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Chair

Mr. James Rajotte

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● (1530)

[*English*]

The Chair (Mr. James Rajotte (Edmonton—Leduc, CPC)): Ladies and gentlemen, we will start our meeting, which is the 53rd meeting of the Standing Committee on Industry, Science and Technology. Pursuant to Standing Order 108(2), this is the first meeting of our study of Canada's access to medicines regime.

Welcome to everyone.

Before we get to the witnesses, in my best French,

[*Translation*]

I'd like to welcome Ms. Brunelle, the Member for Trois-Rivières, who is joining this committee following the departure of Mr. Paul Crête.

[*English*]

Thank you.

We will miss Monsieur Crête. He was an excellent member of the committee. We welcome Madame Brunelle. We know she will do an excellent job as well.

We will go right to the orders of the day. We have four departments and five witnesses with us.

First of all, from the Department of Health, we have Mr. David Lee, director, Office of Patented Medicines and Liaison, Therapeutic Products Directorate, Health Products and Food Branch. Welcome, Mr. Lee.

We have two individuals from the Department of Foreign Affairs and International Trade. We have Mr. Douglas George, director, Intellectual Property, Information and Technology Trade Policy Division; secondly, we have Mr. Robert Fry, senior departmental coordinator, Pandemic Preparedness, Human Security and Human Rights Bureau.

The third department we have is the Canadian International Development Agency. We have Mr. Christopher Armstrong, team leader, HIV/AIDS.

From the fourth department, the Department of Industry, we have Mr. Douglas Clark, director, Patent Policy.

We will start with the Department of Industry. We will then go to the Department of Foreign Affairs and International Trade. Then we will go to the Department of Health. Finally, we'll go to CIDA. It's my understanding that this agreement has been worked out.

We'll have a six-minute opening statement from each department. Mr. Clark, we'll start with you.

Mr. Douglas Clark (Director, Patent Policy, Department of Industry): Thank you very much.

[*Translation*]

Thank you for inviting us here today.

[*English*]

Some of my colleagues will be allocating a bit of their time to me, if that's okay with committee members.

I want to provide a brief overview of the legislation and how it came to be and what the current status is. I've prepared a PowerPoint presentation that you all should have before you.

The Chair: We have 30 minutes in total for presentations, so as long as we don't go over that.

Mr. Douglas Clark: All right.

I know that for some of you this will be old hat, but I can see some new faces around the table since the last time I was here, so I thought it would be useful to prepare a presentation that just set the foundation for the discussion to follow.

As I am sure you all know, a patent provides an inventor with a time-limited monopoly for his or her invention in order to encourage research and development and to promote the diffusion of knowledge. In Canada and in all other WTO-compliant countries, the term of patent protection is 20 years from the date the patent was filed. In certain circumstances, however, governments can override patent protection provided they do so consistent with certain international obligations. They can authorize a third party to make, use, or sell a patented invention.

Both the WTO and NAFTA prescribe the conditions under which a compulsory licence can be issued and a patentee's rights can be overridden. One of these requirements, formerly anyhow, up until 2003 under the WTO TRIPS agreement, was that if a government is to override a patent and issue a compulsory licence, it has to be predominantly for the supply of the domestic market. This was seen as problematic by WTO members because it prevented developed countries like Canada from issuing compulsory licences to generic drug companies to make generic versions of patented drugs to ship to least developed countries that had no such pharmaceutical manufacturing capacity. It was seen as a barrier.

The requirement for the override to be predominantly for the supply of the domestic market was seen as a barrier to developed countries helping to develop the least developed countries. In August 2003, WTO members agreed to waive that predominantly for the supply of the domestic market requirement, but in so waiving the requirement they did insist on a number of terms and conditions that both the exporting party, the developed country, and the importing party, the developing or least developed country, would have to abide by. And they didn't waive a number of other WTO TRIPS obligations that apply specifically to compulsory licences.

Slide 4 sets out some of the terms and conditions I mentioned. The bullets you see here refer not only to the terms and conditions of the waiver, but they also account, to some extent, for the actual remaining applicable obligations that are in the TRIPS agreement. So only certain countries can import drugs under the terms of the waiver. Least developed countries, least developed WTO members, can import. Developing countries can import but are subject to different conditions in terms of what they have to notify the WTO about when they want to avail themselves of the waiver. I'll get into that in more detail in a moment.

You can see some of the other conditions. The country that wishes to import must identify the drug that it wants to import and the quantity. The licensee must pay remuneration to the patentee. The waiver must be used in good faith and not for commercial or industrial objectives, etc.

That waiver was agreed to in August 2003. Canada was one of the first countries to announce its intention to implement the waiver. It's not a positive obligation. It's up to individual developed country members whether they want to implement it. In May 2005, once the subordinate regulations came into force, the legislation that brought in Canada's access to medicines regime, which amended the Patent Act and the Food and Drugs Act, came into force, that legislation included a statutorily mandated review provision given the unprecedented nature of the initiative. So right now, as you know, the departments that you see before you are in the midst of carrying out that review.

Slide 6 is on guiding principles to facilitate access to medicines in the developing world; to provide sufficient incentives to Canadian generic drug companies that want to participate, which is really a subset of the first objective, while maintaining the integrity of the patent system; and to ensure that drugs that are exported under our regime, the access to medicines regime, are as safe, efficacious, and of as high quality as drugs destined for the Canadian market.

● (1535)

Some of the key features to our regime are set out on pages 7 and 8. As some of you may know, there are pre-approved lists of eligible importing countries under the regime and pre-approved lists of drugs that can be exported to those countries. The countries are categorized according to their development status and whether they are WTO members. The obligations this gives rise to reflect the differing status they have. I'll get to that in a moment.

With respect to third parties, although the waiver is an agreement between countries, third parties, non-governments, may purchase drugs under Canada's regime with the permission of an importing country.

The pre-approved list of drugs that can be exported was initially based on the essential medicines list from the WHO, which is a list of the most cost-effective therapies for priority conditions in a basic health care system. That list has been amended twice since the coming into force of the access to medicines regime.

With respect to the application process, I think we'll probably be talking a lot about the details of that process today. In essence, there are really two steps. The generic drug company that wants a compulsory licence to export will go to the Commissioner of Patents and identify the drug and the version they want to make, i.e., dosage, form, strength, route of administration, etc.; the quantity they want to manufacture and export; the patents that apply to that drug and the patentees that own those patents; the country to which they are going to be exporting the drug; and the purchaser, if it is different from the country.

They indicate all those elements of information, which they can simply fill out on the forms. I can provide examples of the forms if you're interested. That's the information they have to provide. Then there are certain other conditions that have to be met. The Minister of Health has to certify that the drug is safe and efficacious and that it's distinctive from the brand name version of that drug sold in Canada. A copy of the importing country's notice, either to the WTO, in the case of a WTO member, or Canada, in the case of a non-WTO member, must be provided. And then the applicant, the generic company, must make different sorts of declarations, again, depending on the development status of the country they're exporting to.

Since Canada announced its intention to implement back in 2003, seven others have followed suit: Norway, the Netherlands, Switzerland, the EU, India, China, and Korea. There are a lot of similarities. Fundamentally, I think they all attempt to do the same thing. They all have different mechanisms to implement. There's obviously more than one way to skin a cat, but fundamentally they're they same. There are a few notable differences between Canada's regime and some of the regimes in these other countries, although they all require royalties to be paid, a website to give notice to people that a drug is going to be exported under the regime, etc.

None of these regimes has a pre-approved list of drugs for export or countries that can import them. One of the requirements that an applicant must meet—and I should have mentioned this before, but I forgot—before getting the licence is that they have to apply for a voluntary licence with the patentee at least 30 days before applying for a compulsory licence from the commissioner. All the other countries have the same requirement, which reflects an obligation in the TRIPS agreement, article 31(b). Many of these countries waive that voluntary licensing requirement in situations of national emergency or extreme urgency.

Some other countries do not provide for the mandatory health and safety review of drugs destined for export under the regimes. For some, it's mandatory. In Switzerland and in the European Union, for example, it's optional.

I guess the reason we're all here today is that the regime has been in force since May of 2005, but to date no exports have taken place and no drugs have been exported from Canada under its regime. The same is true of the regimes in those seven other countries I just mentioned.

This prompted the Minister of Health, at the 2006 International AIDS Conference, to announce an expedited statutory review of the regime. That review got under way in November with the release of a consultation paper. Interested persons had 60 days in which to submit their comments on the regime. That period is now closed.

If you go to slide 11, we've summarized that very crudely. You'll have occasion in the coming week to get more information on stakeholder positions straight from the source, so I won't go into this in any detail. For the sake of time, I'll skip that slide.

With respect to the status of the statutory review, here we are today looking forward to.... Unfortunately, some of the groups we didn't hear from in the context of the consultation paper were the very parties the regime is intended to serve, i.e. developing and least developed countries. As a matter of fact, the government will be participating in an NGO-organized workshop this week that various developing countries and least developed countries will be attending. We hope to get a better understanding of what systemic barriers they may be facing in trying to avail themselves of our and other countries' implementation of the waiver.

Once we've had an opportunity to get that input and we have the benefit of any new information that arises here, that will be incorporated into the report, which the minister must table upon conclusion of the review, hopefully sometime in the spring.

In the interim, all four departments before you are taking advantage of every opportunity to promote uptake of the regime internationally. I can't tell you how many briefings I've given to different delegations, mostly in Africa. We've also established a website, as a users manual for the regime, and a CD-ROM, which we've distributed to various countries in Africa.

● (1540)

Thanks for your indulgence.

● (1545)

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

Now we'll go to Mr. George from Foreign Affairs.

[*Translation*]

Mr. Douglas George (Director, Intellectual Property, Information and Technology Trade Policy Division, Department of Foreign Affairs and International Trade): Thank you, Mr. Chairman.

I will be speaking today on behalf of the Department of Foreign Affairs and International Trade. The department's involvement in Canada's Access to Medicines Regime is in two areas: the first is the World Trade Organization and the second is the foreign relations aspects.

With me to answer any questions relating to foreign policy aspects is my colleague Mr. Fry who works in the Human Security and Human Rights Branch.

