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Chair

Mr. David Sweet

Standing Committee on Industry, Science and Technology

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● (1100)

[*English*]

The Chair (Mr. David Sweet (Ancaster—Dundas—Flamborough—Westdale, CPC)): Order, please.

Good morning, ladies and gentlemen. *Bonjour à tous*.

Welcome to the 37th meeting of the Standing Committee on Industry, Science and Technology, the third meeting of this session.

We have a small piece of business that I'd like to deal with.

Members have in front of them the budget for our study regarding Bill C-393. Could I have someone—

Mr. Mike Wallace (Burlington, CPC): I'll move the items.

The Chair: Mr. Wallace moves the items.

All in favour of this? None opposed.

Thank you very much.

(Motion agreed to)

The Chair: We have quite a full roster today.

Maybe I'll let you start, Mr. Masse, and then I'll introduce our witnesses from the four departments that are represented, and then I'll be introducing the person who I understand is going to actually be the delegate to move the conversation through all the departments.

Go ahead, Mr. Masse. You have five minutes, I believe.

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

I'll be brief. I think it's important for us to talk to the witnesses who are here today.

I want to start by thanking my colleagues for continuing with the study of Bill C-393, as Judy Wasylycia-Leis, the original sponsor of the bill, has moved on. I want to thank my colleagues for living up to the commitment they made to have hearings in this committee. I do appreciate that.

I want to provide a little bit of context. I won't get into many of the details of the bill, but I will maybe talk a little bit about why the bill is important and provide a little bit of the history for members who weren't around at that time.

I was elected back in 2002. When I came to Parliament Hill, there was already a movement to have a bill or a law to deal with some of the world's poorest and developing nations to help them get access to pharmaceuticals and medicines, since the simple status quo was not acceptable.

A year later, the WTO and a series of other global endeavours led to an opportunity for Canada to be one of those countries to actually put a system in place for generic drugs to be produced in advance of patents to help those suffering from tuberculosis, malaria, HIV/AIDS, and other types of catastrophic diseases and health problems. Bill C-56 was tabled in the House of Commons, and a subsequent government tabled Bill C-9, known as Jean Chrétien's Pledge to Africa bill.

At that time, the committee had lots of hearings. We had several different panels come forward. There were really comprehensive examinations. And just so my colleagues know, I actually proposed 100 amendments to that bill at that committee, believing at the time that it was flawed. Now, that's not to say I was right, but, at the end of the day, in the House of Commons all political parties ended up agreeing unanimously to a bill.

The explicit goal of everybody in that room and in the House of Commons was to have Canada put in place a system to be able to get these drugs to children and people across the globe who are suffering. As things stand, each day around 14,000 people die of HIV or AIDS, and when children actually have HIV/AIDS, one-third die by the age of one, and one-half by the age of two. We simply have the tools necessary to correct this situation.

Only one patent has gone through this regime to date. That was to Rwanda. It's been very limited in scope. That's from Apotex. There have been generic drug companies that say they will send more drugs overseas if we fix the legislation, and that's what we're proposing to do.

Once again, I'm proud to sponsor this bill, but, at the same time, I'm ashamed of my record on this, because I voted for a bill, and we promised the world we would do something that hasn't taken place. It certainly hasn't met what people said in the House of Commons and what they said here at committee, so I want to seek solutions to fix that.

I voted for the bill even though I thought it was flawed, because we stand unanimously together, as parliamentarians, to try to make a difference. We put those things aside to see whether or not the bill would actually work and if the problems we thought would happen weren't going to take place. But the reality is that they have.

So I stand here today to once again try to correct this situation, and to work cooperatively with everyone, because I think there was honest and sincere debate from all members and all parties to actually have a country that actually has a solution for this and that contributes and shows leadership. But we have failed people on this. There's no doubt about it. People are suffering. People are dying. People are not getting treatment. We put a lot of weight behind this and we need to solve it. I think it's a moral and ethical obligation for us, and I think Canada has the tools to be, once again, a leader in this field.

I thank you again for continuing with your commitment to have this heard in the halls of this committee, and hopefully in Parliament as well.

Thank you, Mr. Chair.

● (1105)

The Chair: Thank you, Mr. Masse. I appreciate your efficiency.

I'll briefly introduce our witnesses today.

From Industry Canada, we have Colette Downie, director general, marketplace framework policy branch.

I understand, Madam Downie, that you're going to be doing the main presentation and directing the others.

Ms. Colette Downie (Director General, Marketplace Framework Policy Branch, Industry Canada): With my colleagues, that's right.

The Chair: Okay.

We also have with us: Louise Clément, senior director, regional and geographic programs, southern and eastern Africa; Christine Reissmann, director, AIDS and tuberculosis programming and health institutions, multilateral and global programs branch; Brigitte Zirger, director, policy bureau, therapeutic products directorate, health products and food branch; and as well, Robert Ready, chief air negotiator, Department of Foreign Affairs and International Trade.

We will begin with you, Madam Downie. I understand that your presentation is approximately 20 to 25 minutes among all departments. Is that correct?

Ms. Colette Downie: Yes. We're going to try to keep within that timeframe.

The Chair: Thank you.

Please proceed.

Ms. Colette Downie: I think everyone has a copy of our deck before them...? Fantastic. That's what we'll be going through.

I'll start by thanking you for the invitation today to speak about Canada's access to medicines regime, or CAMR, as it's often called, and to speak about the possible implications of private member's Bill C-393, which proposes to significantly change this regime.

Together, my colleagues and I will be speaking about CAMR and Bill C-393. Our presentation will be divided up according to our various responsibilities, but it will, I hope, highlight the following.

First, there is the complex problem of delivering medicines to the developing world and what the Canadian government is doing about that. An access to medicines regime like CAMR, like Canada's, can't by itself solve the main problems of access to medicines, which are really the result of poverty, not patent laws.

A number of risks are associated with removing the conditions that exist in CAMR to give what would be essentially a blanket licence well beyond what would be needed to deal with some of the humanitarian problems that motivate this private member's bill. In particular, it would allow for export of almost any patented drug made in Canada for an unlimited time and to many countries that are relatively well off, like Poland, Mexico, and Brazil. There would be no policing mechanism to ensure good faith in the shipments, all of which potentially would have—at least we're concerned about it—concerns for Canadians' access to innovative new medicines and research and development jobs.

So while the proposed bill raises these risks, at the same time the government's view is that it's very unlikely to achieve its very laudable goals, which are to increase the exports of much-needed medicines to developing countries.

Following our joint presentation, all of the officials here would be happy to answer your questions.

I'll turn over the beginning of the deck to Louise Clément.

Ms. Louise Clément (Senior Director, Regional and Geographic Programs - Southern and Eastern Africa, Canadian International Development Agency): Thank you very much. I'd also like to thank the committee for the opportunity to come and speak about Canada's support to improved health, including access to medicine, in the developing world.

As was mentioned, my name is Louise Clément and I'm with the southern and eastern Africa directorate of CIDA.

The health needs and challenges of developing countries vary greatly. Improving health care, including access to medicines is a multi-faceted challenge, and you will see some of those challenges on slide 1 of your deck. We have to use the most effective, cost efficient, and accountable means to improve the health and the health care of those living in poverty in developing countries.

Through CIDA, Canada is working with the global community to address health needs in developing countries. We are committed to doing so effectively and accountably. We have the lives of millions depending on Canada and our international partners to improve their health and reduce their mortality. Millions are losing their lives from lack of access to medicines that prevent disease and death. This means increasing the medicines available, increasing the access to the right medicines, and ensuring safe delivery and administration of the needed medical interventions.

CIDA's policy is to improve health in the most effective and cost efficient way. To ensure safe delivery and administration of medicines and vaccines, we work with qualified, experienced organizations as partners.

As president of the G-8 in 2010, Canada championed the Muskoka initiative, a major global effort to improve maternal, newborn, and child health in developing countries and to save their lives. Of the Canadian contribution, 80% will go to sub-Saharan Africa, which has the greatest burden of maternal and child mortality.

The Prime Minister recently announced Canada's contribution of $540 million over three years to the Global Fund to fight AIDS, Tuberculosis and Malaria. An estimated 45% of Global Fund grants go to procuring health products, including medicines.

Canada is also a founding donor of the global drug facility and has been the single largest donor country for first-line TB drugs since the facility started in 2001. The global drug facility, a program of the Stop TB Partnership, works to improve access, supply, and distribution of TB drugs in developing countries. It is the only global bulk procurer of anti-TB drugs.

Another example is the GAVI Alliance. This global partnership brings stakeholders in immunization, from private and public sectors, together to accelerate access to new and existing vaccines for developing countries. The alliance works to strengthen health systems in countries and to increase the predictability and sustainability of financing for immunization programs.

Yesterday, Canada announced a contribution of $50 million over five years, bringing our total to $238 million in support of alliance efforts to increase access to life-saving vaccines against hepatitis B, yellow fever, rotavirus, and pneumococcal diseases.

Canada has consistently supported measures that would improve the delivery of needed medicines in health care support to achieve healthier populations in developing countries.

Over the past few years, CIDA has taken significant steps to advance its aid effectiveness agenda to deliver real results for those CIDA is mandated to help.

To reduce poverty, a population must be healthy. To learn and be educated, a child must be healthy, and to improve your livelihood, you must be healthy.

We want to ensure that Canada's aid dollars are resulting in more medicine, more access to safe and quality health care, and, in the end, a healthy, thriving world population.

Thank you.

● (1110)

The Chair: Now we'll go on to Mr. Ready.

Mr. Robert Ready (Chief Air Negotiator, Department of Foreign Affairs and International Trade): Thank you, Chairman.

I'm speaking to slide 4. This part of the presentation really wants to emphasize three broad points: first of all, that the purpose and scope of the CAMR is limited; second, that CAMR is not an administrative burden for countries and applicants; and finally, that eliminating CAMR's administrative provisions could leave Canada vulnerable to challenges at the WTO. I'll just spend a few minutes going over these three points.

