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Mr. Dan Ruimy

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● (0850)

[*English*]

The Chair (Mr. Dan Ruimy (Pitt Meadows—Maple Ridge, Lib.)): Welcome, everybody, to the Standing Committee on Industry, Science and Technology, as we pursue our study of the impacts of Canada's regulatory structure on small business. We have a full panel with us today, so I will be tight with my time.

From Pharmascience, we have David Goodman, Chief Executive Officer and Alain Boisvert, Head of Government Affairs and Market Access. From Consumer Health Products Canada, we have Karen Proud, President and Adam Gibson, Vice-President of Public Affairs. From MEDEC, we have Brian Lewis, President and Chief Executive Officer and Diana Johnson, Vice-President of Regulatory Affairs. From the Chemistry Industry Association of Canada, we have Bob Masterson, President and Chief Executive Officer. Thank you all very much for coming.

Each group will have seven minutes to present and then we will go into our rounds of questions for the remainder of the two hours.

Why don't we start with Pharmascience, Mr. Goodman?

Mr. David Goodman (Chief Executive Officer, Pharmascience): Mr. Chairman and members of the committee, it is with great pleasure that we appear today on behalf of Pharmascience before the Standing Committee on Industry, Science and Technology.

Before we share with you our recommendations to improve and modernize Canada's health product regulatory system, I'd like to first introduce our company and underline its unique contribution to the Canadian pharmaceutical industry and economy.

Pharmascience is a privately owned, entirely Canadian pharmaceutical company founded in 1983 by my father, Morris Goodman, and his partner and fellow pharmacist, Ted Wise, with a goal to offer high-quality, accessible and affordable pharmaceuticals to Canadians and global citizens. Our headquarters and manufacturing facilities are in the greater Montreal area. Over time, our growth has been very significant, and we've become the largest pharmaceutical employer in Quebec, all categories confounded, with a workforce exceeding 1,500 employees.

Through our affiliate Pharmascience International, we export close to $100 million of high-quality, Canadian-manufactured pharmaceuticals to more than 60 countries. Our exports have been growing above 10% per year for the last few years.

Less well known is our contribution to pharmaceutical R and D. We have invested more than $250 million over the past five years in R and D initiatives, which places Pharmascience among the top 10 investors in our field in Canada, and we have been ranked in the top 100 by Report on Business Magazine every year for the past five years. We employ close to 200 people in our R and D lab in Candiac, Quebec.

Pharmascience's R and D contribution goes far beyond product development and formulation. We are currently supporting and sponsoring a major clinical trial in partnership with the Montreal Heart Institute and Dr. Jean-Claude Tardif, its principal investigator.

The COLCOT trial, which we're involved with, will be a global, randomized trial of colchicine, an old agent used in the treatment of gout and in the prevention of morbidity and mortality outcomes related to cardiovascular diseases. This trial generates a great deal of interest in the international cardiology community. It will last 20 years and could shape the prevention and treatment of cardiovascular disease, which remains the number one cause of human death at the global level. Of significant importance, colchicine is a very affordable drug and would not pose the sort of financial challenges to health care budgets that we have become accustomed to with many new specialty drugs. The contribution of the COLCOT trial to Canada's health care system could be unique. Without Pharmascience's support, this trial could not have been undertaken. It is made possible because both the Montreal Heart Institute and Pharmascience are so deeply rooted in the Montreal community.

What truly distinguishes Pharmascience from almost all other pharmaceutical companies operating in Canada is the fact that what we produce and commercialize in Canada and abroad is essentially reinvested here to create wealth and economic growth locally. No foreign-owned company can offer this sort of contribution to the Canadian economy, with all the decision-making done locally.

This outstanding business contribution to the Canadian economy is completed by our philanthropy. More than $70 million worth of drug products have been donated by Pharmascience through Health Partners International of Canada to more than three million people in more than 100 countries since 1985.

The Goodman Foundation has supported the creation of the Goodman Pediatric Formulations Centre at the CHU Sainte-Justine in Montreal to help support the development of child-friendly formulations of essential drug products. The foundation is also a major supporter of the Rosalind and Morris Goodman Cancer Research Centre at McGill University, and is a major donor to the Université de Montréal's faculty of pharmacy, where the main agora bears our name.

While Pharmascience is considered a large player in the Canadian generic space, we remain a small enterprise at the global level. Yet the future of our company will largely rest on our ability to grow in global markets and to create wealth in our country by exporting high-quality, Canadian-manufactured pharmaceuticals. It is from this perspective that we'd like to contribute to the work of your committee, to bring the perspective of a fully Canadian enterprise.

I'd like now to identify a few areas that Pharmascience views as needing significant regulatory modernization and improvement for small Canadian businesses that are involved domestically and globally in the pharmaceutical field.

First we will speak about how Health Canada's regulatory role is essential, and we are the first ones to recognize it. Health Canada has also pledged, as a fair regulator, to apply equal standards to all manufacturing facilities, domestic or foreign, and we have no doubt about its intent to do so.

However, our perception is that it has in fact been difficult to maintain an equal playing field between Canadian and foreign facilities regarding compliance audits. This can have a very significant competitive impact on Canadian manufacturers, which, because of their greater accessibility, are under direct control by Health Canada; whereas foreign facilities are certified indirectly through foreign regulators. In this context, it's difficult to fully harmonize application of the standards.

Our experience is that this has played against Canadian manufacturers such as Pharmascience, a situation that can greatly hurt our competitiveness and ability to create growth and wealth and reinvest it locally. We would ask that this matter be addressed jointly with Health Canada.

Submission fees are also now charged systematically to Canadian manufacturers of pharmaceutical products seeking a regulatory authorization to commercialize products. These fees can be substantial and are applied with a one-size-fits-all approach aimed at ensuring procedural fairness. The fee structure does not distinguish enough between large, small and very small enterprises, and it's not adapted to potential market size and anticipated product revenues. Consequently, submission fees can be disproportionate barriers to the decision to bring in a new product or formulations that would fulfill important health care needs.

The best examples of that are the pediatric formulations. Pediatricians in Canada have complained for more than 30 years that critical drugs they need to prescribe for infants or children are not available in child-friendly formulations and need to be compounded by pharmacists or parents before they are administered to children. Many of these products are available in other international markets. However, manufacturers are de-incentivized from bringing such pediatric formulations to market in Canada. Most of the time, drugs are off patent, and the costs of developing a new formulation would be impossible to recover in small, low-price markets such as those existing in pediatrics.

A solution would be to waive submission fees for pediatric formulations. Such an exception would be perfectly consistent with the public health objective to enhance the availability of child-friendly formulations. We need to have this discussion with Health Canada. Successful development of pediatric formulations will also require a specific pricing grid from the pan-Canadian Pharmaceutical Alliance, and federal and provincial drug pricing negotiation bodies where the federal plans are represented.

International harmonization is also a major goal of agencies such as Health Canada, and there are many trusted regulators with which it could be possible without impeding on public protection. However, we continue to experience multiple examples of Canada-only product standards, such as specifications or in-process testing standards, which make efficient production and market supply difficult, when not outright impossible. We must remember that Canada only represents 1% to 2% of the global pharmaceutical market. A greater collaboration effort to align with trusted regulators is essential.

The list of topics could be longer, but to foster a useful discussion with members of the committee, we'll limit ourselves to the above.

In closing, and before addressing members' questions, I wish to reiterate our gratitude for the opportunity to share our suggestions with the committee, and to assure you of Pharmascience's commitment to co-operating with Canadian governments—federal, provincial and territorial—in the pursuit of our common objectives of local economic growth and wealth creation in the health care field. Thank you.

● (0855)

The Chair: Thank you very much.

Now we're going to move to Consumer Health Products of Canada, Karen Proud.

Ms. Karen Proud (President, Consumer Health Products Canada): Good afternoon, Mr. Chair and ladies and gentlemen of the committee.

My name is Karen Proud. I'm the President of Consumer Health Products Canada. I'm joined at the table by my colleague Adam Gibson, our newly minted Vice-President of Public Affairs, who has been with the association for about a month.

In our previous lives, however, Adam and I have both worked as regulators at Health Canada. I left Health Canada over 10 years ago, but Adam's departure from the public service was much more recent. In his last job with Health Canada, he was the director general of the natural and non-prescription health products directorate. Between the two of us, we have about 25 years of experience in regulating the very sector we now represent.

I will give you just a little bit about Consumer Health Products Canada.

We are the trade association that represents the companies that make evidence-based natural health products and over-the-counter medicines. These are things from sunscreens to vitamins to allergy medicines. They are what Canadians have in their medicine cabinets to treat their minor ailments every day. Within our membership, we have a wide range of members, from the very biggest manufacturers to small companies trying to make a go of their business in Canada. In fact, some of my colleagues who are here today are members of CHP Canada.