[*English*]

Many of the WTO aspects have been covered by my colleague from Industry Canada in his presentation, so I think I'll concentrate on one thing that has happened since the waiver was adopted.

When the waiver was adopted, it was, in essence, perceived as a temporary solution. Some waivers in the WTO can last forever, but it was perceived as a temporary solution. Therefore, the members decided to make a more permanent solution, and on December 6, 2005, the WTO members agreed to transform the August 2003 decision, the waiver, into a permanent amendment.

In essence, this amendment transposes the contents of the waiver without changing the major elements. This amendment will take effect after two-thirds of the WTO members have accepted it. They have until December 1 of this year to do so, but the deadline may be extended if necessary. I should stress that the waiver will remain in force until the amendment comes into effect, so it will be a seamless transition.

Canada strongly welcomed the amendment decision as positively demonstrating how WTO members can work together to respond to the needs of developing and least developed countries. We remain committed to working with other WTO members to ensure its acceptance by the December deadline.

Let me turn now to other programs and initiatives to assist developing countries in dealing with health issues.

[*Translation*]

Canada is committed to assisting developing countries in dealing with health issues and CAMR is just one of the tools used to achieve this objective. While we are talking today about CAMR, it might be useful for the committee to be aware of the breadth of other programs and initiatives.

[*English*]

I'll summarize these.

At the June 2006 UN high-level meeting on HIV/AIDS, Canada committed, along with other member states, to support efforts to move toward universal access to HIV prevention, care, treatment, and support by the year 2010.

The G-8 has also been a consistent and strong supporter of this goal. At the July 2006 St. Petersburg summit, G-8 leaders recognized that improved access to means of prevention, treatment, and care in many countries is essential to curbing infectious diseases. Leaders also noted the possibility for WTO members to use the flexibility set out in the waiver decision.

In addition, the right to the highest attainable standard of physical and mental health is outlined in numerous UN human rights instruments, including the United Nations Universal Declaration of Human Rights and the International Covenant on Economic, Social and Cultural Rights. While that covenant requires each state party to promote the right to health for its own citizens, there is no interstate obligation to protect the right in other countries, and while all international development assistance, including health-related assistance, is a moral and not a legal obligation, Canada has been a major donor to health-related initiatives in the developing world.

In additional to strong political engagement, Canada also supports a wide range of organizations and activities that help promote global health, many of which address the access to medicines issue. Chris Armstrong, my colleague from CIDA, will give you more details on these shortly in his presentation.

● (1550)

[*Translation*]

Thank you for the opportunity to address the committee.

[*English*]

The Chair: Thank you.

We'll now go to Mr. Lee, from Health Canada.

Mr. David Lee (Director, Office of Patented Medicines and Liaison, Therapeutic Products Directorate, Health Products and Food Branch, Department of Health): Thank you, Mr. Chair.

I intend to outline very briefly what Health Canada's role is under the CAMR.

We actually do three things. The first is that the department is responsible for undertaking the regulatory review of drug submissions to verify that the product meets the same requirements for safety, efficacy, and quality as drugs available to Canadians. These are primarily generic drug reviews, so we're comparing a brand and a generic drug and making sure they're comparably acceptable.

Second, we are responsible for ensuring that the pharmaceutical product is distinguishable from the patented version available in Canada, and this is expressed in a regulatory requirement. For example, a solid oral dosage form has to be a different primary colour and it has to have a marking on it so you can tell the difference. This is aimed at preventing diversion or reimportation of the product.

Third, we are responsible for performing pre-export inspections to verify, among other things, that the distinguishing features I've just mentioned are actually in place and that the quantities to be exported are accounted for. These details are stated on the manufacturer's application for the compulsory licence that is sent to the Commissioner of Patents. We really have to coordinate with the commissioner, so when we're done our safety review—our quality, efficacy, and safety—we tell the commissioner we're ready go with the drug and we coordinate our inspections around the product moving from Canada to where it's going.

We have had some experience with the first two stages. In other words, we have received generic drug applications under the regime; they've gotten as far as our reviewing them for safety, efficacy, and quality and then basically putting them on our shelves, so they're ready to go from a food and drug regulations point of view. That includes also the distinguishing features. That means they're sitting waiting for the rest of the process to be completed, namely the licensing part with the Commissioner of Patents.

In terms of our submissions, we actually are very content to keep playing our role in terms of looking at the quality, efficacy, and safety of drug products before they go anywhere. In terms of the inspection, I would caution that we haven't had as much experience with that part yet. It's a newer part under the regime, and until product is ready to move under licence, we won't actually have experience built up around that.

It is Health Canada's view that there should be no question of a double standard—in other words, when we do our drug reviews, it's the same review that we do for domestic purposes for a generic drug—and that there should not be any concerns that a drug leaving Canada destined for humanitarian purposes might be unsafe.

Thank you, Mr. Chair, for the opportunity to present.

The Chair: Thank you, Mr. Lee.

We'll now go to Mr. Armstrong, from CIDA.

Mr. Christopher Armstrong (Team Leader, HIV-AIDS, Canadian International Development Agency): Thank you very much, Mr. Chair.

I work with CIDA's policy branch as a health and HIV/AIDS adviser. It's a great pleasure to be here. My presentation will actually be quite brief. I'm just going to give you a bit of an overview of the status of health in developing countries, present to you some of the challenges facing developing countries with respect to access to medicines, and give you some examples of what we're trying to do through CIDA in supporting developing countries in the area of health.

As I mentioned, it will be quite brief, but I'm obviously open and willing to answer questions and provide further information if you need it.

In my presentation, I will be speaking to a deck. It's the blue one that I hope everyone has in front of them. On the second slide, “Canada's International Commitments in Health”, my colleague Doug George spoke about some of our international commitments, so I won't repeat what he has already said.

With respect to that, I would draw your attention to the millennium development goals that were adopted in 2000, to which Canada is a party. Essentially, they provide the framework for how we work in development, the goals towards which developing countries are striving and the goals to which we as a donor provide support to them.

With respect to health, four of the eight millennium development goals relate directly to health. One is to reduce child mortality. Another is to improve maternal health. The last one that specifically relates to health is to combat HIV/AIDS, malaria, and other diseases.

The next slide, concerning health in the developing world, is just to give you a sense of some of the issues that face developing countries with respect to health. It by no means paints the full picture of health, but I thought some of these statistics might be compelling to you.

If you look at issues of maternal and child health, which relate directly to the millennium development goals of which I spoke to you before, it is estimated by the UN that 99% of maternal deaths due to pregnancy or childbirth and over 90% of child deaths—which is a staggering 11 million deaths per year—occur in the developing world.

Malaria is another example, which accounts for an estimated 1.2 million deaths per year, and approximately one million of those occur in Africa alone. So you can see where the burden is greatest.

With respect to HIV and AIDS, an area specifically in which I spend a great deal of time working, of the 40 million people living with HIV and AIDS, estimated by UNAIDS, over 90% are in the developing world. There are still an estimated 3 million deaths per year related to HIV and AIDS, and just under 5 million new infections continue to occur around the world. Of the estimated 6.8 million people around the world or particularly in the developing world who could benefit from antiretroviral treatment, 1.6 million are estimated to be currently receiving treatment. That's a huge increase over the last number of years, but it has obviously still not achieved that goal that Doug George spoke about, which is universal access.

The next slide deals with some of the challenges that developing countries face with respect to access to medicines. Again, these are just a few examples. It's a complicated issue to which there are many challenges, but just to give you a sense of some of them, and some of the non-TRIPS-related issues as well, certainly weak health systems continue to confront African countries and other countries in the developing world. As an example, Africa has only 1.3% of the world's human resources for health, yet it carries about 25% of the burden of global disease. If you look at sub-Saharan Africa, it's estimated that only about 30% of the population has access to basic health services.

Some of the more specific issues related to access to medicines, issues of capacity in developing countries around procurement and regulatory issues and supply chain, continue to challenge developing countries. These are all things the development community, including CIDA, is working with developing countries to address.

The second point there is lack of ability to use TRIPS flexibilities. This is related to issues of capacity and legislative frameworks within developing countries themselves, whether or not they have the knowledge of the flexibilities or the people who need to have the specific knowledge as to what's available to them through the TRIPS flexibilities and whether or not the right legislation exists in those countries in the way that we've undertaken in Canada to put in place compulsory licensing provisions in our legislation. Does that exist in those developing countries? In many instances, it doesn't.

● (1555)

The final challenge is the one you often hear about, of course, and that's the funding gap. What are the available resources? Just to give you some estimates and examples, it's estimated that in order to achieve the goal of halving the burden of malaria by 2010, an estimated $3 billion will be needed. Currently, about $600 million is being spent. On HIV/AIDS, if you look at the UN AIDS estimates for 2007, it's estimated that about $18 billion will be required annually. That's for all of HIV/AIDS, and not specific to treatment. It's estimated that between about $8 billion and $10 billion is being provided, both through donors and through developing countries' budgets themselves.

On the next slide is a quick overview of the health priorities at CIDA and how we work with developing countries to improve their health outcomes. These items are categorized into two areas, really. The first area is stepping up our efforts to prevent and control high-burden and poverty-linked diseases like HIV/AIDS, TB, and malaria. We're also working on issues of infant and child health and sexual and reproductive health, including maternal health. Finally, there are the issues of food security and nutrition. And the second area is strengthening health systems. As you remember, I just mentioned that this is a very important issue with respect to access to medicines.

Finally, on the last slide, just to give you a quick overview of what we're doing—and again, this is illustrative, not complete—for the fiscal year 2006-07, which has just come to an end, it's estimated that we will have spent about $822 million specifically on health sector support in the developing world. That's approximately 30% of CIDA's overall sectoral spending.

If we have a few minutes, Mr. Chair, I'd just like to give you some examples of some of the programming we do. I'm sure many of you are aware of the global fund to fight AIDS, TB, and malaria. Canada is a significant donor. I believe we're currently the seventh-largest donor to that fund; we recently announced the provision of $250 million over two years to the global fund. The fund is doing tremendous work in terms of providing access to medicines in the developing world, and it will continue to do so. Canada will continue to participate in it, I'm certain.