First, with respect to the purpose and scope of CAMR, I would maybe just note a couple of points of general context.

Approximately 95% of the drugs on the World Health Organization's essential medicines list are currently off patent. The subsequent point is that CAMR can assist in the international supply of low-cost drugs only if there is an external demand for a Canadian-made generic product.

CAMR, and the WTO decision or waiver on which it was based, was not intended to solve the broad problem of access to medicines on its own. It was part of a broader international strategy to combat diseases that impact the developing world: HIV/AIDS, tuberculosis, malaria. CAMR effectively implements the WTO decision, which is a small component of a broader effort to promote access to medicines. The WTO decision was an intensely negotiated instrument in that body that sought to bring together divergent stakeholder views and to respond to specific public health problems on the one hand, while at the same time assuring that intellectual property protection is maintained on the other hand. CAMR in turn was the result of extensive consultations here in Canada to balance differing Canadian stakeholder views. It essentially sought to balance facilitating access to medicines while at the same time ensuring that incentives for innovation for new medicines and technologies remained.

As one of the first WTO members to implement the waiver, Canada faced a number of competing objectives: first, facilitating access to lower-cost pharmaceutical products in countries facing public health problems; second, respecting Canada's obligations under the TRIPS agreement at the WTO, the trade-related intellectual property agreement, and other international treaties; respecting Canada's patent system; encouraging generic companies to participate in CAMR; and ensuring products exported under CAMR met the same safety and quality standards as those in the Canadian market. The bottom line, I guess, is a balanced and focused instrument with important specific elements that provide clarity and safeguards.

The second point I would focus on, Chair, is the issues around administrative burden, in other words, the length of time it takes to ship medicines. Here I think we need to look carefully at two timeframes. The first is the process in general, which began in 2003 when the WTO adopted its decision or waiver; then the coming into force of CAMR in 2005; and then in December 2005, the receipt by Health Canada of a submission for a medication Apo-TriAvir. In June 2006, Health Canada completed a review of the submission that was made, essentially in a period of six months rather than the allowable 12.

That's by way of introduction to the more specific timeline related to CAMR, which I would like to focus on now. CAMR essentially kicked in with respect to this submission on July 13, 2007, with the company in question, Apotex, sending letters seeking voluntary licences to three pharmaceutical companies to use their relevant patents to produce and export Apo-TriAvir to Rwanda.

● (1115)

On July 19, 2007, under WTO rules, Rwanda became the first country to notify of intention to use the waiver, stating it would import this medication.

On September 4, 2007, Apotex filed application with the Commissioner of Patents for authorization under CAMR to produce and export to Rwanda.

On September 19, 2007, the commissioner granted Apotex authorization, completing the government's role in the process.

The point I want to stress there is that for the CAMR part of the process it took roughly two months to complete the required elements, and subsequently, there was a series of next steps that involved Canada notifying the WTO of the first authorization using the waiver.

In May 2008, some time later, Apotex announced that it had won the Rwanda public tender to supply the drug, and in September 2008 the first shipment occurred.

In sum, on the second point, the challenges and delays with respect to Apotex's export of medicines to Rwanda can be separated from the CAMR process itself.

The year that elapsed between Health Canada's approval of Apo-TriAvir in June 2006 and Rwanda's notification to the WTO can be attributed to the fact that no country had come forward to request drugs under the waiver.

[*Translation*]

The third point is potential WTO concerns.

In negotiating the waiver, WTO members adopted certain safeguard provisions to prevent the diversion of generic medicines to unintended recipients. The administrative procedures under CAMR are based on these required safeguards.

In closing, it is important to reiterate that the WTO waiver was very limited in its scope, purpose and what it could achieve and so in turn was the design of CAMR.

Expanding the scope of CAMR beyond the WTO requirements could threaten existing elements in CAMR that secure Canada's compliance with its international trade obligations.

Since the adoption of the WTO waiver, the international environment for procurement of drugs has also changed significantly with the introduction of a variety of other global mechanisms and alliances that offer greater choice to countries to obtain medicines.

[*English*]

Thank you, Chairman.

● (1120)

The Chair: Thank you, Mr. Ready.

Ms. Downie.

Ms. Colette Downie: Thank you, Rob.

I'm on to slide 5 now. I'll just back up for a second to say that Canada's patent system rewards the extensive investment that's needed to develop new, innovative products, including medicines, by giving patent holders exclusive rights to sell the results of their research for a number of years. In Canada, it's 20 years. When the patent expires, of course, others are free to sell the product, as when we see generic drug manufacturers selling copies of formerly patented medicines.

The access to medicines regime is an exception to our patent system. It allows the Canadian government to authorize someone other than the patent holder, whose property the patent is, to manufacture a patented drug or a medical service for export to a list of particularly needy countries. In recognition of the tremendous investment that's needed to develop these products, and because we want to continue to encourage companies to develop innovative new products, and medicines in particular, Canada's access to medicines regime, CAMR, was designed in a specific way to clearly define its limits, essentially.

While the process for applying for a special authorization under CAMR is actually pretty straightforward—and if the committee is interested, I could share the forms that are required, because when you see them they're actually quite straightforward—CAMR does contain some important disclosure provisions, which were designed first of all to promote transparency and prevent abuse, including the diversion of products back to Canada or to other markets where they might not actually be needed for humanitarian reasons, and, as I said, to ensure that the drugs manufactured are actually used for humanitarian and public health reasons and not for commercial purposes. Also, it's to allow the government or the Federal Court to cancel a licence if, for example, it's abused, is not used in good faith, or is used for commercial reasons. It's important to know that the regime relies on patent holders and not the government to police the use of products licensed under CAMR.

What Bill C-393 proposes to do is remove some of the important anti-diversion and transparency measures that make the regime enforceable. For example, it reduces the information that an applicant must disclose before it gets government approval—basic things such as the requirement to identify the patents involved, the name of the patent holder, the quantity shipped, where it's being shipped to; it would make the authorizations unlimited in duration and quantity; it would remove requirements to notify the patent holder when the medicine is being shipped, how much is being shipped, where it's being shipped to, and who will be handling it in transit as well; it proposes to remove requirements that licensed products have special markings, colouring, and labelling, to make them distinguishable from the patented versions available in Canada. It would significantly also narrow the ability of the government to terminate an authorization, and it eliminates the ability of a patent holder to challenge the shipment of goods, if they're for commercial purposes, in court.

What this means is that anyone could apply to the government for a licence to sell unlimited quantities of products outside Canada, and the government would be required to issue a licence on the basis of not a lot of information and without a mechanism at the back end to make sure that products are actually being shipped for commercial reasons, or to the country they're intended for.

Research and development-focused pharmaceutical companies have global reach, they have global perspective, they have flexibility about where they invest their R and D dollars, and they naturally favour jurisdictions that provide strong and predictable IP regimes. We're concerned that reducing the safeguards provided in CAMR will result in pharmaceutical companies' hesitating to invest in Canada for lack of certainty about the protection of their investments. If they believe the patented products they sell in Canada could also be sold in an unlimited way to other countries, including perhaps being diverted to relatively well-off countries like the ones I mentioned earlier, such as Mexico or Poland or Hungary, they might hesitate to invest the time, money, and resources to bring new and innovative products to Canada.

Another key concern with Bill C-393 is that it introduces a double standard: it would no longer require—it makes optional—that drugs manufactured and exported under the regime pass the Canadian health and safety review at Health Canada.

● (1125)

Many of these developing countries do not have the infrastructure in place to make sure that drugs they are purchasing are safe and effective. The Health Canada review process under CAMR makes sure that they receive the same level of protection as is provided to Canadians.

I'll just turn for a moment to Brigitte, who can expand a little on that point.

We're really now just getting to the end of slide 5, and on to slide 6 in a second.

Mr. Mike Lake (Edmonton—Mill Woods—Beaumont, CPC): Just in the interest of getting the accurate information, I don't have a problem if we go a few minutes over in their time to present. I'd rather hear the information to its full extent. If it takes five extra minutes, so be it, I think.

Hon. Dan McTeague (Pickering—Scarborough East, Lib.): Mr. Chair, on the same point of order, the proviso would be to add an additional five minutes at the end of the meeting, if that's the case, Mr. Lake—if that's okay.

Mr. Mike Lake: Sure.

The Chair: If it's required.

Mr. Masse.

Mr. Brian Masse: That's fine as long as the witnesses are going to stick to Bill C-393. I don't think we need to hear about other issues.

The Chair: Thank you, Mr. Masse.

From the rest of the nodding heads, it looks as though we have unanimous consent. So please go ahead, and understand that we're ready to hear all of the information.

Ms. Colette Downie: Thanks very much.

Ms. Brigitte Zirger (Director, Policy Bureau, Therapeutic Products Directorate, Health Products and Food Branch, Department of Health): I'll try to do this on the fly, then.

[*Translation*]

As Ms. Downie has already mentioned, Health Canada's regulatory role within Canada's Access to Medicines Regime is three-fold.

Firstly, the department is responsible for undertaking a regulatory review of a drug submission to verify that the product meets the same requirements for safety, efficacy and quality as drugs available to Canadians.

Secondly, Health Canada is responsible for ensuring that the pharmaceutical product is distinguishable from the patented version available in Canada. This is aimed at preventing diversion or re-importation of the product.

[*English*]

Third, Health Canada is responsible for performing pre-export inspections to verify, among other things, the distinguishing features and the quantities to be exported. These details would be stated on the manufacturer's application for compulsory licence that is sent to the Commissioner of Patents.

Now, the products of most interest under CAMR are antiretrovirals used for the treatment of HIV/AIDS. In Canada, the vast majority of these drugs are still under patent protection, which means that Canadian generic versions have not yet been developed. This was the case with Apo-TriAvir.

