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Chair

Mr. James Bezan

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● (0905)

[*English*]

The Chair (Mr. James Bezan (Selkirk—Interlake, CPC)): I call this meeting to order.

We haven't done this at committee before, but we've asked the veterinary drugs directorate to come before us. It is similar to what we do with PMRA, bringing it in as a Health Canada representative, but with regulatory power over the agriculture industry.

Many of us around the table who represent rural ridings and some of us who are livestock producers are always interested in what's happening in the approval process of animal health products as well as the whole issue of price parity and competitiveness with the international markets we deal with, including the United States.

We want to welcome to the table Dr. Siddika Mithani, who's joined us as the associate assistant deputy minister of the health products and food branch, and Bob Hills, who is the manager of transmissible spongiform encephalopathy at the veterinary drugs directorate of the health products and food branch at Health Canada.

I welcome both of you. I understand you're going to make an opening comment. I remind you to keep it under ten minutes.

Dr. Siddika Mithani (Associate Assistant Deputy Minister, Health Products and Food Branch, Department of Health): Good morning, everyone.

I want to thank the committee for inviting Health Canada to discuss the approval process for veterinary drugs.

I would also like to take this opportunity to introduce Bob Hills, who is accompanying me here today. Mr. Hills is a manager in the veterinary drugs directorate at Health Canada.

[*Translation*]

I want to begin by emphasizing the important role that Health Canada plays in protecting human and animal health and ensuring the safety of Canada's food supply.

[*English*]

This activity contributes to the Government of Canada's overall food and consumer safety action plan, which seeks to modernize our regulatory approaches by focusing on active prevention by providing better safety information to consumers and guidance to industry; establishing effective deterrents; providing targeted oversight by requiring safety tests and information about products in the marketplace so that oversight can be focused on products that provide the greater potential risk to the public; and providing rapid response in order to allow the government to take fast action when a problem occurs, including the ability to recall products.

In the context of this overall action plan, Health Canada evaluates and monitors quality, safety, and efficacy of veterinary drugs. The department also promotes the prudent use of veterinary drugs administered to food-producing animals as well as companion animals.

[*Translation*]

For a drug to be marketed in Canada, a manufacturer must submit data to substantiate the safety, efficacy and quality of their product under the proposed conditions of use. A new drug submission that is filed by a manufacturer must satisfy all the requirements under the Food and Drugs Act and Regulations. These are administered by Health Canada.

[*English*]

A new drug submission must contain the following information: chemistry and manufacturing information about the drug product, pharmacology and toxicology studies, clinical animal studies, and tissue residue studies if the drug is intended to be used in food-producing animals. A new veterinary drug is approved for sale in Canada only if Health Canada is satisfied the drug is safe for the animals being treated, is effective for the purpose for which it is being marketed, and does not leave potentially harmful residues that could pose undue risks to humans eating food products from treated animals.

Health Canada plays a critical role in establishing maximum residue limits together with an appropriate withdrawal period to ensure that the levels of residues can safely be ingested daily over a lifetime and will not pose undue risks to human health.

I need to highlight that the department has taken several steps to develop efficiencies and improve the timeliness of the regulatory approval process.

[*Translation*]

A new drug submission tracking system has recently been introduced to better coordinate the regulatory process for drug evaluation. This system enables manufacturers to monitor the status of their drug submissions throughout the review process.

Health Canada continues to work with industry to develop processes and guidance documents to help them in filing complete and high-quality submissions.

● (0910)

[*English*]

The department also continues to encourage pre-submission meetings in order to inform industry of Health Canada's drug submission expectations. I am pleased to inform the committee that Health Canada is anticipating the elimination of the backlog for veterinary drugs by early 2009.

It is important for the committee to know that Health Canada is working with its international partners in sharing of information on approval and post-market surveillance of veterinary drugs. Health Canada continues to participate in international committees such as the VICH, which is the international cooperation on harmonization of technical requirements for registration of veterinary products, and Codex Alimentarius, in order to move forward on international harmonization issues.

[*Translation*]

Health Canada, together with the Canadian Food Inspection Agency, has recently established an external advisory committee that will assist in improving efficiency, capacity, responsiveness, cost-effectiveness and timely availability of veterinary health products.

Health Canada is aware of the desire from livestock producers to increase regulatory cooperation. The department is working toward increasing its efforts in developing standards and regulatory requirements with international bodies.

[*English*]

In conclusion, Health Canada is committed to ensuring timely access to safe and effective veterinary drugs, to working internationally to develop standards for veterinary drugs, to continuing to work with its stakeholders to improve efficiencies and provide clear and transparent guidance, and to ensuring the continued protection of the health and safety of Canadians and their food supply.

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

The Chair: Thank you.

We will open with seven-minute rounds.

Mr. Steckle.

Mr. Paul Steckle (Huron—Bruce, Lib.): Thank you very much for appearing this morning.

Similarly to the PMRA, we from time to time want to meet with you to set stakes to see whether there has been measurable progress made in terms of our movement towards harmonization. I know that isn't the word we generally use, but those of us around this table like to think we need to harmonize the kinds of things we do with our American counterparts because we work so very closely with them in terms of our exports and our imports.

Given that you're Health Canada, where you're dealing with human health issues, and now this morning we're talking about human health and we're talking about animal health as well, how do you reconcile between Agriculture Canada and Health Canada? Is there an issue between the two departments, the two ministries, in terms of finding common ground? I realize you have your jurisdiction, but is there an overlap here sometimes that can perhaps cause delay in the progress that could otherwise be made?

Dr. Siddika Mithani: Thank you for your question.

With respect to veterinary drugs, the fact is that from a Health Canada perspective, our objective is the health and safety of humans and animals. There is some overlap in terms of Agriculture Canada. They also have a mandate to look at animal health, which is the reason we have the veterinary biologic products that are regulated by CFIA, versus the veterinary drugs being regulated by Health Canada.

When you look at the bottom line and the fact that we are looking at health, we recognize some of the concerns the Department of Agriculture may have, and it's really a partnership with them. We are able to look at how to balance the health and safety of animals as well as humans, which is of primary concern, and at some of the issues that arise from the livestock producer industry, from the Canadian animal health industry. The overarching objectives are very similar. There are some nuances and some specifics when you look at veterinary drugs and the interaction, but it's truly a partnership between Agriculture Canada, CFIA, and Health Canada. We have very similar objectives of looking at a real balance between health and safety, the protection of humans and animals, as well as not stifling innovation and being able to have a competitive market as we move forward.

● (0915)

Mr. Paul Steckle: An issue that comes to mind is a recent issue with our hog industry involving sickness that it was possible to mitigate with medication. How closely can we mirror what the Americans are allowed to use, given that meat flows back and forth and that we have a protocol whereby basically we accept here in Canada the standards that they deem safe for their people?

How do we mirror what they are allowed to use? In many cases, as PRMA would have us know, products are used in the States to produce product there that we buy into Canada, and yet we're not allowed to use those, in that case, pesticides.

In the case this morning, we're talking about animal medicine. There are medications that are used down there. How can we justify to the consuming public in Canada that the product bought from the U.S. in this case, and we'll stay with the U.S. for a moment, is safe for us to consume, when we can't use that medication here? How do you justify that to the producer of hogs, swine, cattle, or whatever, who is coming to you and saying, we want this product because we know it works, but it's not yet proven here in Canada? How do you make that justification? Rationalize that against the argument.

Dr. Siddika Mithani: For a product to be approved in Canada, a manufacturing industry has to file a new drug submission. The issue that a drug is available in the U.S. and not available in Canada may be because the company has decided not to file the new drug submission here in Canada.

You know that in the past we've had a backlog of submissions, but we are at a stage right now wherein we are anticipating eliminating the backlog by 2009. So within the next year there will be a possibility for industry to be filing a new drug submission for approval in both countries at the same time.

The fact that we are lagging behind and do not have those types of drugs has been really a regulatory process issue up to now, but there have been process improvements put in place to make sure that in our market we create an environment that is conducive to competitiveness coming into Canada.