We've provided support to the WHO, particularly for its work in access to HIV/AIDS treatments. When I spoke earlier about how 1.6 million people are now accessing treatment, that was in large part due to some of the very good work of the WHO's HIV/AIDS division, to which Canada was a leading donor.

We've announced recently that we will spend, over the next two years, $450 million to invest in African health systems initiatives. We provide support to ministries of health on HIV/AIDS strategies throughout Africa and around the world. Mozambique and Tanzania are two specific examples.

I've provided an example of a small initiative in terms of money, but one that we think is quite important with respect to this particular issue. I won't go into it in detail, because I believe you're hearing from U of T later this week on the access to drugs initiative. It's essentially support that we've provided to U of T to work with the Government of Ghana, to assist it in making use of the TRIPS flexibilities. Some new work that the U of T is doing is also looking at regional approaches to access to medicine.

Finally, the last one is the global TB drug facility, to which Canada was a founding donor and has provided significant funding. To date, it has provided treatment to over 6 million TB patients. Our support to that has been about $90 million to date.

Thank you, Mr. Chair.

● (1600)

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

We'll now go to questions from members. For the first round, we have six minutes in total for questions and answers, so I'd just ask members and witnesses to be as brief as possible in their questions and their comments.

We'll start with Mr. Byrne.

Hon. Gerry Byrne (Humber—St. Barbe—Baie Verte, Lib.): Thanks very much, gentlemen, for appearing before us and for some succinct presentations.

I just want to get to the last slide of the deck that you presented to the committee, Mr. Armstrong. You talked about CIDA's support to the health care sector, establishing the fact that $822 million was spent on support to the health care sector last year, representing 30% of CIDA's sectoral spending. You also mentioned that Canada's commitment to the global fund to fight AIDS, TB, and malaria is providing some significant benefits in regard to access to medicines.

Can I ask you a question? Who is the champion of this process in Canada, for an eligible country to access Canadian patented medicines produced by generic producers? Which department is it? Or is it a global fund?

● (1605)

Mr. Christopher Armstrong: The champion? Do you mean within the Government of Canada? I would suggest that we're all—

Hon. Gerry Byrne: Okay, I'll tell you what. I'll be a little more direct then. An eligible country identifies malaria as a massive health concern and an epidemic is established, a state of emergency declared. Who do they go to, to actually get this whole process in motion? The question here, in the hearts and minds of every legislative member on this Hill, is this. How do we make this system work? The question is, is it broken, or is there something else that's not being done? My question would be quite simply this. Does CIDA interact with an eligible country to make a bulk order of medicines produced by a generic producer for availability in Africa, South America, or elsewhere? Do we do that, yes or no?

Mr. Christopher Armstrong: Absolutely. It would vary from country to country. We're not obviously involved in the health sector in every country in which CIDA operates. The health sector is certainly one of our major areas, but it's not in every particular country. And that decision is taken based on CIDA's experience in that particular country, on Canadians' experience in a particular country, but also on working with the developing country to determine whether or not that's an area where they're looking for support from CIDA. So on the first part of that question, it would vary from country to country. Where CIDA is actively involved in development countries, absolutely, we're working and participating with ministries of health and other relevant—

Hon. Gerry Byrne: But we haven't had any success whatsoever because there's not one pill that's been produced by a generic producer.

Mr. Christopher Armstrong: If you're talking specifically about the medicines having been exported from Canada, then no, to the best of my knowledge, and as presented, not a single pill has gone from Canada. But that's not to say that CIDA isn't working with developing countries in terms of accessing those medicines. We're providing support in the health sector. We're providing support through the global fund, through other initiatives that enable those developing countries to purchase medicines from where they deem it is most appropriate for them to get the most affordable and most efficacious medicines. Now, at the end of the day, if that's Canada, then yes, CIDA is providing support to those countries and they will access that.

Hon. Gerry Byrne: I'm curious here, because you're saying that the real barriers to access to this program are a lack of an ability to use TRIPS flexibilities due to capacity, knowledge, and domestic policy or legislative framework and a funding gap. These are all things that I thought CIDA was supposed to do. Say, for example, an eligible country comes forward and says we have a huge HIV/AIDS epidemic, or we have a malaria epidemic, and we need assistance. Who is the champion in Canada? I just wonder whether or not CIDA is actively engaged in advocacy in Canada.

In this room right now we have a whole lot of government relations specialists for Canadian brand name and generic pharmaceutical companies. I don't think there are very many of the least developed or developing countries that have a whole lot of capacity in Canada to get this whole access regime in motion. Is that CIDA's role? Have you done it, and would you be prepared to apply specific funding envelopes for specific applications, by specific countries, to get this process in motion?

Mr. Christopher Armstrong: There were a few questions embedded there. They would come to CIDA if they said, we have an HIV/AIDS problem and we want support from Canada. They would come to CIDA. We are the development agency that exists on the ground and we are the ones that would provide funding to do it.

With regard to your latter question as to whether or not CIDA would be in a position to provide direct support, perhaps I can just rephrase your question to understand it better. Are you asking whether CIDA would provide direct support to a country to purchase medicines from Canada?

Hon. Gerry Byrne: Yes. We do it with other suppliers of our international development assistance program. We favour Canadian companies to provide that assistance.

Mr. Christopher Armstrong: To be honest, it's not a decision that we've taken, that we would do. It's something we would need to look at carefully with respect to our aid effectiveness principles, our principles of country ownership, allowing the flexibilities of developing countries to access the medicines that are most affordable, most efficacious for them. At the same time, though, we would certainly bring their attention—and have done so on many, many occasions—to the legislation that exists in Canada. We have made them aware that those flexibilities exist in Canada, that our manufacturers do have the ability through this legislation to provide it through compulsory licensing. But it's a question of putting the decision and the country ownership within the hands of the developing country to make those decisions.

● (1610)

The Chair: Thank you.

Hon. Gerry Byrne: This seems to be what CIDA does. Eighty-five percent of our development assistance envelope is Canadian companies.

Thanks.

The Chair: You'll have another chance, Mr. Byrne. Thank you, Mr. Byrne.

Thank you, Mr. Armstrong.

We'll go to Madame Brunelle.

[*Translation*]

Ms. Paule Brunelle (Trois-Rivières, BQ): Good day and thank you for joining us.

Good day, Mr. Clark. This framework legislation was enacted in 2004, but there is still no pharmaceutical manufacturing capacity in developing countries. I'm trying to understand the reasons for this state of affairs. Regarding the WTO's terms and conditions for waiving certain obligations, you note the following in your document: “Licensees must pay adequate remuneration to the patentee(s)”.

What exactly do you mean by that? Is this the sticking point?

You go on to say this: “Waiver must be used in “good faith” and not for commercial or industrial objectives.”

Can you tell us what you mean by “adequate remuneration”? I'd also like to know if it is easy to obtain a waiver in good faith?

Mr. Douglas Clark: As far as remuneration is concerned, it is difficult to determine what is adequate. What may be adequate in certain circumstances may not be in others. Here in Canada, we have adopted a formula that calculates the royalties payable by licensees to patentees based on the level of development of the importing country. When a licensee must calculate the royalties owing to the patentee, he consults the United Nations' list of developing countries and does his calculations on the basis of the country's ranking on the list.

For example, Sierra Leone is the least developed country on the list. It ranks 176th among the 176 countries listed. According to the formula established under the regulations, royalties of .02% would be payable in this case. If the country ranked first on the same list, the amount would be around 4%, which would be the highest rate.

Canada is not alone is using this formula. Although we developed it, Switzerland has adopted it as well. I believe other European nations have set royalty levels at 4%. As you can see, the rate falls somewhere between .02% and 4%. Our rates are in the same ballpark. Admittedly, from 1969 to 1992, Canada had a mandatory pharmaceutical licensing regime in place which provided for royalties of 4% to be paid in a business context.

In terms of using the waiver for non- commercial purposes, Canada has endeavoured to maintain the obligation set out in sections 21.16 and 21.17. Pursuant to these provisions, a patentee may challenge the granting of a licence to a generic drug manufacturer if the price of the product is equal to or greater than 25% of the average price of the equivalent product sold in Canada by the patentee. This is how Canada applies this provision. Of the eight countries that have implemented the decision, Canada is the only one to have brought in a specific provision for upholding this obligation.

● (1615)

Ms. Paule Brunelle: Are you saying then that these provisions would prevent pharmaceuticals from being exported to these countries?

Mr. Douglas Clark: I don't think so. As I explained, royalties can easily be calculated. They are quite reasonable, between .02% and 4%. I don't see this as an insurmountable obstacle.

Regarding the obligation that the product not be used for commercial purposes, the 25% threshold is in fact viewed as a disincentive by generic drug manufacturers. They made this clear to us in their submissions following the release of our discussion paper. The risk of litigation discourages them from participating n the regime. At least, that's the position they have taken.

Ms. Paule Brunelle: Mr. Lee, you stated that pharmaceuticals are ready to be shipped. Why haven't they already been shipped?

[*English*]

Mr. David Lee: That's a matter for the generics. They have to approach, next, the patentees and make arrangements with the Commissioner of Patents. So there's work to be done on the patent side.

On the food and drug side, they're ready to go in the sense that we think it's safe, efficacious, and of high quality. The differentiating features are there. The labels are all set. So our part is complete.

It's really up to the negotiating part to find the country to provide to and to have those licensing discussions. Those would be the next steps.

The Chair: Thank you, Mr. Lee.

We'll go now to Mr. Carrie.

Mr. Colin Carrie (Oshawa, CPC): Thank you very much, Mr. Chair.

I'd like to continue with the line of questioning of my Liberal colleague. Is CAMR broken, or is there something else not being done?

I've heard the criticism that it's all good that we're going to provide drugs, maybe, to a country in Africa, but what if the drugs need to be taken with water and they have a poor water supply, or they need to be taken with food and the guy hasn't eaten in days, or the government where we're sending these pharmaceuticals is corrupt and they're willing to sell them on the black market? I was wondering if you could describe for us what the Government of Canada does to address issues like clean water, roads, bridges, and the recruitment of doctors and nurses. And how do these efforts fit in with CAMR?