I would add that submissions that are received and have been received under CAMR are taken into review immediately upon arrival and are completed well within the performance target. These reviews are undertaken with the same diligence as any domestic submission review we undertake, and that is mainly because at the end of that review, and when the patents expire, those drugs can come to Canada.

Companies, whether they are brands or generics, don't develop risk-free products. If they did, Health Canada would never have to issue a negative decision. And it is Health Canada's view that there should be no question of a double standard, nor should there be any concern that a drug leaving Canada destined for humanitarian purposes might be unsafe. Bill C-393 could put this in jeopardy. By removing the mandatory review, it is unclear what safety, efficacy, and quality standards would be applied to drugs exported from Canada under a government-issued compulsory licence.

Maintenance of quality once drugs are in that country and the trade of substandard, falsely labelled, counterfeit, and falsified medicines are serious public health problems. These pose significant challenges to developing countries, which receive drugs from many different sources, including Canada, and where the capacity of national drug regulatory agencies varies significantly. Removing Health Canada's review of drugs exported under CAMR simply moves the drug assessment to lesser-resourced agencies in developing countries or to WHO, which itself depends on regulatory agencies such as Health Canada to do the reviews.

Health Canada, its regulatory counterparts, and organizations like WHO work collaboratively to build regulatory capacity in developing countries. For example, there are quite a number of international harmonization projects, which I've named here but will skip, which focus on the development of lesser-resourced regulatory agencies.

In 2009, Health Canada replaced numerous annual ad hoc visits from these agencies with an international regulatory forum aimed at providing training. The forum is being repeated in two sessions this year and it involves some 27 participating countries. One of them is taking place next week.

We have an HIV vaccine initiative, which is a collaboration between the Government of Canada and the Bill and Melinda Gates Foundation, that is aimed at advancing the science of HIV vaccines and the prevention of mother-to-child transmission of HIV. An element of this collaboration, again, is aimed at capacity-building in the area of vaccines.

Most importantly, Health Canada works with WHO's pre-qualified program, which is actually mentioned in the bill. It aims to ensure that medicines and vaccines for high-burden diseases meet the global standards for safety, efficacy, and quality. The pre-qualified list is used by UN procurement agencies as well as by developing countries when making procurement purchases. Health Canada and many other countries undertake product reviews for this program, and it's because of this work that Apo-TriAvir was added to the pre-qualified list on the basis of Health Canada's product review.

In summary, Canada is committed to increasing access to high-quality medicines and health care in developing countries. Health Canada's role in CAMR is one aspect of this commitment, and so is Health Canada's contribution to building capacity in lesser-resourced regulatory authorities.

● (1130)

Ms. Colette Downie: Thanks, Brigitte.

In conclusion, CAMR addresses only one small part of the problem of global access to medicine, and that's to make generic versions or copies of patented medicines available under certain tight conditions, as I explained.

[*Translation*]

The proposed changes will not resolve other global problems associated with access to drugs. These include the delivery of health care and disease prevention in developing countries. Without solutions to these other key problems, it is possible that the health-related problems of many countries will not be resolved.

[*English*]

For these same reasons, it's unlikely to result in more countries demanding to use CAMR. There are already many publicly available mechanisms to procure low-cost off-patent drugs to treat public health diseases in the developing world, and it's unlikely that developing countries will use CAMR when less expensive sources of generic medicines exist.

Changing CAMR won't lower drug supply and labour costs in Canada, and it can't, by itself, make medicines manufactured here more competitive with those made in, say, India or China. This has been acknowledged by the CGPA, the Canadian Generic Pharmaceutical Association, during the CAMR review. Some of the witnesses, from whom you may be hearing and who appeared before the Senate committee on Bill S-232, also pointed that out.

Canada has the only access to medicines regime in the world that works.

[*Translation*]

In the case of Rwanda and Apotex, this objective was reached because of the regime which made it possible to ship over 14 million doses of an AIDS-fighting drug to Africa. For now, we are concerned that the proposed changes could adversely affect the way in which CAMR works, without providing sufficient performance guarantees and in the process weakening Canada's patented medicines regime and making our investment climate less attractive.

● (1135)

[*English*]

I'll end there.

I'll simply point out a couple of things. There is an annex to the deck presentation we gave you that, hopefully, gives you some useful background on CAMR, and there's a chart that explains how it works, on slide 10, the process, which I hope is simple.

We've also provided the committee with a copy of the timeline of the events that led up to the shipment of medicines to Rwanda, which I hope you all have. It's a fairly long piece of paper. It shows you in black the different events that happened on the timeline and in red the parts that relate to the access to medicines regime itself.

With that, we'd be very happy to answer your questions.

The Chair: Thank you very much, Madam Downie.

Does everybody have those documents? I noticed a couple of members didn't. I'm certain the clerk will be glad to get you more if you need them.

We'll go to our regular rounds of questioning, with seven minutes for this round.

Mr. Garneau, for seven minutes.

Mr. Marc Garneau (Westmount—Ville-Marie, Lib.): Thank you, Mr. Chair.

If I had one word to describe my personal experience with Bill C-393, it would be the word “agonizing”. Let me define what I mean here, because it's not often a politician will talk about an experience as being agonizing. It's agonizing in the sense that I believe so much in the high-level objective of CAMR, which is to provide much needed medicine to people who are in need of it, and I've been solicited by a huge number of people who feel passionately about it. At the same time, I have not been convinced that this particular bill will solve that problem. Your testimony today generally supports my thinking, in the sense that you have pointed out what it can do and what it can't do and what it risks causing in terms of problems and other realities.

I want to start with something you said, Ms. Downie, at the very beginning. It is that the biggest problem is the result of poverty; it's not the result of a problem with our patent law. I'd like to ask you, perhaps, to expand a little bit more on that statement.

Ms. Colette Downie: I think my colleagues from CIDA would be the best people to talk about what the situation is like on the ground and in reality.

Mr. Marc Garneau: Very good.

Ms. Louise Clément: When it comes to improving the delivery of health services to developing countries where poverty is very prevalent, it is a very complex issue that involves a number of challenges, including, for example, not having access to health care. There are countries where people have to walk several miles to be able to have access to basic health services. That's one problem. Another problem is lack of predictable resources to be able to put in place a solid health plan in the country. Another problem, of course, is access to medicine. There are others. There are issues related to the capacity of the government.

What Canada is doing, as I mentioned earlier, is dealing with key partners who have experience, working with them in collaboration in order to take a holistic approach to support improved health in developing countries. I've mentioned a few examples: the Muskoka initiative, the Global Fund, the GAVI Alliance. There are others.

Maybe another example that I can provide is the Africa health systems initiative, an initiative that was announced in 2006 by the Prime Minister. It involves $450 million over 10 years, directed to Africa, and the objective is to build health systems in Africa. Specifically, it has three dimensions. One is to increase the number of health workers. That's a key problem. The other is to improve access to ensure that there are health services provided to people in the most difficult areas in the country. The third element is to build health information systems for better planning and better delivery of health systems.

It is a very complex issue that involves a partnership of many global players—Canada and many donors—as well as increased coordination with the partner countries with which we work. Essentially what we're trying to do is to build the capacity of our partner countries to be able, in the long term, to deliver their health services on their own.

I hope that answers the question.

● (1140)

Mr. Marc Garneau: Yes. Indeed, it is a complex problem, there's no question about it.

Reference was made to the fact that some of the countries in Africa are getting their medicines from other, cheaper sources, and it's in many ways a challenge for Canada, because of labour costs and other things, to actually undercut those prices.

Another issue related to it is the consequence of our reputation with respect to our IP regime. I think that is something we can't overlook. I've read some of the testimony from S-232, the Senate bill, that's very similar to C-393.

One of the witnesses was Richard Dearden. He was representing Gowling Lafleur Henderson. He went so far as to say:

> First, Bill S-232's one-licence regime is not authorized by flexibilities that are found in the TRIPS Agreement. Second, TRIPS Article 30's limited exceptions provision does not authorize Canada to abrogate its compulsory licence obligations.

I won't go on. I know that's not agreed to by those who feel that TRIPS is not violated, but I would like to hear from you, sir, from Foreign Affairs, on your interpretation of whether or not that is the case, that we are in danger of violating our TRIPS agreement with respect to C-393.

Mr. Robert Ready: Chairman, thank you.

With respect to the issue of the relationship between amendments to CAMR and WTO obligations, the first thing I need to say is that of course it's only at the conclusion of a dispute settlement process in the WTO that you know with any complete certainty that there's been a violation found. Up until that point, it's a series of allegations, arguments, and interpretations.

Certainly the policy analysis that has been done in the Department of Foreign Affairs and International Trade on this issue suggests that to the extent that the CAMR is amended in such a way as to no longer reflect or implement the terms of what is a waiver from TRIPS obligations, the risk increases that we'll be off-side of those TRIPS obligations. I think that's the best answer I can give you at this point.

The Chair: Thank you, Mr. Ready. And thank you, Mr. Garneau. That was a few seconds over.

[*Translation*]

Mr. Malo, you have the floor for seven minutes.

Mr. Luc Malo (Verchères—Les Patriotes, BQ): Thank you very much, Mr. Chair.

Like Ms. Wasylycia-Leis, I am also my party's health critic. Basically, she expressed what we are all feeling. Since the regime was first implemented, only one drug has been shipped overseas for humanitarian purposes. In an effort to resolve this issue, she tabled Bill C-393. However, you have looked at the proposed legislation and you indicated to us during your opening remarks that this option presents a number of risks, as we feel it does. In fact, you do not believe that the solution she is advocating is the right one.

As we consider Bill C-393, Mr. Chair, we also need to ask ourselves why a number of NGOs believe the regime is not working. We need to look at whether the regime can be made more flexible. That's why we came up with a list of about twenty potential witnesses, to help us conduct a more in-depth study and look beyond Bill C-393. I hope committee members will agree to this proposal, Mr. Chair. I really think that we need to take a closer look at this regime and ask the questions that need to be asked. It has been in place for some time now and the only example that applies is the case of Rwanda and Apotex.