Mr. Paul Steckle: Would you suggest to us this morning that the arguments being made for allowing further drugs here...that we're at a level where we're equal to or above what the Americans would have? For instance, take the chicken influenza. Are we behind or ahead of the game when it comes to that particular disease? Would you say we're there, that we're not quite there yet, or that they have something we should have? This is something that doesn't regard borders as an issue. This disease can go across borders very quickly.

Dr. Siddika Mithani: On specific issues that are transborder and more like pandemics, there is a lot of international cooperation on the types of vaccines you would use. In a case of an emerging disease where there was a company or a therapeutic product that looked promising and that really needed to be introduced in Canada as well as in the U.S., I imagine we would be on fire; we would not be lagging behind.

We have been in a situation in the past where there has been a backlog. Particularly, for example, when you look at the number of generic products that are on the market in the U.S. versus those in Canada, these products have not been introduced into our market. But the intent now is to create an environment that is conducive to bringing in those particular products, so that we are able to have the same access to these products as the Americans, or for that matter even the Europeans.

The Chair: Thank you, Mr. Steckle. Your time has expired.

Monsieur Bellavance.

[*Translation*]

Mr. André Bellavance (Richmond—Arthabaska, BQ): Thank you, Mr. Chair.

My questions will be along the same lines as those asked by Mr. Steckle. We have a similar problem with the PMRA regarding product registration. Have you looked at the situation whereby products registered in the United States could be used in Canada and are not because there was not enough time to do the required analyses? Perhaps you think that some products should not be on the Canadian market for particular reasons. Has your branch made any effort to provide better product harmonization?

● (0920)

Dr. Siddika Mithani: People are working very hard at the moment to put in place a process to ensure harmonization between the two countries.

[*English*]

A lot of effort has been made. The issue is to ensure the products are made available because companies have to file submissions in Canada as well, so there is a system to encourage companies to come to Canada to file those submissions.

[*Translation*]

Mr. André Bellavance: We have to raise the issue of the length of time it takes for some products to be registered. For example, in the document we received which compared competitivity, we see that European veterinary drugs are registered much more quickly. Generally, it took less than two years to do a risk management study for a group of four archetypal drugs that were reviewed. Whereas here, it takes between five and eight and a half years to do the same work on the same four products. Comparison shows that the registration process does not work very quickly here.

Why is that? Is there a staff shortage, or is it simply that we require more in-depth studies, for safety reasons?

[*English*]

Dr. Siddika Mithani: The reasons for the difference between the U.S. and Canada, in terms of the IFAH report you're talking about, have been because we have had a backlog, but processes have been put in place.

The registration system in the U.S. is a little different from the one in Canada, in that throughout drug development you have a system whereby companies will be interacting with the U.S. at all stages during the process. We haven't implemented a process like that. We are beginning to implement that process so we can be on a par with the way the system works in the U.S.

[*Translation*]

Mr. André Bellavance: I was referring to Europe, but you have confirmed that the process is faster in the United States as well. When can we look forward to having this process not only in place, but actually functioning, so that we have some assurance that the time required to approve drugs will really be reduced?

[*English*]

Dr Siddika Mithani: *Absolument, parce que* the report was up till 2006. The process improvements have now been in place since 2006. We are encouraging industry to come in. We have just set up an expert advisory committee that I talked about in our opening remarks that brings in industry at the beginning, during drug development, so we get the experience of their new drug, just as the U.S. does, just as Europe would do. Therefore, when the drug comes in for a submission, the time taken will be decreased and there will be increased efficiency in the regulatory process as we move forward.

[*Translation*]

Mr. André Bellavance: Will you be setting some very specific objectives in terms of years?

[*English*]

Dr. Siddika Mithani: *Absolument. Nous avons* the deadlines. Within a submission, we have a guidance that talks about timelines for approval or for evaluation and they are comparable to those in the U.S. They are 300 days, which is comparable to what the U.S. does.

At this point, we do have a backlog. By the end of 2009 that will go, and we will be reviewing on time, which is why I said in my earlier response that we will be at a stage as of 2009 when a company will be able to file a submission at the same time and will be able to get a response at the same time.

[*Translation*]

Mr. André Bellavance: We hear talk about a market for non-approved products. Does that mean there is a black market or a grey market? Clearly, veterinary drugs do not make the headlines very often, while drugs for people do. For example, it is possible to order products on the Internet from elsewhere, and this is a rather dubious way of proceeding.

In the context of your work, has the branch found that the same type of problem exists in the case of veterinary drugs? If so, do you have a way of trying to manage and control this practice?

● (0925)

[*English*]

Dr. Siddika Mithani: We have a similar system, in terms of the fact that there are systems in place to ensure that we don't have that black market you are talking about. We are moving forward with looking at or exploring avenues where we can put in strategies that are going to minimize the kind of personal use importation you might be talking about, getting drugs through the black market. We are looking at those strategies.

Again, we have a task force that was struck about a year ago, in 2007, that is clearly looking at personal use importation, the fact that there are certainly potential health and safety concerns about products that may be coming from China and India via the U.S. or other countries that may pose a risk to humans. We are looking at those strategies.

[*Translation*]

Mr. André Bellavance: Do you think that there is a risk? Have you analysed any products from this market that, in your opinion, were not compliant and that could put not only animals but also the human population at risk?

[*English*]

Dr. Siddika Mithani: We haven't had an issue like that so far, where we've done an analysis showing that we have adulteration. But we certainly have MOUs, memoranda of understanding, with other countries, so that if there are international issues that are identified, they will provide us with an opportunity to look at our market and to be able to do these kinds of tests and inspections and investigations as we move forward.

[*Translation*]

The Chair: Thank you very much.

[*English*]

Mr. Lauzon.

[*Translation*]

Mr. Guy Lauzon (Stormont—Dundas—South Glengarry, CPC): Thank you, Mr. Chairman.

First, I would like to welcome our witnesses, Ms. Mithani and Mr. Hills.

[*English*]

As we know, various agricultural sectors in the last number of years have gone through some very, very challenging times. Our government did a lot of consultations with various sectors to find out what was needed to try to put in place a long-term solution, something we could go forward with and to have something in place that would resolve these problems over the long term.

Some of the suggestions that various sectors of the industry brought forward were that if we were going to be competitive on the world stage—and of course we're living in a world market—we need to have innovative research and development. That was one of the solutions or criteria they suggested that we should have in our "Growing Forward" framework. They said that if we are going to remain sustainable, we must have leading-edge research and development.

How do you see it from a Health Canada perspective? How does the "Growing Forward" framework help you to address the agricultural sector's needs?

Dr. Siddika Mithani: As you know, the "Growing Forward" national consultation document did propose targeted investments in the area of veterinary drugs to improve efficiency and to have predictability and reliability in the regulatory approval process.

It's a very interesting question you bring forward, because with some of the process improvements we have put in place and that we are beginning to talk about with the industry—there's a lot of dialogue with industry—the question is, how do you bring the initial studies into Canada so that we can have that research and development part that will allow Health Canada to get a lot more experience with a drug during drug development? Therefore, when you have a submission coming in for approval at the end of drug development, you will have experience, you will have experts who are aware of what's going on, and you will have veterinarians outside and inside Canada who have real experience with your product and know how to use it appropriately. The real balance between safety and efficacy is the appropriate use of these products.

So this is the dialogue we are having with industry. It is saying that we really need to bring in these products earlier on, at that stage, and to have that dialogue with them so that we are very clear about our expectations in terms of regulatory requirements. If we can tell industry very clearl that these are what the requirements are, they will not be going out for three years or five years doing studies that will not meet or fulfill the regulatory requirements of the regulator. That's what we are doing. So "Growing Forward" will provide us with some of the resources to be able to put those strategies into place as we move forward.

The goal, the real objective, of this initiative is really to be competitive. It's good public policy to have good drugs available. We recognize that livestock producers are here and that at this point in time they may not have access to good management health tools. The objective is really to be able to give them, or to create, an environment that is going to move us to that environment.

● (0930)

Mr. Guy Lauzon: Thank you very much.