I'm really pleased to be here today to share our experiences and thoughts regarding this important study. I thank the committee for the opportunity to present.

I'd also like to offer our support to the witnesses you heard on Tuesday from both the Chamber of Commerce and the Canadian Federation of Independent Business. You heard a lot about red tape and administrative burden from those witnesses. We are fully aligned with what they presented to you on Tuesday. We would therefore like to offer input in some additional areas of the regulatory system. We won't touch on those areas that were already very well represented by those witnesses.

At CHP Canada, we are advocates for the necessary benefits of regulations. Our industry has long recognized the positive role that regulations play to ensure market fairness, consumer safety and investor confidence.

We have been around for well over 100 years and have witnessed the additive impact of new regulations over time and the resulting challenges faced by our members, particularly the small businesses. We've faced these challenges in the past by remaining engaged with government.

For example, we applaud the recent rounds of regulatory modernization that have been undertaken by the Treasury Board Secretariat. The renewed cabinet directive and the supporting suite of policy tools published last September represent a real step forward and, when applied by departments, will have a significant impact on businesses both large and small.

My experience over the years has been that the Treasury Board has not frequently consulted with stakeholders outside of government on these types of policies, and they really should be congratulated for the work they've done and the consultations they've had that have helped to contribute to the development of these new policies.

That said, we have not seen a consistent application of these sorts of policies in the past. Staying engaged with government has also become increasingly difficult, especially for small businesses. I hope to provide some insights from the point of view of our sector as to how we may improve the situation, so I've broken up the presentation into a few theme areas that we would like to raise for your consideration.

One relates to regulatory competency and capacity. One of the greatest challenges we have seen over the years relates to achieving a shared understanding between industry and the regulator of how the industry actually functions. Essentially, a well-informed regulator is one who will propose and ratify the most effective laws. However, the value of understanding industry is influenced by public service attitudes, management changes and perceived and real conflicts of interests, as well as resources.

At CHP Canada, we have taken it upon ourselves to offer education to our Health Canada regulators about how our industry works. We have an ongoing program whereby we provide access to our member experts at least twice a year to explain how our business functions. While our education efforts have been very well supported by the Health Canada officials, the challenge is that this form of industry comprehension is voluntary and is not a prerequisite to becoming a lawmaker. A lack of comprehension of small business factors only compounds these concerns.

● (0900)

The policies I mentioned earlier from the Treasury Board would help address issues through improved consultation; however, we have not seen their consistent application over the years. As a result, we believe more rigorous application of Treasury Board policies, as well as sector education within regulatory bodies, are partial solutions that are already before us.

I also want to speak briefly about the volume of regulations and the planning for input into regulations. There's always a challenge for both associations and government to effectively engage small businesses. They're busy. Because they have fewer staff performing multiple roles, they may often find themselves learning about issues as they face them, as opposed to being part of the consultative process in shaping those regulations.

The environment inherently puts small business at a disadvantage during regulatory consultations that may impact their operations. They're always at risk of not being represented and, therefore, appearing complacent or in agreement with regulatory proposals when their voices are not heard.

For example, in order to stay engaged over the last four months, small businesses in our sector would have had to have participated in 24 different regulatory-related consultations coming out of Health Canada alone. Almost half of those were only shared with industry associations, with some requiring as few as 10 days to respond. Many small businesses are not even members of industry associations and don't benefit from the input that we provide, and their voices are not heard.

While not all of these consultations that I mentioned introduce new burdens, the sheer volume, timelines and communication practices mean that in many cases there is neither the ability nor the time to engage small businesses.

I don't want to suggest that the government stop consulting with industry, or that the pace of the necessary changes be slowed. We support the vast majority of what our regulators are working on and really greatly appreciate the opportunities and the efforts to engage with us. We'd simply encourage government to tailor their engagement activity to small businesses.

I know I've run a little bit over time. I'll just touch very quickly on one last point that was raised by the witnesses on Tuesday with regard to the lack of an economic mandate. We would just like to confirm and support the commitment in the fall economic statement requiring regulators to look at things like economic competitiveness. We're very happy to see that the government was looking to explore legislation that would include regulatory efficiency and economic growth as an integral part of regulators' mandates.

In conclusion, I'd like to thank the committee again for the opportunity to appear. We believe Canada has a great opportunity to lead the world in our regulatory approaches for small business, and see this study as an important part of that effort. I'll be happy to talk in more detail about the efforts that we are undertaking, including some research that we're currently involved in to look at the economic impact and competitiveness of our sector in Canada.

● (0905)

The Chair: Thank you very much.

I encourage you to submit a brief that has everything that you weren't able to get through today. That would be good.

That applies to everybody, of course.

Now, from MEDEC, we have Brian Lewis, President and Chief Executive Officer. You have seven minutes, sir.

Mr. Brian Lewis (President and Chief Executive Officer, MEDEC): Thank you so much.

Diana and I both represent MEDEC, the trade association representing the medical technology industry in Canada, which includes surgical equipment, pacemakers, in vitro diagnostic blood tests and medical imagining equipment; that's the breadth of our membership.

I'm going to give you a little bit of background in terms of the environment for small technology businesses.

What we know is that jurisdictions that have robust technology business ecosystems have efficient regulatory processes and health system adoption practices that enable timely adoption of medical technology solutions that improve patient outcomes. We absolutely need that sort of situation to occur in Canada.

Access to the Canadian marketplace is very complicated. There have traditionally been licensing hurdles to overcome at the federal level and procurement issues at the provincial level. The other thing to remember, which has been stated by some of the other witnesses around the room, is that human and financial resources are very limited. Some companies have fewer than 10 employees, so it's important that we look at red tape and the amount of burden that we have in terms of processes to actually better enable these businesses.

In the seven minutes, we'd like to quickly go through some of the licensing hurdles that exist out there, including authorization timelines and slow or unpredictable regulatory approval times for medical technologies. We have global harmonization efforts, which we applaud and which should absolutely be made, but they should not introduce Canada-specific requirements. Implementation should be harmonized as much as possible. With regard to the auditing process, which is very important for safety, there needs to be recognition of small business capacity and reduction of red tape in terms of multiple short-term audits. What we're talking about there is duplicative audits within a short time frame. We need to relieve the burden on small Canadian businesses.

Another hurdle is the difficult clinical trials framework for devices. Conducting clinical trials is important and it's a real draw for business and an important aspect for business. Novel and digital technologies are another hurdle.

Next we will go through each of these very quickly and also talk about what Health Canada has been putting into place. For about the last year, we've noted that Health Canada's consultations have increased dramatically, and the amount of work that has been done by Health Canada to try to improve the situation has increased. There has been progress, but what you're going to see here is that it's important that it continue. The work done to date is appreciated and it's been well accepted by small Canadian businesses, but it must continue.

For authorization timelines—that's the approval of your product—slow or unpredictable regulatory approval times for medical technologies are a disincentive for those particular companies. For the companies that want to launch products in Canada, want to export products or want to invest in R and D, it is highly important that this regulatory approval occur in Canada.

One of the great things is that Health Canada has been addressing those processes, as I mentioned earlier, to meet the target timelines. They've been developing the process, and have also been providing training and new guidance documents. Under something called MDSAP, close to 200 companies have participated in Health Canada training so that situation could get better, but as I said earlier, it's really important that this continue, because it's just starting.

With regard to unique Canada requirements, as I mentioned earlier, we're dealing with the process of global harmonization, which is key if someone is exporting from Canada. Canada is only 1%-2% of the world, so our Canadian-headquartered companies have to be able to export, and global harmonization is key to reducing that regulatory burden. We and Health Canada play an active role in these particular processes. It is key, but no harmonization effort should introduce Canada-specific requirements. Harmonization with global initiatives, such as those taken by the International Medical Device Regulators Forum, IMDRF, must be maintained. They must go on. The challenge with these is, at present, the need for regulators to implement the agreed processes across the board, which means all countries doing it at the same time.

A recent example highlighted here is the implementation of the medical devices single audit program, with only Canada mandating its use. MDSAP can be used with the four other authorities, but it has not been mandated. It's really important that we maintain that degree of harmonization.

● (0910)

Health Canada did react well to the input provided by the auditing organizations and industry to ease the burden on manufacturers, but in the future it would be good if we were more harmonized.

On the increased audit burden, scheduling multiple audits within short time frames is inefficient for small business. For example, small Canadian companies have reported to us undergoing an extensive medical device single audit, followed approximately three months later by a Health Canada MDEL audit. This is a large drain on their resources. The audits are essentially very similar in process, so we have to realize the impact of that red tape when conducting audits in the future.