Mr. Christopher Armstrong: Thank you for that question. We do a huge number of things in those areas. I was here to speak to you specifically on the health sector area, about which I am better versed, so I may have to get you further information in terms of the other sectors, like environment, transport, and infrastructure. Some of those are areas that CIDA is not as invested in as we are particularly in the health sector. The health sector is our largest single sector.

That said, all those things do relate, as I mentioned, in terms of the challenges for developing countries. I was just outlining a few of them. But the important message to take home is that these are things that are being overcome. It was just a few years ago that if someone came before your committee and talked about HIV and AIDS treatment, you'd hear challenges that there's almost nobody receiving HIV and AIDS treatment in Africa. The numbers were really quite small. Now we're seeing in Africa well over a million people receiving HIV/AIDS treatment. That's due to innovative ways of delivering medicine, to strengthening health systems, to donors putting in more money, and to developing countries themselves putting in more money and investing in health systems and ensuring nutrition and safe water.

Those are challenges that have not gone away, but we have seen, really, some good successes, and Canada has certainly been quite involved in them. In that timeframe, the global fund, which I mentioned before, has put huge amounts of resources into HIV/AIDS health, malaria, and tuberculosis.

All of those, absolutely, relate specifically to CAMR in terms of creating the conditions within which developing countries can deliver the medicines. CAMR is a very specific initiative in terms of, hopefully, creating greater availability and more options for developing countries to access medicines and making Canadian suppliers, through compulsory licensing, able to do that. So there are many options, and greater options, through which developing countries can access the medicines.

That's very specific to the purchase and availability of affordable medicines. But you're right. There's a much bigger picture around all that in which Canada is very heavily invested and where it has had some very good successes. We continue to invest in those, and we'll continue to do more.

● (1620)

Mr. Colin Carrie: My colleague also asked if there is any champion. I'm just curious. It seems that even with other countries, nobody has really come up...no pill has been delivered, say, to Africa. Are there coordinated efforts between the different ministries? How is the communication between your ministries? Which generic companies have attempted to use CAMR so far? What have been the results, and what has happened with that? What's been your experience?

Mr. David Lee: In terms of the generic companies, one has been made public, and that's Apotex. It's at least made an attempt to submit its drug submission. We have it on hold. That's been publicly announced.

There is another company. I've actually sought permission from it to talk about its submission, but I haven't received that back yet. I don't know, Mr. Chair, if you could direct me on that. Usually the matter of whether there's a drug submission is held in confidence. I've sought permission from the company to reveal that, but I haven't quite got that permission. I'd be hesitant to identify the drug. It's another drug company that manufactures generics.

The Chair: Keep it confidential.

Mr. Colin Carrie: I'm wondering how the process is actually going. When we talk about a champion or somebody bringing this forward, is it up to the individual companies to track it through each ministry to see how things are following along, or is there some type of coordinated effort? In your experience, is the communication going well? You've only had two experiences with it. How has it been going?

Mr. David Lee: There has been an interdepartmental team reflected here in this departmental group. It actually features many more officials who have worked both inside Canada and outside at numerous opportunities. So we have tried, and there's a whole history of attempts to educate colleague regulators.

We've done a lot of speaking with the WHO, with the USFDA, with other regulators, including regulators in Africa and in other countries, trying to promote knowledge about the system. It is very detailed to do that, so communication itself can be challenging, but this group has actually tried to coordinate a lot of that messaging, and we keep in, I would say, fairly regular contact departmentally. The lead shifts, depending on which part of the system you're in.

The Chair: Okay. Thank you.

We'll go to Mr. Masse.

Mr. Brian Masse (Windsor West, NDP): Thank you, Mr. Chair, and thank you to our panel for appearing here today.

Whether this is a political or a practical problem with the bill, we have to sort out both of those issues. Does the bill work in its current context? I'd like to hear from every department. Does it work right now?

Mr. Douglas Clark: If you're asking whether it is working, then I think the answer is fairly straightforward. The purpose of the legislation is to produce cheaper generic versions of patented drugs for export to developing countries. No drugs have been exported, so I think that's your answer. If your question is whether it works, I think it can. I think operationally it's sound. But the fact remains that to date no drugs have been exported.

Mr. Brian Masse: There were a lot of problems brought up this time at the hearings, regarding former Bill C-56 and then Bill C-9. I was here at those hearings. We made over a hundred different amendments to the bill. At that time there were a lot of warnings that internationally this country would be embarrassed. And I, quite frankly, believe that we're participating practically with a blind will to not actually help people. I would like to know if the CIDA minister, either past or present—maybe you can't speak to the past, and I understand that—actually approached a colleague from another country about accessing this regime, what the result of that conversation was, and where it went from there.

● (1625)

Mr. Christopher Armstrong: To be honest, I'd have to get back to you on that. I don't know specifically whether or not there has been direct contact between the CIDA minister and a colleague. That is something I can follow up and get back to you on.

I know that certainly at the official level, we have on numerous occasions raised this issue with our developing country colleagues. We've made presentations in numerous settings, including AIDS conferences, direct interaction, and direct bilateral interaction with our developing country counterparts. Those efforts have been made. Perhaps some of my colleagues would like to speak to some of the other outreach efforts that the Government of Canada has made.

Mr. Douglas Clark: We've all had occasion, each one of us here at this table, to interact with those countries. We've actually prepared a list, in addition to the website that we established, and the online users guide and the CD-ROM that we've distributed, of all the outreach activities we've engaged in. It's quite a lengthy one.

At least from my part, from what I've heard.... It's threefold, basically. I've given presentations on the regime to the African group at the TRIPS Council in Geneva and to various African delegations. Initially what I heard was that they're more interested in technology transfer—understandably so. They want to be able to take care of their public health issues themselves in time. That's one thing.

The other is that they lack the administrative infrastructure to actually avail themselves of this. As I mentioned at the outset, there a number of strict terms and conditions under the waiver that importing countries have to abide by. That includes figuring out whether the drug is patented in that country and indicating, if it is patented, whether they've issued or can issue a compulsory licence. If they're not a least developed country, they have to indicate that they have insufficient or no manufacturing capacity to produce the drug.

It sounds fairly simple to people in developed countries, but to them it does seem to pose a barrier to use.

And then the last thing is financial resources, and that's obvious.

Mr. Brian Masse: I understand some of those things, but here's a good example. This *Perspectives* magazine is the African journal on HIV/AIDS. It's a pretty sophisticated African publication on the whole issue and how they're dealing with the situation. So it's not whether we're dealing with individuals and organizations that don't understand how these things move.

What is wrong? Is it on this side here, or is it over there? I mean, we've had this argument before, when we actually went through this bill. There were a lot of different individuals who liked to paint that the problem was actually on the other side. I think it's on our side here.

So what I want to know is does this legislation need amendments to make it work? Does it need amendments like in other countries, where they're removing some of the pre-approved lists—lists that we created that we didn't have to? Does it need amendments like waiving the duration of time, for example, for two years, so it can go for a longer period of time? People who are taking medications for HIV and AIDS need it for more than two years.

If we do those things, will it actually work? Will Canada become a player in the field? We're not a player. Other people are. I want to know why.

Mr. Douglas Clark: As I said, there are many different ways to skin a cat. The way Canada implemented the waiver is not the only way to implement. That's clear. Other countries have waived certain things. They've waived the voluntary licence requirement in instances of national emergency or extreme emergency. We haven't done that. Other countries don't have pre-approved lists of drugs in eligible importing countries. In my mind, speaking as an expert in the patent field, that's an advantage to our regime, not a disadvantage. Having a pre-approved list makes it a lot easier for the patent authority to figure out whether they can grant a licence or not, and it minimizes the opportunity to litigate that decision.

Obviously, one of the options before us at this point is to consider harmonizing ourselves more closely with these other countries that have implemented in a somewhat different way. But the fact remains that those regimes haven't given rise to any exports either.

So whatever the problem is, it's a shared problem among all the implementing countries. I don't think Canada has singled itself out or stigmatized itself in the way that you suggest.

The Chair: Thank you.

Mr. Brian Masse: We told the world we would be the ones to do this and be the leaders.

● (1630)

The Chair: Thank you, Mr. Masse. Your time is up.

We'll go to Mr. Boshcoff.

Mr. Ken Boshcoff (Thunder Bay—Rainy River, Lib.): Thank you very much, Mr. Chair.

It seems this issue of why there hasn't been any popular response to applications for something we feel is going to be addressing an international crisis.... Our perception is this is going to help. All these countries need this desperately, so you would think there would be one, two, or three.... Actually, you'd think there'd be 35 or 50 who would take advantage of this if there were some kind of practical or easy way to access this. We know there's some generosity on behalf of the companies. Still, the bottom line is that it doesn't seem to be happening.

With that in mind, I just want to ask a question about Canada always seeming to be first for many of these WTO decisions. I'll use agriculture as an example, in terms of our complying and doing the Doha thing. In your list of the nations that have jumped onboard here, it still seems this issue is not there. You mentioned Sweden, Norway, and the Netherlands, but aren't they part of the European Union? And then you mentioned the European Union. So that would only give us South Korea, India, China, the European Union, and Canada in this. Perhaps you could just start with that.

I appreciate that Canada likes to be a leader and needs to be a leader, and that it demonstrates this because we have compassion and care and a skilled public service that wants to carry this out, but it doesn't seem that anyone is coming, although we've made everything ready and it's built.

Mr. Douglas George: If I could address that, the only duplication in the European Union is the Netherlands, and I believe they moved before the EU as a whole did. The EU represents 27 countries; Switzerland and Norway are outside the EU. Norway was in fact the very first to implement this, and they beat us by a fairly short period.

There are a number of us who've implemented this in different ways, but it's interesting to note that we're all running into the same issue of why no one is taking it up. Canada has been very active in explaining to other WTO members what we were intending to do, what we were doing and what we've done, and in explaining to them the review process and how they could access our system. Other countries, as they've implemented this, have done it. We've worked with some of them, including the EU, to explain how we implemented our system.