I think you mentioned the magic word—or which we like to think is the magic word—"dialogue". You mentioned dialogue with the industry, and obviously you're mentioning dialogue with the pharmaceutical industry, but I'm assuming—and I better be correct here in this assumption—that you're dialoguing with the agricultural industry too. The whole idea is that everybody has to work on the same page here, because if we're not, obviously other countries are going to be eating our lunch on the world market and we won't remain competitive.

So are the producers, for example, part of the dialogue? Are they part of the solution?

Dr. Siddika Mithani: Yes, they are. We have just set up an external advisory committee—a joint committee with CFIA and Health Canada—to look at some of the strategic directions in which we need to move to satisfy the regulatory requirements, health and safety, and competitive issues such as cost. Livestock producer associations are also involved. We have the Canadian Cattlemen's Association in that expert advisory committee, along with the Canadian Pork Council. In our task force, we talked about personal-use importation. The key issue was the price differential, which is a big issue for the farming industy. We've also consulted with provincial organizations. We've had the livestock producer associations involved in order to provide us with recommendations on strategies that will allow us to balance health and safety with some of the competitive issues we are seeing as we move forward.

Mr. Guy Lauzon: So you can reassure this agriculture committee that the producer is at the table giving you input on the solution and the concerns. That is extremely comforting.

In your presentation you mention that in the overall action plan "Health Canada evaluates and monitors the safety, quality and efficacy of veterinary drugs. The Department also promotes the prudent use of veterinary drugs administered to food-producing animals"—which is something I'd like to take a second to clarify. You go on to say in another part of your talk: "A new veterinary drug is approved for sale in Canada only if Health Canada is satisfied that...it does not leave potentially harmful residues that could pose undue risks to humans eating food products from treated animals." Then you say that "Health Canada plays a critical role in establishing maximum residue limits...".

Can you explain how the consumer can be confident that, for the product they are eating, you have guaranteed that the maximum safe residues haven't been exceeded? You mentioned "prudent residues". Can you explain that a little further?

Dr. Siddika Mithani: I'll try to explain it in two parts. Maximum residue limits are based on basic toxicology studies. These look at the product metabolized in the animals and make extrapolation calculations. Toxicity studies in animals are considered. They study the maximum tolerance, the maximum areas where there may be issues. For example, they take into account carcinogenicity and mutagenicity studies to ensure that a person who eats food treated with those particular drugs will not be subjected to levels of exposure that would cause harm in the long term. These types of calculations, these types of study requirements, are internationally harmonized. Therefore, Canada is not asking for any more than what is there internationally.

There are also international organizations such as the Codex Alimentarius Commission that bring people together to talk about where to draw the line in terms of safety, what the maximum limits are. When you look at the maximum residue limits that Health Canada has set for a lot of these veterinary drugs, they are very specific, and they are internationally harmonized.

● (0935)

The Chair: Thank you.

Mr. Atamanenko.

Mr. Alex Atamanenko (British Columbia Southern Interior, NDP): I have a couple of questions from someone who has contacted our office, Dr. Mithani.

What is the product rBGH, used by folks in the dairy industry? What is that? Is it being used? Is it something to do with a growth hormone in the milk? I'm not sure what it is. Could you answer that question first?

Dr. Siddika Mithani: I would imagine it's rBST that you're talking about. It's a drug approved in the U.S. It hasn't been approved in Canada. Obviously the concern when we looked at this particular drug was not human health but concern in terms of animal health. Therefore, the drug was not approved for use. The drug is also not approved for use in Europe and many other countries.

It's very important to remember that the door is always open for industry to come in with studies that will justify why the concerns Health Canada has raised can be alleviated. So as a drug company, if you were developing rBST or any other drug, you would file a submission. We would provide you with comments as to the reasons this particular product is not approvable and that additional studies would be required, or for you to be able to justify the rationale for that particular drug to be on the market.

Therefore, at this point in time, rBST is not a product that's approved for use in Canada because of animal health concerns, certainly not human health concerns. But there is no reason why, if the company had additional studies to justify our having a rethink, a re-examination of the information that's available, there wouldn't be an opportunity to reconsider any submission, not just rBST.

Mr. Alex Atamanenko: Am I right then in assuming that when we refer to there being no growth hormones in our milk, that is what that is?

Dr. Siddika Mithani: That's right, no artificial growth hormones.

Mr. Alex Atamanenko: So that's really also a human concern.

Dr. Siddika Mithani: It really depends. If you go back to the decision that just came out yesterday regarding beef hormones and the WTO challenge, clearly our decisions are based on sound science and the information we had reviewed on the issue of beef hormones. We came to the conclusion that based on the MRLs we really didn't see a human health concern or an animal health concern. With rBST, clearly the studies actually did not show a clear sign in terms of animal health concerns, so that still is an outstanding issue with the rBST.

Mr. Alex Atamanenko: Thank you.

The other question this person has is in regard to antimicrobial resistance. Apparently this issue is being handled, according to her, very slowly by VDD. Could you comment on that, please?

Dr. Siddika Mithani: I think antimicrobial resistance is an international issue. Everybody is concerned about antimicrobial resistance. I'd like the committee to note that we have, with the Public Health Agency of Canada, something called CIPARS —"Canadian Integrated Program for Antimicrobial Resistance Surveillance". There is a mechanism by which we look at antimicrobial resistance. Every antibiotic that is approved for use in Canada will go through a risk assessment, and we'll talk about the appropriate use of this product, to ensure that we are not developing antimicrobial resistance. There is a lot of international activity as well. Health Canada is right now chairing an international committee on antimicrobial resistance. So this is not only a Canadian issue, it's a global issue, and it's being dealt with as we move forward.

● (0940)

Mr. Alex Atamanenko: Thank you.

The research paper talks about the Canadian Animal Health Institute, and they were the ones my colleague referred to in speaking of the difference in approval times between two years and five to eight and a half years. You mentioned that the backlog is being cleared up. Would it be safe to assume that by the end of 2009 we will also have a two-year approval process, as opposed to five to eight and a half years, as it is now?

Dr. Siddika Mithani: Absolutely. I'm very confident in that, once we get rid of the backlog. We are putting process improvements in place right now, whereby industry can come in earlier. We are having dialogues with livestock producers about the generic products that are available in the U.S. We can encourage those companies to come into Canada and file their submissions. Our priority for next year is really looking at generic submission guidelines, so that we are not asking for any more than any other country in terms of regulatory requirements. I think we are really looking at a situation whereby, if we can get industry to come and file their submissions, we certainly will have a very competitive market.

Mr. Alex Atamanenko: Thank you.

Lastly, the Animal Health Institute once again gives us reasons for some of the problems, and I'd like you to clarify this, because I don't understand it.

It's right here in front of me. They say, "Risk acceptance has declined within the VDD leading, in some cases, to risk aversion." I don't understand what that means.

Dr. Siddika Mithani: Again, I'm not here to interpret what CAHI is saying, but I think science has evolved. I think the processes that we have in the veterinary drugs directorate have also evolved.

I'd like to give you one example. In 20 years, we've never had the approval of a product at the first round where a manufacturer files a submission. It is always three or four years later that a letter goes out with deficiencies. This year, two drugs have been approved at the first cycle, so there has been a considerable improvement.

Some of the improvements are not in terms of looking at risk aversion and risk assessment but really being able to go out and get the expertise to help us in providing us with recommendations. One of the process improvements that we've implemented as we've moved forward is that when there are issues that are scientific in nature where there isn't the expertise within the veterinary drugs directorate, we've partnered with the CVMA, the Canadian Veterinary Medical Association, to identify experts in the field so that we can bring in a panel of expert advisers who will help us identify and address the issues that come in these submissions so that we can move forward.

I'm sure that's coming from the IFAH report, or part of it is coming from the IFAH report, but some of the processes we've put in place will help us move forward. Some of these strategies are really going to help us in bringing that balance between health and safety and being able to do those risk assessments. There's no sense in doing an assessment when you're not aware of what's happening practically in the outside world. So our interactions with CVMA, livestock producers, and industry are extremely important.

The Chair: Thank you very much.

We're going to start our five-minute rounds.

Mr. Easter.

Hon. Wayne Easter (Malpeque, Lib.): Thank you, Mr. Chair.

Thank you, folks, for coming.

On what we call the rBGH issue, I would say that if it weren't for this committee in 1995, that would have been allowed.

