You have time.

[*Translation*]

Mrs. Djaouida Sellah: Yes, that is right.

As for my second question...

[*English*]

The Chair: Yes, go ahead.

[*Translation*]

Mrs. Djaouida Sellah: ...you have somewhat answered my concern, but I am still asking myself questions about the fact that it is an American and not a Canadian institution that is doing the monitoring. I would also like someone to answer my question about a mandatory system versus a voluntary reporting system.

Mr. Jim Keon: We are currently reporting on a voluntary basis because there are no regulations. As we have already explained, our companies are doing everything possible to report on current and future shortages. We are therefore working with all of the stakeholders in the sector and in cooperation with Health Canada, and we are prepared to continue doing this. Should the system become mandatory, we will comply, but we do think that our voluntary reporting system is good.

Mrs. Djaouida Sellah: Could Mrs. Boyle answer my question?

[*English*]

The Chair: Thank you.

[*Translation*]

Mrs. Djaouida Sellah: She was saying that, among...

[*English*]

The Chair: My apologies, but time is up.

Go ahead, Mr. Norlock.

● (1025)

Mr. Rick Norlock (Northumberland—Quinte West, CPC): Thank you very much, Madam Chair, and through you to the witnesses, thank you for appearing today.

I'm not usually a member of the committee, but like every Canadian, especially when you get up to my age and you see your doctor, you have to occasionally take certain medications. This is very important, not just to me as a legislator, but to every Canadian.

My question would be to our Rx&D folks, particularly Mr. Williams. You told us you were making progress on your one-stop website for notifications. You also realize, of course, as we all do, that timely information about anticipated drug shortages is very important so that our health care system can respond, and can, if necessary, find alternatives to change their contracts so that drug therapy isn't interrupted for patients who need it.

I have a couple of questions. First, how quickly will you have it up and running? I think you somewhat indicated that. We need to know how quickly you anticipate having it up and running.

Second, would your organization be willing to give six months' notification of any drug shortages? Health practitioners are very busy. I know my doctor has at least 3,000 patients that he sees, some monthly, some every other year, but there are a lot of them.

In particular, I'm very much interested in this one-stop shopping. We can sit around this table and each of the parties here can have a whole lot of "gibbaldy gabbaldy" about what the policies should be, but the basic fundamentals of our society are that we're driven by profits, we're driven by price, and those other things.

I'm looking at page 4 and the third and fourth paragraphs, where you talk about an unequivocal answer, and that you do not favour—or that the current Canadian policy environment does not favour—better access to prescription drugs, and you talk about the sole sourcing. I guess people sometimes just don't trust big companies—big pharma—when they see these huge profits. You might want to talk about the research and development that goes into it.

Primarily, if you would answer the first couple of questions...and then let's talk turkey about sole sourcing.

Mr. Russell Williams: Thank you for the question.

The website isn't ours anymore. We share it, coming together with the associations and others of the working group. We're very proud of our leadership role, but it is a joint effort. You can go through all the websites to get to the one. I think that was an important place. There were four up before, so people were confused about where they could find the best information.

We've all worked together. It's not a perfect model yet, but it's coming together so you can get the information. Let me tell you, I get notices and they're coming in all the time. So we're tracking that.

In terms of the first step, we're in good shape. Timely information is important. I do want to put a little caution to this, though, because I've also heard anecdotally that we have to be careful, when we're talking about so-called anticipated shortages, to watch out for human nature, behaviour of hoarding, protecting supply, and all of a sudden magnifying the problem we're talking about. That's a difficult thing. On one hand—I think HealthPRO mentioned it—you're trying to balance competitiveness, information, and supply, so it's that right balance that we're trying to get at. On the first part, I think we're in good shape.

Ultimately, my point was that we can have the best reporting in the world, but we need a new system, because drug shortages will occur for the multiplicity of reasons that we all listen for. If we don't have multiple suppliers—

Mr. Rick Norlock: Give me your best new system then. Talk about your new system, and be succinct, please.

Mr. Russell Williams: It's to move away from sole-source procurement strategies. Find a way to have multiple sources of supply, in which you can adjust and gear up when things happen.

Mr. Rick Norlock: So what does your collective prefer? What system would you prefer?

Mr. Russell Williams: I think that's it. Right now we believe that if you do sole-source contracting, you're driving away competition, you're driving away choice, and you won't be able to adjust later on, notwithstanding the great efforts we're going to do in terms of reporting.

Mr. Rick Norlock: Who should referee that?