All I can say, as Doug Clark pointed out, is that as yet, no one has accessed this system. When we were negotiating the amendment, some countries indicated they were not going to amend their own domestic legislation to take advantage of it when it was under waiver because it was perceived as a temporary instrument—although some waivers have lasted for a very long time. So the amendment, once it comes into effect, will give them the assurance that this is a permanent amendment to the WTO, and it might at least remove the perception that was causing some of the developing countries not to implement it.

Mr. Ken Boshcoff: Is there a technical or a procedural issue in the process, in which you have an international conference where the least developed countries are saying, we need your help? Does someone from Canada actually go to that person and say, we can do this for you, or is there a gap in how that's communicated, or in making these connections?

Are we talking of some simple human dynamics here?

Mr. Douglas George: As we pointed out, we've engaged in outreach on a number of occasions. Mr. Clark and I made a presentation of some length to the African group in the WTO, but that's just one of many instances where we've been working with the groups.

I think maybe some of my colleagues could detail some of the others.

Mr. Ken Boshcoff: Perhaps you could add something on the health infrastructure on the receiving end also, please.

Mr. Christopher Armstrong: Thank you for the question.

There is no shortage of health fora around the world, where these things are brought up. Developing countries come together with donors, UN agencies, and other multilateral bodies, such as the global fund, to discuss health issues.

There's absolutely no shortage in Canada. As a participant in global health issues, I wouldn't say we're present at every single health conference. But we are there when it's relevant and when we feel it's an important issue. Absolutely this is an issue that we raise and discuss on every occasion when it makes the most sense. We are doing this from international AIDS conferences to high level fora on health.

A colleague of mine is going to a meeting on access to medicines later this week in the United Kingdom.

We're supporting a meeting here in Ottawa, which my colleague Doug Clark spoke about, that's bringing developing countries together with government officials, NGOs, and members of industry to talk specifically about access to medicines and to look at some of the challenges faced by both developing countries and industry in accomplishing this.

One of the key issues, which we need to understand, is that the Government of Canada is not providing the medicines. Canada's manufacturers and pharmaceutical industry will ultimately be providing the medicines around the world. Efforts are called for to bring these together as well.

● (1635)

The Chair: Thank you.

Thank you, Mr. Boshcoff.

We'll go to Mr. Shipley.

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

I appreciate that you came out today. It was interesting, and obviously there are sincere concerns around the table. Basically I would phrase it by asking, why hasn't a drug moved yet? This is the question that shows up on the floor.

We have a number of ministries sitting here. As I listen to some of the discussion, I wonder, is there a concern about the rollover, or the lack of communications between the responsibility and involvement of each of the ministries? Do you see that in any way? For some reason, we have a process problem that doesn't seem to get resolved.

Then I'll have a follow-up question.

Mr. David Lee: When the legislation first came into place and we got all the way down to making regulations, we had some early discussions with the Canadian Generic Pharmaceutical Association. We had some of the generics in, and we figured that we needed a good end-to-end account of how you apply through the various parts of the process, because there are some complications there.

We made a description, along with the person over at the Commissioner of Patents office. We all sat together and figured out how to get from one end to the other. We were called on to do that on a number of occasions.

It still remains complicated whenever you put drugs together with patents. These are two very complicated areas to explain. It has certainly been a big challenge to explain exactly how the whole system works. Usually people have the patience to do it. We sit down together with our colleagues from Industry Canada, and so on.

We don't get to talk very often to our colleagues in other regulatory jurisdictions—for example, in Africa. We have had some occasions to sit down together. I know my health minister has talked to colleagues in Tanzania and Kenya. We've been trying to do some outreach with colleagues who are regulators there, but sometimes the way they communicate or not with their patent office is questionable.

How we all sit and talk together really is the issue. In our departments we try to keep some rapport, but it is complicated.

Mr. Bev Shipley: We'll take that as sort of a group answer, perhaps because we don't have the time in my five minutes.

When one of you was speaking French, you mentioned that you've been working with the groups in Africa.

Mr. Armstrong, you also talked about it in terms of CIDA, and that's a bigger issue. So are you talking to the nations?

Mr. David Lee: Yes, at least to our regulatory counterparts there, to the extent that they represent their countries.

Mr. Bev Shipley: Those are the representatives who represent their countries. If they were to make the request to Canada, are you talking to the right departments?

Mr. David Lee: Usually it would be the department of health there or some other representative like that, yes.

Mr. Bev Shipley: So then why aren't they asking?

Mr. David Lee: That I can't.... That you would have to ask them. I don't have evidence to offer you on that.

● (1640)

Mr. Bev Shipley: Okay.

We've mentioned several other countries besides Canada—China, India, the United States, the EU—that have medicine regimes similar to what we're experiencing. Are they experiencing the same challenges? Are they doing the same discussions as Canada is with the other countries?

Mr. David Lee: We have on a number of occasions spoken with colleagues. For example, we've made presentations along with the EMEA, and we've panelled together with the FDA, the WHO. We're all sitting in the same rooms with colleagues from Africa and other places that could potentially use the system. We make joint presentations. The same issue comes up for all of us—namely, that drugs are not moving under the various programs.

Mr. Bev Shipley: Do they have drugs moving? Have they moved any drugs either?

Mr. David Lee: Every indication I've had from them is that they have the same issue we do: they're not moving.

Mr. Bev Shipley: How does CAMR compare with legislation in other countries? Is ours similar?

Mr. Douglas Clark: It's similar in many respects. There's a slide in the presentation I gave at the start that breaks it down. The fundamentals are pretty much the same. Other people may disagree with that assessment; that's our assessment. But there are some notable differences.

Mr. David Lee: No one is notified under the WTO process internationally. That's part of the application they would have to make here. No country has actually gone through that yet. We have to wait for that as well.

Mr. Douglas Clark: That's a condition precedent to anybody exporting under any of the regimes. It's a requirement of the WTO waiver.

The Chair: Mr. Shipley, you're out of time.

We'll move on to Monsieur André.

[*Translation*]

Mr. Guy André (Berthier—Maskinongé, BQ): Good day. I'm delighted to be here this afternoon.

HIV/AIDS is a serious problem. I've travelled to Africa several times and, having also read up on the subject, I've observed that this epidemic affects a number of countries. We need to move in another very clear direction in the near future because more and more people are dying from HIV/AIDS. We have the statistics to prove it.

However, in terms of Canada's level of supply and the policies governing the drugs used to treat AIDS, do countries — you mentioned Sierra Leone, Burkina Faso and some of the other least developed countries in Africa - know that they can have access to these pharmaceutical products? Do they have the means to obtain these pharmaceuticals? As you recall, they must pay royalties, which can range anywhere from .02% to 4%, depending on the country. Can they afford these royalties?

On another note, what is the nature of your relationship with CIDA? How do you work with this agency that currently carries out field operations in Africa and in a number of countries? How do you work with these countries in an effort to meet the needs expressed? We talk about cities, but we can't lose sight of people who live in remote rural areas, people who need information and ways of preventing and treating diseases.

Mr. Douglas Clark: Regarding information requirements, as was just mentioned, all of my colleagues here have had opportunities to present and explain the Canadian regime to our counterparts in other countries, particularly to African nations.

Quite simply, I think the best approach would be to circulate the list, in both languages, of all international meetings in which we have taken part to date and at which we attempted to share this information with our counterparts.

Once these discussions have occurred, I don't know if these individuals return to their county and disseminate...

Mr. Guy André: Disseminating the information is a problem at the present time.

Mr. Douglas Clark: It would seem so, but that brings us around to your second question concerning measures. Let me recall something that my colleague from CIDA said earlier. What we're dealing with here is a facilitating regime. It allows the private sector — we're not talking about a government program — to take advantage of opportunities to sell and export at low cost to developing countries patented generic drugs. Now then, if there are no opportunities, if the countries... That doesn't affect the means. If the means do not exist, everything else is purely "academic", in some respects.

In terms of level of involvement, I'll let my colleague from CIDA field that question.

● (1645)

Mr. Guy André: How involved are you with CIDA in the field?

Mr. Douglas Clark: He wants to talk about CIDA's cooperation in the field with countries abroad.

Mr. Guy André: Would one option be to increase the level of cooperation with CIDA?

Mr. Christopher Armstrong: If you don't mind, I'll answer that question in English, since it's easier for me and my answer will be clearer.

[*English*]

What I tried to do was present an illustrative example of where CIDA is engaged in health, and as I mentioned, we're not in every country. You named a couple of countries; as I say, CIDA can't engage in the health sector in every country, but in those countries in which we are very active, yes, we are helping them through their ministries of health and through civil societies that engage in health. We are very active and very engaged, both in dialogue and in providing support to present those means for those countries to be able to access medicines.

Absolutely, there continue to be challenges. You mentioned, I think, a couple of the poorest countries in the world. Those are obviously where the challenges are the greatest, where the health systems are not what they need to be and should be. Collectively, as a global community, we need to address those things, and Canada is participating in that.

The Chair: Thank you. *Merci.*

We'll go now to Mr. Van Kesteren.

Mr. Dave Van Kesteren (Chatham-Kent—Essex, CPC): Thank you, Mr. Chair. Thank you, everybody, for attending.

This is a very complex issue. It's somewhat confusing. On the one hand, it would appear that we're responsible, and on the other hand, it would appear that there's responsibility on the other side, and we're all trying to find the same logical conclusion.

I'm going to ask you to give me a very clear answer to explain the straightforward process—and it should be a straightforward process—to obtain drugs under CAMR. I'll ask Mr. Armstrong first. What's the process?

The Chair: Maybe we should have Mr. Clark answer that one.

Mr. Christopher Armstrong: In terms of the process of using CAMR, Industry Canada is in a better position.

Mr. Dave Van Kesteren: I'm sorry. Okay, Mr. Clark.

Anybody else can jump in. I have another question as well.

Mr. Douglas Clark: I'll sketch out notionally what the process could be, although the steps I will describe in sequence will be intuitive. They're not necessarily under the legislation chronologically.

Notionally the first step would be for a developing country, an eligible importing country, to notify the WTO, if it's a WTO member—or Canada, if it's a non-member—of its need for a particular drug. It would identify the drug and the quantity needed.

