Access to Medicines and Intellectual Property:

An International Expert Meeting on Canada's Access to Medicines Regime, Global Developments, and New Strategies for Improving Access

19–21 April 2007
Ottawa, Canada

MEETING REPORT

Acknowledgments

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This report and the presentations delivered at the meeting are available on-line via www.aidslaw.ca and www.nsi-ins.ca.

Ce document est également disponible en français.

Background

Under the *Agreement on Trade-Related Aspects of Intellectual Property Rights* (TRIPS), countries belonging to the World Trade Organization (WTO) must grant exclusive patent rights on medicine. However, they also retain the right to grant "compulsory licences" that legally authorize the production of lower-cost, generic versions of patented drugs in exchange for "adequate remuneration". Breaking the monopoly of patent-holders allows market competition, which brings down prices.

Many developing countries cannot afford patented, brand-name medicines and lack the industrial capacity to manufacture their own generic ones, meaning they rely on imported medicines. In 2001, under significant pressure from civil society, WTO Members unanimously adopted a *Declaration on the TRIPS Agreement and Public Health* (the "Doha Declaration"), in which they recognized that countries have the right to grant compulsory licences on the grounds that they see fit. But they also recognized that countries with insufficient manufacturing capacity to produce generic pharmaceuticals domestically face difficulty "in making effective use" of compulsory licensing, because TRIPS also states that products made under compulsory licences must be "predominantly for the supply of the domestic market." This restricts the use of compulsory licensing to export generic medicines from WTO Members to other countries, undermining the ability of countries lacking manufacturing capacity to secure lower-cost treatment for patients through compulsory licensing. On 30 August 2003, WTO Members unanimously adopted a Decision of the WTO General Council with an ostensible "solution" to this problem: a waiver of the restriction in TRIPS Article 31(f) to allow compulsory licensing in a WTO Member to produce generic pharmaceutical products for export to eligible countries in need.

In September 2003, Canada became the first country to announce it would implement the WTO 30 August 2003 Decision ("2003 WTO Decision") in domestic law. In May 2004, Canada's Parliament unanimously enacted the *Jean Chrétien Pledge to Africa*, legislation that amended the *Patent Act* and the *Food and Drugs Act* to implement the decision and create what is now described by the government as "Canada's Access to Medicines Regime" (CAMR). Canadian civil society organizations and generic manufacturers warned that, notwithstanding some improvements secured in the legislation during its drafting, a number of the remaining flaws could hinder its usefulness. They indicated they would support efforts to use the legislative regime to benefit developing countries, notwithstanding its limitations, but that they would also seek to have it reformed should it not prove workable. The legislation came into force in May 2005, but more than two years later, despite efforts by NGOs and Canada's largest generic pharmaceutical manufacturer, no generic medicines had yet been exported under CAMR.

The legislation that created CAMR requires that the federal Minister of Industry review the law within two years of its coming into force (i.e., by May 2007), and to report the results of that review to Parliament shortly thereafter. In August 2006, during the XVI International AIDS Conference in Toronto and in response to widespread public criticism of the failure to date of

CAMR to assist patients in developing countries, the federal Health Minister committed to reviewing the regime, and to making the necessary changes for it to work.[1]

In this context, and with a view to informing this review, the North-South Institute and the Canadian HIV/AIDS Legal Network jointly organized an international expert meeting to discuss Canada's Access to Medicines Regime, broader global developments related to intellectual property (IP) and access to medicines, and alternative approaches for addressing the global deficit in both research into the health needs of the world's poor and access by patients in the developing world to current or future medicines. The meeting took place from 19–21 April 2007 in Ottawa, Canada.

The agenda for the meeting and a list of participants are appended to this report of the deliberations, as is a list of background materials shared with participants in advance of the consultation.

[1] Isabel Teotonio, "Clement vows to get cheap drugs flowing", *Toronto Star*, 16 August 2006: A1.

Thursday, 19 April 2007

Welcome and introductions

Joanne Csete, Executive Director of the Canadian HIV/AIDS Legal Network, and Roy Culpeper, President of the North-South Institute welcomed participants on behalf of the co-hosting organizations. John Foster, Principal Researcher (Civil Society/NGOs) with The North-South Institute, and Richard Elliott, Deputy Director of the Canadian HIV/AIDS Legal Network, reviewed the agenda and the objectives of the meeting.

I. Intellectual Property and Access to Medicines: Recent Developments, Current Concerns and Initiatives

The objectives of the presentations and discussion on this first day of the meeting were:

- *to place legislation on compulsory licensing of pharmaceuticals for export (e.g., Canada's Access to Medicines Regime) in the context of broader global debates and developments over intellectual property and access to medicines; and*
- *to provide orientation as to issues facilitating access to medicines in developing countries, including practical considerations regarding procurement and scale-up, so as to inform recommendations.*

(1) TRIPS, the 2003 WTO Decision and CAMR: A short overview

Professor Fred Abbott of the Florida State University School of Law provided an overview of the conflict between intellectual property rules and access to medicines since the advent of the TRIPS Agreement. He argued that the fundamental problem surrounding TRIPS Agreement and access to medicines arises from a basic characteristic of the global pharmaceutical system. It is a system which relies on the functioning of the market, and in which market incentives are strengthened by patent grants to accommodate high levels of risk, but which is at the same time relied upon to supply public goods. But a core characteristic of public goods is that the private market does not function to adequately supply them. That is why we have and rely on governments — and today increasingly on NGOs because of government failure — to supply public goods in the form of essential medicines. It is "in the nature" of private, for-profit pharmaceutical companies to seek to protect profits and the mechanisms that generate them; that is what they do.