Mr. Russell Williams: I think the individual buyers. As you see, HealthPRO is talking about it. I think the provinces and the federal government—

Mr. Rick Norlock: Should it be the government or should it be the industry—

Mr. Russell Williams: In terms of purchasing?

Mr. Rick Norlock: —and the marketplace?

Mr. Russell Williams: It's the marketplace that will control that. So if the private sector is buying, they will control it. If governments are buying it, they should control it.

Mr. Rick Norlock: Who should referee to make sure that the best interests of Canadian safety—

Mr. Russell Williams: The government. For instance, if it's a government program—

Mr. Rick Norlock: So you're saying that you would like to be regulated.

● (1030)

Mr. Russell Williams: You're talking about purchasing here.

The Chair: Okay. Thank you so much.

Mr. Russell Williams: We're not talking about regulation.

The Chair: We'll now go to Dr. Leitch and Ms. Block.

Dr. Leitch.

Ms. Kellie Leitch: Thank you very much.

The Chair: You're sharing your time with Ms. Block?

Ms. Kellie Leitch: Yes.

I want to go back to one of the previous comments made by the representative from Sandoz.

Quickly, if you knew, whether it be based on market research, or I guess in the case of many firms.... Many firms do risk analysis, anticipating what problems will be down the road. I know in the OR where I worked we always thought about the worst-case scenario. What would be that worst-case scenario and how would we deal with it? Even in a school, we do fire drills so little kids can make sure they get out the door when there's a fire. We don't expect one ever; we don't ever want one, but it's a worst-case scenario. So we do that risk analysis and we prepare for that worst-case scenario. I would anticipate, having worked as a professor at the Ivey School of Business in this particular area, knowing something about pharmacies and the pharmaceutical industry, that other firms have done that worst-case scenario risk assessment.

I want to ask you why you did not take that step before, of being able to be prepared? You said now you've gone out internationally and you found those medications so that Canadian patients can be taken care of. Why didn't you do that before? Why weren't you prepared?

Mr. Michel Robidoux: Sandoz has been manufacturing products, key medicine, for the last 30 years. It is the first time that our company in Boucherville received a warning letter.

The way the system works in regard to...each of our applications for a new product is linked with one manufacturing site. This is the way it is today. This is definitely a big lesson learned for us, and I think now we have the opportunity in the future, for the same product, to provide that key medicine, either produced at plant A, which is Boucherville, or plant B. I think this is definitely a big lesson learned for industry and for Sandoz. That's why we have rapidly identified alternate sourcing, to be able to go to HealthPRO in the future and say, this is a key medicine and you can source it from Sandoz, either from plant A or plant B.

There's no doubt that the current situation is really making us think differently about the way we source products. In some cases, we are the sole provider.

The Chair: Ms. Block, you're sharing your time, so you'll have to go now.

Mrs. Kelly Block: Thank you very much, Madam Chair.

I don't want to leave out the Canadian Association for Pharmacy Distribution Management. I want to make sure that we hear from you today.

Your organization also signed the letter to Minister Aglukkaq, back in September, committing to do a better job at sharing information about drug shortages. I'm wondering if you would like to share with us, in the brief time that you have, what your association is doing to honour that commitment.

Mr. David Johnston: Sure. We're very much a part of the working group that everyone has spoken of here, providing our expertise and knowledge. The important thing to note is that with pharmaceutical wholesalers, we're responsible for the distribution of available product. We don't have the access to root causes of a shortage or to the situations that may occur with some manufacturer or another.

What we do is become a part of the allocation process so that if there are restricted amounts of a product, we make sure it is evenly and fairly distributed, based on historical usage patterns, to the appropriate areas within the marketplace. Our role within drug shortages is to help facilitate the distribution of available products and to help that system make sure the vital medications get to the right areas of the country.

The Chair: Thirty seconds.

Mrs. Kelly Block: Okay. I just want to follow up. You said you have no influence over the factors that create a shortage, but do you have any advice to companies? Being that you're a distributor, what would you tell them in terms of doing a better job alerting the public when there is a shortage?

Mr. David Johnston: Well, I think it's what the working group and people are focusing in on, which is making sure that when information is available, it gets posted through the website or other means possible. We fully support the process that's in place now.

As we mentioned, the working group is working on these sites. They're at iteration one or two, and they are certainly going to be developed further to be more robust and effective for the distribution of that knowledge. We absolutely support that process.

● (1035)

The Chair: Thank you so much.

Now we'll go to Mr. Hsu.

Mr. Ted Hsu: Thank you, Chair.