Then it depends on their development status. If they're a least developed country, they don't have to indicate anything. If they're a developing country, they have to indicate that they have insufficient manufacturing capacity for that drug. If they're another category of developing country, which has agreed to avail itself of the regime only in situations of extreme urgency or national emergency, they would have to indicate that.

That would be notional step one.

Mr. Dave Van Kesteren: Can I just stop you there? Has that happened?

Mr. Douglas Clark: No.

Mr. Dave Van Kesteren: I have another question.

If this is profit driven.... I really get kind of cynical, because I'm looking at all sides here, and I was really surprised to see that China was part of this process too.

First of all, can a generic company—say, a Chinese company—get a licence from a Canadian company, or does it have to be under the framework of that individual country?

Mr. Douglas Clark: Patent law is territorial in nature, so if you're looking to avail yourself of a Canadian regime, you have to do so in Canada. It could apply to that Chinese company if the manufacturing was taking place in Canada.

● (1650)

Mr. Dave Van Kesteren: All right. Does anybody else want to add to that?

I, too, think you've answered that question pretty well.

Now—and maybe this can go across the floor—explain your role and responsibilities of involvement within Canada's access to medicines regime. What is your role?

Maybe Mr. Clark could reply and then Mr. Armstrong. I want to get CIDA in.

Mr. Douglas Clark: Well, we're policy. We're responsible for the legislation that provides the legal framework to the regime, to some extent, at least on the patent side.

And then, David....

Mr. David Lee: At Health Canada, we're responsible to make sure that before any drug is exported from here under the patent regime, it's safe, efficacious, and of high quality. So it's the same as a Canadian citizen would get; no double standard. Plus, we have to make sure that the markings for diversion are present so that the drug is sent over and is different from the brand-patented product here in Canada.

Mr. Dave Van Kesteren: So is it standard across all the different countries? Would it be about the same as the Canadian standards? Is it universal?

Mr. David Lee: They're not perfectly universal, but in terms of generic drug review they're fairly similar.

Mr. Dave Van Kesteren: In all the talking we can do, the fact of the matter remains that before this process can begin, you need an application from a host country, a country that has an epidemic or something, and that quite frankly hasn't happened.

Mr. Douglas Clark: It's not that it has to start by that step. As I said, that's a notional, logical sequence of events. All I'm saying is that before the licence could be granted, that would have to happen, and that hasn't happened.

We've already had generic companies approach Health Canada and seek approval for a generic version of a patented drug that they were contemplating exporting under the regime. There's nothing to prevent them from doing that in the absence of a notification to the WTO, but before that can ever crystallize into an actual licence under the regime, that notification has to take place.

I was just saying, notionally, logically, you would think that would be the first step in the process, but it hasn't happened.

Mr. Dave Van Kesteren: Do I have time for one more question?

The Chair: You have three seconds.

Mr. Dave Van Kesteren: Okay. Very quickly, did I hear correctly that generic companies are allowed to charge 25% above the cost? Did I catch that right?

Mr. Douglas Clark: No. There's a provision in the Patent Act that allows the patent holder to challenge the generic's export licence if they're charging 25% or more to the importing country, the developing country—25% or more of the price of the equivalent brand name drug in Canada.

Mr. Dave Van Kesteren: So that's 25%, and they get a royalty of up to 4% as well. I caught that, too, I think.

Mr. Douglas Clark: Well, it varies between, as I said, 0.02% and about 3.8%. It would depend on the development status of the country you're exporting the drug to.

Mr. Dave Van Kesteren: Okay, good.

Thank you.

The Chair: Thank you.

We'll go to Mr. Masse again.

Mr. Brian Masse: Thank you, Mr. Chair.

This past Sunday I had a chance to be with my community to participate in ceremonies to remember the 13th anniversary of the Rwanda genocide. Part of that genocide, in its darkest chapter, was the fact that we all stood by and didn't do anything. Also, in Rwanda now, we have an explosion of AIDS and a number of different diseases because of what happened there. They're infected quite seriously with it now.

This seems to be happening as well with a number of nations now. We have legislation. It's always helpful to see where you're going or where you want to go by revisiting where you started from. Where we started from, it was quite clear that we wanted to be the role model, to set the example for other nations, to institute legislation that actually would produce drugs that could go to developing nations across the planet, not just Africa, for tuberculosis, malaria, a series of different diseases.

Now we've run into these problems on our side, being the forebears of this. Have there been discussions between your different departments or the ministers with our other sister nations who are once again in this situation, where our legislation, whatever intent it might have had, is not producing the real results tangibly for individuals who are affected by these diseases and the countries that we were professing to be able to support...coming from the original nation request to WTO to actually do this in first place? That's where it started from. Has there been that discussion among our colleagues who have actually presented legislation or crafted legislation that doesn't work for all of us combined together?

The Chair: Mr. George.

Mr. Douglas George: I think it has been mentioned that we have been talking with other nations who've implemented it, to find out what's happening in their system and whether they've been having any success. As of yesterday, when I checked the website, there were no notifications from any developing country. We've been discussing this in Geneva, but there are a number of factors, and I think most of them are outside the WTO.

Mr. Brian Masse: So none of the ministers or none of your departments pick up the phone and say to whatever country—the Netherlands was the first, beforehand, having granted it through their king, I believe, at that time—"Okay, listen, this is the problem we're running into here. This is what the NGOs are telling us, this is what the generics are telling us, this is what the drug companies are telling us. We're not going anywhere. We're stuck."

Does that type of behaviour happen, or is it basically that we just go around to different seminars and talk about our legislation and have similar problems but don't actually start to look at what we can do for a joint solution?

● (1655)

Mr. David Lee: We do have encounters with fellow regulators. We are trying to understand how to make this work. To be fair, most of the people I've met involved in this kind of legislation or a health ministry in another area are trying to make it work. I've seen a lot of smart people in the room—a lot of them medically trained, and so on—but it's complicated to take patents and put them together with drugs. To make sure our discussions become productive, I've certainly been in many encounters where we've tried to get down into that. I'm sure there is will. As I mentioned, my minister has been talking to colleagues. So there's an attempt to try to find that, but not as a broad, systemic study.

Mr. Brian Masse: You're absolutely correct, Mr. Lee. I think that's where it takes political will to do it, at the end of the day. I've always believed that this legislation was built so it won't actually be applicable and achieve results. There is so much bias, in terms of not getting an end result, that it's stuck here.

What is happening in your particular case? You actually have the process completed to the point where people can access it if they want. Is it because there are no timelines in negotiations between generics and pharmaceuticals on the price of it? Is that the holdup? What has been the feedback at this point from your cases on why it's not going to the next level?

Mr. David Lee: When you canvass other witnesses about that, it may be more productive for you, because we're not actually part of the negotiations that go on to that next step. I can certainly describe for you—and have to some small extent—the fact that we've received applications. We've sat down together with our colleagues in the commissioner's office and explained to the company how it all works and what each step involves. But the next step is the exchange between the generics and the brands in the country. We're not involved in that discussion.

Mr. Brian Masse: So essentially it just sits on the shelf at Health Canada until it's actually triggered to be released.

Mr. David Lee: Yes. We have it on our patent hold.

The Chair: You have 20 seconds.

Mr. Brian Masse: Thank you, Mr. Chair.

I know there are some people who have been here through this process, but I find it particularly troubling that we don't seem to be taking leadership. I'm certainly not blaming individuals in front of us here. I understand how things work, but it would seem that we were supposed to be taking political leadership of this three years ago—four years ago, in fact, because it took another year to actually get going. But I would have liked to have seen the same thing happen bureaucratically amongst your colleagues in other countries who have similar jurisdictional responsibilities.

The Chair: That will have to stand as a statement, which I think it probably was.

We'll go now to Mr. Byrne.

Hon. Gerry Byrne: Thank you very much.

Will the global fund to fight AIDS, tuberculosis, and malaria, to which the Government of Canada just announced a $250 million contribution, provide drugs for those diseases in those epidemics, and how so?

Mr. Christopher Armstrong: Absolutely. The global fund is a funding mechanism to which countries and civil society organizations can apply.

Just to speak specifically to the issue of medicines, with the current state of funding within the global fund it's projected that through that funding about 1.8 million people will receive antiretroviral treatment for AIDS and about 3 million people will receive treatment for tuberculosis.

Hon. Gerry Byrne: How will it provide those drugs? Will it be done through the WTO's TRIPS waivers or through some other mechanism?

Mr. Christopher Armstrong: The global fund does get involved to some degree in procurement. That's a bit of an issue, but it's more —

Hon. Gerry Byrne: So it does get involved.

Mr. Christopher Armstrong: It provides the funding to developing countries to be able to purchase the medicines. That's probably the best way of describing it. Then it's up to the countries—with funding they get from the global fund and other donors like Canada, the United States, and the United Kingdom, and put in through their own budgets—to make decisions about how they can best access the most affordable and effective medicines they have put within their plans to provide to their populations.

CAMR is intended to provide them with another option through which they can access medicines. The intention of the WTO decision was for Canada and other WTO members to enable them to access medicines through compulsory licensing. If they decide that is the best means through which they can purchase the medicines to address the public health needs in their countries, that's the way they would undertake to do it.

● (1700)

Hon. Gerry Byrne: So here's what we know. We know that roadblocks were eliminated in providing cheap access to medicines, but that didn't actually facilitate an efficient way of getting the drugs into the medical facilities that treat the one million children, the people who die of malaria every year, and the three million who die of HIV/AIDS every year.

On the normal modus operandi of CIDA in supplying most aid to developing countries, take, for example, the provision of food aid. CIDA normally goes out, solicits proposals, and contracts with Canadian food suppliers to package and transport goods. A cheque for that mackerel, herring, or grain is cut by CIDA and given to the Canadian supplier of the food aid.

It seems really strange to me that we've identified all of the background as to why this program is not working—the capacity within the importing country, in the developing country; formulating contracts; and getting through Canadian legislative and regulatory hurdles. But I'm puzzled as to why Canada has not taken the position that we would become a direct first-party provider of these services using the WTO TRIPS waivers, Canada's access to medicines regime, and our own statutory powers. Why doesn't CIDA simply go in, solicit an importing country that has identified an epidemic, and provide the championship on the ground in the host country's own health facilities, and on the ground here in Ottawa, in getting this process through? It seems highly consistent.