I will say this upfront, that we were not very impressed with Health Canada's position on allowing it for health reasons. It was stopped for animal health reasons at the end of the day, but I know both Paul and I reviewed a lot of that documentation at the time, in 1995, and I still have concerns over the health issues of that product. I do not believe that Canada should be allowing into this country products that are produced from cows injected with rBGH. I think it's a legitimate concern.

That moves me to my point, that one of the major concerns of producers, which we've heard increasingly over the last number of years, is that products are allowed to enter this country, whether from the United States, our major competitor, or from China—and increasingly from China—products that don't meet the same veterinary standards or health standards as Canadian producers are expected to meet. It's a serious problem.

We've suggested in a previous report that if a product is coming into Canada that doesn't meet the same standards as our producers had to meet, then that product shouldn't be allowed in. I think you're going to hear that increasingly loud from this committee.

If it isn't safe, if a product from our producers goes on grocery store shelves and they're not allowed to use a certain herbicide, pesticide, feed additive, or whatever drug because it's so-called "not safe" either for worker reasons or consumer reasons, then how the heck can a product using it end up on our grocery store shelves and drive our guys out of business?

Guy made the point on residue levels. That's one thing, but there's another side of the issue. There are certain products that farmers here are not allowed to use because of the human safety factors related to the people applying the product on the land. Our producers can't use that product because of the worker concern, yet the product ends up on the shelves. So how do we deal with that issue? Are we exporting our moral responsibility for workers? Are we saying they can breathe the spray dust but Canadians can't, and then we allow that cheap product onto our shelves?

● (0945)

Dr. Siddika Mithani: You make a valid point. When we look at the review and evaluation of products, it's really important that we look at all aspects. So part of the regulatory process really focuses on the human health component as well as the animal health component. That is our mandate, when we look at Health Canada and the way we review and evaluate drugs.

I would like to be very specific, in that the review and evaluation is really based on sound science decisions. And if the information in a data submission points to the fact that there are issues with respect to human health and appropriate use of the drugs, and if there can be any risk management strategies that can be put in place to be able to manage the product appropriately, then Health Canada is obligated to make a decision on how to move that forward.

Hon. Wayne Easter: But the issue here on these sound science conditions is that some Mexican labourer's health is at risk because they're allowed to apply a product—a pesticide, a herbicide, or whatever—on a crop. Our producers are not allowed to do that in this country because of concern for the health of the people applying the product, yet that Mexican product ends up on our shelves.

Now, is there a way of dealing with that one? I understand your concerns within Canada, but for our producers on the ground, producing.... It may be the cost of human lives in Mexico in terms of their labour, or wherever else, but our producers are being driven out of business because although that product doesn't have residue in it, it's not allowed for use in Canada for reasons of the health of the workers. Yet the product still ends up on our shelves and drives our guys out of business.

Is there a way that Health Canada can deal with that issue?

In your veterinary and drug strategy plan—it relates mainly to Canada and the United States—it says that you would prepare by April 30, 1999, and that was nine years ago, a side-by-side comparison of veterinary drugs approved for use in both countries. I think that was to try to ensure that both countries have the ability to access the same drugs. Has that been done? Is it available to us, and does it include the factors I just talked about, where they have different worker restrictions from ours? It's a huge problem. It's the same thing in China—you can kill a worker, but don't allow residue to come in.

● (0950)

Dr. Siddika Mithani: In response to your—

The Chair: Just so you know, Mr. Easter's time has expired, so I do ask that you provide a brief comment.

Dr. Siddika Mithani: I'm going to be very brief.

In response to your question, our mandate really looks at the health and safety of Canadians and the processes that are in place in Canada. However, in terms of products that are coming from Mexico that may have residues that are not allowed in Canada, there is certainly an effort right now between Health Canada, CFIA, and Agriculture Canada to look at some of these. So we have some targeted budget funding that is going to look at this as we move forward.

The Chair: Thank you very much.

Ms. Skelton, the floor is yours.

Hon. Carol Skelton (Saskatoon—Rosetown—Biggar, CPC): You mentioned that Health Canada, CFIA, and Agriculture Canada work through all these steps—the three departments. Now, it has taken five to eight years. So how long would a drug be in each department? Where has the backlog been?

Dr. Siddika Mithani: When you look at a drug submission evaluation, that is the sole responsibility of Health Canada. Our interactions with Agriculture Canada and CFIA are really based on some of the policy initiatives as we move forward. So when we talk about personal use importation and the fact that farmers are able to bring drugs across the border for personal use, that's a bigger policy issue; it has implications for the agricultural industry. So our interactions with Agriculture Canada are based on policy initiatives.

CFIA does a lot of our enforcement actions. For example, when we had the issue of carbadox in pigs, the CFIA was responsible for the enforcement of some of the MRLs that we talk about.

So our interactions with CFIA and Agriculture Canada are really on strategic or policy issues, on how we move forward. Health Canada cannot look solely at what they do in terms of their own responsibility; we have to make sure we understand other people's issues, other organizational issues, as well.

The backlog is going to be reduced. As we said, there will be an elimination of the backlog by 2009. That's clearly the responsibility of Health Canada; it's within Health Canada's control. And these submissions are not farmed out to Agriculture Canada or CFIA. But there's certainly interaction in terms of how the products would be used, what kinds of enforcement or risk management strategies we may want to have as we move forward, especially if it's a drug that might have specific safety issues in animals, or where MRLs may be difficult to establish, etc. So those are the interactions that occur with the other departments.

Hon. Carol Skelton: And you said you do have some specific funding now to help you move forward with speeding up this whole process?

Dr. Siddika Mithani: Right.

Hon. Carol Skelton: I gather there are some loopholes, though. Could you give us more details about those loopholes and the size of the market you feel Health Canada has been looking at, and how can we eliminate those loopholes?

Dr. Siddika Mithani: The most worrisome loophole we have right now is personal use importation. It was also identified in the IFAH report that came out in 2007, the fact that within the regulations, farmers are allowed to bring in drugs from across the border—

● (0955)

Hon. Carol Skelton: For example, ivermectin?

Dr. Siddika Mithani: Ivermectin, exactly.

CAHI is reporting there is a considerable issue in terms of the market share for industry, and this is decreasing competitiveness. Industry does not want to bring in these drugs, because if people are going to be able to get them more cheaply from across the border, then why should industry go through the regulatory process to do that?

One of Health Canada's concerns with personal use importation is if products are coming from China, India, or other countries where the standards are not identical or similar to the standards we have in Canada, we would have an issue. All you would need would be a safety issue because of an adulterated product coming across the border, and it would be huge.

So we've put together a task force. We did this in early 2007. Livestock producers are involved, CAHI is involved, and Agriculture Canada is involved as well. We brought them together and said we recognize the price differential issue for agriculture. We have to create an environment that's conducive to competitiveness for people to want to come in and file a submission, so that we would have these types of products. How do we restrict personal use importation? How do we make sure that what we are getting from across the border is not substandard or adulterated?

This is what we are working on right now. We are hoping that the task force will come up with some recommendations that will allow us to move forward.

Hon. Carol Skelton: When is the task force going to report?

Dr. Siddika Mithani: They have told us that it would be mid-June.

The Chair: Thank you. Your time has expired.

Madame Thi Lac.

[*Translation*]

Mrs. Ève-Mary Thaï Thi Lac (Saint-Hyacinthe—Bagot, BQ): Good morning.

My first question is a follow-up to the discussion between you and Mr. Bellavance. You mentioned certain drugs that could be sold even if they are not yet authorized in Canada. Besides, I read in the document that the veterinarian must entirely assume the responsibility for protecting the animals he treats and for potential infection. However, you are currently allowing the sale of drugs that have not yet been authorized.

Are these drugs being studied? I would like to know more details about the sale in Canada of drugs that have not yet been authorized.

[*English*]

Dr. Siddika Mithani: Thank you very much for your question.

Drugs that are not authorized for sale, which means those that have not had the issuance of a notice of compliance, can be made available to veterinarians for use through two processes. One is the emergency drug release process, and the other is the investigational new drug submission process. So the emergency drug release process allows for the use of these products that are not authorized, because they are not on the market and there is a therapeutic need to use them in animal care.