Clinical trials are a very important element we were talking about earlier. Canada needs to stay competitive with the rest of the world, and we need to change the process regarding investigational testing authorizations, ITAs, to future-proof the regulations and bring innovation to Canada. At this time, Canadian start-up companies are being forced to go outside Canada for studies on low-risk products for timely adoption. This has huge impacts on small businesses. Health Canada tried to address this by coming out with guidance to facilitate the process. Unfortunately, that guidance had the opposite effect: it doubled the review time and the bureaucracy required by the investigator is significantly more.

We know Health Canada has an action plan to continue, and we look forward to their addressing this particular issue.

In the area of novel technologies, a new approach to the Canadian approval and adoption of innovative medical technologies would enable growth for the sector and deliver better patient outcomes. Health Canada has already begun to focus on this area with the creation of a new digital health division within the medical devices bureau and a new standing scientific advisory committee. The division is welcomed by industry, but more work is required there.

For the regulatory review of drugs and devices, we see very positive comments from Canadian-headquartered organizations on the early pre-submission scientific advice discussions with manufacturers during the development stage of innovative products. You get to talk to the regulator about how you should improve your submission and what information will be required to make this submission more efficient. Further, it allows the regulator to see what types of capability they'll need inside to conduct that review.

I have some final thoughts as we move into these areas of novel technology and digital health. Health Canada should focus more on developing guidance documents rather than regulations because there's going to be a lot of change management in the regulations as they develop them. Guidance documents are easier to revise than regulations, so they should stay on top of it and, wherever they can, put out guidance rather than regulations.

They should continue to drive global harmonization and implementation, and always consider additional burden when introducing new initiatives to reduce that audit burden. We made prior submissions.

Again, as I stated at the beginning, the biggest thing is that Health Canada is moving forward. I think if your committee can put forward a plan so they continue to be resourced to go forward, we'll end up very shortly in a much better situation.

Thank you.

● (0915)

The Chair: Thank you very much.

Finally, from the Chemistry Industry Association of Canada, we have Bob Masterson.

You have seven minutes.

Mr. Bob Masterson (President and Chief Executive Officer, Chemistry Industry Association of Canada): Thank you, Mr. Chair and committee members. I will be brief.

Canada's $55-billion-a-year chemistry industry is a significant contributor to the economy. We're also a fast-growing industry. Many would not know it, but we added $10 billion in new chemistry investments in Canada, announced during the past year. Nevertheless, to be perfectly frank, we believe Canada has a very serious problem with regulatory competitiveness.

According to the World Economic Forum, Canada ranks 14th out of all OECD countries in its overall competitiveness but 38th out of 40 when it comes to the overall burden of government regulation. Just imagine how far up the rankings we could move in our overall competitiveness if we could tackle this chronic issue of regulatory under-competitiveness.

What are our major concerns as a regulated community? Well, let's start with the serious levels of overlap and duplication across all levels of government, all jurisdictions. Add to that the rushed-out and poorly thought-out regulations that very rarely ever take into account the regulated entity's willingness to achieve the policy objectives but in a manner that will allow them to do so in a least-cost manner. We don't get that opportunity often enough. Then there are the uncertainty and timeliness issues we've heard about. Obtaining an approval in Canada generally takes an average of 249 days. That's double the OECD average and triple the amount of time required in the United States.

In short, we see a regulatory system that's multi-layered across departments and jurisdictions without clear authorities, which often results in delays, administrative burdens, and unnecessary costs to both government and business.

We're often asked in fora like this to identify one thing that could be done better to address this issue of regulatory competitiveness. I would encourage this committee to forgo simplistic solutions. You don't get to be a poor performer in any field by doing just one thing wrong. If you're at the bottom of the heap, there are a lot of things you're doing wrong, and you need to make systematic changes. This issue of regulatory competitiveness, to quote the deputy minister in Ontario, is a chronic disease with a heavy economic drag across the whole country.

While the regulatory burdens do cross multiple jurisdictions, we are here today to share our concerns specifically with the federal regulatory regime. We are also very, very pleased to see that our concerns are shared. In his fall economic statement, Minister Morneau did identify regulatory competitiveness as a key concern and did announce a number of measures to address it. Those measures included the recent cabinet directive on regulation. That's welcome, but I would suggest that there will be no meaningful improvement at all, whatsoever, unless the central agencies drive adherence to that directive with the same zeal and timeliness they drove government renewal and program review efforts more than two decades ago. Presently, we see absolutely no sign of this on a day-to-day basis.

I might also note, and perhaps this is most important of all, that the directive is completely silent on the question of jurisdictional issues within Canada and, unlike program review, poses no challenge for federal entities to consider the extent to which the issue in question is, or should be, the responsibility of our provincial governments and territories. The smart regulation initiative of 2004-05 offered a much more critical examination of the needs and benefits of cross-jurisdictional regulatory co-operation. As the issue of jurisdictional overlap and duplication is so prominent—perhaps the most perennial and important issue of all—this is an area in need of further urgent attention within that directive.

In my remaining minute, let me point out to you two examples of what in our view are actually very good practices of regulatory effort within the federal government. They both avoided many of the shortcomings that plagued the regulatory competitiveness issues in the system more broadly.

Within Health Canada and Environment Canada, the development and implementation of the chemicals management plan, first launched in 2006, has been a welcome exception. It's a complex program. It's difficult. But they've done a very good job managing the competitiveness aspects. The program remains on track to achieve all its objectives, and is being emulated by other jurisdictions across the world. Likewise, Transport Canada's multi-faceted approach to better managing the risks associated with the transportation of dangerous goods is also a complex policy and regulatory effort that has been remarkably well delivered. I encourage you to invite representatives of those programs to your committee to share their perspectives on why their regulatory initiatives are working so well when most of the others are simply not.

Finally, the Province of Ontario has also started important efforts in this area. A comprehensive red-tape challenge process was initiated by the previous government. The recommendations out of that are being delivered by the current government. Deputy Minister Giles Gherson has been at the helm of that exercise throughout. He too would make an excellent witness to this study. The deputy minister is guided by a vision of eliminating those regulations that add cost to business and to government but that do not add any benefit to the province or its citizens.

● (0920)

I'll just conclude by saying that the study being undertaken by this committee is most welcome and, in our view, urgently overdue. I encourage you to be honest and frank about Canada's regulatory competitiveness problems and to be just as broad and creative in your recommendations for addressing them.

Thank you for the opportunity to share our perspectives with you, and I certainly look forward to your questions.

The Chair: Thank you, all, for presenting to us today.

We're going to jump right in to our questions.

Mr. Baylis, you have seven minutes.

Mr. Frank Baylis (Pierrefonds—Dollard, Lib.): Thank you, Mr. Chair.

I'll start with you, Mr. Goodman.

All of you have touched on the same topic, which is that none of you are against the regulator, but that there's that balance between the regulator and innovation and between the regulator and overburdening companies, specifically small companies. If that balance is lost, we're actually hurting, not helping, Canadian consumers and our citizens. We're actually making it worse for them.

You brought up the example of the pediatric formulation, which is near and dear to my heart. Could you expand a bit on the challenge that you're having to bring drugs into the country that are formulated for children so that we are not just saying to parents, “Take an adult pill, cut it up, crunch it and try to make it work for your child”?

Mr. David Goodman: Certainly. The problem with pediatric formulations is exactly what you said: products are not formulated for children. I think the real problem in Canada has been that many of these products that are formulated for children—they may not be optimal, but they're improvements over the crushing—are available in many other markets in the world, but for different economic reasons, the brand companies have never introduced them in Canada.

One of the initiatives that we supported, at the request of the CHU Sainte-Justine, was to make some of these products available to Canadians. One of the things that we discovered was that Health Canada was treating many of these products—that were 20 years old and had approved indications in children—almost like they were new products, like they were products that it had never heard of. Second, they were assessing fees on them to bring them to market that were almost at the same cost as new chemical entities. We started this initiative to think about how could we make pediatric formulations and bring innovation to them. We started off with the lowest level of innovation by just introducing things that were available elsewhere and seeing how the market would accept them, and we found this huge barrier to getting even those products to market.

Where did Health Canada hurt us? Health Canada helped us by paying attention to us. Health Canada listened to the issues, but its regulations, as we were told, forced it to charge us fees that made the development of these products really uneconomical.

Second, Health Canada followed its rules about looking at health and safety, but it did not look, as many of us on the panel have said, at the foreign regulatory bodies that have looked at this. It has access to those communications, yet it insisted on things being redeveloped here, which became another burden.

The centre has done a pan-Canadian study of all of the children's hospitals across Canada. They are all suffering from the same issue of inaccessibility to products. The alternatives to compounded products are well known to be inferior and to have potential safety issues. There's a will, but the regulations do not permit the fast adoption of these products.