He described the state of access to medicines pre-TRIPS and at present. Global concern about the impact of the TRIPS Agreement began to grow in the late 1990s, particularly with the passing of the *South African Medicines and Related Substances Control Amendments Act* and the subsequent litigation initiated by 39 multinational pharmaceutical companies aimed at blocking implementation of certain of its features. That litigation sought to misuse the TRIPS Agreement to advance the originator industry's grievances with generic substitution requirements, price controls and parallel importation. That litigation, in addition to the conduct of U.S. and EU trade authorities in pressuring South Africa to refrain from taking steps that would interfere with the industry's pricing practices and market advantage, turned into a lightning rod drawing attention

to the concerns about the impact of IP rules on access to medicines particularly in the developing world, a concern magnified by the burgeoning AIDS pandemic.

One particular feature has been the subject of considerable controversy and debate for several years. Prof. Abbott outlined what has been commonly referred to as the "Doha paragraph 6 problem" or the "TRIPS Article 31(f) problem" — namely that restrictions on the use of compulsory licensing for export by WTO Members with generic pharmaceutical production capacity make it difficult for countries with insufficient manufacturing capacity to make effective use of compulsory licensing to secure lower-cost generic products to address domestic public health needs. This concern is heightened after 2005, the year when certain developing countries that had hitherto been significant exporters of generic pharmaceuticals — such as India in particular — were required to bring domestic legislation into compliance with TRIPS. This would include granting product patents on newly-developed pharmaceuticals, as well as processing those patent applications on existing medicines that had, until that time, been held unprocessed in the "mailbox" required by TRIPS pending the new recognition of product patents in the pharmaceutical sector. As a result, it becomes even more important to ensure the ability of countries to make effective use of compulsory licensing in order to procure generics and put downward pressure overall on medicine prices — hence the importance of a "solution" to the "Doha paragraph 6" problem, such as the mechanism agreed in the 2003 WTO Decision.

Prof. Abbott identified three core issues at stake in the WTO negotiations over a solution to the "Doha paragraph 6 problem":

- the scope of diseases to be covered by any solution;
- defining eligible importers; and
- whether the solution would be based on Article 30 or 31 of the TRIPS Agreement.

In his view, developing countries were generally successful in these negotiations. They obtained a broad provision on scope of diseases, and relatively broad provisions on the eligible importers. However, the solution ultimately adopted in the 2003 WTO Decision, which takes the form of a waiver of obligations under Article 31(f), requires, depending on the applicable domestic patent law and the patent status of the product(s) in question, back-to-back issuing of compulsory licences by both the exporting and importing countries/Members. Prof. Abbott noted that the 2003 WTO Decision explicitly states that it is "without prejudice" to other flexibilities that exist under TRIPS and therefore does not prohibit the use of approaches to solving the Doha paragraph 6 problem based on Article 30 of the treaty.

Based on his close involvement in the negotiations, Prof. Abbott observed that Canada's initial response to the 2003 WTO Decision was highly ambiguous. A senior Canada government official stated that the government had to be cautious in interpreting the Decision because there was uncertainty concerning the scope of diseases — even though the final text of the Decision, by consensus among WTO Members, does not contain a restriction. This outcome was not accidental; every word in the Decision was carefully negotiated. Abbott made brief comparisons of CAMR with legislation that had since been adopted in other jurisdictions to implement to the WTO Decision, and noted that points of comparison were to be explored in more detail later in the deliberations as part of an in-depth analysis of CAMR. He concluded that the access

problem is getting more serious. Prices of first-line antiretrovirals (ARVs) have come down, to a considerable extent as a result of generic competition, but prices of second- and third-line regimens are high. There are some 9000 mailbox applications being processed in India, 6000 pharmaceutical patent applications are pending in Brazil and 3500 in Colombia. Increasingly, through bilateral and regional agreements, there are efforts, particularly by the United States, to link the patent system with the drug regulatory regime, such as through data exclusivity provisions — which can have a similar effect as direct patent barriers in preventing access to generics. Ultimately, this is a public goods problem and the waiver of the Article 31(f) restriction via the 2003 WTO Decision is but one small step towards solving a much broader public health problem.

Discussion Points

The discussion opened up the issue of the "linkage" problem, namely turning drug regulatory agencies, whose primary role is to protect public health through ensuring safety, efficacy and quality of marketed pharmaceuticals, into "patent police". Questions were raised with respect to whether an importing country must register the product prior to issuing a compulsory licence. Prof. Abbott did not believe so. Compulsory licensing is part of the patent system and regulation is a separate system, therefore existence of registration is not an issue at the compulsory licensing stage. When registration is needed to put a medicine on the market, then it could act as a barrier to distribution unless there are national exceptions. That said, there is nothing at the international level that prevents the local government from rapidly registering the medicine.

Ellen 't Hoen of Médecins Sans Frontières (MSF) suggested that bilateral or regional free trade agreements (FTAs) with provisions on IP, such as those already negotiated or being pursued by the U.S. with a number of countries, may prevent effective use of compulsory licensing if there are data exclusivity rules in place without exceptions for compulsory licensing. This would be because the regulatory agency would not be able to look at the dossier of the original patentee in making determinations relevant to registering the generic product (e.g., bioequivalence). Ms. 't Hoen explained how patent policing occurs through data exclusivity. Often, agencies or countries are not aware of the consequences of these agreements until they see them implemented in their day-to-day work. She suggested that the European Communities (EC) and Canada should speak out against these new rules because it hampers their abilities to make effective use of their regimes on compulsory licensing for export, as well as having domestic implications for entry by generics into their own markets upon patent expiration. It is not a technical legal matter, it is a political matter: how come countries that have celebrated their implementation of the 2003 WTO Decision, such as Canada with its CAMR, are not speaking out against these new rules that will undermine the potential for developing countries to benefit from such regimes? Prof. Abbott agreed with Ms. 't Hoen's comments and provided the example of the U.S.–Central American Free Trade Agreement (CAFTA) preventing the regulatory authority from registering a generic medicine without the acquiescence of patent holder.