For example, some of the aquaculture drugs come through the emergency drug release program. They are not authorized through that program without a review and an evaluation, so some element of review and evaluation occurs. We set up maximum residue limits for those products if they are used in food-producing animals, and there are withdrawal times. That is one process by which drugs that are not authorized for sale in Canada can be used appropriately and very prudently for animals.

The other process is the investigational new drug submission. That is the process I talked about earlier, where we are encouraging industry to come in with these types of trials. It's a controlled study that will collect both safety and efficacy data about a drug. This information is useful when they file their new drug submissions so they can get approval for these products. So there are mechanisms by which these unauthorized products can be made available in Canada if there is a need.

● (1000)

[*Translation*]

Mrs. Ève-Mary Thaï Thi Lac: You spoke of emergency sale programs for animals. Is there some procedure for evaluating the urgent nature of certain products such as those which you just mentioned and which could answer to real urgent needs?

[*English*]

Dr. Siddika Mithani: With the emergency drug release program there is an evaluation process and we look at the data there. The data may be very limited; it's obviously not enough to issue a notice of compliance. That is why the drug comes in through the emergency drug release program.

There is also evaluation in the IND process. If there is an emerging disease where clearly there is enough data, then we have a case-by-case process whereby a company can come in and say that this is a priority review. Priority reviews of new drug submissions can be picked up very quickly and authorized or reviewed in a very timely manner.

So it really depends. We have a risk-managed approach within the system to allow those emerging drugs to come in very quickly when there are no other therapeutic options available.

[*Translation*]

Mrs. Ève-Mary Thaï Thi Lac: You said that the veterinarian assumes full responsibility for protecting the animals he treats and for potential infection due to the presence of drug residues in animals raised for food.

This is a responsibility that you have thrown into the veterinarians' court. What are the further implications of this responsibility?

[*English*]

Dr. Siddika Mithani: The appropriate use of drugs in any situation, whether you're talking about human drugs or veterinary drugs, is a shared responsibility. Industry has the responsibility to develop drugs that are safe and efficacious. Health Canada's responsibility is to review that information, evaluate, and make a decision as to whether those drugs are issued a notice of compliance and put on the market.

Veterinarians, as well as physicians, when you look at human drugs, have the responsibility to use these drugs appropriately. That's the reason for having our package inserts and the information that accompanies a drug when it is marketed in Canada. There is information there. There are systems in place. Obviously, CFIA does monitoring of residues, and where there is an issue, these things are followed up.

So I think we need to look at this as a real, shared responsibility. That's the reason why, when we look at a lot of our policy initiatives, when we look at personal use importation, and when we look at off-label use of drugs, which is when drugs are approved for one species and used in another, CDMA is also at the table. It is so they understand that they also have a responsibility.

The Chair: Thank you.

We'll go to Mr. Storseth.

Mr. Brian Storseth (Westlock—St. Paul, CPC): Thank you very much, Mr. Chair.

Thank you, Ms. Mithani and Mr. Hills, for coming today.

I have some concerns. I'm not exactly convinced that Health Canada necessarily understands the importance of the competitiveness issue and the price disparity between the United States and Canada for drugs such as IVOMEC. It's not an uncommon story to hear of producers who fly down to the United States, buy a truck, fill it up with their quarterly use of IVOMEC, bring it back up, pay the GST and everything else on it, and actually save the price of the truck in their drug costs alone. So this is a very important issue, and I'm a little concerned.

It doesn't seem that you're a big fan of personal use importation. I'd like you to walk me through it a little bit. There is an application form the producer would have to fill out for Health Canada before going down to pick up this drug. Is that correct?

I've seen these application forms. They're not exactly small forms. They're very detailed and very onerous for the producers, which I have a problem with, as well. Nonetheless, how would you have these drugs coming from other countries like China or somewhere else that we don't want coming into Canada? Do they not have to get approval from Health Canada first?

● (1005)

Dr. Siddika Mithani: Personal use importation does not mean approval from Canada. So you're right that farmers can go across the border and get ivermectin that is cheaper than when it comes into Canada. Health Canada understands the issue of the price differential, which is why we have our personal use importation task force. When we talk to companies or when we talk to livestock producers about why there is a price differential and why these companies aren't coming to Canada and filing their submissions....

It would be easier if these drugs were available at the same price in Canada instead of having livestock producers going across the border to get these particular products. One of the issues is the regulatory approval system. We have a cumbersome, onerous system in which requirements may be different for the U.S. and Canada.

So one of our process improvements and one of our priorities for this year is to come up with a streamlined process for generic submissions so companies in the U.S. don't have extra requirements in Canada. They are able to file their generic submissions here in Canada so that these drugs can be made available. Only if you have these drugs available in Canada are you going to increase the competitiveness of the marketplace here in Canada.

That's what we've been working with on the task force. The intent is that when we eliminate the backlog, when we have an environment that is conducive to competitiveness, and when we have these generic companies coming here to the Canadian market, the price will go down for the innovators and for the other generics that are available. It will be a competitive market. When we get to a stage, which is going to be very soon—within the next year—when we are reviewing on time, industry will be able to file virtual submissions in both the U.S. and Canada.

Then we have to really look at personal use importation. Is there really a need for livestock producers to be going down south? The concern is the potential adulteration of these particular products and where they're coming from. How do you restrict? It's not closing the loop; it's how you restrict to ensure health and safety.

Mr. Brian Storseth: Once you have these generics up here in Canada, then there won't be the need for the personal-use importations and the farmers won't do it anyway. So I don't think we need to be looking at restricting it in the meantime. You're looking at a year before the process even starts to become streamlined. My producers can't wait for this process. We need to have access to those markets now. The own-use import program with Clearout 41 Plus is a prime example. The ability for our farmers to go down to the United States has closed the gap from $4 a litre to $1 a litre—and that's our farmers doing it on their own, without Health Canada's help.

You've raised a couple of good points. You talked about two drugs that have been approved in the first application process. In total, how many drugs were put in?

Dr. Siddika Mithani: Right now, we have about fifty.

Mr. Brian Storseth: And two were approved, while the rest were denied?

Dr. Siddika Mithani: No. The number of submissions we have right now I believe is about 193, in-house. In the last 20 years, we have never had a situation whereby a drug has been—

Mr. Brian Storseth: I don't mean to be rude, but I understand that during the last 20 years you were very optimistic about the latest round. In the latest round, in which two were approved immediately, how many were in the process? Were only the two submitted?

Dr. Siddika Mithani: No, there were many in the process. We can get you the numbers. This is an ongoing process, so we've had a few notices of compliance. It's not just two that have been approved.

My example was to illustrate that when someone talked about the issue of risk aversion, this was a demonstration of some of the processes we have put in place to give us the necessary expertise. This then allows us a first-time cycle in order to approve a product.

Mr. Brian Storseth: If you could get us those numbers, it would be much appreciated.

The Chair: I ask that you submit that information to the committee as quickly as possible.

Mr. St. Amand.

● (1010)

Mr. Lloyd St. Amand (Brant, Lib.): Thank you, Mr. Chair.

Doctor, I just wondered if you are to any extent involved with pet food.

Dr. Siddika Mithani: The pet food issue comes under CFIA. If a pet food has a health claim—and I don't think we have any pet foods with therapeutic health claims—they are reviewed by Health Canada. So the pet food issue is CFIA's.

Mr. Lloyd St. Amand: The manufacturers of drugs or medications for pets are based where? All over, I assume. But principally, where do most of the drugs come from?

Dr. Siddika Mithani: Most of the drugs come from either the U. S. or Europe. Those are the two areas.

Mr. Lloyd St. Amand: To what extent are they manufactured in Canada, if at all?

Dr. Siddika Mithani: The manufacturing of drugs in Canada is fairly limited. We could get that information for you, if you like. CAHI would be able to provide you with that information, and we can get it for you.

Mr. Lloyd St. Amand: Is there a reason why so few drugs, if any, are manufactured here in Canada?