Mr. Alain Boisvert (Head, Government Affairs and Market Access, Pharmascience): If I may add, Mr. Chairman, I think that the pediatric example is a perfect one of a regulatory problem that has become chronic. I'm a pharmacist by training, and I was trained as a hospital pharmacist at the Sainte-Justine hospital in the 1970s. Already the problem was in existence, and very little has evolved over the past 30 years because of the reasons that Mr. Goodman has mentioned: regulatory barriers, lack of consideration for the economics of introducing child-friendly formulations, and the presence of—

● (0925)

Mr. Frank Baylis: Thank you for that; I appreciate it.

I'm going to move to you, Mr. Lewis, because you did touch on something about harmonization. Then you gave an example of where harmonization, which is supposed to help our companies—and specifically our Canadian companies—went awry. I'm talking about MDSAP, where Canada worked with other jurisdictions to harmonize a process to the market, but then became the only one to mandate it. To my understanding, that's had a very negative impact. Can you elaborate on that, please?

Mrs. Diana Johnson (Vice-President, Regulatory Affairs, MEDEC): Thank you. I'll take that question, if I may.

One of the things with the MDSAP audit was that it's a great idea. The idea is that one audit could potentially get you approvals from a quality system perspective for five different jurisdictions at the same time, thereby reducing the audit burden. However, that only works if all of the countries are really looking for that MDSAP certification.

At the moment, Canada is the only one that's insisting on an MDSAP certification. It take longer to get your certificate because the audit report has to be reviewed by five different authorities at the moment, so it's a lot of work for a company to undergo that MDSAP audit if they're really only seeing a benefit in Canada. As we've heard before, Canada is a relatively small market. If the U.S. had mandated it.... Europe still hasn't gotten to that point yet. If those markets were mandating it, then we wouldn't have had this issue, because manufacturers would have seen the benefit and been able to adopt it much more easily and readily.

Mr. Frank Baylis: You also touched on another point about the rate of change and the need to introduce innovative changes, for example, when something needs to be regulated that didn't even exist before. You mention guidance documents as opposed to always the regulator trying to drop it in.

Can you elaborate on that?

Mrs. Diana Johnson: The difficulty is that regulations take a long time to promulgate and bring to fruition, and sometimes you really need to be able to adapt to changing circumstances more quickly.

With a guidance, you don't have to go through the Canada Gazette process, which automatically makes it a long process. You can still put your guidance out for comment, get feedback and put it into practice much more quickly. If you could, for example in regulation, have content satisfactory to the minister—that's what the regulation requires—then in guidance define what that satisfactory evidence would look like, it would be easier for people to react and manage.

The Chair: Thank you.

We're going to move on to Mr. Lloyd.

You have seven minutes.

Mr. Dane Lloyd (Sturgeon River—Parkland, CPC): Thank you, Mr. Chair.

Thank you to the witnesses.

First off, Mr. Masterson, I was really pleased when you were talking about new investment in the chemicals industry. In my constituency, Pembina Pipeline just announced quite a large project with many jobs, so I was very pleased about the contributions of our chemical industry to this country.

My question is going to go into the overlapping jurisdictions and issues of internal trade. We had the Agreement on Internal Trade that was negotiated in the 1990s and updated under the previous government. Now we have the new Canadian Free Trade Agreement.

I was wondering if you could comment on whether this agreement was able to harmonize some of these overlapping jurisdictions or eliminate them in order to make it easier for the chemicals industry to compete in a regulatory environment in Canada.

Mr. Bob Masterson: No. Our products are freely traded across provincial boundaries, so that's a non-issue. The key issue of regulatory overlap and duplication in large, complex industries, absolutely not.... There's been no science. Any positive progress that's been made in jurisdictions like British Columbia and now jurisdictions like Ontario is entirely homegrown and them looking at their own affairs.

Mr. Dane Lloyd: Is it currently a major issue that provinces have their own regulatory regimes?

Mr. Bob Masterson: That's not the issue. We have the Constitution with a division of powers. I think the challenge is that there's a lot of fuzziness, especially in key areas like environmental regulation and transportation regulation. Rather than just pretend that there isn't fuzziness and each level of government proceeding full steam ahead, maybe they ought to have a conversation.

Let me share an example of what has gone well and another recent example that's going less well. For most of the last eight years, we've had a very comprehensive, multi-stakeholder, federal-provincial process to discuss how to improve the important issue of air quality across Canada. That process has been complicated. It's complex, and there's going to be a lot of money spent to achieve the objectives, but from day one there's been clarity on what the role of the federal government is and then what the role of the provincial governments is. Yes, it's a complex process, but it's moving very well.

We're currently in discussions with Health Canada on a consultation where they're positioning or proposing a very significant new role for the federal government that would involve managing the risks of workplace exposures to different substances. We are committed to continual improvement in managing workplace exposures, but until today, until this consultation started, that was clearly a role for the provincial governments. I could list at length all of the requirements they have.

It's not that we oppose a federal role. Perhaps there's a gap that the federal government needs to fill, but we would only say that, before they jump into that arena and start to play, perhaps they need to have a discussion with the provinces to really identify what that gap is and then figure out the appropriate role for the feds.

● (0930)

Mr. Dane Lloyd: Thank you. I appreciate that.

My next question is to Mr. Goodman from Pharmascience.

I am hearing in my constituency, usually from pharmacists and the front lines, that Canada has less access to drugs today than it did even a few years ago. They've been critical of some changes to regulations.

Could you elaborate? Are you seeing that recent changes to regulations are having an impact on Canadians' access to drugs?

Mr. David Goodman: There are two types of denial of access. There are drug shortages, which people know of all the time. These are products that people are used to taking, and for different reasons they are not available in the market. The second part is products that are approved in other markets and brand companies aren't bringing them into Canada.

Mr. Dane Lloyd: Is there a particular reason why these drug shortages are happening, or is it just a supply and demand issue? Is there a regulatory reason?

Mr. David Goodman: A key part of it is regulatory and another part is economic. The prices of the generic products have been reduced substantially, and the regulatory burden to support them has gone up enormously.

In the plans that we're hearing of from Health Canada, the cost of maintaining products on the market—which are already approved—is going up substantially.

While the margins are going down, the cost to operate or to keep it are going up.

That's one of those points where I say the big picture is being lost in the cost recovery.

Mr. Dane Lloyd: Are you aware of whether the government has had to engage in the use of the special access programme to procure drugs that are in short supply in Canada over the past few years?

Mr. David Goodman: We're well aware of that, but most of the special access products are for products that were never registered in Canada. It's a workaround to get them into the country.

Mr. Dane Lloyd: Is that a regulatory problem that you would identify that we're having today, where we have products that we need to use the special access programme to access because they're not registered in Canada? Is that a regulatory barrier?

Mr. David Goodman: It is a regulatory barrier because the solution to it is to register them. The cost to register them and the barriers to support that registration are so high that in some ways companies that have these products in other markets say, “Why bother going through this burden when, if the patient needs it, they'll import it?” These are typically for small-market products for small needs.

Instead of doing the right thing about registering them, they can do without it. No one is forcing them to do it.

I think a better approach would be to look at these needs and have Health Canada say, “We want to have these products approved. We want to review them. Let's do it the right way, but let's realize that these aren't blockbusters, and let's not charge a fee. Let's use policy the right way.”

Mr. Dane Lloyd: From an economics perspective—a cost-benefit analysis—is the cost higher to purchase these things when the government has to engage in these special access requests, because they're not registered? If we were to lower the regulatory requirements for registration or the fees, do you think it would it actually save the Canadian government money in the long run, because they would have better access to these drugs?

● (0935)

Mr. David Goodman: The bigger issue is if we go to Canadians, the Canadian consumer is paying a huge price for the special access because they are not getting it reimbursed in their plan. The consumer is being killed in these cases. They're getting denied. If they can get it, it's coming out of their pockets.

If it were to be registered, then it becomes a fair game. It gets to be evaluated on its merits, and its pricing gets to be discussed through other mechanisms.

The Chair: Thank you very much.

We're going to move to Mr. Masse. You have seven minutes.

Mr. Brian Masse (Windsor West, NDP): Thank you, Mr. Chair.

I am curious about the waiver of fees for pediatrics. It would seem that would be a reasonable approach—when the company may be making no profits in other divisions, that it wouldn't consider that as the loss leader for brand development, and so forth.

Is it the fees so much so that it basically makes it non-competitive? If we have a low market here—despite Ontario being one of the largest consumer commercial markets in North America compared to many states—just waiving the fees or the regulations would make the difference for putting drugs on the market. Do you have an example of that, that we could pull for this study? That would be really interesting.

Mr. David Goodman: Well, if you were to ask me, I now have submitted two products. One got approved. One is waiting for approval. I'm in discussions with Health Canada about the fees they are charging. We haven't resolved it, so I prefer not to discuss that.

I could say, from a company that started this as a service project—because we've also supported the foundation, the centre, and we continue to support it—that we're taking a step back from doing additional ones because of the experience we have had, and the pending regulations that are proposed that will make it even more expensive. Health Canada has created a climate not to do this, versus to do it.