Nicoletta Dentico of the Drugs for Neglected Diseases Initiative (DNDi) raised the issue of how much scope countries had to use TRIPS Article 30 in the context of regional and bilateral FTAs. Abbott believed that the developments in the U.S. with respect to an interpretation of patent

exceptions — such as the Supreme Court decision in the *Merck v. Integra Lifesciences* case — were positive, and supported a constructive interpretation of Article 30. That said, the EU previously filed a WTO complaint against Canada in which it argued for (and to a certain extent was successful in securing) a narrow interpretation of "limited exceptions" to exclusive patent rights under Article 30 (the *EU — Generic Pharmaceuticals* case). There is no reason that governments should refrain from using Article 30, but they should expect the U.S. Trade Representative (USTR) and European Commission to raise diplomatic problems. Prof. Abbott argued that a country could reject U.S. and EU arguments that data-related marketing exclusivity rules are required under TRIPS Article 39.3 as measures to prevent "unfair commercial use" of data.

(2) U.S.–Morocco Free Trade Agreement and access to medicines

Nadia Rafif of the Association de lutte contre le sida (ALCS) described the situation in Morocco with respect to TRIPS implementation and the separate U.S.–Morocco FTA. Prior to the implementation of TRIPS in December 2004, Morocco only protected process patents in the pharmaceutical field. After implementation of TRIPS, their patent law included a transition period and compulsory licences for non-commercial use, but provisions were also included that blocked the use of parallel importation and extended data exclusivity. Furthermore, the law did not incorporate use of the 2003 WTO Decision. Morocco has the second largest generic pharmaceutical industry in Africa.

The U.S.–Morocco FTA agreement was signed in 2003. It includes a large scope of patentability, data exclusivity for four years with the possibility of renewal in case of new clinical trials, and patents for new uses. It also includes provisions for extending patent terms to "compensate" for delays in the patenting process or in getting marketing approval. Parallel imports are banned and linkage was made between patent status and marketing approval.

The consequences of the FTA are dramatic. Generic competition will be significantly delayed. There is limited use of compulsory licences and even then, it will likely be blocked by data exclusivity provisions. As parallel importing is not permitted, this blocks the possibility of importing brand-name patented products sold more cheaply in other markets by the patentee. Data exclusivity rules effectively extend patent protection beyond the 20 years that is the TRIPS standard, and drug regulatory authorities are taking on the role of patent policing.

(3) U.S.–Dominican Republic–Central American Free Trade Agreement (U.S.–DR–CAFTA)

Eugene Schiff of the Agua Buena Human Rights Association provided a brief overview of the IP provisions in the U.S.–DR–CAFTA agreement. Data exclusivity provisions were included in the agreement. Costa Rica has yet to sign the agreement.

Recently, the WHO released a report that showed Latin America is leading the developing world in access to treatment, but Central America is still problematic. Mr. Schiff went on to describe treatment challenges across countries in Central America. Belize has no access to second-line medicines at all because the government has refused to buy them up to this point. Belize is one

of the richer nations but the government seems to be disinterested. It has the highest rate of HIV in Central America and third highest in the Americas after Haiti and Guyana. Nicaragua has a low rate of HIV/AIDS (but possible under-reporting) and very few people with drug access (348 people). El Salvador was the first country to sign CAFTA. Currently, prices for second-line therapy in El Salvador run from US$6,000 to 7,000 per patient per year. Honduras also has significant access problems. Heat-stable products are particularly important there but companies refuse to reduce their prices. The Dominican Republic lost US$40 million from a Global Fund grant due to corruption. Guatemala recently issued new guidelines that will move some second-line treatment to first, but this has significant cost implications. The U.S.–DR–CAFTA will have a significant effect on newer medicines in particular, including second-line treatments.[2]

II. TRIPS and Access to Generic Drugs Post-2005

(1) Current and future impacts of TRIPS on access to generics

In her presentation, Ellen t'Hoen of Médecins Sans Frontières' (MSF) Access to Essential Medicines Campaign asked whether the TRIPS agreement is a bad bargain for developing countries due to the fact that, according to the recent 2006 report of the WHO's Commission on Intellectual Property, Innovation and Health (WHO CIPIH), "[t]here is no evidence that the implementation of TRIPS agreement in developing countries will significantly boost R&D in pharmaceuticals on Type II and particularly Type III diseases. Insufficient market incentives are the decisive factor." MSF has huge concerns over India's implementation of the TRIPS Agreement as of 2005, the effects of which are now playing out and will continue to play out in the months and years ahead: is the "pharmacy of the poor" closing up shop? The effective use of compulsory licensing, as affirmed in the 2001 Doha Declaration, will largely depend upon generic production capacity and that is undermined by ever-expanding TRIPS implementation without effective protection of TRIPS flexibilities.

The 1970s Indian *Patent Act*, and the generic pharmaceutical industry it helped create in India, is the reason that MSF can treat so many patients and this is fundamentally why drug prices have dropped. Purchase agencies are starting to use the Doha Declaration (Paragraph 7) and there is growing use in Africa of compulsory licensing for government use, but there still has been little use of the 2003 WTO Decision, to a great extent because India has been a key source of generics. This situation may change in the near future, now that India has become TRIPS-compliant, there is a need for newer AIDS drugs and WHO has changed its recommendations for first-line treatment to include second-line drugs like tenofovir. The eventual "shut down" of the Indian generic pharmaceutical industry has grave implications for access to newer patented medicines, because there will be a lack of generic competition.