Dr. Siddika Mithani: There's a lot of globalization of industry, and the fact that a lot of these drugs are approved in other countries before Canada may be one of the reasons. I'm not sure. But I would imagine that there is truly an opportunity here in Canada, once we become competitive, to undertake a lot more R and D.

Mr. Lloyd St. Amand: As I understand it, the competitiveness study that was done, looking east and comparing Canadian performance with performance in Europe, shows that the process is two years or less in Europe and four and a half to five years here in Canada. It's my understanding that, as a result, significant research and development opportunities have left Canada and gone elsewhere. Is that the case?

Dr. Siddika Mithani: That's actually the case, I think, on both the human side and the veterinary side. Studies may be cheaper in other countries. That could be one of the reasons. But if it has to do with the regulatory approval process, we can be assured that there is an opportunity for these types of studies to come back, especially with some of the strategies that we have put in place in the last couple of years.

Mr. Lloyd St. Amand: Is there anything on the ground, though, to reflect your confidence about that possibility?

Dr. Siddika Mithani: The proof is in the pudding. Look at what we have done since 2005. If you look at 2002 or 2003, you would have never imagined that we would be where we are right now. The fact that we have put these processes in place and that they are working.... Our interactions with the industry, with the livestock producers, and the policy initiatives that we are moving forward with are a real demonstration of the commitment Health Canada has in balancing health and safety with innovation and being competitive.

Mr. Lloyd St. Amand: That's no doubt the case. But that being said, is there any tangible evidence that research and development has come back to Canada?

Dr. Siddika Mithani: We don't have tangible evidence that it has come back, but we certainly have a commitment from CAHI, which is coming in for pre-submission meetings.

One of the conversations we've had with CAHI through the advisory committee is about coming in very early during the drug development. If they come in early, if we are able to very clearly give them what our requirements are, if we provide them with clarity and guidance in the regulatory requirements, these studies will be done in Canada. And if these studies are being done in Canada, then that will bring R and D.

We are having that dialogue. It's in their best interest to be able to bring these particular products very early on. It will bring R and D and it will improve efficiency in terms of the approval process.

Mr. Lloyd St. Amand: I have one last question, if I may, Mr. Chair.

Following up on what my Bloc colleague Madam Thi Lac asked, to what extent do veterinarians utilize drugs that have not yet been approved?

● (1015)

Dr. Siddika Mithani: It has really levelled off in the last little while, because we haven't had as many investigational new drug submissions come in.

The beauty of having the clinical trials done in Canada is that you really have the veterinarians engaged in the development process. That's where we are going and that's what we want to do, which is why we are bringing these people to the table.

Optimally, the objective is to be able to have these studies conducted in Canada. If veterinarians are engaged, they are the ones who would provide the recommendations to Health Canada in terms of "Sure, there's a regulatory review and approval process, but by the same token, in the real world this is how these drugs are used or may be used, and how do you reconcile that?"

Mr. Lloyd St. Amand: To what extent does it occur? Is it the exception? Is it twice yearly? Or are there any data on that?

Dr. Siddika Mithani: We may be able to get data from CAHI on this. But we can give you some of the information we have in terms of investigational new drug submissions and how many we have had in the last little while.

What will be interesting is to see how we will fare—that will be our benchmark—in the next couple of years, with all the dialogue we are having.

The Chair: Your time has expired, Mr. St. Amand.

Mr. Allen.

Mr. Mike Allen (Tobique—Mactaquac, CPC): Thank you, Mr. Chair.

Thank you for being here today.

You made a statement on page 6 of your brief. I'm always interested in the words people choose to communicate something. You said that Health Canada was aware of the desire from livestock producers to increase regulatory compliance and that the department was working toward increasing its efforts.

Are you increasing your efforts or are you working toward that? What are you doing with these international standards and international bodies to get alignment of these regulatory requirements? I'm assuming that's part of the way to addressing the backlog in the long term.

Dr. Siddika Mithani: Yes, and you make a very good point. We are looking at international cooperation. When we look at the MRLs we have in Canada versus those in the U.S., we are 75% harmonized. Our default position is the Codex, where there are issues.

The calculations of maximum residue limits are not harmonized, so every country has its own methodology for assessing them. It's one of those things we really need international cooperation on so we are able to have similar or identical standards as we move forward.

We are actively pursuing international cooperation. For example, right now we have an MOU with the U.S. and an MOU with Australia. We are looking at their systems. We get review reports through industry that facilitate the review of the products we are looking at right now, because obviously some of the products in queue right now in the veterinary drugs directorate are products that have already been on the market for several years in the U.S. The idea is you're looking at a pre-submission package, but a lot of the real safety information, the drug use, may be in the post-marketing area. So how do we leverage or capitalize on the information that's available internationally to facilitate our review process?

So there is a lot. We are actively working on the cooperation.

As we look at generic guidelines, that's another thing we're looking at: the requirements there are in Europe, in the U.S., in Australia, and how we create a regulatory requirement for these types of submissions so we are not onerous.

Mr. Mike Allen: Have you set a target date in these discussions to close that gap of the remaining 25%? You said 75% was harmonized in one of those areas. What is your target date for closing this gap?

Dr. Siddika Mithani: We are taking slices of the 25% that is not harmonized and looking at ways in which we can look at the calculations of MRLs and withdrawal periods. So we are looking at specific sectors as we move forward.

Mr. Mike Allen: So there's no target date?

Dr. Siddika Mithani: We don't have a target. I cannot tell you there's a target for 2009 or 2010, but we are actively pursuing each sector and are able to do that within that particular sector.

Mr. Mike Allen: My next question is about the veterinary drugs directorate. Given the fact that you work with CFIA and Agriculture Canada a lot, is there a portion of your budget or are there cost-recovery mechanisms within VDD? How is that managed? Who is charged? Because CFIA obviously has a significant cost-recovery component in some areas.

● (1020)

Dr. Siddika Mithani: We do have cost recovery for review and evaluation. Cost recovery for veterinary drugs was introduced in 1995. Right now, our cost recovery is just 7% of our budget, so it's very, very small.

On the human side, we are looking at a cost-recovery initiative. At this point, we have not gone into re-examining the cost-recovery situation in the veterinary drugs area. We are targeting 2010, but before we do that there will be a lot of stakeholder consultation. We will be looking at how we calculate the cost recovery. Are we looking at 50%, 75%? What kind of percentage are we looking at in terms of—

Mr. Mike Allen: Excuse me, but that's 50% to 75% of what?

Dr. Siddika Mithani: Of the cost of doing business, the cost of each submission evaluation. As submissions come in, the cost is based on the cost of reviewing that submission. Right now it's only 7% of our budget; however, we really need to re-examine how we are going to do cost recovery for veterinary drugs after the elimination of the backlog and be able to go back to our stakeholders and come up with a system, a process, a mechanism to implement cost recovery.

Mr. Mike Allen: Can you tell me how that compares with other jurisdictions with respect to their cost-recovery mechanisms? Are we doing something that could end up hurting R and D in Canada?

Dr. Siddika Mithani: Right now, when you look at cost recovery, we are much lower than the U.S. The U.S. is probably $300,000 per submission. We go around $100,000 per submission. Again, it depends on the type of submission, but the average new active substance is $100,000, versus the U.S, which is $300,000, so we are much lower. We really need to look at our cost-recovery system once we've eliminated backlog.

The Chair: Thank you.

Mr. Easter.

Hon. Wayne Easter: Thank you, Mr. Chair.

On Mike's point, we're seen as a high regulatory cost area by companies applying for drug approvals. We're not a big market. We like to think we are, but Canada as a whole, compared to the United States, is not. That's just to point out that I think certainly most of us around this committee feel that the cost should be kept very low, that we can't be a higher cost regime than our competitors or it's difficult for our producers.

I want to make one point as well on emergency approvals, based on Lloyd's question. I don't want to leave the impression, at least from my own point of view, that we're opposed to that, because sometimes it is necessary. I've made requests myself for the horticultural industry, where there is a pest and there is a product in the United States that may be approved by their system and not in ours. I think there was a product in Mike's area in aquaculture that we had to approve one time under emergency approval. So that system is important to us and is necessary, as long as the proper guidelines are in place.