The pediatric population is an unmet need, but it's small. There are so many of these unmet needs that are small, and Health Canada puts on one price, really, for every product that they want to register and manage. The proposed new regulations say that if you're a small company, they will give you a fee reduction, and if you're a large company, you get nothing. What we're saying is, shouldn't it be more about how well the product sells? If somebody is going to keep something that people need in the pharma space.... We do things that people need. Don't make it so impossible for us to do things as a service.

Mr. Brian Masse: I understand. I guess I just have a hard time understanding what drugs for pediatrics are being denied to Canadians right now. I'm on the Windsor-Detroit border. If we're looking at people having to modify their own medications, as opposed to a pharmacist, and we're being denied that with Ontario's market economy, which is much more robust than those of most U.S. states, it would seem that this economic argument isn't always valid.

It would seem that perhaps there are other things that might be barriers. Maybe it's packaging or some other type of regulatory burden. I don't know. Especially given the fact that we've done a number of different initiatives since I've been here, everything from lowering corporate taxes.... We've been pushing, and I know that for this committee in particular, it's the SR and ED tax credit system, which is very difficult even to this day. It's getting a little better, but it's been a nightmare for many.

It would just seem that it may be very much a harsh thing, which is that Canadians are dividing their medications and so forth for pediatrics because companies just can't make a buck here. Is that what's happening? Is that what you're saying?

Mr. Alain Boisvert: I think the answer to this is that, from the start, the patient populations are very small in pediatrics. Also, these are disease states that are almost regularly rare diseases. The formulation problems happen with drugs that have been on the market for many years, have become generic and are now accessible at a very low price for Canadians. Formulating a pediatric drug requires some additional R and D investment in formulation at a time in the life cycle of the product where this product is no longer profitable, so it's this joint—

● (0940)

Mr. Brian Masse: If I could just comment, how much would a fee cost? What *x* amount of dollars would that be? If you're saying that if the fees were waived—the suggestion was to waive the fees on that—how much would that cost? I'm just trying to get a practical.... People are going to be looking at this report.

I'm sorry to interrupt. I'll let you finish, Mr. Boisvert.

Mr. David Goodman: The fee that was proposed for us to pay for just Health Canada approval was $167,000.

Mr. Brian Masse: That's important evidence that we need to know, right there.

Mr. Alain Boisvert: Sometimes—often—the whole of the Canadian market for these products can be much less than $1 million in all provinces, all jurisdictions.

Just your regulatory fee is $170,000, and you also have to pay a fee for the Canadian Agency for Drugs and Technologies in Health, CADTH, to assess the cost-effectiveness of the drug, which is another $70,000. INESSS in Quebec has a fee of about $40,000 to do the exact same thing. Just in fees, you're covering almost half of the market for the drug, and there is development work that has to be done by the company to formulate the product and get it through Health Canada. Adding in all of these costs becomes a real barrier.

Mr. David Goodman: You never know if Health Canada is going to approve it or not, so there's a risk at development.

Mr. Brian Masse: There's risk. This is very helpful to get to it.

Once they pass all those hurdles—the word hurdles was used—is then that process not applicable anywhere else other than just Canada, in terms of any of our trade agreements and so forth? Once you've invested all those fees and stages, are you then able to transfer any of those costs anywhere else?

Mr. David Goodman: The fees, no—every jurisdiction wants its own fees.

Mr. Brian Masse: Okay. This is important.

Mr. David Goodman: Yes.

Mr. Brian Masse: This is where we're trying to get a distinguishing difference; walk it right through the entire—

Mr. David Goodman: In the case of Health Canada, there's no value added outside.

Mr. Brian Masse: It's no good for you in the U.S.

Mr. David Goodman: No.

Mr. Alain Boisvert: In fact, U.S. comparison can be detrimental to Canada because the fees are roughly the same in the U.S. and in Canada except that the market is 10 times smaller here. The cost of getting the drug to market, with this fee structure, is disproportionate in Canada.

Mr. Brian Masse: Thank you.

The Chair: We're going to move to Mr. Sheehan.

You have seven minutes.

Mr. Terry Sheehan (Sault Ste. Marie, Lib.): Thank you, Mr. Chair.

Thank you to all our presenters. That was very informative.

Karen, you had mentioned that you had watched Tuesday's testimony from the Canadian Federation of Independent Business and the Canadian Chamber of Commerce. During that time, I had started some questioning, but I didn't get into this one particular question that I would like to propose to you.

As you know, I used to work a lot with small businesses, helping them start but also scale up and grow. I'd like you to comment on the health regulations as they relate to small and medium-sized business' ability to scale up and, in particular, raise that necessary capital. You're in a pretty capital-intense business in the health business. Would you care to comment on that?

Ms. Karen Proud: Our sector is highly regulated. The testimony I heard on Tuesday talked about just running any kind of a business and all the red tape that's involved in that. That applies to our sector as well, just the red tape involved in running a business and the CRA and all of that. On top of that, our companies also require approvals for products from Health Canada, depending on whether they're trying to manufacture here. There are all sorts of rules around packaging requirements.

So it is very difficult for a small company to get a foothold in Canada. One of the very difficult things, as well, is with regulations that are not harmonized between Canada and the U.S. In many cases, while they're growing their business here in Canada, it's not easily transferable to then growing globally. If we have different requirements here that are not recognized elsewhere, we can have a good run at the Canadian environment, but not outside of Canada. If we have—which we do now—very different packaging requirements, for instance, for our products, we have to then look at a completely different approach if we're going into other countries.

Certainly in developing the regulations, there is no view to how they affect small business. I think it's important to make clear that health and safety for our sector is the number one priority and we fully agree with that and we think that's highly important. On top of that, there's no look from Health Canada at the economics of what they do, which is why we were so encouraged to see, in the economic update, this idea that even the regulators who regulate in the health space would have some responsibility to look at how their regulations affect companies from an economic perspective. That is not to say that would trump health and safety; it never should, but it should be a consideration, which just doesn't happen in this country.

It's very hard, especially in a highly, highly regulated sector, for any company to start small and grow.

● (0945)

Mr. Terry Sheehan: Thank you.

Sticking on that, then, I'm also on the international trade committee and we're undertaking a study on how small and medium-sized businesses can take advantage of the new trade agreement with Europe, CETA, and the comprehensive and progressive trade agreement, the former TPP.

You made a comment about Canada and the United States. What about looking at Canada-Europe and Canada-Asia? Could you comment on that, please?

Ms. Karen Proud: We're actually doing a study right now, as I mentioned, with Deloitte. We've just started looking at Canada's competitiveness. It's to try to assess where we are in relation to some of the major trading partners. Our study looks at Canada in relation to the United States, in relation to the U.K. and in relation to Australia, specifically looking at the regulatory burden and the return on investment for companies investing in Canada. While we may have the same types of regulations as we do in other countries, the return on investment is very different depending on which country you're in and where some of the incentives are.

On some of the trade agreements, as we were inputting into them, we were looking for similar incentives as they had in other countries. For instance, in the United States they have three years of data protection for consumer health products—not the prescription side, but the consumer health products. We were looking for something similar so our companies here could benefit from that, but in those trade agreements Canada had the option to opt out of that sort of protection. It's the same with the EU where there's a year of protection; but Canada doesn't have that. If we're looking at how these trade agreements can help, we're seeing that our position was really trying to get the same benefits for Canadian companies as the companies have in other countries so we can work on an even playing field.

Mr. Terry Sheehan: Thank you.

I'd like to turn over my time to the parliamentary secretary for health, John Oliver. He has a quick question.

Mr. John Oliver (Oakville, Lib.): Thank you very much.

My question is for Brian and MEDEC.

In December, Health Canada released its action plan on medical devices. It had three principal focuses. In part, it came out of the concerns that some media had with complications from some devices.

First—and you've commented on it—is improving how medical devices get to market. Your presentation really hit on that, and the advice that you've given appears to be heard well by Health Canada.

There are two other areas, though. One was strengthening monitoring, and following up that would include increasing inspection and enforcement by Health Canada regulators. The second was improving information to Canadians. Right now, if there's an incident with an existing licensed piece of equipment, it requires an FOI request to get that information released. Health Canada is looking at, I believe, creating a database of information so that Canadians can more readily access it.

Could you comment on those latter two areas of focus by Health Canada to improve safety for Canadians?

Mr. Brian Lewis: I'll start on it, then Diana will finish.

What we found with Health Canada, with everything that was identified when the International Consortium of Investigative Journalists was looking at this, is that 80% of the work that the consortium was indicating needed to be done, Health Canada had already started. They were well ahead in the process, realizing that there was a need there for all the things you're talking about.

Diana, you have some of the specifics.

● (0950)

Mrs. Diana Johnson: To your point about the surgical database, that went online just at the end of last month, which was actually much sooner than predicted in the action plan. It had quoted December of this year for that to be available.