Ms. Downie, you stated in your closing remarks that the regime is working. Several NGOs would disagree with your assessment and would argue that only one drug has been exported as a result of the CAMR mechanism. So then, how can you claim the regime is working?

● (1145)

[*English*]

Ms. Colette Downie: To answer your question, the regime does what it can do. We do have a regime, the only one of the others in the world that has actually resulted in a shipment.

The reason there haven't been more shipments is not because of the structure of our patent regime and CAMR; it's because of all of the other problems and issues my colleagues have mentioned that make it very, very difficult to get medicines to the developing world.

It's not to say—and I hope I didn't leave you with that impression—that the one shipment is the only shipment of patented medicines, or copies of medicines, that has been sent to the developing world. There are lots of other mechanisms by which they're getting there.

Clearly there will be concern by some of the witnesses you'll probably hear from that more needs to be done. But the solution is not to open up the CAMR regime. That by itself won't result in any more shipments.

[*Translation*]

Mr. Luc Malo: Are there other options that we could be exploring? In your concluding remarks, you stated that CAMR is only one of the tools that Canada uses. Are there other lesser known tools? NGOs maintain that the regime isn't working. This morning, I'd like us to try and answer the question as to why the regime is failing. You made it clear in your closing remarks that Bill C-393 will not result in more applications being filed under CAMR. Could we be exploring other options?

[*English*]

Ms. Colette Downie: Canada does do some outreach to make it clear what the regime does, and maybe Rob could expand on that a little.

I think, though, when Canadian manufacturers face competition, when developing countries can get cheaper medicines from other countries such as China and India.... They may be aware of CAMR and a mechanism by which to get them from Canada, but they would have no reason to use it when they can get cheaper medicines from elsewhere.

[*Translation*]

Mr. Luc Malo: So then, there are other examples internationally that we could be looking at and evaluating?

[*English*]

Ms. Colette Downie: Other access to medicines regimes?

[*Translation*]

Mr. Luc Malo: For instance, yes.

[*English*]

Ms. Colette Downie: There are regimes that have different characteristics in Canada. Some of them are laxer or less specific in some areas, but none of those has actually resulted in a shipment of drugs under those regimes. I don't think the solution lies there, because if there was a solution, we would have seen those regimes used.

[*Translation*]

Mr. Luc Malo: So, we shouldn't be looking at this regime as the ultimate solution to increasing our humanitarian aid efforts to provide access to medicines, or to addressing disease prevention and health care issues.

● (1150)

Ms. Colette Downie: That's correct.

Mr. Luc Malo: What other solutions would you suggest?That's more or less the question I put to you earlier.

[*English*]

Ms. Colette Downie: Okay.

[*Translation*]

Ms. Louise Clément: Thank you for your question.

I think I listed a few examples in my opening statement. The Government of Canada is involved through CIDA in a wide range of initiatives designed to support health and access to medicines in developing countries. Among others, I mentioned the Africa Health Systems Initiative, the Global Fund to Fight AIDS, TB and Malaria and the GAVI Alliance. These are just a few examples.

CIDA works closely with a great many partners on an international level, including developing countries, to improve health. You are correct in saying that this enormous challenge requires a great effort not only on Canada's part, but on the part of the international community. The leading role taken by Canada at the last summit with respect to the maternal, newborn and child health initiative is another example of efforts in this area.

Perhaps my colleague would like to cite a few more examples.

[*English*]

The Chair: Thank you, Madam Clément.

Any additional comments will have to wait. We're well over the time.

[*Translation*]

Thank you very much, Mr. Malo.

[*English*]

Now on to Mr. Lake for seven minutes.

Mr. Mike Lake: Thank you, Mr. Chair.

I thank the witnesses for coming before us today and laying out such a good presentation at the beginning. It's very informative. I listened to my colleague, Mr. Garneau, and he used the word “agonizing”. I thought it a very appropriate word. Those of us on this side of the table would share that we've all been visited by many people advocating on behalf of the people of Africa for help with some very serious issues they have, with regard to not only health but all sorts of things.

You mentioned poverty and all the challenges. Many of us are very aware there's been lots of discussion, with the G-8 and G-20 having been here. Of course, this isn't a left-right issue or a party issue. This is something we all want to try to find an answer to. I'm glad we're having an opportunity to talk about this.

One of the things I think I'm hearing over and over again, a common theme in terms of the discussion, is the theme of potential unintended consequences with the legislation. No one is denying that the legislation is well-intentioned. It sounds as though there are significant concerns with unintended consequences. Could you speak to some of those unintended consequences? Specifically, the first thing that comes to mind is the anti-diversion measures proposed. That would be a good starting point.

Ms. Colette Downie: I'll just try to go over some of those quickly because there are probably a number. Mostly, though, what they stem from is that ultimately the changes in the bill would expand what is now fairly limited, and limited in design, around getting medicines to developing countries that need them for humanitarian purposes or on certain emergencies. It would broaden that to allow for shipments without any limit in quantity, without any of the markings and other requirements that are currently in CAMR that would allow for the identification of medicines if they happened to come back into Canada accidentally or deliberately.

What you could end up seeing is products diverted either to other countries for commercial reasons, countries like Mexico or Hungary or Poland, or Singapore, where really they're not needed for humanitarian reasons, so for commercial reasons, or you could see the medicines potentially coming back to Canada as well and being indistinguishable from Canadian medicines.

By making the Health Canada review optional, you could also see medicines that haven't been through Health Canada's safety review shipped to other countries, to developing countries, without the same kind of rigorous health and safety regime that Canadians benefit from.

● (1155)

Mr. Mike Lake: It's interesting. Taking the combination of the two issues you're talking about, you could hypothetically see a situation where a drug that hasn't met Canadian requirements for testing actually comes back to Canada as well, right?

Ms. Colette Downie: That's right.

Brigitte.

Ms. Brigitte Zirger: Yes, that's right. It would be possible, and certainly with the fact that the distinguishing features are verified by Health Canada through the submission review, we know what they are. We know that they're there and we've already designated what those markings are. When they leave, we know they are on there.

Mr. Mike Lake: There is lots of reference to the fact that only one approval has been given, or one drug has actually made it to Africa under the regime. I understand that Canada is the only one that has done it under these World Trade Organization agreements. But there are other drugs making their way to Africa to solve this problem. They're just not happening under this regime. Is that correct? Can you speak to that a little bit in terms of how other drugs are getting to Africa from other countries that might not be part of this?

Ms. Christine Reissmann (Director, AIDS, TB Programming and Health Institutions, Multilateral and Global Programs Branch, Canadian International Development Agency): Yes, I'd be happy to answer that question.

My colleague already provided some indication of the kinds of multilateral partners we work with. The Global Fund, which is a large multilateral fund to which Canada has just recently provided a large contribution again, spends approximately 45% of its considerable resources on bulk procurement, at good prices, of high-quality drugs.

Another example that we haven't talked much about yet is the Global Drug Facility, of which Canada was an originating partner, and since 2001 Canada has provided over $130 million to what is effectively a bulk procurement system for quality TB drugs.

Those are two good examples. There are many more like that.

Mr. Mike Lake: There are so many different questions that I have, but I am going to switch over to the trade side of things for a second.

It strikes me that in leading to these agreements there was a really high intensity of negotiations and literally probably hundreds of people working from several countries around the world on coming to these agreements in the first place in a way that honours international trade rules of law and things like that. Maybe speak to the intensity of negotiations to get to the point where we could actually have a CAMR.

Mr. Robert Ready: Thanks, Chairman.

I wasn't a participant in those negotiations, but I am aware that they were very intensive. They involved a wide range of the WTO membership and, at the end of the day, resulted in a consensus decision at the WTO, which, as somebody who has been involved in the Doha Round, I can tell you is pretty rare and means that the balance has really been finely struck and people's interests have been protected, respected, but there has been a balance. There was not only a willingness to make progress but a willingness to make sure that the spectrum of issues, ranging from access to medicines but also to protection of intellectual property, was clearly protected all around.

The Chair: Thank you, Mr. Ready.

Mr. Lake, sorry, your time has expired.

Mr. Masse is next for seven minutes.

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

This is a critical issue. I find it interesting that in the conclusions it says that Bill C-393 would not overcome the systemic issues of health care delivery and disease prevention in the developing world.

That's almost an absurd statement. I don't know of any organization, group, or interested party that has ever made that claim. Nobody here is saying that this will be the one single solution to human suffering. At the same time, we have a bill that Parliament passed that has only been triggered once. I suppose we have a Parliament that likes to set up legislation that doesn't work or isn't used. We spent a lot of time and money on this, so there's a problem here.

Ms. Downie, you almost indicated that if this is changed, we're going to have all kinds of generic drugs flying out across the world and not be able to track them. But the reality is that the generic drugs must have different markings and different packaging. It has to be stated what country they're going to and the quantity.

What other mechanisms are necessary to protect? You would have a company publicly doing something fraudulent out there. What is the real risk? I don't understand, especially given the Rwanda situation, where we had one out there. What is the threat here? They're still going to be identified, the company still has to identify where they're going, and they're going to be tracked.

● (1200)

Ms. Colette Downie: Almost all of the requirements to identify where the goods are going and allow the identification and tracking of the goods would be eliminated from the bill. There would be the remaining requirement to post some information on a website. On top of that, enforcement mechanisms in CAMR now would allow if drugs were diverted back to Canada or sent to countries besides countries in the developing world.

There would be no mechanisms by either the government or the Commissioner of Patents to withdraw the licence, challenge it, or say we think these are being used for commercial purposes. The patent holder might not even be aware, in some instances, of what was going where. If they did become aware, there would be no mechanism for them to apply to the Federal Court to say, “These are actually being used for commercial reasons, not humanitarian reasons.”