You'd mentioned in your opening remarks that a number of companies have decided not to file their submissions here, implying probably the high cost of doing so. I'm not sure why. Is it because there's a backlog? Is it because there's a high-cost regime?

When we get over this backlog, does Health Canada have any strategy to inform industry that we are a place for R and D, that they should be asking for approvals under our system parallel to the United States? That's important. We have to have access to the same kinds of drugs as they do.

I'll tell you how serious this is from a producer point of view. A producer in my riding couldn't use a feed additive for pork for five years. It got approval last year. He went broke on December 19, just before Christmas, as a hog producer. The cost, according to his calculation, of not being able to use that feed additive on his production base over that five-year period was $470,000. It had made that much difference, and he might still have been in business today.

So that's why I think you see us raising the concerns on the cost end. That is an example of how our cost regime and our lack of quick access to the same products as are available everywhere else has an economic impact on rural Canada.

Anyway, my question is on your backlog and the reason for submissions not being done here. Do you have a strategy?

● (1025)

Dr. Siddika Mithani: In response to your question, I believe the reason that companies are not coming is not because of cost recovery or the cost of submissions. It was because of two reasons. One was the fact that when submissions came in, they were evaluated on a case-by-case basis and there were no clear-cut guidelines on what requirements were. We've moved forward in articulating what our requirements are, and we continue to do so. We have a guidance document that articulates the requirements for drug submissions. So we are very clear in what we want. We weren't clear before.

Secondly, we had the backlog, and there was no incentive for industry to come in at the time when their submissions would take three years, five years, or eight years for approval. We've put in place process improvements such that we are beginning to eliminate the backlog. Our strategy as we eliminate backlog is the sustainability of being able to continue to review on time.

We've had discussions with the CAHI in encouraging their members to understand that we're getting rid of the backlog. We're eliminating backlog such that we are going to get submissions coming in. We've also talked to the livestock producers in saying that when you go to those companies in the U.S. you are buying drugs from, you have to tell them that we've reduced the backlog, that there will be elimination of backlog, and that there is a real opportunity to bring those drugs in.

I think we also need to understand that in order for us to be competitive, it's a shared responsibility. Health Canada's responsibility is to review on time, and we are committed to do that by early 2009. There has to be a commitment from CAHI to bring these drugs into the Canadian market, because Health Canada cannot make people bring in drugs, cannot make a manufacturer file a submission. They have to be encouraged to bring those in.

I think livestock producers also have a role to play in encouraging companies to come in with these submissions. If these are the drugs they truly require, it really has to be a partnership, and we're committed to that partnership.

The Chair: Thank you.

I want to follow up on Mr. Easter's comment.

You're saying you want to reduce this backlog within 12 months from now. What are we looking at, then, for length of time for approval of new products? How is it going to reduce the cost and regulatory burden that so many companies are facing right now, which makes it difficult for them to make the decision to bring new products to Canada?

Dr. Siddika Mithani: There are a couple of things. We're talking about elimination of backlog. By early 2009 there will be no backlog; it will be review on time. Our review-on-time timelines are 300 days.

We've also said to industry that if they brought in submissions earlier, during the early drug development phase when we are able to tell them what our requirements are, and were developing those products based on our requirements—which, by the way, would be very internationally harmonized, so we would not really be asking for any more than what any other regulator would be asking—there would be an opportunity to further decrease that timeline.

The fact that companies will be able to file a virtual submission in two or three or four countries will decrease PR costs by allowing them to use that same submission with the same data across the world.

The Chair: Which countries are we then comparing ourselves with? I would think it would be the Americans, the European Union regulatory burden, Australia, New Zealand. Are those the countries we're modelling ourselves after or that we're working collaboratively with so that we can have our livestock industries on the same level playing field?

● (1030)

Dr. Siddika Mithani: Yes, we are. We also hope or anticipate that in the next year, when we have eliminated the backlog, there will be real opportunities to discuss submissions with the U.S., with Europe, with Australia when they are filed, simultaneously in all these countries. You would really be looking at virtually all countries being able to approve a product almost at the same time. That's the objective.

The Chair: That's fantastic.

Mr. Storseth.

Mr. Brian Storseth: Thank you very much, Mr. Chair.

We all talk about the backlog, and maybe I'm out of the loop here. First, how big is the backlog?

Dr. Siddika Mithani: It's about 180 submissions right now.

The Chair: Mr. Hills, you can make a comment.

Mr. Bob Hills (Manager, Transmissible Spongiform Encephalopathy(TSE) Secretariat, Veterinary Drugs Directorate, Health Products and Food Branch, Department of Health): Thank you.

There are approximately 180 submissions that were in backlog when we started at the beginning of this year. We have addressed that backlog by targeting greater than 90% of that backlog. The backlog is basically saying that if a submission is beyond our published time under our management of regulatory submissions, which is, say, 300 days for a new drug submission, it would be considered backlog if it were at 301 days.

We have addressed over 90% of that this year, meaning that this year—right now, as we speak today—there are approximately 50 submissions that we would consider to be in backlog right now. So we've made a significant difference between that and this year.

By the time we finish the fiscal year this year, towards the end of 2008 or the beginning of 2009, those 50 submissions as well as any new submissions coming in will be picked up and be reviewed on time, meaning that by fiscal year 2009 we'll be in a position such that all submissions will be reviewed within our management of regulatory submission timeframes.

Mr. Brian Storseth: In your backlog, which it seems you've made tremendous progress on—

Mr. Bob Hills: Yes.

Mr. Brian Storseth: —of the 130 you have gotten done—

Mr. Bob Hills: Approximately.

Mr. Brian Storseth: —how many were approved?

Mr. Bob Hills: I'd have to dig out the exact numbers.

Mr. Brian Storseth: Give me a percentage?

Mr. Bob Hills: A percentage? We've increased our notices of compliance, which is the authorization for market access, in a number of ways.

If I look at new drug submissions or abbreviated new drug submissions, out of those 130 I would estimate that somewhere between 70% and 80% went to notice of compliance, meaning that the ones that are carrying over this year will be ones for which we've maybe gone through one review cycle and on which more information will come out.

It means, then, that our overall time between picking up a submission and then getting it out to a notice of compliance would be very consistent with that of our international people with those backlog submissions.

Mr. Brian Storseth: But notice of compliance is not an approval.

Mr. Bob Hills: It's an approval process. It gives the companies the ability to market the products in Canada.

Mr. Brian Storseth: So roughly 80% have been approved?

Mr. Bob Hills: Yes, it's somewhere around there—of what we picked up this year.

Mr. Brian Storseth: Was the problem with them before the maximum residue levels, or what was it?

Mr. Bob Hills: It wasn't necessarily. If I would look at the submissions, some of them may be for companion animals; some of them may be for food-producing animals. If it was for companion animals, it would not be a maximum-residue-level-type issue, primarily because they're not food-producing animals. For those ones, we would run into some difficulties with some of the requirements we have around some of the studies that would be required or some of the specifications we're looking for to ensure the safety and quality of the product as it comes into Canada.

Mr. Brian Storseth: By early 2009, will we still have products coming from the United States onto our grocery store shelves that contain drugs that our producers cannot access due to issues such as maximum residue?

Dr. Siddika Mithani: If you are talking about maximum residues, again, everybody does their own review and evaluation. The thing is that companies have to file those submissions. A Canadian farmer may not have access to those drugs because the drug submission has not been filed with Health Canada. That is why I say we all have a responsibility to encourage industry to bring those drugs to be filed with us.

I cannot tell you that by 2009 drugs will not be cheaper in the U. S., because we will need those generic companies to be filing drug submissions. It's all to do with industry's commitment to filing drug submissions, and that's what needs to be encouraged.

● (1035)

Mr. Brian Storseth: In those cases, farmers would still have access to the personal use imports to offset those diversities, and I think that helps substantiate why we need to continue to have this all throughout the process. It does help hold back on some of the loopholes that we have in the generic industry while we are trying to get our country competitive in that industry.

Do you have a comment, Mr. Hills?