We know that Health Canada had been working on that database for a number of years and we're really pleased to see that it managed to get brought forward as a result. So that's already in play.

With regard to the inspections, that is a concern, based on what we said earlier. The number of audits, especially for small businesses, can be very stifling because you're using the same resources that you would be using for your innovative product development as well.

We don't know any of the details that are being proposed yet with regard to that. We don't know whether it's more to increase foreign inspections, which is a good thing, or whether it's to increase local inspections, which we're already having a lot of. There is a grey area where we don't know what the plan is as yet.

The Chair: Thank you.

Mr. Albas, you have five minutes.

Mr. Dan Albas (Central Okanagan—Similkameen—Nicola, CPC): Thank you, Mr. Chair.

I'd like to thank all of our witnesses for their expertise today, particularly on sharing how red tape interferes or can sometimes take valuable time and resources away from the work we do.

I'm going to start first by speaking with Mr. Masterson from the Chemistry Industry Association of Canada.

Sir, you've pointed out that there seems to be a bit of confusion as to who has responsibility for dealing with your industry and protecting the environment. Obviously, there is jurisprudence that has happened over time, saying that there is a shared responsibility by the federal and provincial government.

Can you give us an example? You said there's about $10 billion of investment that's come in. Can you give us an example, in some of these newer investments, as to where you would have overlaps between the federal and provincial, and perhaps even local government?

Mr. Bob Masterson: I think the first thing to note is where those investments are taking place, largely in Alberta. I think one of the reasons is that Alberta continues to have a reputation of not having a lot of problems with regulatory competitiveness.

Ontario has historically had a very large and important chemistry industry and it has not seen very much investment for nearly three decades. I think that is one of the reasons we're seeing the Ontario government now being much more focused on that. What happens if they can't make a case with the global investors to put their money into Ontario?

There is a lot of overlap, and it's not to say that all areas go poorly. I gave the example of air quality, but it depends on every issue that comes up. Workplace regulations for chemical exposure would be other examples. Transportation, rail issues...people forget that yes, we have class I railways regulated by the federal government. We also have the provincial railways. They all play important roles in moving products from facilities to customers. There's a wide range.

Right now, if I were given the opportunity to say what's chronic and very concerning for the economic future in our sector, it is the overlap, duplication, lack of collaboration on the climate change file and it goes across all levels of government.

Mr. Dan Albas: Can you give us some examples? Obviously the national carbon tax, I'm sure would be of interest in Ontario. What other things would you have, because costs are associated with that? However, there could be other provincial regulations that might make it more difficult to see an investment.

Mr. Bob Masterson: The so-called federal backstop is not as big a concern. I think we can get to the right place. The sectors like ours that had big exposure in Ontario will have to work very quickly after the change of policy in the government, and we're working very closely with officials. We wish they'd take a bit more time so we can get to the right place, but I'm confident that will be there.

But it's the realm of other policies.... Certainly the clean fuel standard is one that you've heard a little about, but I guarantee you're going to be hearing a lot more about in the months to come.

We've had formal submissions to the government from provinces such as Ontario and Alberta, saying they don't understand what you're doing. We need to take our time with this. There are a lot of concerns about that policy. We don't see a lot of engagement on that.

Again, provinces like British Columbia, Alberta and Ontario already regulate fuels. The federal government has a role too, but what is the correct balance of the role? They're uncertain, and that is a very problematic area.

Almost everything on the climate change file—and this was talked about also—is the volume and pace of work. So it's not just the regulation, the price on the emitter. Our individual member companies probably have seven different initiatives under way—emissions from cogeneration, federal and provincial; emissions on boilers, federal and provincial.

It's not just climate change and greenhouse gas emissions, it's also air quality emissions and what you're doing to produce emissions on greenhouse gases could drive up your air quality. Are these two groups of people talking to each other across government and governments? The answer is no.

Even within a department, are the air quality people talking to the climate change people? No. Are the federal people talking to the provincial people? No. That creates a lot of confusion and time.

The gentleman next to me spoke about the costs, paying fees, but when you get involved in processes like this, you're talking about very high costs to the companies involved as well.

Mr. Masse, just to share one example for you in our sector, which would be similar, we have a chemical distributor that has asked a very large client when it is going to bring those biocides to Canada. As we now have all these water-based paints you have to use a lot more biocides in them. We didn't have that problem with solvents.

One of the large companies in the U.S. has a new product; it's environmentally friendly, it's a better product for everybody. The company in question said they'd never bring that to Canada. Why? They said because it's going to take seven years and it's going to cost us way too much money. If they just blend it into the paints and coatings in the United States, where we're already allowed to do it, they'll just ship those paints and coatings into Canada with that product already in them.

All you've done is disadvantage the Canadian producers of paints and coatings, and you have not given any benefit or protection of the public or the environment.

Those are the examples. We're just saying take your time, think about the reality of what you're doing and listen to the good advice from the people who are really affected.

● (0955)

The Chair: Thank you.

We're going to move to Mr. Jowhari. You have five minutes.

Mr. Majid Jowhari (Richmond Hill, Lib.): Thank you, Mr. Chair.

Thank you to the witnesses for your testimony.

Mr. Goodman, at the outset of your remarks you mentioned compliance audits and you highlighted that Canadian companies go through the audit with Health Canada, and the foreign entities are now audited by foreign regulators and that puts both companies on an equal level. Can you expand on that? I want to make sure I understood it correctly.

Mr. David Goodman: The majority of the surveillance of foreign companies is done by foreign health authorities, because Health Canada doesn't have the resources to go around to all the countries where the products are made and do the inspections themselves.

Mr. Majid Jowhari: Does that mean we easily accept their certification and bring the products to Canada whereas Canadian health standards are much higher?

Mr. David Goodman: There are a number of agreements mutually recognizing other health authorities' inspections, but when it comes down to whether the foreign health parties are asking all of Health Canada's questions the way that Health Canada is asking those questions, I don't think that's the case.

If Health Canada is going to be very concerned about one issue and come to us when we are producing something in Canada and make us expend a lot more to remain compliant, it's only fair that Health Canada would expect foreign companies to follow the same practices. That's the part where there are differences.

Mr. Majid Jowhari: One would say our standard is higher and their standard may or may not be at the same level as ours, yet through the free trade agreements now these products are allowed to come to Canada.

Mr. David Goodman: That's correct. The example Mr. Masterson gave also applies in some cases to pharmaceuticals and the treatment of excipients or other products that are incorporated in the products. If we do it here, we have to go through a rigorous pedigree and an audit, and the other side will probably not look to see if the other foreign companies are doing the same thing. That gives us a lot of costs and a disincentive to produce the products in Canada.

Mr. Majid Jowhari: Okay, thank you. I'm going to go to Ms. Proud next.

You talked about the consistent application of the policies. Specifically one solution you suggested was sectoral education. Can you expand on that one vis-à-vis the small businesses and the fact that they may not have the ability or the time to do this? How is sectoral education going to help?

● (1000)

Ms. Karen Proud: I think it's so important for the people who actually regulate industry to understand what the industry does and how it works. We find more and more frequently that while there may be people within departments who have regulatory expertise, they don't actually understand the industries that they're regulating at all. We've run into that problem where in theory what the government is trying to do may make a lot of sense, but in practice it's just disastrous.

Mr. Majid Jowhari: In what sense do they not understand the industry? Is it how it operates, the SWOT analysis within the industry, or what the constraints are? What is it that they need to understand?

Ms. Karen Proud: I'll use a great example of a regulatory initiative we recently went through whereby we were asked to relabel all of the products in Canada, all of the Consumer Health Products in Canada. The lack of understanding of how we actually package products led to the case now where our companies are having to make completely made-in-Canada solutions on their packaging, which don't exist anywhere else in the world because we can't fit the information on our existing packaging. There's a lack of basic understanding of how decisions are made and the global supply chain, and how it's not just up to the Canadian company to decide that it will change all of its packaging. It doesn't work that way. It's the global companies that make some of those decisions, and as a result, we may not even be able to bring those products to Canada anymore.

It's one of the reasons why at CHP Canada we broke down everything we do in business from research all the way to post-market surveillance. We created these modules, and we invited the Health Canada officials to understand a little bit about how we do things, how decisions are made, how we bring products to market, and what it takes to get a product on the market. When a decision is made to change a product formulation or product packaging, why is it that industry says we need two years or five years to make this change when in the government's mind, it should be really easy: you change your packaging all the time, so why can't you just change this in a year? We have to explain why it is that we can't change things in a year.

That's where I think it's really important that if I'm a regulator and the regulation, for instance, is going to look at labelling of products, I should first be required to understand how products are labelled. We've invited them—and thankfully Health Canada have taken us up on it—to our packaging companies to stand there and see how it works and to get a better understanding, so that when they're working on the details, they're able to understand why we have concerns. Otherwise they're really operating in a vacuum and are not able to understand how their decisions are affecting big business and small businesses.