Mr. Brian Masse: My understanding—and we'll seek clarification to make sure—is that markings would not be removed and there still would be an identification process.

Ms. Colette Downie: Maybe I can clarify that.

Mr. Brian Masse: I don't know whether a mistake has been made here, but those are interpretations we've had in the submissions we've made. We'll seek clarification on that, because it's a critical component. We wouldn't want to have drugs not identifiable. I think it's an important piece of evidence that needs to be examined here, because there's no intent to try to have less accountability about where these drugs are going.

I would like to turn my attention to the WTO, TRIPS, and Doha.

Mr. Ready, do you believe this CAMR bill goes as far as what was permitted in those organizations in those decisions, or is it less...in what's permitted?

Mr. Robert Ready: I'm trying to understand the question with respect to “permitted”. I think the CAMR legislation in Canada seeks to implement the elements of the WTO declaration, and in doing so tracks the WTO declaration pretty closely.

Mr. Brian Masse: I guess what I'm getting at here is that this bill has limitations that aren't in the WTO, the Doha, and the TRIPS. I'll give an example. The two-year provision was never there. A list of drugs was never there. The language that's used in TRIPS and Doha is that they have availability without prejudice, other flexibilities are found in TRIPs, and limited exceptions are explicitly intended in that agreement.

I'd like your opinion on whether Canada, in adding those elements to this bill, is not more restrictive of what is available to us under TRIPS, Doha, and the WTO.

Mr. Robert Ready: Perhaps my colleagues would have an additional comment, but from my understanding of the situation, those elements add some administrative clarity to the users of this process as to the way in which it will be implemented. It's not an attempt to subvert WTO—

Mr. Brian Masse: We added lists, though, of drugs that were never contemplated for that, so I defer, I think, to many other experts out there who believe that Canada added a series of components that were hurdles, or more restrictive than what's permitted.

If I may, I would like to move to a comment—this has always been out there—that if we change the legislation of CAMR and it creates an environment where there will be less scientific research and development.... What evidence do you have to back up that statement? Have Rx&D said, for example, if CAMR is used 10 times over 10 years, they're going to invest less than Canada? Has there been any scientific research done to show that this bill is going to undermine Canadian pharmaceutical industries?

● (1205)

Ms. Colette Downie: No, there is no scientific research to back that up, simply a concern that that would happen. We haven't been told by Rx&D that that's definitely what would happen. You'd have to see what would happen with the changes in the bill to know that that would be the result, though there is economic evidence, and certainly pharmaceutical companies and other patent holders make it really clear that their investment in developing products is really contingent on having strong patent protections.

Mr. Brian Masse: Can you provide that economic evidence to us at this committee? Maybe not today, but if you could present that to us at a future date, that would be appreciated.

Ms. Colette Downie: Yes, and it's not going to relate directly to the development of medicines. It's general economic evidence and studies about the importance of patents to innovation.

Mr. Brian Masse: I really find it hard to believe that Rx&D would say, for example...because the Rwanda agreement—

The Chair: Mr. Masse, sorry, you're well over time.

Mr. Brian Masse: I realize, yes. It's restricted.

I can get it in the next round. Thank you, Mr. Chairman.

The Chair: You can get it in the next round, absolutely.

That concludes our first round. Now we're going to our second round, which is a five-minute round, and on to Mr. McTeague for the Liberal Party.

Hon. Dan McTeague: Thank you for being here.

I bear a bit of an explanation to preface my question.

In 1999 I spoke to the Prime Minister and to our caucus about the need to provide access...given the growing problem in sub-Saharan Africa with respect to the proliferation of AIDS and other attendant diseases such as malaria. It was felt at the time that this was the best approach Canada could take, given its very robust international presence in aiding other nations. It's one I'm very proud of. It's also one of the reasons I think our party is very, very strong, the Liberal Party, on the question of helping Africa where we can.

I know that despite the best intentions.... I've served a bit of time in Foreign Affairs, and I've served well over a decade consecutively on this committee, so I'm painfully familiar with the best attempts by this committee and parliamentarians to do the right thing, but frankly, it has fallen short.

It would appear to me that none of you have been able to bring this together in terms of dealing with the fact that this current arrangement as it stands isn't user-friendly. The process by which negotiations took place to allow a contract to provide, through a generic, as an example, to a particular country is complex, is cumbersome, and it is mired in legalistic and nevertheless important considerations. I'm wondering, among the three departments here, Health, Industry, and in particular Foreign Affairs, where the objective was set, why was there no attempt, in your view, to actually coordinate to ensure that the process could be streamlined in such a way that, for instance, the Canadian government itself would undertake to serve as the contractor to designate to a particular nation AIDS antiretroviral drugs, etc., which was really the intention of the legislation?

Ms. Colette Downie: I'll look to my colleagues to answer.

I'll simply say that I don't think the legislation was intended to allow the Government of Canada to contract itself. It's really aimed at manufacturers having the ability to—

Hon. Dan McTeague: No, I understand that. I'm simply wondering, given the difficulty, obviously, of the host countries having to go through hurdles with respect to the UN tender, recognizing the in-depth, prolix nature of the 65-page documents that I think some of the companies have had to acquire.... If we're looking at the only example we have, of Rwanda, three separate companies providing three separate drugs, all combined together, how it is that the Canadian government itself, or between yourselves at the departmental level, didn't see red flags going up to suggest that there ought to be better coordination? Because this is not going to work. The intent that Parliament had simply isn't user-friendly. It has not had the desired results.

Why has there been no interdepartmental discussion as to how to fix this problem?

● (1210)

Ms. Colette Downie: Do you want to talk about the first part of the question?

Hon. Dan McTeague: Has that discussion taken place?

Mr. Robert Ready: Mr. Chairman, the comment from me won't be particularly satisfactory. I'm just not in a position to respond to the honourable member on that point.

Hon. Dan McTeague: Let me go specifically to the question. None of you have talked about the UN tender process, that a host country doesn't have really the public service infrastructure.

[*Translation*]

Ms. Clément, I don't believe you addressed one important issue, namely the possibility that patents will be eliminated or used for unintended purposes. I haven't heard your agency comment on an issue that affects everyone, for example, on what to do in the case of a country like Botswana that doesn't have the capacity to procure.

[*English*]

It cannot respond to the UN tender process itself. Why is this not a concern of your department?

Ms. Louise Clément: The capacity of African governments to procure—and there are issues of capacity when it comes to the procurement in developing countries. CIDA is involved in partnership with some of its multilateral initiatives, such as the Global Fund, as well as through its bilateral programming, where it provides support to governments to help them build that capacity. It's an issue that's being dealt with.

Hon. Dan McTeague: Can you supply information specific to countries that have a concern, where there is a substantial presence of AIDS, where Canada has in fact helped the civil service, the public service, to have the capacity to respond, to build, and to formulate the UN tender? That's a rather rigorous request. Do you have examples of where Canada has in fact helped countries streamline the paperwork, as it were?

The Chair: Very briefly, Madam Clément.

Ms. Louise Clément: I don't have an example here with me.

I don't know if you have an example with respect to the Global Fund.

I know that's one of its main components, to build the capacity with respect to access to medicine.

The Chair: Are you asking for them to tender some documents?

Hon. Dan McTeague: If you wouldn't mind. I would like to see this, because it seems to me that a lot of the countries, which have not been mentioned here, have not been able to make the request because of the cumbersome nature of the paperwork and the rather in-depth UN tendering process.

Ms. Brigitte Zirger: There are two tendering processes. The UN procurement agencies will go through their own tender process. They look to the pre-qualified list, but in the countries themselves... Rwanda, for example, had a law where any procurement would be done by tender. So you're talking about the UN—

Hon. Dan McTeague: I'm referring to Rwanda—

The Chair: To be fair, I need to move on to the next member, but there is a request for documents, of who is participating through the Global Fund to build capacity.

Now we're on to the Conservative Party.

Mr. Braid, for five minutes.

Mr. Peter Braid (Kitchener—Waterloo, CPC): Thank you very much, Mr. Chair.

Thank you to all of the witnesses for being here this morning.

I certainly appreciate the discussion, and we all certainly share the goal of wanting to address this very serious issue of HIV/AIDS and the very tragic consequences that we see of the disease, particularly on the continent of Africa. We all want to find more effective ways for Canada to address and to respond to that issue.

I'm presuming my questions might be best directed to you, Ms. Downie. I'd like to understand the 2007 example just a bit more. Are you perhaps the person who is most familiar with—

Ms. Colette Downie: Probably between Mr. Ready and I, we can kind of walk through the timing and the process.

Mr. Peter Braid: I'm going to try to go as quickly as I can.

Apo-TriAvir, obviously, was a generic of...who owns the brand name equivalent?

Ms. Colette Downie: There were actually three patents involved.

Mr. Peter Braid: And how far along were those brand name patents within the 20-year patent protection?

Ms. Colette Downie: That I'm not actually sure of. I don't know whether my colleagues who are with me are aware or not, but I can certainly let you know.

Mr. Peter Braid: Apo-TriAvir was manufactured by Apotex.

Ms. Colette Downie: That's right.

Mr. Peter Braid: Had Apotex had that drug in its production, or did it receive the licence to produce it and then quickly turn it around? Is that what happened?

Ms. Colette Downie: I'm not actually aware of that.

Do you know?

● (1215)

Ms. Brigitte Zirger: That particular triple therapy was at the request of Médecins Sans Frontières. They had discussed it with Apotex, to produce it; it didn't exist, and it doesn't exist in the brand version either, because the two products are the property of one company and the third is another company's. So we don't even have the triple therapy in the Canadian market as a combined therapy.

Mr. Peter Braid: That's interesting.

We've heard that one of the reasons that CAMR has only been used once and that developing countries aren't coming to Canada to purchase more generic medications is that they can find them in other jurisdictions—like India and China—more cost effectively. So what circumstances existed in 2007 to allow this example to be cost effective?