Mr. Bob Hills: While I can understand where you're coming from with respect to personal importation, one of the concerns we continue to have is with the ability to bring in drugs that have not been approved in Canada—or perhaps have not even been approved in the FDA—because maybe they are bringing them in from a country such as India or China or some place like that where we may have a little bit more concern because of the regulatory system that's in place. We haven't gone through that same confidence-building exercise there that we've gone through with the FDA or with others.

The concern would be under personal importation that any drug product, effectively, could be brought in under that particular guise. That means that a drug may not have been approved in the U.S. either. So from a Health Canada point of view, we would always have to have some concern around the loophole that would be there, because the consumer who goes to buy the meat from the Canadian producer or elsewhere doesn't have that choice, so we have to have some mechanism by which we can monitor it. While I can understand what you are saying, we do have to look for those areas where there hasn't been an approved drug product that could be of particular use. -

Mr. Brian Storseth: I have two points to finish off, Mr. Chair.

The Chair: Go ahead briefly.

Mr. Brian Storseth: First of all, they still have to file the application with Health Canada, so Health Canada is still aware of the product they're bringing over. Second, if we start getting local producers who are importing from China and India, there is a huge price disparity there for them to be able to get those shipment costs over and still make a profit. I think that really speaks to the uncompetitiveness and some of the roadblocks that are put up by Health Canada on some of these issues.

The Chair: Thanks.

Monsieur Bellavance.

[*Translation*]

Mr. André Bellavance: Thank you, Mr. Chairman.

Ms. Mithani, I would like you to give me some details about some points that you raised during your presentation, at the beginning of the meeting. First, I would like to know how many people are assigned to the Veterinary Drugs Directorate at Health Canada, how many of these people are working on registration and how many of them are more involved with drug safety.

[*English*]

Dr. Siddika Mithani: We have about 98 people working in the veterinary drugs directorate. The veterinary drugs directorate is made up of veterinarians. We have toxicologists. We have pharmacologists. We have chemists who specialize in chemistry and manufacturing. We have some people who do policy. I could come back with some numbers for you.

We have three divisions. One is the clinical evaluation division, which looks at a submission from the animal health and safety perspective. We have another division, the human safety division, that's involved with antimicrobial resistance. They are involved with the setting of MRLs, the international cooperation in terms of harmonization with MRLs, and withdrawal periods. Then we have the chemistry and manufacturing division, which looks at the chemistry and manufacturing of the products coming through.

There is real interaction here. When a submission comes in, it's divided into three parts—chemistry and manufacturing; if it's a food-producing animal, then a chunk of the submission will go to the human safety division; and then it's clinical evaluation. So there's real interaction between these three, coming in at regular intervals to talk about the drug so that everybody is aware of what's going on before a decision is made to approve, to send a letter for additional data, or to reject.

[*Translation*]

Mr. André Bellavance: Do any of your people report to the Department of Agriculture and Agri-Food, or to the Canadian Food Inspection Agency? Some departments work in this way. If not, are you collaborating very closely with the Department of Agriculture and Agri-Food?

● (1040)

[*English*]

Dr. Siddika Mithani: The people who are in the veterinary drugs directorate report to a director general, and are within the Health Products and Food Branch. We have close ties with Agriculture Canada.

For example, if there are enforcement issues, the human safety division will talk to CFIA, or if CFIA finds an adulterated product, they will ask for a risk assessment from Health Canada that will provide them with recommendations on whether it's a level one recall or a level two recall, what they need to do, if the risk of this particular adulteration would high or low, and what strategy CFIA would use then to enforce the compliance of these types of products.

So it's fairly different, but there are very close ties with CFIA and Agriculture Canada.

[*Translation*]

Mr. André Bellavance: I am referring to the number of employees, because you said at the beginning of this meeting that the department has taken measures to save money and improve the registration process. As parliamentarians, we take satisfaction in seeing that taxpayers' money is well-spent and that savings are being made. Nonetheless, our experience tells us that savings often mean cuts.

For example, have there been any reductions in personnel, and if so, in which sector? Did the government ask you to cut down on staff and on expenditures? I think that cuts to staff or other resources run counter to the fact that you want to improve the registration process, in particular.

At the same time, you said that savings have been made and that you want to improve the registration process. Exactly how are you going about it?

[*English*]

Dr. Siddika Mithani: In order to cut costs, process improvements have been put in place. In order to do an efficient job, it doesn't always mean more money, more staff. The systems that were in place in the veterinary drugs directorate were not harmonized, were not coordinated. We've brought a lot of coordination into the system. We did not focus on international cooperation and harmonization in those times.

So whereas we have introduced efficiencies, we have also introduced cost-cutting, not in terms of having less people but in terms of being able to work more efficiently within the system. That's what was being referred to.

The Chair: Mr. Steckle.

Mr. Paul Steckle: Just as a brief follow-up on the whole issue of own-use importation, the product IVOMEC has been spoken about a number of times this morning. Given that the price differential is so great between Canada and the U.S., where is the problem? Is this a problem with the manufacturer in terms of how it prices to Canada and how it prices to the U.S., in terms of volume? What is the reason for this? Is it our people who want to profit from this product? Where is the problem? I think a lot of people would like to know. Or, maybe you don't know.

Dr. Siddika Mithani: I certainly don't know what the issue is, but I would imagine that the price differential is because there's a much bigger market in the U.S. than there is in Canada. One of our challenges is going to be how we get those generic companies to file submissions so we can have those same products at those same prices available here in Canada.

The Chair: I think it's a generic ivermectin. It's not IVOMEC itself that people are buying. My brothers and I buy ours in the States because it is very affordable down there.

Are there any royalty issues or licensing issues, like patents being held by certain companies in Canada, that prevent the generics from registering here before they do in the U.S.?

Dr. Siddika Mithani: We're not aware of any sort of real patent issues. The fact that we do have a couple of generic ivermectins here in Canada begs the question as to why we cannot have more generic ivermectins. We have also spoken to the livestock producers in terms of what types of drugs are causing them the highest price differential and how we can move those strategies forward.

● (1045)

The Chair: A couple of times today some of the committee members have mentioned the Canadian Animal Health Institute's study benchmarking the competitiveness of the Canadian animal health industry. In there, they're suggesting that 20% of the market now is being brought in through the personal use imports, and they made a recommendation to Health Canada to have that so-called loophole closed. I'm just wondering if you are following that recommendation or if you're going to be taking all sides of the argument in this issue, in determining future policy.

Dr. Siddika Mithani: We've obviously had an opportunity to discuss the IFAH report with the Canadian Animal Health Institute. We have set up a task force, as I have mentioned before, on personal use importation that includes the Canadian Cattlemen's Association, as well as CAHI, some provinces, and PMRA, to see whether there is any hope or strategy that we may use, based on some of the programs they have in place—for example, the GROU program.

So as we move forward in addressing the personal use importation issues, we will be looking at all sides. We've got everybody at the table, and we hope we can come to a consensus. Based on the recommendations they will provide, there will be lots more dialogue in how we move forward in restricting the personal use importation based on the fact that there are certainly potential safety issues Health Canada would be concerned about, but recognizing that the price differential is really an issue. With the kinds of process improvements we have—the elimination of backlog—I think time will tell as to how important personal use importation is going to be in the next year or so, as we have these process improvements.

The Chair: One of the things PMRA is doing in its harmonization is looking at NAFTA labels. Are you considering that as well?

Dr. Siddika Mithani: We have not had the opportunity to do any joint reviews because of our backlog. Once we clear the backlog, there will be the opportunity to look at NAFTA labels, to look at harmonized labels in the future. So we are very excited about all these other strategies that we can bring in once we eliminate the backlog.

The Chair: As a cattle producer, I can tell you I'm excited about the future and you guys really using your ability to reduce this backlog and have this harmonization. I think that is critical. But just don't throw out the baby with the bathwater, with the personal use imports, because one thing that does bring is true competition and making sure we do have that price discipline in the market because of the competition from the U.S. lower-priced products. The only way we can achieve that is with those imports and always having that ability to use them. I'm not sure that PMRA has completely bought that argument yet, and I'm hoping you will.

I don't see any other questions coming from the floor. Without any, I want to thank you very much for taking your time today to appear before our committee and share this briefing.

With that, we are adjourned.

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