The consequences of these developments on AIDS treatment projects are huge. Based upon MSF's projects, 10 percent of all their patients are on second-line drugs and they consume 60 percent of their overall treatment budget. If the pre-grant challenges to patent applications

[2] For more detailed discussion of concerns about the impact of the U.S.–DR–CAFTA on access to medicines, see also: R. Weissman, "Dying for Drugs: How CAFTA Will Undermine Access to Essential Medicines" (Washington, D.C.: Essential Action, March 2004), on-line at: http://www.cptech.org/ip/health/trade/cafta/weissman032004.doc.

currently being brought by Indian NGOs, such as the challenge to the patent on Novartis' cancer drug Gleevec (imatinib mesylate) do not succeed, the generic pipeline will be significantly affected. Ms. 't Hoen provided many examples of the ARVs that may be affected and those coming in the pipeline. She also explained that the negative effects of monopolies are not just the prices. Even when brand-name companies announce price reductions, they do not necessarily register or market their drugs in some countries where there is great need. For example, Gilead Sciences, Inc. announced a discounted price for its ARV Viread (tenofovir) for 98 countries, but only marketed the product in 17. Sometimes drugs are only made available in selected countries through special importation channels. Finally, the unavailability of affordable heat-stable ritonavir is a barrier to the use of WHO-recommended protease inhibitors.

Ms. 't Hoen emphasized that patents do not only affect AIDS medicines. Cervical cancer is a disease of the global south and is the second most common cancer in women in developing countries. The HPV vaccine is approximately US$160 per shot and there are two boosters needed. However, the vaccine was developed for use in the north. The subtypes prevalent in Africa were not even tested. Production capacity will be an issue. When Kenya asked for an order, the company replied that it would provide a discount of US$90 per shot.

Ms. 't Hoen urged that "we must stop tinkering in the margins". There is a desperate need to develop pro-public health management of IP, more routine use of compulsory licensing, increased political support of compulsory licensing, voluntary licences that actually aim to increase competition, and mechanisms like patent pools to solve patent-based price barriers to medicines. Solutions need to separate the cost of R&D from drug prices, because otherwise one will always have a system that rations and excludes people based on ability to pay. The recently-constituted Intergovernmental Working Group on Public Health, Innovation and Intellectual Property (IGWG), created by a resolution at the 2006 World Health Assembly, is a good opportunity to pursue these debates. Referring to recent statements by the Chairman and CEO of Novartis, Ms. 't Hoen observed that even some multinational brand-name pharmaceutical companies have acknowledged that we need a different system.

(2) Patents, compulsory licences and oppositions: the Indian perspective

Chan Park of the Lawyers Collective HIV/AIDS Unit in India summarized the importance of India as the "pharmacy of the poor". He explained how India had become the largest supplier of generic medicines for the developing world, as a result of India's regime of granting only process patents and not product patents. Currently, India supplies approximately 50 percent of ARVs in use in developing countries. But India had to become TRIPS-compliant in 2005, meaning that product patents must now be recognized.

Mr. Park described key provisions in the Indian *Patents (Amendment) Act* passed in 2005 to become TRIPS-compliant, and the implications of these provisions and other developments in India regarding access to generic medicines, in India and other developing countries.

Section 92A allows compulsory licences for export and is a fairly open procedure although it has yet to be used. In those cases where some countries have issued compulsory licences domestically in order to import generics from India, they have done so without need for recourse

to section 92A for a compulsory licence in India, as it has been for products not subject to patents in India. This provision will be increasingly important in future for the possibility of generic exports from India as new pharmaceutical products come under patent under the new, TRIPS-compliant legislation.

Section 11A(7) is an "automatic licensing" provision that aims to "grandfather" generic products being manufactured in India before the 2005 deadline for TRIPS compliance. It applies in cases where a patent is granted on a product for which an application has been on hold pending the 2005 amendments to recognize product patents. Even if a patent is granted, patent rights for applications in the "mailbox" (that India was required to set up under TRIPS pending full TRIPS compliance in 2005) do not occur until the patent is actually granted. Furthermore, if a generic manufacturer has already made a "significant investment" and marketed the product before 1 January 2005, the new patent holder cannot bring patent infringement proceedings, but is only entitled to receive a "reasonable royalty" from the generic manufacturer. This section is yet to be invoked or challenged. What constitutes "significant investment"? What constitutes a "reasonable royalty? Mr. Park noted that if Novartis succeeds in getting a patent on the cancer drug Gleevec, which it is pursuing now through legal proceedings to overturn the original decision to deny its patent application, it will likely challenge this section.

Section 3 sets higher criteria for granting of a patent, which will be particularly important in keeping the new product patent regime in India from over-extending, especially through the practice of "evergreening", thereby further restricting scope for generic production. Section 3(d) provides that if the patent applicant wants a new form of a substance, it must show significant enhancement of efficacy. This provision was aimed to counter evergreening and also prohibits the patenting of new indications. In addition, section 3(e) indicates that mere admixtures are not patentable. Section 3 is currently at the centre of the Novartis proceeding regarding Gleevec.

Section 25 is the section providing for challenging the grant of any particular patent. Section 25(1) allows for pre-grant oppositions by "any person", and section 25(2) allows for post-grant oppositions (by "person interested"). Currently, an initial question is the scope of "person interested". The first post-grant opposition has recently been filed by civil society against the granting of patent to Bristol-Myers Squibb Company (BMS) on the ARV efavirenz; BMS is challenging civil society as not "person interested." Other post-grant oppositions (e.g., against Roche's patent for pegylated interferon) are in the works. And, as is well known, section 25 is central to the current Novartis proceeding regarding the patenting of Gleevec. After the passage of the *Patents (Amendment) Act*, in 2005 the Cancer Patients Aid Association (CPAA) along with generic companies filed pre-grant oppositions to Novartis' claim for a patent against Gleevec (imatinib mesylate). In January 2006, the Indian Patent Office denied Novartis' patent application on the basis of section 3(d) of the new legislation, saying that it did not meet the criteria for patentability as it was merely a new form of a known substance. Novartis subsequently appealed the patent examiner's decision, and has also challenged the validity of section 3(d) of the new legislation, claiming that it is not constitutional and not in compliance with the TRIPS Agreement. Novartis is arguing that TRIPS — specifically Articles 27.2 and 27.3 on "patentable subject matter" — do not allow for such exclusion from patentability. CPAA has responded to the Novartis challenge on the grounds that Art 27.2 and 27.3 are non-exhaustive. The argument on the validity of section 3(d) of the Indian legislation has closed.