Ms. Colette Downie: I believe that in this case there was a subsidy by the Clinton Foundation of the product that was being produced by Apotex, which made it cost effective.

Mr. Peter Braid: Thank you.

In the presentation—I forget who mentioned this—we saw reference to the fact that 95% of drugs are off patent. What percentage of HIV/AIDS medications are off patent? Are there any?

Ms. Brigitte Zirger: Some...[*Inaudible—Editor*]

Mr. Peter Braid: Okay. Thank you.

Mr. Ready, turning to you, sir, with respect to the trade obligations, you mentioned that Bill C-393 could violate the terms of TRIPS and WTO. I just want to push back a little bit on that. When I read the word "could", I read "may or may not", so I just wanted to ask what the probability is of Bill C-393 violating trade obligations. What does that look like? Can you give an example? What would the consequences be?

Mr. Robert Ready: It's very difficult to speak of a probability, as I said. The only sure thing, the only time you really know, is when there's been a panel decision against Canada. Up to then, it's a question of risk and assessing risk.

As I said earlier, we've looked at the proposed amendments that would eliminate elements such as the capture WTO notifications, and at the information that wouldn't necessarily be provided, such as recipient country, the drug amounts, the delivery dates, and so on. Those are elements that draw inspiration from the WTO waiver, which in turn is what protects you from the obligations in the TRIPS agreement. So the argument is that if you're not fully respecting the waiver, you could be in violation of elements of the TRIPS agreement itself, and that's a risk. I can't characterize the risk beyond that.

Mr. Peter Braid: Okay. There's a $60,000 question for me, then. If we understand that Bill C-393 has flaws and CAMR has limitations, then the question is, how can Canada provide an increased quantity of HIV/AIDS medications to the developing world?

Ms. Colette Downie: I think the answer is really the answer that my colleagues from CIDA have been giving. It's really to participate in and contribute to a number of high-priority initiatives that Canada participates in—

The Chair: That will have to be the conclusion of that answer.

Thank you very much.

[*Translation*]

Mr. Bouchard, you have the floor for five minutes.

Mr. Robert Bouchard (Chicoutimi—Le Fjord, BQ): Thank you, Mr. Chair.

Thank you also to our witnesses for joining us today.

We have seen one case where generic drugs were shipped to a country. Based on this experience, can we conclude that this country had the necessary infrastructures in place to ensure that the sick received the drugs?

Ms. Louise Clément: We'll have to get back to you with an answer, since we do not have that information handy at this time.

Mr. Robert Bouchard: We've only had one experience involving this particular country. Is that right?

● (1220)

Ms. Louise Clément: Of exporting medicines under CAMR?

Mr. Robert Bouchard: Yes.

Ms. Louise Clément: Medicines were shipped using the regime to only one country.

Mr. Robert Bouchard: Is CAMR a one-of-a-kind regime? Is Canada the only country to have a regime of this nature in place? If not, if other countries have similar regimes, can you tell us a bit about them?

[*English*]

Ms. Colette Downie: A number of other countries besides Canada have access to medicines regimes: countries of the European Union, including the Netherlands, as well as Switzerland, Norway, India, Hong Kong, Korea, Singapore, and the Philippines. They all differ in many ways.

Perhaps it would be most useful if I provided that information to the committee. I could walk you through it, but it's actually quite complex. For example, there are different requirements and different ways of setting out the quantities exported. There are different approaches to product labelling and diversion as well, depending on the country. The types of products that are eligible are different as well. There are different requirements for importers. There are some differences in notification depending on the system they set up. The duration and the enforcement mechanisms are all different in different ways, though they are all meant to be in line with the WTO waiver.

[*Translation*]

Mr. Robert Bouchard: You say that a number of other countries have access to medicines regimes. Can you tell as a bit about some regimes that have proven successful?

[*English*]

Ms. Colette Downie: Canada is the only country of the ones I listed that has actually successfully seen medicines shipped using the regime. There are no other examples.

[*Translation*]

Mr. Robert Bouchard: Thank you.

My next question is directed more to industry officials. Negotiations took place between the pharmaceutical companies that produce patented medicines and those that manufacture generic drugs. How did these negotiations go? Was the process easy or difficult?

[*English*]

Ms. Colette Downie: I can tell you a little bit about that, although I think the best people to answer the question would be the companies that were involved in the negotiation. There were, I gather, some lengthy negotiations, though they were not required under CAMR. So at the time they didn't relate to the actual requirements of the regime.

The regime requires that when, say, Apotex notifies the company that holds the patent, it has to say it would like to do this voluntarily and ask if the company would agree to a voluntary licence. The owner of the patent has 30 days within which to reply. If they don't reply within 30 days, then Apotex or the generic company can go on to the compulsory regime. So there is a time limitation on that negotiation. And there might be no negotiation in that period. Once the 30 days runs out, you're on to the next steps in the process.

In the example of Rwanda, there were extensive negotiations, but they didn't relate to the timing that's built into the bill, which is really meant to limit that period and allow the generic company to move on to the next stage.

[*Translation*]

The Chair: Thank you, Ms. Downie.

[*English*]

Monsieur Bouchard, your time has expired totally.

Now we move on to Mr. Wallace for five minutes.

Mr. Mike Wallace: Thank you, Mr. Chair.

I want to thank our guests this morning. The presentations have been excellent. We hear the other side of the story in our offices and so on, so it's nice to hear from those who are involved directly in representing the government on the other side of the story. I appreciate that.

I would like a couple of clarifications, just for the record. AIDS drugs are being provided by other countries around the world at a lower cost than Apotex was providing them at, or maybe they won that. But it's not as though there are no drugs at all from other countries around the world going to Africa. Is that correct? And who are their main suppliers? What countries are the main suppliers?

● (1225)

Ms. Brigitte Zirger: Approximately 80% to 85% of the ARVs supplied to the developing countries are being supplied by India.

Mr. Mike Wallace: By India. I appreciate that, just for clarification.

I have five points in front of me that are from the grandmothers organization, which I'm sure you are aware of. They are concerned with CAMR and its effectiveness. I'm going to say what they state and maybe you can respond for me:

> CAMR, originally adopted for humanitarian reasons, does not work in its current state.

They are claiming this access to medicines regime does not work.

Based on your submissions today, including the submission that shows it took 13, maybe 14, months from the beginning to the end within the CAMR regime, would you agree with them that it's CAMR's issue, or would you say other issues are causing the difficulty?

Ms. Colette Downie: We would say that CAMR is not the solution to the terrible problems the grandmothers have pointed out, and even if these changes were made to CAMR, they wouldn't result in an increased shipment of these medicines.

Mr. Mike Wallace: Right. Following up on Mr. Braid's comments, Canada recognizes that and we are doing other things, which you have indicated, to make sure that from a drug perspective we are supporting Africa in general in these areas. Is that correct?

Ms. Louise Clément: Canada has a number of programs to support health in Africa. I've mentioned a few. Yes, that does include providing funding and helping to build the capacity to procure medication and to seek effective use of those medications.

Mr. Mike Wallace: The second point they'd like to make is that CAMR will save lives and that fixing it will save lives. We heard from Health Canada—which I didn't know—that there is a mandatory review of any drug that is shipped overseas now.

Ms. Brigitte Zirger: No. The mandatory review is if the Commissioner of Patents receives a request for a compulsory licence under CAMR. Then the Commissioner of Patents will turn to Health Canada and ask if it meets the requirements of the Food and Drugs Act. We will say yes or no. So those drugs will have had to have gone through a Health Canada review.

Mr. Mike Wallace: Okay. If this bill were to pass, is that still required or is that bypassed?

Ms. Brigitte Zirger: It's optional, and the Food and Drugs Act component of this bill is extremely confusing, but it is one option whereby they can choose whether or not they want a Health Canada review. Right at the moment it is mandatory.

Mr. Mike Wallace: The grandmothers also say, and I don't disagree with them, that sub-Saharan Africans are among those desperately in need of lifesaving, affordable medicines, which is a nice statement, but will the changes in this bill, in your view, make any significant difference in the ability of Third World countries in Africa to be able to either afford drugs or get them there?

Ms. Colette Downie: No, we don't believe it would make a difference, for the reasons we've explained.

Mr. Mike Wallace: We've had some discussion here on number 4. They have people who are claiming that it complies with the WTO and with the TRIPS issues, but based on the bill that is being presented, there are issues within the bill that give us cause for concern that it may not meet those requirements. Is that correct?

● (1230)

Mr. Robert Ready: That's the assessment of Foreign Affairs and International Trade, yes.

The Chair: On that confirmation, thank you very much, Mr. Ready.

Mr. Wallace, your time has expired. You are well over, actually.

Now we will move on to Mr. Masse for five minutes.

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

I'll provide this to the clerk to follow up. This is the *Journal of the International AIDS Society*. They studied the Indian experience with the supply of drugs into Africa. The conclusion is that it's now at risk in the pricing because of the WTO, TRIPS, and other movements they have made. I will table this for the committee, because the current status quo from India is not going to maintain itself and there are going to be rises in costs and prices.

One of the statements you make in your deck here is that Bill C-393 is unlikely to increase demand to use CAMR. Ironically, it is also a threat for Canada with the WTO and everything else. What evidence do you have of that? How do you square that with Apotex, which has said they would use the CAMR more if it were changed?

Ms. Colette Downie: The evidence we have that it wouldn't change is based on what we see and what we experience in the developing world.

Mr. Brian Masse: But your only customer taking advantage of this so far has said they would use it more if the legislation were more efficient.

Ms. Colette Downie: Right, but we have to stop to see what.... It could potentially be used for far more than sending drugs to the developing world; it could be used in a broad number of ways.

Mr. Brian Masse: So you are suggesting that Apotex has a motivation to use this for other purposes than to do simply more work in Rwanda, for example. Because of the way the legislation is written, when Rwanda found out later on that they needed more medications, they had to actually go back and re-apply; they can't get an extension for more treatments.