I want to start out with a really quick question to every individual. What was the earliest date that you or your organization came to Parliament Hill to talk to MPs about the drug shortage?

Mr. Johnston—and we'll just go around—could you give me a quick approximate date? When was the first time you ever came here to talk to MPs about the drug shortage?

Mr. David Johnston: To talk to MPs? I don't believe we have spoken to MPs. As an association, we've been working through the working group.

We have regular interaction with Health Canada and the people within that part of the government, certainly in the development of regulations and those elements that impact our business, but as an association we have not approached MPs.

Mr. Ted Hsu: Could we briefly go around to each of the organizations to find the earliest date that you talked to members of Parliament about a drug shortage?

Mr. Mark Ferdinand: My recollection personally is that it was last fall sometime, I believe—late fall.

Mr. Jim Keon: I think the issue of drug shortages has been in the media and has been known for some time. Somebody made reference to surveys that pharmacists have done. We've been addressing this, among other issues, with MPs for quite some time.

The other point I would make is that we also address this very regularly with the provinces when we talk to them. Some provinces have talked about going to sole sourcing and tendering for a much broader range of products that they purchase and reimburse for retail. Again, I think some of the lessons we've learned from this current situation would be relevant there.

Mr. Michel Robidoux: We've been talking via the industry in regard to shortages, and obviously most recently related to the warning letter.

Ms. Kathleen Boyle: We haven't been speaking to MPs, but we have certainly been talking to our professional associations about drug shortages since 2002.

Mr. Ted Hsu: Okay. Given all the answers I've heard—and I'm inspired a little bit by the question from Ms. Leitch about risk assessments and whether companies have done risk assessments—do you think the government has been doing a proper risk assessment of the overall drug supply for Canadians?

Ms. Kathleen Boyle: I would like to make a comment. If we're talking about risk assessment, I don't think we should be looking at procurement strategies to be the one solution for risk assessment. If you start to introduce a variety of products into hospitals that have very specialized health care delivery schemes, introducing multiple products will introduce risks into those sites as well. A sole source is in fact the safest source strategy for health care delivery professionals within hospitals.

Mr. Ted Hsu: Let me ask the question again. If pharmacists and others have been talking about drug shortages for a couple of years now, shouldn't the government have been doing a risk assessment and perhaps not blaming individual companies or individual situations?

The Chair: Mr. Williams.

Mr. Russell Williams: If I can offer part of an answer, I think the government has done that. Through the correspondence that's been quoted on a number of occasions, I think the government has instructed the entire chain to work together and come up with a solution.

I actually think the government has played an important role in pushing us all together to come up with a solution. Without getting called by the chair, it is a complex issue, and we are trying to work through the issues. But I think they have.

Mr. Ted Hsu: Okay.

I have a question for Mr. Robidoux. Going back to another question earlier, there was a particular presentation on morphine. There was a packaging issue. Is that issue related to the overall problem of drug shortages, or is it a different problem?

Mr. Michel Robidoux: Regarding the correctly labelled morphine product put in a wrong box, we've acted rapidly to not only secure patients' safety by recalling the products and putting all of the products in quarantine, but we've worked rapidly with Health Canada to reinspect the 10,000 boxes of 10 ampoules and resupply the market.

As of today, Madam Leitch, this format is available to pharmacists in the country.

Mr. Ted Hsu: Was the problem that caused the packaging issue related to drug shortages?

Mr. Michel Robidoux: It's clear that a recall could potentially create shortages.

Mr. Ted Hsu: You're telling me that those two problems, the drug shortage problem and that particular presentation, the packaging issue, had the same root causes. Do they share root causes?

● (1040)

Mr. Michel Robidoux: I think one is creating the other.

Any recall of any particular drug in a market, depending on that drug and the situation—is it a single source or is it multi-source?—might lead to shortages.

The Chair: Thank you, Mr. Robidoux.

We have time for one more question, and next in line is Ms. Davies.

Ms. Libby Davies: Thank you very much.

First of all, Madam Chair, I'd just like to say that it's duly noted that you've intervened to tell witnesses when they haven't answered the question, so we'll certainly expect the same standard when government officials or the minister appears. So that's good.

I am concerned by the responses today, because it seems to me that we're being told on the one hand that this is all terribly complex and on the other hand not to worry about it—we have a good system in place, the government has done a great job, and things are okay. Yet I don't feel that way at all, and I don't think many Canadians feel that way.

We will be focusing a lot on the motion that was passed to find out what this national strategy would look like and what the required reporting will look like.