Is there any contemplation at CIDA to actually conduct one or ten pilot projects to see if the model I've presented to you works? It seems to be the model CIDA has used for every other international development project it has ever embarked upon.

Mr. Christopher Armstrong: I understand your question. At the moment we have not undertaken to use that model. It's one we'd have to look at in terms of issues of aid effectiveness and putting ownership and decisions in the hands of developing countries to enable them to access the medicines most relevant, affordable, and efficacious to them. So we'd need to look at it from that perspective.

We'd also need to look at the overall objective of the WTO decision, which was to provide greater flexibility for developing countries to access affordable medicines. So I absolutely understand your question. The model is worth looking at, but CIDA would have to give it consideration within the context of those issues.

Hon. Gerry Byrne: To the panel, have any companies approached you to say, "Listen, we are not in the business of international development; we are in the business of profit. We'll help out where we can, but this is a really low-profit margin business for us, and the risks related to this environment are huge. We're not interested. We'd like to present the fact that we're interested, but until something changes in terms of.... If we're actually supposed to be the delivery mechanism for international assistance, we're not onboard."

It seems to me that is the attitude or position of the private sector in this country. I don't necessarily like it, but I can understand why. I thought it would be the role of government to actually facilitate, as we have done, because I don't think international development assistance is normally a really high-profit area for most companies.

The Chair: Thank you.

Mr. Armstrong, would you like to comment?

Mr. Christopher Armstrong: I have not been approached specifically about those issues from generic companies, so you'd have to ask them directly. I don't have any evidence of that perspective from them.

On their engagement in it and whether or not it's viewed as a humanitarian or profit-making issue, certainly the overall intention of the WTO decision was humanitarian. There's no doubt about that. But as Mr. Clark has mentioned, it's facilitating legislation to enable the engagement of our private sector, so it does rely on private sector engagement, and I don't have the answer on how that happens.

The Chair: Thank you.

We'll go to Monsieur Arthur.

[*Translation*]

Mr. André Arthur (Portneuf—Jacques-Cartier, Ind.): Thank you, sir.

As you were making your presentations, I tried not draw up a list of the successes that have been achieved with this system. It was a struggle.

Thirty or so countries have worked with the WTO to draw up agreements to waive obligations under certain important laws. Canada has entered into negotiations with two firms, namely Apotek and one another, whose name remains confidential, in an attempt to reach some kind of arrangement. As of 3:30 p.m. this afternoon, when our meeting convened, not one single pill had been shipped to a developing country by one of the thirty countries, including European Union nations. Not one! At 5:06 p.m., thousands of words later, I would bet that still not a single pill has been shipped.

I see here representatives of a prestigious body like Health Canada, which tells me that care is being taken to ensure that the pills that one day will be shipped will be distinct from those sold in Canada. Foreign Affairs, a serious-minded department, maintains that it has contacted international agencies as required to ensure a certain measure of efficiency, but it is still not able to issue passports on time to Canadians who need them. I see the HIV/AIDS team leader who has become somewhat of a Santa Claus with a maple leaf in the eyes of the entire world. Yet, he still doesn't think it would have been a good idea to ship drugs that companies could have made available.

If I had purchased a bottle of Advil before coming to this meeting and had shipped it to a hospital administrator in Ouagadougou, I would have done more than what all of you have managed to accomplished with 30 countries in two years.

Since Industry Canada has a mandate to review this agreement with a view to improving its terms and conditions, I'm trying to understand what more you need to admit that your initiative has failed miserably. What more do you need to stop gadding about in an attempt to convince people? What more do you need to make this system even a tiny bit efficient? What are you waiting for to give up on this system and weigh another alternative?

● (1705)

[*English*]

The Chair: Who wants to start with that one?

[*Translation*]

Mr. Douglas Clark: I'm not sure how to answer that question, sir.

Mr. André Arthur: I'm realizing that you don't quite know how to answer. You are loyal public servants. You were asked to do a job because we had a prime minister who was nearing the end of his term and wanted some praise from Africa. The House of Commons ended up voting unanimously to adopt legislation that couldn't and doesn't work, either for us or for anyone else.

I understand why you cannot answer the question.

Mr. Douglas Clark: I do believe the legislation can work. It's premature to conclude otherwise. We're making a sincere effort here to explore possible changes and improvements to the regime. Judging from all of the discussions that we've had to date, not much will happen because of a lack of money. Basically, it boils down to a question of funding.

Mention is often made of the regime's regulatory impediments. All of the obstacles that we've talked about are far more serious than those faced by generic drug companies when they wish to market a generic version of a patented drug. Companies manage to overcome these obstacles daily.

It really comes down to a question of incentives and it's not up to Industry Canada to...I don't know what to tell you. The regime was set up, but it is not being funded.

● (1710)

The Chair: Mr. Arthur.

Mr. André Arthur: Before we adjourn, could someone phone my office to ask if a single pill has been shipped in the last 10 minutes?

[*English*]

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

Mr. André Arthur: Thank you, sir.

The Chair: We'll go now to Mr. Boshcoff.

Mr. Ken Boshcoff: Thank you very much.

We seem to be onto something that perhaps has taken us off on a tangent, but maybe only a bit. We're talking about pills as opposed to other forms of medicines—pharmaceuticals, vaccines—and we're also talking about this one particular component of our service delivery. Do we not deliver anything whatsoever through the whole umbrella of the family of Canadian public servants or NGOs in terms of these products, whether it's Advil, vaccines, these kinds of things, not necessarily through this particular protocol but through the agencies that you represent? At this stage, I'm almost feeling that we're not sending anything to anybody in any country that's been asking us for materials or support. So can we clarify that? You've been answering the questions within the box, but you haven't mentioned that there are other people who care or do deliver services. Or are there not?

Mr. Christopher Armstrong: I have been trying to present that, and I apologize that I haven't presented it as clearly as possible. There are numerous things to delineate. But it's a very long list of organizations that we provide support to that are helping to provide medicines in developing countries through multilateral institutions. As I mentioned, we were the largest donor to the World Health Organization initiative to provide treatment for HIV and AIDS, which has resulted in huge increases in access to HIV treatment. We're providing support for bed nets for malaria. We're providing huge amounts of support to provide drugs for tuberculosis, and vitamin A to deal with micro-nutrient issues with respect to children and child survival. There's a long list of things we're doing. I'm sorry that hasn't come out clearly. So, absolutely, Canada can be proud of a number of things we're doing.

Mr. Ken Boshcoff: Is that the qualification between “patent” and “generic”? Also, while you have the ice time, to address things like Rotary International's PolioPlus, is the federal government involved in the delivery mechanism? If I left this meeting and I thought one MP who could deliver a bottle of Advil had done more than the entire weight of the Canadian government, I'd feel that the Canadian people would be rather shortchanged.

Mr. Christopher Armstrong: You're right. It's putting this piece of legislation, which is facilitating legislation to enable compulsory licensing, as one possible mechanism for providing generic versions of otherwise patented medicines in the developing world. Not every drug that's delivered in the developing world requires compulsory licensing, whether it is off-patent or whether or not they're accessing those medicines from Indian generics, Chinese generics, or Brazilian generics. All of those issues are happening, and Canada is providing the support. Not all the medicines, as I said, that are needed in the developing world are under patent. So we are providing support to all of those things. Rotary is another example that I didn't name. Absolutely, Canada has been a leading supporter of polio vaccines.

Mr. Ken Boshcoff: When we look at the list of countries then that are going through this exact same process that we are doing now, is someone somewhere out there closer—whether they feel it's their particular system, such as the United States versus another nation—to being able to come up with the formula outside of the United Nations protocol, or the WTO, that they think will do that job better in terms of generics?

Mr. Douglas Clark: As I said, I think we're all in the same boat. Just for your own information, the United States does have a government program, in contrast to what this is, which is a private sector program, in place to facilitate access to meds in the developing world. But insofar as the actual countries that have implemented the waiver are concerned, I think, again, we all have the same sort of fundamental legislation or regulations in place. But we're all in the same boat. And nobody is any closer, I don't think, to having a pill exported tomorrow than Canada is. I think if we get a test case at some point and it does work its way through the system somewhere, then we'll have something to compare it to and figure out, how did they manage to overcome the barriers that we're facing here?

● (1715)

The Chair: Thank you.

As the chair, I'm going to ask a few questions, since we've gone through everyone at least once.

Mr. Clark, you mentioned some information on outreach activities that you've done in developing countries. You don't have to go through them all now, but if you have them there, can we get all the initiatives that you've taken, perhaps in written form? The CD you mentioned would be very helpful.

The second issue that I want to raise is the issue of the schedules. On page 11 of your presentation, you have "Stakeholder Positions on CAMR", under which you say the NGOs "want immediate liberalization of the regime (eg eliminate restrictions on eligible importers and drugs...)".

You also mentioned earlier on, on page 9, that of the other countries that have developed legislation similar to ours, "None rely on pre-approved lists of eligible importers or drugs." I think today you said that having these schedules actually facilitates or would facilitate quicker delivery of the drugs. Can you explain why Canada has chosen to go this route, and whether it would in fact be quicker, as some have suggested, to eliminate these schedules?

Mr. Douglas Clark: The reason is a simple one. In the absence of a pre-approved list, some government body, some decision-maker, is going to have to look at the law, interpret the law, have an application before them—obviously, the patent authorities in all the countries that I'm aware of, in any event—and decide if this is a pharmaceutical product within the definition set out by the WTO, which we've adopted word for word; if it is needed by a country suffering from a public health problem; if it's a developing country, not a least developed one; if that country has established that it has insufficient or no manufacturing capacity; if it is a country that qualifies in the first place; and if it meets the WTO definition.

All of these things require an exercise of some discretion. As soon as you have that, you have the legal basis for challenging them. This is aside from the fact that patent authorities are not the best-placed decision-makers to make calls of that kind. They're not experts on the development status of countries or the public health problems that afflict them. By having a pre-approved list, you avoid those problems and you insulate the decision from litigation to the extent that it is possible to do so.