Mr. Park concluded that "effective litigation against big pharma involves action inside and outside [the] courtroom". Apart from the legal aspects of the litigation, the petitions, demonstrations, and politicians asking Novartis to drop the case are critical. A significant development is the threat by India's Minister of Health to issue a compulsory licence on Gleevec if Novartis persists with its case. One key legal issue at stake is whether the provisions of the TRIPS Agreement can be enforced by a private party in an Indian court. If section 3(d) of the Indian legislation gets struck down or weakened, then India has lost a potentially stringent safeguard against frivolous patents and the practice of evergreening patents to block generic competition.

Some participants raised the question of whether the Indian law's provisions regarding compulsory licensing could be challenged as not complying with the parameters envisioned in the 2001 Doha Declaration or the 2003 WTO Decision. Mr. Park noted that no one has challenged Section 92A but it has yet to be used in India because most of the medicines that are needed have not yet been granted patents in India. Even then, most such products will likely fall under the automatic licensing provision of Section 11A(7); the greater impact will be on new medicines in the future that had not been genericized by January 2005.

Richard Elliott of the Canadian HIV/AIDS Legal Network asked whether the Indian legislation as finally enacted included specific calculations for the royalty rate payable in the event of a compulsory licence, as had been suggested by some NGOs during the legislative process. Mr. Park noted that the legislation does not have specific, defined rules about royalties, and that this vagueness was a major complaint raised by NGOs, but that precedents for royalties in countries such as Malaysia, Indonesia and Thailand should help. It was also noted that regulations could be adopted to provide more certainty about royalty calculations, as had been done with Canada's legislation on compulsory licensing for export.

(3) Compulsory licensing for access to medication in Thailand

Prof. Vithaya Kulsomboon of the Health Consumer Protection Program at Chulalongkorn University outlined the different elements of Thailand's approach to universal health coverage and summarized the process leading up to, and events following, the Thai government's decision to issue compulsory licences. At the end of November 2006, the Ministry of Public Health issued a compulsory licence on the AIDS drug efavirenz (Stocrin®, patented by Merck Sharp and Dohme), followed in January 2007 by compulsory licences on the second-line, combination AIDS drug lopinavir/ritonavir (Kaletra®, patented by Abbott), as well as the heart disease drug clopidogrel (Plavix®, patented by Sanofi-Aventis). All three medicines have been on the National Essential Drugs List since 2004. He explained that about 8 percent of Thais are covered under a medical benefit scheme for civil servants, another 20 percent go to private facilities and pay out of pocket, and over two million foreigners also pay for care at private facilities. The present compulsory licences would have little effect on these three groups; rather, it will primarily benefit those who do not have this kind of coverage or these resources, and cannot afford to pay for higher-priced patented products. Prof. Kulsomboon argued that compulsory licensing cannot kill the entire patent regime, as critics and apologists for the

patented industry have suggested. He stated that the compulsory licence is only relevant for less than five percent of patented drugs.

Of the mechanisms available for Thailand to take advantage of TRIPS flexibilities such as compulsory licensing, Thailand invoked the public, non-commercial use provision (also known as "government use"), which does not require prior negotiation, reflecting TRIPS Article 31(b) and as stipulated under the Thai patent law (sections 46–52). Nonetheless, Thailand has made extensive efforts at negotiating price reductions with the relevant patent-holding pharmaceutical companies, but after a year and a half of negotiations, the Thai government did not get very far. They were offered an 18.7 percent reduction in the price of Stocrin (efavirenz) by Merck and a 33 percent reduction in the price of Kaletra (lopinavir/ritonavir) by Abbott, but these were offset by sharp depreciations in the Thai baht. After the government announced the compulsory licence, the price of Stocrin was reduced by 45 percent and the price of Kaletra by 57 percent. But Abbott has also retaliated by removing the dossiers on nine medicines, including Kaletra film-coated tablet, from consideration for marketing approval in Thailand.

Prof. Kulsomboon explained that drugs produced under a "government use" compulsory licence have quality assurance procedures. The Government Pharmaceutical Organization (GPO) has WHO-prequalified products, tested by the Department of Medical Sciences, review and approval by the Thai drug regulatory authority, GPO testing, and post-marketing surveillance of products. This refutes the claims by critics that claim GPO-manufactured generics will be a threat to Thai public health.

Pursuant to the compulsory licence, the GPO has imported a generic version of efavirenz at a price that is 20 percent lower than that offered by Abbott (650 baht versus 770 baht). The current strategy of the companies is to refuse to engage in discussions for royalty rates. The Thai government continues to hold negotiations with companies whose drugs are in process of compulsory licensing by government. For example, Thailand plans to continue discussions with Bristol-Myers Squibb Company regarding price reductions for the ARV atazanavir, a second-line ARV that can replace Abbott's lopinavir in some regimes, and will keep the option of compulsory licensing on the table. The process of compulsory licensing continues alongside negotiations but for any product that reaches satisfactory agreement, there will be no compulsory licensing announced or implemented.

Discussion centered on the reactions and strategies of Abbott. Senator Jon Ungphakorn of the AIDS Access Foundation in Thailand stated that Abbott's withdrawal of Aluvia (a heat-stable formulation of Kaletra) from the Thai market is pure intimidation and blackmail, which sends a global message of what will happen if countries even think about issuing a compulsory licence. Prof. Kulsomboon noted that the withdrawal could attract attention as an anti-competitive measure under Thai competition law.