The Chair: Thank you.

Mr. Albas, we'll go back to you for five minutes.

Mr. Dan Albas: Thank you, Mr. Chair.

I'd like to go back to Mr. Masterson. A number of new regulatory provisions are coming out. You mentioned one from Health Canada, in terms of workplace safety, and how that may conflict with provincial matters. Can you explain that just a bit further? What's being proposed?

Mr. Bob Masterson: Through the chemicals management plan, which has been around since 1999 and really reinforced in 2006, there's broad agreement that the federal government's role is to assess new and existing substances, and identify those that pose unacceptable risks to human health and the environment.

Largely, the federal government will take action in certain areas, but when it comes to the workplace, legislation is regulated by provincial departments of health and labour. It's comprehensive. There's training. There's signage. There's personal protective equipment. They have robust and lengthy sets of occupational exposure limits that are strictly enforced, with auditors and enforcement agents visiting sites all the time.

When we're talking with the federal government, now that they perceive the need for a new role for the federal government in managing those risks, what gaps are you trying to fill? Where's the evidence that those gaps are there? Have the provinces agreed with you? We see a scenario where suddenly not only do we have to meet the requirements of the provinces, but also something from the federal government.

I go back to your earlier question. Can you imagine a year ago, when both Ontario and the federal government were working on the climate change file, and both levels of government put out requirements on how to regulate emissions from coal-generation equipment? The federal government's proposal came out, somewhat out of the blue, about a week after the provincial requirements had been tabled. They didn't line up. In fact, they conflicted with each other. The federal government would prevent you from meeting the provincial requirements.

Have you guys not talked to each other about this? If you're going to do something, and you know the provinces are already doing it, can't you talk to each other? No.

I'm trying to say this again. It's a chronic, daily thing. It's not that any one level of government is right or wrong. It's just that if we're serious in Canada about addressing the issues of regulatory competitiveness, we're in a very different structure from the United States. Roles are often much clearer there. We understand there's vagueness and uncertainty. That encourages us to have much more detailed conversations at the start about the proper roles for different levels of government.

I would say again, the directive on regulation is a very good document, but you will not see the word “provinces”. You will not see the word “jurisdiction” anywhere. There's an assumption from the first stage that the action being proposed is legitimate for the federal government. We would say you need to go back to the very conversations that were had through the program review, which asked one very direct question: Is it a federal role?

● (1005)

Mr. Dan Albas: I've spoken with a CEO in my province, who has found an identical situation. Again, we're fine with having a process, but who, ultimately, should be responsible for this? I think that's a very important question to ask.

Mr. Lewis, I have to state for the record that I'm against red tape, but when you talk about audits, and the timing of audits, I will say that from speaking to regulators, I know that sometimes they go in because there is an issue, concern or complaint. Even if there is no issue, and these things are mandated over a period of time and a series of checks, it's to make sure that the company doing business in this particular area—and I would say health care is probably one of the most important areas, and a very mature industry—is maintaining paperwork in a proper way, and that a company has all the records it needs to engage meaningfully if something goes wrong.

What do you say to that? Maybe you can give us some more particulars, because I want to make sure that the public interest is maintained.

Mr. Brian Lewis: We absolutely agree with the idea that a quality audit must be conducted to make sure that patient safety and quality standards are being met. The auditing process has to be efficient, and make sure it exposes what needs to be exposed, and that any issues are dealt with. In this particular case, what we're talking about is two different pathways within Health Canada, or whatever, in terms of the audits. The MDSAP audit, which is very extensive, is conducted, and then out of a different department or division, the MDEL audit comes along, and is doing most of the things that the MDSAP is doing. It's repetitive. That's what doesn't make sense.

Mr. Dan Albas: Mr. Masterson originally asked whether these people were talking. You're talking about the same department. They're overlapping the same materials.

Mr. Brian Lewis: Do you want to go into it a little bit more specifically?

Mrs. Diana Johnson: The department that's responsible for the medical device establishment licence is one department, whereas the MDSAP quality audit system is under the medical devices bureau as opposed to the inspectorate, so there are two departments. We're currently working on a proposal to bring to Health Canada to show them how similar these audits are and to see whether there's a way that it can realistically be addressed. We're in the process of putting that together.

Mr. Dan Albas: It's gobsmacking to me that we have these. I can understand Mr. Masterson's concern between governments, because governments don't always communicate well. With co-operative federalism, we would hope that it wouldn't happen, but within the same Health Canada, that's unconscionable.

The Chair: Thank you very much.

We're going to move to Ms. Caesar-Chavannes. You have five minutes.

Mrs. Celina Caesar-Chavannes (Whitby, Lib.): Thank you very much, Chair.

Thank you to our witnesses for being here today.

It really is nice, because my past life was working in clinical trials in pharmaceuticals, so it feels good to return to a really nice, comfortable area.

I just want to pick up on Mr. Albas's last point. I think it's rare that we may agree on something, but I tend to want to agree with him on the MDSAP and MDEL frequency of audits and the overlap between them.

How far would you say it is between those two audits? Is it months? Is it days? Is it years between those two audits? What would you say, in the past, in your historical context, has happened?

● (1010)

Mrs. Diana Johnson: The MDSAP audit is a regular audit. People have annual audits as part of the MDSAP program. For the MDEL, depending on whether you're a manufacturer or an importer and distributor, it will be two- to four-year cycles. You have two cycles going, but when the two coincide, and we're within three months, and you're essentially looking at the same elements that are being audited, there's very little difference. It's more the scope of the product that changes.

Mrs. Celina Caesar-Chavannes: Could you give me and the Canadians who are watching a sense of what an audit means? I know what an audit was like when we ran clinical trials. All operations stop. The auditor's in there for days going through everything, and you're just kind of sitting around waiting for them to leave. Is this what happens in your operations?

Mrs. Diana Johnson: It's a bit more active than that. For the MDSAP audit, the inspectors will go out into the warehouse and pull product. They will verify that those products are labelled according to the regulations and manufactured according to the regulations. If it's the actual manufacturer that's being audited, it's very in-depth. It looks at the design history file of the product to make sure that all the changes are appropriately documented, and the appropriate evidence is all part of the file. It's very extensive.

Mrs. Celina Caesar-Chavannes: I have a question for Mr. Goodman and his colleague.

A constituent in Whitby came to me within the last couple months talking about valsartan and that recall.

You talked about equalizing or normalizing the playing field for compliance audits. This is clearly a case where, in another jurisdiction, we have a product that clearly is a carcinogen that has now entered the Canadian market.

Can you explain again why it is so necessary to have that compliance to level the playing field? When you ask for a level playing field, are you asking for an increase of Canadian audits in other jurisdictions, or are you asking for a decrease in the number of audits that happen on this side?

Mr. David Goodman: We're looking not to decrease what we have. The truth is, it would make life easier if we did have fewer, but that wouldn't, I think, be in the public good. I think we're saying that we think that the amount, the severity and the depth of an audit on an outsider should be the same as it is on an insider in Canada.

This valsartan case is a particular one. There was nobody producing valsartan in Canada at the time. The market had been consolidated to two players, and they made some changes that were overlooked by the Chinese health authorities and by a lot of other people who visited them. It could happen again, but if somebody were to make valsartan in Canada, you would say they should have their process controlled the same way and audited the same way, and they should look at all the other parameters that could cause this type of defect in the product.

Mrs. Celina Caesar-Chavannes: I also want to talk about the submission fees and the case for pediatric submissions. When I think about the exorbitant costs associated with bringing pediatric medications to the Canadian market, I look at the safety and compliance side. The safety for my children in taking their medication—if I could be selfish and talk in that realm—and the compliance should outweigh.... That should be the principal focus.

Are you saying through your testimony that you may feel that's not the principal focus, and that the economics are interfering with looking at the safety and compliance of ensuring that children across Canada have access to the medications that are in the right quantities for them?

● (1015)

Mr. David Goodman: No, I'm not saying what you're saying.

Mrs. Celina Caesar-Chavannes: Okay.

Mr. David Goodman: First of all, I think the problem is that.... And this is not coming from us. This is coming from the head of pharmacy of CHU Sainte-Justine. This is coming from pediatricians. This is coming from pharmacists across the country. When they adapt a product and they compound it, it's not the same quality as a product that is made commercially. The quality of the product from a physical perspective is so much greater when it's registered and developed commercially than when it is adapted on an ad hoc basis for a patient, whether it's done in a hospital or it's done in a community pharmacy.

Mrs. Celina Caesar-Chavannes: What I'm saying is that this should be the primary consideration, then.