I want to switch to one question, though. We know that the Auditor General identified problems with the approval process in the fall of last year. We know that the minister has said that there's now an expedited process in place. But in the longer term....

What are some of the problems you've had with the approval process? We know that it takes up to two years. Are there things we should be doing in a more systemic way to look at the length of the approval process?

Mr. Jim Keon: From the generic company perspective, we have been urging Health Canada to put more resources into drug approval for some time. We have been unhappy with the length of time it takes for drug approvals. On average, it can take 17 to 18 months for a new generic.

There is a process in place, and the minister has now responded with an expedited system when necessary drugs are in shortage.

The Auditor General reported, and we have been working with Health Canada to try to address that. In general, I think the fact of the matter is that there has been a lack of resources on the drug approval side, which we have been concerned about.

Ms. Libby Davies: I have one quick question. Could you tell us whether any of your member companies hold market authorization for certain products but don't market them? Do any of your member companies have an authorization to produce certain products, but they're actually not doing that?

Mr. Jim Keon: That can happen sometimes.

Ms. Libby Davies: How frequent is that? How common is that?

Mr. Jim Keon: I don't have data for you today. Companies sometimes get approval and then find that they are unable to supply a product.

Ms. Libby Davies: Is it possible to get that information from your association? Could you supply that to the committee?

Mr. Jim Keon: Sure.

It's fairly common among all manufacturers.

Ms. Libby Davies: Right. My next question is to the patented products.

Is that also an issue? Are there companies that have an authorization but they are not actually putting their products on the market?

Mr. Russell Williams: I can't answer that question. Let me get you that information. I'll supply it to the committee.

Ms. Libby Davies: Okay.

I'd appreciate it if both associations could let us know that information.

Is there more time?

The Chair: You have one minute.

Ms. Libby Davies: I would like to come back to this question of sole source, because there has been a lot of debate about that. I think HealthPRO has said that they are now looking at other backups, and I think that's very important.

I just wanted to focus on the patented drugs. We focus a lot on the generics, but in actual fact, each patented drug is a sole source. I'm not clear about how one would deal with that, because you're dealing with an individual product.

I don't know if the HealthPRO representative would like to answer. I don't know whether you deal exclusively with generics or whether you're dealing with patented drugs as well. How would you deal with the sole source?

Ms. Kathleen Boyle: We receive competitive bids on genericized products only. Although we contract for patented products, we don't have an opportunity to find alternate sourcing when the product is still under patent protection. What we will be doing in the future is looking at where a product has come off patent and either other market authorizations have been issued in Canada or other companies globally can apply for market authorization.

Those are the areas where we will be putting our efforts to bring additional supply to Canada.

● (1045)

Ms. Libby Davies: I think I have just a few more seconds.

The Chair: You literally have three.

Ms. Libby Davies: According to our stopwatch we have about 15 seconds left.

The Chair: You'll have to get a new stopwatch for the clerk then.

Ms. Libby Davies: Oh no, it works like yours too.

That's fine.

The Chair: Thank you, Ms. Davies.

I want to thank the witnesses very much for coming today. I know this has been a grave concern to you, and it has been a grave concern of this committee. We had an emergency debate on it, a motion was passed on it, and I know some hard questions have been asked today because we needed to have the answers to them.

I want to thank you for being here. Thank you for your patience. We look forward to more dialogue with you in the future.

The committee is adjourned.

Published under the authority of the Speaker of the House of Commons

SPEAKER'S PERMISSION

Additional copies may be obtained from: Publishing and Depository Services
Public Works and Government Services Canada
Ottawa, Ontario K1A 0S5
Telephone: 613-941-5995 or 1-800-635-7943
Fax: 613-954-5779 or 1-800-565-7757
publications@tpsgc-pwgsc.gc.ca
http://publications.gc.ca

Also available on the Parliament of Canada Web Site at the following address: http://www.parl.gc.ca

Publié en conformité de l'autorité du Président de la Chambre des communes

PERMISSION DU PRÉSIDENT

On peut obtenir des copies supplémentaires en écrivant à : Les Éditions et Services de dépôt
Travaux publics et Services gouvernementaux Canada
Ottawa (Ontario) K1A 0S5
Téléphone : 613-941-5995 ou 1-800-635-7943
Télécopieur : 613-954-5779 ou 1-800-565-7757
publications@tpsgc-pwgsc.gc.ca
http://publications.gc.ca

Aussi disponible sur le site Web du Parlement du Canada à l'adresse suivante : http://www.parl.gc.ca