Most discussants agreed that it was important to show public support for Thailand's decision to use compulsory licensing, taking advantage of TRIPS flexibilities for the intended purpose. Ms. 't Hoen of MSF emphasized the importance of showing political support for Thailand's compulsory licence. She repeated Prof. Fred Abbott's sentiment, expressed at the outset of the morning, that applying political and legal pressure to protect profits *is* what drug companies do.

In this respect, she finds the deafening silence and the lack of support from WHO and other governments more alarming than the industry's actions.

Questions were raised about impacts of product withdrawal on access to data for purposes of registering generics if that step were taken. Ms. 't Hoen argued that Abbott's withdrawal is not imposing data exclusivity indirectly because product information is in the public domain. Ultimately, it depends upon the country's rules. Rob Weissman of Essential Action noted that the Thai national drug regulatory authority relies exclusively on the public domain for safety and efficacy data.

Counsellor Tom Mboya of the Permanent Mission of Kenya in Geneva added more anecdotes regarding the industry's strategies. He described a situation in Kenya where recently, an unknown official tried to sneak a clause into patent law amendments that would effectively kill the use of parallel importation. While this was subsequently addressed, he stressed the realities that developing countries face in defending their TRIPS flexibilities, not to mention trying to use them.

III. Medicines Procurement: Importing and Compulsory Licensing

Having examined, at the global level, the importance of current and future access to generics and the policy environment in which measures such as compulsory licensing were being considered or used, the next session turned to examine how these factors affect procurement practices at the national level and by international organizations. A series of case studies helped illustrate the challenges.

(1) Generic ARVs: practical procurement considerations

Caius Kim, North America regional manager for International Dispensary Association (IDA), summarized the role of the IDA in drug procurement and how this relates to compulsory licensing and other IP flexibilities. The IDA supplies medicines to 47 countries worldwide and since 2004, they have provided ARV treatment to over 150 000 patients. IDA works in 28 countries in Africa, 9 countries in Latin America, and 10 countries in Eastern Europe and Asia. They work with a number of organizations including the Global Fund to Fight AIDS, Tuberculosis and Malaria, the United Nations Development Programme, Management Sciences for Health, Partners in Health, Harvard University, Catholic Relief Services, and the Clinton Foundation.

Use of generic ARVs through the IDA increased substantially in recent years, from 34 percent of the total value of ARVs supplied in 2004 to 60 percent in 2006. The impact on the number of units purchased is even more pronounced: an increase in generic units purchased by IDA (from 63 percent in 2004 to 83 percent in 2006), and a corresponding decrease in the purchase of brand-name units. Mr. Kim noted that the IDA always respects and adheres to international and national rules governing procurement, and relies on the decisions of individual governments and relevant departments.

The IDA provides some technical assistance (e.g. draft letters or templates to notify WTO of compulsory licence or various TRIPS flexibilities). He mentioned that the determination of patent status in many countries is very difficult. The IDA relies on partner organizations and does not address the patent landscape. They simply want to ensure that the documents provided to the government are valid — i.e., documents to ensure that they are abiding by international and national laws. (A caution was raised later in the discussion that efforts are needed to make sure that such statement are not interpreted by countries as meaning that they should avoid using TRIPS flexibilities.)

(2) Zambia generics procurement

Billy Mweetwa, Senior Pharmacist with the Centre for Infectious Disease Research in Zambia (CIDRZ), presented the procurement landscape in Zambia. The CIDRZ currently supports 42 sites across Zambia delivering ARVs to a total of 56 000 patients. Until recently, the funding received by CIDRZ was only for procuring branded products. Most of the time, their funders do most of the negotiations for them. International agencies are contracted out to supply drugs. Rarely, the sponsor contacts the manufacturers directly.

Mr. Mweetwa outlined the main conditions that local authorities attach to the procurement of generics: they must be registered in the country of origin (which can be problematic), the labels must be in English, the drugs must be WHO pre-qualified, they must retain at least 75 percent of the shelf-life upon landing, and they must be registered by the Zambian drug regulatory authority. Additional conditions imposed by their sponsors include: FDA and/or WHO prequalification, cost analysis, and the requirement that it must be registered in Zambia (or else the sponsor will not purchase the product).

More than 90 percent of the generic products used by CIDRZ sites come from Indian manufacturers. When the program began, funds could only be used on branded products, which was costly; the purchase of generic products has meant the same amount of funding can significantly increase the number of people with access. For example, for the first-line regime of stavudine, lamivudine and nevirapine (d4T/3TC/NVP), using branded products cost US$45.66, but using generics brought the price down to US$13, a 71 percent cost saving.

Ensuring quality control is a significant consideration. CIRDZ relies on U.S. Food and Drug Administration (FDA) approval or WHO prequalification, since the local drug regulatory authority has little capacity to carry out independent quality control analyses. Problems include the misperception held by some clients that branded products are higher quality. Also, when the generics are not registered in the country of origin it can be problematic. Information on the package inserts is not always up to required standard. With respect to use of a regime such as CAMR, Mr. Mweetwa stated that they would appreciate Health Canada's regulatory review of exported generics to address the quality control aspect.

Mr. Mweetwa concluded by emphasizing the importance of generic products while respecting intellectual property rights. Zambia has the right under the 2001 Doha Declaration (paragraph 7) to not grant or enforce patents until 2016, but he emphasized that they still recognize the value of patent protection, especially for innovation.

(3) Access to medicines and intellectual property: the Kenyan situation

Edward Buluma, Procurement Manager with the Kenya Medical Supplies Agency (KEMSA), outlined the procurement process that his organization engages in. KEMSA is a state corporation established with the mandate to procure, warehouse and distribute medical commodities on behalf of the Ministry of Health to public health institutions countrywide.