Mr. David Goodman: That's right. And what we're saying is that, similar to the incentives, if there is a need for this for the population, Health Canada should look around to see how they can make these things more accessible. Maybe it's to give incentives where, if you do develop it, you have some exclusivity, as we talked about with regard to OTC and new indications. Create the climate. Don't create disincentives. A big part of—

Mrs. Celina Caesar-Chavannes: [*Inaudible—Editor*] small market.

Mr. David Goodman: That's correct.

Again, the big issue on this topic is about innovation. You have people coming to you and telling you they have a problem. The mother of invention is knowing that there is a problem and an unmet need. How do we make sure that those unmet needs end up being products that are developed in Canada, which then can be exported elsewhere? We have the capacity to do so, but if we tax and tax all the inventive processes so highly, those products won't be developed in Canada. They'll be developed somewhere else.

For me, that's the real crux of the matter.

Mrs. Celina Caesar-Chavannes: Thank you.

The Chair: We have time for two more sets of questions.

We'll jump to you, Mr. Albas. You have five minutes.

Mr. Dan Albas: Thank you.

I have just a quick question for you, Mr. Goodman. You mentioned earlier that the compounding has extra costs. In response to Mr. Lloyd, you also mentioned that for the special access program, ultimately it's the person who pays for it, because their insurance won't pay for it.

Who pays for the compounding in cases where you might have a child who just cannot digest the regular product and needs to have it further compounded? Would that be picked up by the family or would that be picked up by an insurance program?

Mr. David Goodman: I guess there are really two different things. Special access products are products that aren't approved for sale in Canada. Compounding is a way to adapt something that is approved for somebody else. Who pays for the compounding? It depends on the province and it depends on the person's plan. It could be done by the pharmacist. It could be paid for by the formulary in that province or by the patient. Special access products are not paid for that way.

Mr. Dan Albas: Okay. I appreciate that. I just wanted to get a sense of whether we were driving up further costs for a particular family that's just trying to access medicine in a way that's sustainable to their child's health.

Mr. Masterson, you mentioned fuel standards and how that would have an extremely detrimental effect for both the provinces that have significant opportunities...for your industry but also the companies themselves. Can you explain what you meant by that?

Mr. Bob Masterson: It's one thing to say that there's a price on emissions and you have opportunities through process changes, product changes and energy efficiency to try to meet that. What's being proposed for the clean fuel standard is that the fuels themselves will have to have a carbon content. For renewable natural gas and renewable propane, what is that and how much does it cost?

I don't want to disparage my colleagues in the upstream energy industry, but at the end of the day they probably don't care. They're going to have to make a product that meets those requirements and put it in the marketplace, and everybody else is going to have to absorb those costs.

When we've met with the federal government on that particular policy, we've expressed the concern that the potential cost to us will be dramatically above the up to $50 a tonne that we're soon going to see.

I'll go back to good regulatory governance and what looks good. We were especially concerned that when ECCC started down the road to implement or to develop this clean fuel standard, the one thing everybody in the industry asked was where the economic analysis was. They said they're going to let a contract that will start in 2019 get the analysis. That it ought to be done in a couple of years. They're proposing to regulate us today. How can we wait two years for the economic analysis?

I give them credit. They've upped that a little bit and moved a little faster, but I don't think you would have one stakeholder from anyone in the energy-consuming sector that would come before you and say they're comfortable that this is a well-thought-out instrument that will achieve its objectives without significantly harming the economy. That ought to be a test back to the regulatory directive.

When I made my comment that it's a great document, but we're not seeing a zeal to implement it, that would be one of the first instruments that we'd encourage treasury to look at very carefully and assure themselves that it meets the test they put in that directive.

● (1020)

Mr. Dan Albas: In regard to the Treasury Board cost-benefit analysis from here, that usually has to be all done as one part of the process. Are you saying that they are literally going ahead with a fuel standard consultation, without actually having done any of the economic analysis to see what it would cost the industry?

Mr. Bob Masterson: I'm saying that when the process started, that was clearly absent. There's been some effort to address that.

Mr. Dan Albas: Obviously, competitiveness is critical because we are competing with the United States for these kinds of investments. Is there anything like that in the United States?

Mr. Bob Masterson: No.

Mr. Dan Albas: Thank you.

The Chair: We're going to move to Mr. Baylis. Are you sharing your time?

Mr. Frank Baylis: I'll split a bit of my time with Mr. Oliver.

Ms. Proud, you have a unique perspective. If I understand, you worked for the regulator.

Ms. Karen Proud: Yes, I did at one point.

Mr. Frank Baylis: Now you are subject to the regulator.

Ms. Karen Proud: Yes.

Mr. Frank Baylis: You touched on an interesting point about packaging and how it's not something that's as simple as that. I know you've had problems in your industry even with something like a lip balm and the amount of packaging you try to squeeze on that.

What are the lessons you could tell us from what you knew as a regulator and what you know now, working for a regulated industry, that can help our regulators? What did you not know, that you learned? How should we make sure that the regulators now are better? How could we help them?

Ms. Karen Proud: Certainly, the first point I touched on is essential. The people regulating need to understand the sector. Before they undertake a regulation, they need to take the time to meet with the industry that they're regulating and have those conversations, so they actually know what they're talking about.

Mr. Frank Baylis: That's part of what Treasury Board is asking to task—

Ms. Karen Proud: That is not what Treasury Board is asking. It's not a requirement of a regulator to actually know the sector they're regulating at all. There's only so much you can do through a formal consultation process to actually get that understanding. I knew that as a regulator myself. I didn't know the industries I was responsible for regulating to the extent I should have.

Ultimately, you end up with much better regulation if the person drafting the regulation or instructing the drafters really understands the sector. That needs to be a requirement.

Mr. Frank Baylis: We should put a requirement. How should we implement the requirement that you need to know more?

Ms. Karen Proud: I think potentially the Canada School of Public Service has a role to play. I've spoken to Neil Bouwer over there about perhaps being a conduit to bring together industry sectors and regulators to have very focused, detailed education for people working in those specific sectors. I think that is very key to get the baseline understanding.

I also think following Treasury Board policies and guidelines in the spirit they were put forward is essential as well. We don't see that in all cases. We see consultation being done very differently depending on how quickly one is supposed to get the regulations completed. We see cost-benefit analyses not really being done when they are supposed to be. We've heard of cases where they've already moved forward with the regulations and the cost-benefit analysis happens at the end. I've never actually seen any regulatory initiative where they've done a cost-benefit analysis first to see whether or not they should even—

● (1025)

Mr. Frank Baylis: Although Treasury Board has mandated that, it's not being implemented, is that...?

Ms. Karen Proud: It's not being implemented to the extent it should be and to the extent that Treasury Board would expect it to be. I think there are two reasons for that. I think one is we have regulators who are not as familiar as they should be with all the steps they should be taking and we have a Treasury Board that hasn't always had the big stick they need to use to ensure departments are following the procedures and guidelines. I think supporting Treasury Board more in their challenge function, and Treasury Board ministers in sending things back that have not been done correctly, is very helpful as well.

I firmly believe the policies that Treasury Board have put forward are excellent policies and the changes the Treasury Board has made are really progressive and would make a big difference. I've just not seen in my history, both inside and outside of government, a real adherence to those laws. I think it comes from both a lack of understanding by the regulator of those policies, but also perhaps a lack of commitment to what those policies stand for.

Mr. Frank Baylis: Okay, thank you.

Mr. John Oliver: I just want to come back to MEDEC one more time.

Thank you, all, for your presentations. It's been very insightful.

Once you get your licensing at the federal level—and I've heard the issues and concerns there—then you need to go out to all the different health technologists. I served on OTAC, in Ontario, for three or four years. I know the cumbersome provincial-territorial environment.

Is there more that could be done to improve uptake and industry adoption of technology or new drugs? Could CADTH being doing more? Is there a federal role in that to coordinate provinces and territories better?

Mr. Brian Lewis: One of the things we see is that when CADTH or OTAC comes out with a positive recommendation on a new technology, it's well done. The review is completed very effectively. But what happens is it gets into the system and the system doesn't adopt the product because of cost constraints within the hospital. People tend to look at one or two elements, but it's really a system problem. Even though we get a great recommendation, and there are several examples of it coming out of OTAC, those products get minimal adoption and minimal uptake.

One of the things we're looking at when we talk to ISED and other departments in the government is a role for the federal government to champion what's called “value-based health care” and to actually show examples and to actually help the community. The change management at the hospital level comes down to cash flow. When one budget exists within a hospital or a department in a hospital and the other budget is outside the hospital, the benefit of a truly valuable solution from a cost perspective is not seen. It will be from a patient perspective.

Does that answer your question?

Mr. John Oliver: Yes, that's good. Thanks.

The Chair: That takes us to the end of our session today. Thank you for a very enlightening presentation and lots of good questions, lots of good answers. I think it will feed nicely into our report.

Thank you, all, very much for coming, and we are adjourned for the day.