So are you suggesting that Apotex is going to try to use this legislation to do something different from what they have done?

Ms. Colette Downie: Not Apotex—no, of course not—but almost anyone can use this regime if it is broadened. It wouldn't necessarily have to be Apotex that would use it.

Why Apotex says it would use it more is I think really a question to ask Apotex.

Mr. Brian Masse: But you are suggesting in your deck that you are unlikely to increase demand for CAMR, but then you're saying that the threat is that all of a sudden we're going to have all these other applications by, I guess, other Canadian companies—we could name them all—and yet your only customer is saying that if it were fixed, they would actually use it more.

Ms. Colette Downie: Right. So it's not going to make a difference in the developing world—that is the point we're trying to make—because there are other reasons why medicines aren't going to get there.

Why Apotex says it would make a difference is not clear to me.

Mr. Brian Masse: I think it's a little bit conclusive to suggest that Canadian companies would then go on the lurk to try to rip off or undermine the system. Somebody has to do it; you are suggesting that somebody will do it and use the legislation for something unintended.

Ms. Colette Downie: I'm just concerned that it could be the case. I'm not pointing the finger at any particular company or saying that it would be the case.

Mr. Brian Masse: No, but you're drawing a conclusion that I think is not fair to the industry and I don't think is representative of the legislation.

I would like to point out another thing that you talked about, respecting the double standard about Health Canada. You've given the interpretation that you would basically have a double standard, such that drugs would go out to other countries without having the Canadian seal of approval. But at the same time, those countries could choose to use their own drug policy. All the bill does is allow a country that may, for example, use the USFDA or the European Union or the World Health Organization.... What's the problem with allowing that? You're suggesting a drug would be made in Canada that is not for sale to Canadian people but then goes through another screening process for another country.

Ms. Brigitte Zirger: I'd like to address that.

Under an exemption, we already export medicines as a country. There is an export exemption in there already. Health Canada doesn't review them. They are labelled for export only, and everybody knows that we have not reviewed them; we will not attest to the safety, efficacy, and quality.

What happens in that case is that the developing countries will require what is called a certificate of pharmaceutical product, a CPP. One of the questions on it is whether the product is marketed in the exporting country. Most developing countries are very suspicious of any products that are coming to them and being sold to developing countries that are not also on the other market. They ask why not.

We were able—

● (1235)

Mr. Brian Masse: But they would still have the choice.

Ms. Brigitte Zirger: They still have the choice.

As I indicated, the developing countries have regulatory organizations that are very varied in terms of their sophistication. Some smaller countries have no regulatory authority, some have two pharmacists, some have hundreds of pharmacists or a regulatory capacity. It really varies.

What we're saying is, here is a copy of a drug that is exported under a government compulsory licence, but it's for you to figure out whether or not it meets your needs. They are concentrating at the moment on quality of drugs coming to their country and not necessarily on safety and efficacy.

The Chair: Thank you, Madam Zirger.

Thank you, Mr. Masse.

Now we go on to Mr. Van Kesteren for five minutes.

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

Thank you for coming.

I, like Mr. McTeague, have been on this committee...not quite as long as he has, but I remember that we did a study in which we looked at this same issue.

Dan, was it in 2006?

Hon. Dan McTeague: Or was it 2005?

Mr. Dave Van Kesteren: But this was prior to the success we've seen with at least one drug coming to Africa.

I get a feeling, though—and I don't think it's just a feeling, but the elephant in the room—that it's rather like trying to give infrastructure to a country, saying “these people need trains”, and you send them a bunch of trains and there are no tracks. We're talking about all these things and we're asking the question, is it efficient? Are there things we can change? Would that change anything?

Some of you have stated in your opening statements that there are other serious problems. Before we administer these drugs, before we can bring them to market, before we can give the people that which they're in need of, there have to be some other things that line up.

I think we have to bring this home. There's no one here who doesn't look at Africa without our hearts just aching. I saw a program the other night on TV Ontario about the Congo. It's a different issue, but we all wish we could do something, that we could be more effective.

But I want to bring us home, and I'm going to give you the opportunity just to talk about what else is necessary. Before we can administer these drugs, what is the prerequisite for all of that?

Maybe you could elaborate on this.

Ms. Louise Clément: As I mentioned in my opening statement, providing health services and accessing the population is a complex issue. It's multifaceted, and yes, it requires a number of elements; medicine is one. It also involves being able to plan effectively for the medicine you need, having the health care workers to do the diagnosis and provide the treatment that is needed, having the facilities available so that the people can access health care. It means governments having the capacity to procure. It means having the financing to be able to plan your health system.

There are other elements; these are a few major elements. And as I've mentioned, CIDA and its partners have a number of programs that work to address this continuum, the whole of the health challenge. I've mentioned a few examples in my statement. I don't think it's worth repeating those examples.

Perhaps I can share some results. I have some information here; maybe that would be helpful.

Mr. Dave Van Kesteren: Please do.

Ms. Louise Clément: Through the Global Fund, for example, to which Canada announced an increased contribution recently, 2.8 million individuals living with HIV/AIDS currently receive treatment; 7 million people have received treatment for TB; and 142.4 million malaria drug treatments have been delivered.

Through the WHO “3 by 5” initiative, to which Canada contributes as well, we helped facilitate three million people receiving treatment for HIV by the end of 2007. Through the global polio eradication initiative, another one to which Canada contributes, they've succeeded in reducing the number of annual polio cases by 99%. Through the GAVI Alliance, between 2000 and 2001, immunization programs have averted an estimated 4.4 million deaths in developing countries.

I have one last one, the Global Drug Facility. This has supplied more than 60 million patients in 100 countries with TB treatment.

These are examples of areas in which the types of intervention that are supported are producing results.

● (1240)

Mr. Dave Van Kesteren: So we do have some good news stories, and the effort....

I see, Ms. Reissmann, that maybe you want to jump in as well.

There are some areas that we are being successful in. I think what I'm hearing from you is that we need to concentrate our efforts on those areas. Is that correct?

The Chair: Be brief, Ms. Reissmann.

Ms. Christine Reissmann: That's correct.

I wanted to add to my colleague's answer a few other issues related to your earlier question.

There are also issues or gaps in laboratory and diagnostic services. In some of these countries, people are misdiagnosed—quite badly misdiagnosed—for a long period of time while their real illness flourishes. Distribution and delivery networks are in some cases non-existent. Vaccines requiring a cold chain are not always there. In the end, you can have—and we have experienced—situations in which large shipments languish somewhere and expire and then create another problem of disposing of those products when they have expired.

The Chair: Thank you, Madam Reissmann. I'm sorry to interrupt. I am always at the mercy of the clock.

Now on to Mr. McTeague for five minutes.

Hon. Dan McTeague: I just want to follow up Mr. Van Kesteren's questions.

I thank you for those answers. It's my understanding that WHO is taking a rather different tack now and has begun the process of identifying children's AIDS as being a priority. If that's the case, and in terms of what you've given as far as therapeutic outcomes are concerned, what has Canada done to address that more recent priority, if you will, of the WHO?

Ms. Christine Reissmann: Canada has just recently committed an additional $30 million to the prevention of mother-to-child transmission of HIV as part of the Canadian HIV vaccine initiative. That is one example. We have other funding with various multilateral organizations, UNICEF and the WHO, whose considerable and significant treatment programs for mothers and children in the field we have also supported.

Hon. Dan McTeague: The vaccine of choice in this case would be produced by whom and under what regulatory regime? It would not necessarily be within Canada, but another country I presume would.... We'd be purchasing or contributing to a global fund, and one company that has the vaccine would then distribute at a particular rate.

Ms. Christine Reissmann: The HIV vaccine at this point, unhappily, doesn't yet exist. The initiative is about providing incentives to the development of such a vaccine.

Hon. Dan McTeague: Oh, okay.

Ms. Christine Reissmann: The prevention of the mother-to-child transmission component of that initiative was put in place. We insisted on it as a stop-gap measure while a vaccine was still under development, and we hope it will be soon, but we don't know how long that process will take. The infection rate is still approximately three million new infections every year, so CIDA felt it was important to put something in place to address the ongoing infections at the moment.

Hon. Dan McTeague: Could I just shift back to a piece of legislation that may have been a precursor to this or that happened at the same time, Bill S-232? The senator has now retired. I did speak to him at one point.

With reference to streamlining the applications process within CAMR, I wonder if the following has been considered by the departments involved, where one obtains a licence in order to renew that licence and they have to go through the same process. I think part of the legislation was to minimize that period of time and to have one licence for one particular product for one particular case.

Is that something that's been considered by the Department of Industry as being acceptable if we were to continue down the road of trying to gain momentum? As we all know, Apotex has made it very clear that it no longer intends to produce or supply under the current regime as it stands.

● (1245)

Ms. Colette Downie: Every time the government considers a bill, a private member's bill or otherwise, of course it goes back and looks again at the processes and the proposals to change them. I don't think I can go into the consideration, obviously, by cabinet of what might or might not be done. I will say, though, that one of the things about the Apotex example was that it actually did allow for multiple shipments, in that the authorization was for a total amount, a large amount, which was then shipped as individual shipments. So that is actually possible under the regime.

Hon. Dan McTeague: Am I correct in assuming that what was shipped over the period of time was two shipments, 17 million tablets targeting 22,000 patients over a three-year period? Does that jive with your...?

Ms. Colette Downie: I don't have those exact numbers. About 15,600,000 tablets were authorized. About that in total was sent. A first shipment of about 6.7 million tablets was sent, and then another 7.6 million.

Hon. Dan McTeague: Can anyone tell this committee if anyone had attempted to do any other country, such as the Congo and Botswana? There's a whole list of countries considered hot spots. Was there ever any approach to the Canadian government or to the use of CAMR other than Rwanda in the case of Apotex?