Kenya's public procurement law borrows largely from World Bank guidelines and it is likely similar in many countries. The specifications in their procurement procedures are aimed at avoiding bias towards manufacturers and at attracting many bidders to get competitive pricing. Their method of procurement is "open international bidding". They do not engage in direct procurement. Tenders must be advertised and open for a set period of time. To ensure quality control, their agency conducts a technical evaluation. The product must be registered for use in Kenya if it is to be imported. "Good manufacturing practices" (GMP) certification of the manufacturer is mandatory. Bidders must provide samples of products and these are evaluated for conformity to specifications. WHO pre-qualification is "considered" for some essential medicines. Compulsory licensing has yet to be used, however there was one voluntary licence granted to a local manufacturer for ARVs. Parallel importation of ARVs is allowed and has been used.

Jane Masiga, Head of Operations for the Mission for Essential Drugs and Supplies (MEDS) presented another dimension of drug procurement in Kenya. MEDS is a private NGO that procures medicines for church-run health facilities and NGOs, and receives donor support from the Global Fund and the U.S. President's Emergency Plan for AIDS Relief (PEPFAR). MEDS purchases approximately 50 percent of the country's requirements for ARVs. Prior to the year 2000, drugs were very expensive, at about US$600 per patient per month. At that time, only 4000 of 200 000 HIV-positive patients were receiving ARVs. After the global movement for access to medicines, prices started to drop. The brand-name companies offered reduced prices to Kenya around the price of US$60 per patient per month, but with importation of generic ARVs (including fixed-dose combination products), MEDS secured prices of US$25–30 per patient per month. Now, MEDS supports more than 120,000 patients on ARVs. Almost 100 percent of their generic drugs come from Indian manufacturers. The need for second-line treatment is growing.

Ms. Masiga referred back to the earlier remarks by Counsellor Mboya, explaining that one month after amendments to Kenya's *Patent Act* were passed in 2001, changes were snuck in that required permission from a pharmaceutical company to engage in parallel importation. This restriction was reversed in August 2001, but in 2006 another restriction was snuck in. This is a lesson for all: "you must 'guard' your patent act vigilantly". Ms. Masiga also described the reactions of the brand-name industry when Kenya tried to use flexibilities in IP law. Prior to 2001, MEDS received threats over the telephone from a company when they attempted to import generic ARVs. In 2006, they received a letter from Boehringer Ingelheim threatening legal action when MEDS tried to import generic ARVs.

(4) HIV treatment programs from demonstration projects to scale-up — and ART procurement

David Hoos of the International Center for AIDS Care and Treatment Programs at Columbia University provided a perspective from a PEPFAR-funded treatment program. In 2001, low prices were not always available and ARV registration was limited. ARV prices were still quite high and in general, countries did not have national tenders for ARVs. Companies generally did not have regional or country representatives. The Columbia MTCT-Plus Initiative (in collaboration with UNICEF) was the first multi-country, multi-company ARV procurement mechanism for drugs from both originator and generic companies. Their ARV procurement criteria were based upon WHO prequalification, lowest price and delivery time. UNICEF had already established arrangements with drug manufacturers, and because UNICEF was a relief organization, they were able at times to gain exceptions from national drug regulatory authorities; therefore, even though a drug wasn't registered, a framework allowed its purchase and importation.

PEPFAR-funded treatment programs can conflict with national AIDS control programs and national drug procurement policies or protocols. For example, the U.S. government decided that WHO prequalification was not acceptable and that originally restricted programs such as Columbia's to procuring only U.S. FDA-registered products (which were all originator ARVs). As other sources of funding became available, such as the Global Fund, PEPFAR funds were used for second-line ARVs while other funds allowed them to procure lower-cost, generic first-line treatments approved through the WHO Prequalification Programme.

Dr. Hoos outlined some key future challenges. Current needs for second-line ARVs are limited but the expectation is that with toxicity and drug failure, therapeutic switches will increase. Also, there is increasing pressure to use viral load as a measure for drug failure and this will increase the need for a widened formulary and more second-line treatments. Originator companies will introduce new formulations (e.g., heat-stable Kaletra) when older drugs start to move off patent. Also, it is unknown whether the USAID-funded procurement mechanism will remain optional. In some countries, U.S. Government-funded procurement is rumoured to be of higher quality than the national procurement mechanisms. These rumours have been damaging a movement towards national ownership of drug procurement. The time lag between WHO prequalification and the U.S. FDA's expedited approval for ARV might increase. Finally, there may be increasing pressure to procure through USAID instead of UNICEF, which is more complex.

Discussion points

Sophie Logez, Policy Analyst (Global health supply) with the Global Fund to Fight AIDS, Tuberculosis and Malaria, mentioned that it is important to separate the IP issues from the quality issues, which often get confused. One of the major principles of the Global Fund is country ownership, and procurement is done according to international and national laws. On the quality side, the Global Fund has a policy, updated in 2005, that goes beyond the WHO Prequalification Programme to include other options to ensure quality and low price (including those regulators like the U.S. FDA that have stringent standards). Ms. 't Hoen of MSF noted that

many countries interpret "abiding by national and international standards" as not being able to use TRIPS flexibilities. This misperception must be addressed.

Dr. Hoos mentioned that there was some discussion about using the Global Fund or other international agencies as tools of public policy. However, based upon the premise of national sovereignty, they decided that agencies like these should not insist that countries explore parallel importation or compulsory licensing to obtain lower prices. Ms. 'T Hoen of MSF responded that these agencies need not insist — simply encouraging the use of such flexibilities would be positive. Prof. Abbott noted that since 2004, the World Bank has encouraged countries to take advantage of TRIPS flexibilities and even published a guide for implementing the 2003 WTO Decision. Examples provided by IDA are useful and should be encouraged. UNICEF routinely relies on Doha paragraph 7 letters from countries saying that they need not enforce patents until 2016. These are tools that can further encourage the use of flexibilities by countries.