The Chair: My second question deals with the issue of my understanding that the number of companies and NGOs....

There are two cases. One is a public case and one is confidential, in terms of take-up of the system. On page 10, you have a statement:

- The Minister of Health announced an early review of CAMR....
- On November 24, 2006, the Government released a consultation paper....
- During the subsequent 60-day consultation period, Industry Canada and Health Canada received approximately 30 submissions from interested parties....

Clearly there's interest in the legislation, in the issue. There's a system in place. I'm not sure whether the system is what's wrong or whether it's the take-up in the system. Mr. Byrne certainly raised some valid questions in terms of whether you need CIDA to take some leadership.

In terms of the system, we don't have a lot of cases to go on in terms of analyzing whether it's working or not. The one case that is public and that we can talk about is the case with respect to Apotex and a drug that I believe is called APO-TriAvir. According to Apotex's submissions to the government's statutory review of this legislation, this has not happened because of the complexity of the process, so nothing has moved since.

Just using this one case, because it's the one case we can talk about, can you explain to the committee the development of that process and why it has not moved forward from a regulatory point of view?

Mr. Douglas Clark: We've all heard that criticism of the regime: that it's unduly complicated and difficult to navigate. But anybody who is familiar with patent litigation in the pharmaceutical industry, particularly under the patented medicines notice of compliance regulations, with which some of you are familiar, will find that criticism hard to accept.

We're talking about some of the savviest, most sophisticated, smartest legal entities out there. As I mentioned earlier in French, the regulatory burden that generic drug companies face in trying to get into the domestic market is far in excess of the regulatory steps they have to go through here. It's really a question of will and it's a question of enticement. If you told a generic company that they had to get a man on Mars to be the first with a generic version of a blockbuster drug, they'd have a guy there in six months, not including travel time. So I don't find that objection credible, from my own perspective.

In terms of the actual Apotex example, my understanding is that it got bogged in the voluntary licensing phase. But David knows the facts of that case better than I do, so I'll turn it over to him.

● (1720)

The Chair: We don't have much time, so could you very quickly answer that?

Mr. David Lee: There was at least an initial attempt on the part of Apotex to seek voluntary licences. It's a triple-fixed dose so they tried to seek licences from the relative patentees. At that time, there wasn't a country of mention, so there was some discussion on whether that was a bona fide attempt to seek a licence. There was some correspondence sent into us, but we deferred it to the Commissioner of Patents, where it belongs. It's really, as I said, an issue that has to go between the generic company and the patentees. We've only had an opportunity to watch it from a distance.

The Chair: Okay. I appreciate that.

Members, we have about eight minutes left, so I'm going to give two minutes to each party. I'll start with the Bloc. I'll start with Madame Brunelle.

[*Translation*]

Ms. Paule Brunelle: Mr. Clark, are companies really interested in selling pharmaceuticals? I note that costs are minimal. You mentioned fairly complex regulatory processes. Wouldn't it be simpler to award tax credits to companies that supply pharmaceuticals? What difference would that mean in terms of cost, given that putting the required structure in place along with a renewable mandatory licensing scheme are costly propositions?

Mr. Douglas Clark: Your question concerning the interest expressed by Canada's generic drug industry is excellent. Only two of the 30 submissions received in response to our consultation paper were from generic drug companies. I think that speaks volumes about the situation.

As for other incentives, that's really not my area of expertise. I know that some measures are already in place. The government recently announced similar measures, but I'm not familiar with the details. A number of innovative companies do take advantage of this type of tax credit to supply various pharmaceutical products to developing countries.

[*English*]

The Chair: Thank you.

We'll go to Mr. Byrne, please.

Hon. Gerry Byrne: Mr. Clark, you mentioned that one of the biggest barriers or obstacles to would-be importing countries accessing this program is money. I take it that as a least developed country you have decisions to make, and sometimes you may find that you don't have the capital to invest in medicines purchased from overseas. CIDA does have the cash, and Foreign Affairs has a role to play as well. We do have a $250 million two-year commitment to the global fund. I'd like to hear from each player at the table on this. Does the concept of CIDA embarking upon pilot projects in the variety I've described—consistent with CIDA's normal delivery mechanisms—make sense to provide Canada a baseline of data and a track record as to whether or not this enabling legislation works or whether this is a systemic process problem we are engaged in?

Mr. Lee, would you be able to kick off the answers as to whether or not you would find it helpful to have a pilot project to study?

● (1725)

Mr. David Lee: It would be very helpful to have a pilot. CIDA is not my area. I do drug regulations.

Hon. Gerry Byrne: What I'm looking for is whether or not it would be helpful, in terms of completing the regulatory environment, from Health Canada's point of view, from the patent office point of view, from CIDA's point of view, and from Industry Canada's point of view.

Mr. David Lee: It's well observed that when we get companies in or countries in and we are having discussions, we play our regulatory role. We talk about what we do with the generics from a Health Canada point of view, and then CIDA will have to come in. The funding always comes up as an issue.

The Chair: Let's quickly go down the line here then.

Mr. Clark.

Mr. Douglas Clark: I think I've made it pretty clear so far that in the absence of funding, there's not going to be uptake now. I also take Mr. Armstrong's point about not wanting to be paternalistic. If you provide funding to these countries, you should enable them to determine where best to source their drugs. If the generic versions of these patented drugs are much cheaper in India, why on earth would you insist on their spending the money that you give them in Canada?

Hon. Gerry Byrne: Well, that's what we did. That's our whole modus operandi for development assistance.

The Chair: Mr. Armstrong.

Mr. Christopher Armstrong: I think I've answered this question a few times.

I'm not going to deny that absolutely some of our funding is "tied", for lack of a better word, to Canadian products; in this particular sector, we don't do a whole lot of it, and we haven't considered it under CAMR. As I said, we'd be willing to consider it and to look at it from all of the perspectives, including the one Mr. Clark mentioned.

On the specific issue of the global fund, the understanding is that when we provide funding to those types of mechanisms, we're not in a position to be able to tie our funding—in this case, to the global fund—even if we wanted to.

The Chair: We're way over time here, but just quickly, Foreign Affairs—yes, no?

Mr. Robert Fry (Senior Departmental Coordinator, Pandemic Preparedness, Human Security and Human Rights Bureau, Department of Foreign Affairs and International Trade): I don't have much to add, other than the fact that, as Mr. Clark said, in terms of our foreign policy objectives, we support this regime but also support finding the best mechanism for doing it without being paternalistic, without wanting to impose things.

The Chair: Thank you.

Mr. Masse.

Mr. Brian Masse: Thank you, Mr. Chair.

Mr. Clark hit it right on the head when he talked about this legislation being a facilitating legislation. That's because the previous government and this current one decided not to actually put the funds into foreign aid, be it the 0.7% GDP or actually having a strategy to do so. That's why their outreach was there to the generics and the brand name companies, to actually see if they wanted to play a role.

I agree that nobody's hands are clean on this. The fact of the matter is that if a brand name company wanted to take a 0.2% profit—or 1%, or 2%, or 3%, or 4%—on their drugs being shipped out somewhere else, they could do so. We wouldn't even need the legislation.

I guess one thing I am concerned about, Mr. Clark, is somewhat of a legitimate sticking point, I think. Isn't the two-year time limit a little bit restrictive in terms of going through the process and getting an actual application through? What do you do about the fact that people will be living with HIV and AIDS, on some of the drugs we can provide, much longer than the two years on the prescriptions they have? Isn't that kind of a problem with the whole issue? Or do you see it as not a problem? I think it really is, from a health and human aspect—there are many Canadians who take HIV and AIDS medication longer than two years and benefit from it very strongly—and also a production aspect.

The Chair: Okay, let's let them answer.

Mr. Clark.

Mr. Douglas Clark: Just as a point of clarification, it's two years and renewable for an additional two years.

Mr. Brian Masse: Renewable, yes, but you only get it for two years. Then you have to go back, and that renewal may not happen.

Mr. Douglas Clark: It may not happen, but if you haven't shipped out the quantity that you were originally authorized to ship, it is pretty much automatic on application.

I will say that this issue was debated extensively, as I certainly recall, back when Bill C-9 was under development and was being examined by this committee. Several members of the committee suggested a longer term or a term set at the discretion of the commissioner. One issue that was raised was that you don't want to lock countries into a specific price and contract for an extended period of time while prices have been spiralling downwards, as they have been these past few years.

So that's one answer to your question. The other answer is that some other countries that have implemented it have left it to the discretion of their patent authority. They all prescribe a finite term, but set at the discretion of the patent authority hasn't made a difference in terms of exports.

I take your point about—

● (1730)

Mr. Brian Masse: We could have a simple clause to lower it. I mean, if those prices can go down, we could have a simple clause in our own legislation saying it may be lowered.

The Chair: Mr. Clark, do you want a final word on that?

Mr. Douglas Clark: No, that's fine.

The Chair: Mr. Carrie, two minutes.

Mr. Colin Carrie: Thank you very much.

I think you made a good point, that a lot of this does sound somewhat paternalistic—or it does to me. Should we be dictating? Should you be even buying these drugs? Should you be spending it on wells or irrigation systems or feeding your population? I'm not sure.

To my understanding, Canada has some of the most expensive generic drugs out there.

Mr. Clark, you brought that up. Can you explain to me how drug pricing factors into this whole equation? And logistically, can Canada even compete with some of these other countries?

Mr. Douglas Clark: I'm not an expert on pricing. You just hear anecdotally that not only Canada but also generic drug companies in developed countries can't compete with generic drug companies in developing countries. I think that's just an obvious thing.

As for Canadian generic drug prices, a number of studies lately have said different things. That question would best be directed to the industry. I don't want to pronounce on it. I'm a patent guy, not a price guy.

Mr. Colin Carrie: Does anybody else have a comment on that?

The Chair: No?

Thank you very much, Mr. Carrie.

I want to thank all of you for coming in and being with us today. I thought it was a very informative session. I want to thank you for your time and your presentations. If you have any further information for the committee, please submit it to me or the clerk and we'll distribute it to all the members.

Again, thank you very much for your time here today.

The meeting is adjourned.

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