Ms. Colette Downie: I'm aware of that, but it's second-hand information and concerns some of Rob's predecessors. There have been lots of discussions in the past, I understand, of other possibilities. But again, it's second-hand information. These didn't come to fruition for various reasons, which I'm not actually aware of.

Hon. Dan McTeague: And I think we're here because of that.

Thank you, Chair.

Thank you, witnesses.

The Chair: Thank you, Mr. McTeague.

Actually, you were right on time, Ms. Downie.

Now, on to Mr. Lake for five minutes.

Mr. Mike Lake: Thanks, Mr. Chair.

A fairly quick round, hopefully. I'm interested in process, actually, as I've been listening. In terms of how a CAMR request is actually initiated, would it come from the country originally? It's the country itself, the receiving country, that would initiate a request. Is that how that works?

Ms. Colette Downie: Yes, it would be the country that would initiate the process.

Mr. Mike Lake: The process or whatever.

Ms. Colette Downie: Yes, although a manufacturer can also approach a country and say it's interested in providing medicines. There's a notification process, and then it's over to the supplier company to comply with the requirements in camera.

Mr. Mike Lake: So a company might work to educate countries on the process, but ultimately it's the country itself that has to actually initiate the ask, I guess, in a sense.

Ms. Colette Downie: It certainly has to notify, that's right.

Mr. Mike Lake: Has that happened? Have there been countries out there en masse requesting medications? Or is the problem, really, that there aren't countries actually even requesting medications under CAMR?

Ms. Colette Downie: My understanding is there's only been the one notification.

Mr. Mike Lake: And it was fulfilled.

Ms. Colette Downie: And it was fulfilled.

Mr. Mike Lake: Okay. That's very interesting to know.

In a sense, it might be or is the fact that countries who have identified the need are finding other sources, competitively, in a sense. They're going to India and finding that's a better option for them than the regime we have here.

Ms. Colette Downie: It's our understanding they are going directly, with the assistance of one of the international organizations, to get the medicines in other ways, when they can and when they have the infrastructure and the other mechanisms to do so themselves.

Mr. Mike Lake: So I'm not incorrect in understanding that...there are not countries out there making requests and then the “flaws” with CAMR are causing drugs not to be able to be delivered.

I know that was a very oddly worded question, I'm sorry.

● (1250)

Ms. Colette Downie: We're certainly not formally giving notice.

Mr. Mike Lake: Right. Okay.

In terms of the 45% of the Global Fund, I think you said, being spent on procurement of medication, in effect we're contributing money to this Global Fund, which is then being used to buy medication from India and China and wherever medication might be able to be produced at a lower cost.

Ms. Christine Reissmann: That's right. It's a tender process, and it also has to its benefit the bulk-buy aspects, so they can get a lot better price and insist on good quality. That's how the Global Fund actually does it, through a mechanism called the voluntary pooled procurement system, and it is actually quite highly encouraged by the Global Fund, particularly in countries where they are aware there's no infrastructure whatsoever.

Mr. Mike Lake: Okay. Are there some numbers? Can you quantify the amount of drugs that are actually getting to Africa through this process? I am not referring only to Canada's contribution, but maybe Canada's as well as the rest of the Global Fund's.

Ms. Christine Reissmann: I don't have the actual numbers of the drugs here per se. I mean, it's also bed nets. Well, maybe I do actually.

No, I don't, but I can give you a quantification in terms of the actual resources.

The Global Fund, until this week's replenishment, had at this point a $20 billion fund of resources over time. Doing the math, that's roughly $10 billion to date spent on drugs and nets.

Mr. Mike Lake: It's very, very significant.

Ms. Christine Reissmann: Yes.

Mr. Mike Lake: Can you provide for us the numbers actually having to do with the amount of drugs being supplied under that program? That would be helpful to the committee, if you could do that.

Ms. Christine Reissmann: Sure.

Mr. Mike Lake: I want to get back to a couple of different things.

I guess this is our last round of questioning. Maybe what I'll do, as opposed to trying to get into a whole new question with the short time I have left, is ask you if there is anything we haven't covered in our questions that would be of concern and you would want to highlight before the end of the meeting.

Ms. Colette Downie: I think we've covered everything we think is relevant.

Mr. Mike Lake: Okay. I think I'll pass, then, on the rest of my time. Or is that it?

The Chair: Actually, you have just eliminated your time now.

[*Translation*]

Mr. Malo, for five minutes.

Mr. Luc Malo: I'll use Mr. Lake's ten remaining seconds.

I'd like to try and summarize what was said about CAMR. It is my understanding that Canada's and other similar regimes around the world are patterned on WTO agreements, to guard against potential complaints. That explains your concerns about possible changes to CAMR.

We've learned that 85% of the medicines used to treat AIDS in Africa are exported from India. Mr. Masse also informed us that a certain number of complaints against India could be filed with the WTO. Earlier, you also told us that since the regime was first put in place, the global environment has changed.

Therefore, I'm wondering if within the context of WTO negotiations that have been ongoing for several years, issues tied to access by developing countries to cheaper medicines are broached in the same way as they have been discussed here this morning.

[*English*]

Mr. Robert Ready: Very quickly, there is an annual review of these provisions that takes place in the TRIPS committee at the WTO. There is another one coming up at the end of this month, where members will have an opportunity to discuss experiences with implementation, and so on. Canada will of course be participating in that review with other member states.

It continues to be a preoccupation in the international organizations in Geneva. There's cooperation between the WTO, the World Health Organization, and other organizations, to sponsor symposia, training sessions, and so on. I'm sure the researchers are aware of this, but there is information on the WTO website that links to the fair bit of work that's been done in that area.

● (1255)

[*Translation*]

Mr. Luc Malo: Do you feel that there is an awareness or realization that developing countries need access to cheaper drugs to deal with the AIDS pandemic? Do you feel that this is a genuine concern, that there is more to this than nice speeches and meetings, that this concern is shared by all parties involved in the negotiations?

[*English*]

Mr. Robert Ready: Again, quickly, I'm convinced it's an issue that is taken seriously by all members. I think it's fair to say that there is not a consensus that there's a problem in the WTO instrument itself that needs to be fixed to provide the solution. As we've heard, I think there are other impediments, other structural issues outside of the WTO system, that are perhaps more important.

[*Translation*]

Mr. Luc Malo: My final question is for Ms. Zirger from Health Canada. Unless I'm mistaken, before any new drug can be marketed in Canada, it must past product safety tests. Isn't that right?

Ms. Brigitte Zirger: A product must pass Health Canada tests before it can be marketed in Canada. Currently, medicines exported under CAMR must be tested.

Mr. Luc Malo: If medicines are manufactured in Canada and destined for export, they do not need to be safety tested, because they are not intended for the domestic market.

Ms. Brigitte Zirger: That is true for medicines that are not sold in Canada.

Mr. Luc Malo: If the drug is not going to be sold in this country, it doesn't need to be tested. Testing is done by the country to which the drug is being exported. Is that right?

[*English*]

Ms. Brigitte Zirger: There's an export exemption in the Food and Drugs Act that allows drugs manufactured in Canada to be exempt from the Food and Drugs Act if they are labelled for export only and they do not contravene the laws of the country to which they are consigned.

[*Translation*]

Mr. Luc Malo: In that case—

[*English*]

The Chair: Thank you, Madam Zirger.

I'm sorry, Monsieur Malo, it's way over time.

[*Translation*]

Mr. Luc Malo: I still have Mr. Lake's 10 seconds.

Voices: Oh, oh!

[*English*]

The Chair: You actually consumed that proper.

Mr. McTeague, you have the fumes of the meeting, so go ahead.

Hon. Dan McTeague: I'll be predicting the price tonight, so don't worry, we won't be running on fumes.

You had cited a number of countries that have so far been successful in getting drugs to Africa. I think you cited tuberculosis, antiretroviral drugs, as well as, if I'm not mistaken, malaria. Are these countries using a different process in order to address the pandemic, or is this something the committee here is not aware of?

Ms. Louise Clément: In terms of procurement processes, they vary from country to country.

Hon. Dan McTeague: Yes, I understand that.

Ms. Louise Clément: UNICEF, for example, provides vaccines to many countries. The Global Fund, which we've talked about before, offers procurement to a number of countries. In other countries they're building their own capacity to procure on their own using revenues from domestic tax from donors. They are doing it according to international standards. Given the fact that they're doing so with funds coming from the donor community, it's followed very closely, and of course competitiveness and international standards are very important. You have mechanisms, and I'm sorry to repeat the Global Fund again, but the Global Fund helps these countries build their capacities.

● (1300)

Hon. Dan McTeague: Can you help me with—

Ms. Louise Clément: There's a wide range of processes they can use.

Hon. Dan McTeague: Just give me an idea of what the Philippines might be provided. It seems a little unusual.

Ms. Louise Clément: I would be unable to provide you with this information right now. If you require that information, we would have to get back to you on what processes are used in the Philippines.

Hon. Dan McTeague: I'm not so much interested in the process as opposed to the actual therapeutic product they may be using, if this has been cited as an example. I can understand the European Union and others that ran vaccines through India, but I didn't know the Philippines was involved.

Thank you.

The Chair: I'll leave it open if you wish. That would be helpful to the committee.

Hon. Dan McTeague: Could you forward that information to the committee, then?

Ms. Louise Clément: To provide information on...?

Hon. Dan McTeague: To provide information as to what countries are providing what product to Africa as it relates to the AIDS pandemic.

Ms. Louise Clément: Yes.

Hon. Dan McTeague: Thank you.

The Chair: The time of the meeting has expired now. I know that our numbers have diminished.

Let me wish you all a very happy Thanksgiving time with your family.

Thank you very much to the witnesses. I apologize that we couldn't give you some concluding remarks, but we expired all of the time with questions.

Thanks again.

The meeting is adjourned.

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