Overall, the "fit" between compulsory licensing with procurement mechanisms is critical. Whoever receives the compulsory licence must still compete with international bidding processes. These are national laws and policies that cannot be violated.

In addition, Mr. Mweetwa of CIDRZ highlighted some challenges with drug donations, including issues with short shelf-life, labelling issues such as language (must be in English for Zambia), and packaging problems.

Much discussion centered on drug company strategies and practices. Ms. Masiga described the letter MEDS received from Boehringer Ingelheim in 2006, stating that it had the exclusive legal right to supply nevirapine in Kenya and threatening legal action for importing generic NVP. After protests by civil society at the XVI International AIDS Conference in Toronto in 2006, the company withdrew the letter saying that we "misunderstood their intentions". Christa Cepuch of Health Action International (Africa) commented on the actions by Pfizer in Kenya. Pfizer has initiated legal proceedings over the importation of two generic medicines in small amounts. The hearing has been delayed by 45 days to allow Kenya to file a defence, which is still to be done at this time. Pfizer argues that it possesses the exclusive right to manufacture, import and sell the medicines to which they hold the patent. Ms. Cepuch argued these claims are unfounded given the provisions of Kenya's patent law.

Counsellor Mboya of the Kenyan Mission in Geneva added that these industry threats and subversive actions against their IP laws are just a part of their daily context, which makes it difficult to do even routine procedures. He urged that monitoring and assistance must be provided to counter the kinds of actions described by Ms. Masiga and Ms. Cepuch.

Jim Keon of the Canadian Generic Pharmaceutical Association (CGPA) suggested that the industry's legal action should not surprise anyone. Part of their product life-cycle management includes suing companies and governments. Rather than being intimidated by that, NGOs and governments need to be aware of it, build it into their activities, and be prepared to defend it in court.

Counsellor Mboya also adverted to the challenges in Kenya with increasing numbers on treatment and the need for second-line drugs; governments are at a loss as to how they will manage this financially. Furthermore, multiple donor conditions, restrictions and initiatives make management of the health care system difficult. He suggested that Canada can play a strong role in supporting Kenya to address issues of sustainable financing for ARVs. Canada's generic manufacturing capacity can be used but the legislation must ensure that the products will be competitive price-wise and will contribute to bringing down the prices worldwide. What is also needed is support for local manufacturing capacity and financing in Kenya. He provided the example of the Kenyan manufacturing company Cosmos that manufactured ARVs in Kenya but then went out of business because they could not pay the US$5000 required for WHO prequalification.

IV. Managing Intellectual Property for Access, and Alternatives to Patents for Health R&D

(1) Drugs for Neglected Diseases Initiative: turning neglect into action

Nicoletta Dentico, Policy and Advocacy Advisor with the Drugs for Neglected Diseases Initiative (DNDi), provided an overview of the mission and vision of DNDi, its portfolio and its team. DNDi was founded in July 2003 as a new collaborative, patients' needs-driven, not-for-profit model for researching and developing medicines for "neglected diseases". She described the "global dimension of neglect": tropical diseases and tuberculosis account for 12 percent of the global disease burden but only for 1.3 percent of all new drugs developed from 1975–2004 (18 products out of 1556, with only 3 for tuberculosis). DNDi's primary objective is to develop new medicines for such neglected diseases — specifically, to deliver 6–8 new treatments by 2014 for leishmaniasis, sleeping sickness, Chagas disease and malaria. DNDi engages in new product development partnerships. Only 16 percent of DNDi's funding comes from governments; 79 percent comes from philanthropic organizations. There has been an increase in products developed and in the pipelines (42 drugs registered or in development since 2000), but they have yet to reach patients.

Success rates for product development partnerships (PDPs) are likely to be lower because of many reasons: they seek breakthrough products rather than incremental innovation, the long-term attrition rate is higher, the "low-hanging R&D fruits" have already been picked, and while R&D costs may be lower, failure rates may be higher due to inadequate funding. PDPs are insufficient. As has been identified by the WHO IGWG, we need a stronger commitment from governments for an "articulated and sustainable effort to address the research gaps".

DNDi is part of a movement towards a paradigm shift in IP policy, drug research as a public good, and science in the public domain. One example is DNDi's partnership with Sanofi-Aventis on the production of anti-malarials. This partnership has produced artesunate-amodiaquine (AS-AQ), an antimalarial combination treatment that contains artemisinin, as recommended by the WHO. The product is patent-free. It is registered in Morocco to increase and use a production capacity that exists, which Ms. Dentico characterized as "good science in the South for the South". The reaction to the development of this product through a PDP was

extremely positive. The European Parliament said that DNDI provides evidence against the thesis that innovation requires the patent system: "…deepest congratulations to DNDi and Sanofi/Aventis, as you finally give us the tangible evidence that patents can be skipped in the interest of public health, especially for poor people with no purchasing power…. Thanks to the AS-AQ solution, it will be more difficult now for the big pharmaceutical companies to defend the thesis according to which it is not possible to make progress in pharmaceutical innovation, without the patent profit mechanism."

The creation of the WHO IGWG provides an historic opportunity to increase appreciation of the requirements linked to R&D into public health needs, and to project WHO and government commitments globally (well beyond the mid-term framework defined by the World Health Assembly resolution that created the working group). Ms. Dentico urged health advocates to become involved, as this is an opportunity for spurring broader thinking and action that "we cannot afford to pass up."

(2) Patent pools as a policy tool for access

Judit Rius Sanjuan, an attorney with Knowledge Ecology International (KEI), described the potential of patent pools as policy tools for increasing access to medicines. Patent pools are the collective management of intellectual property and provide "methods of managing larger portfolios of IP assets." A patent pool may be defined as "an agreement between two or more patent owners to aggregate (pool) their patents and to license them to one another or to third parties, whether directly by patentee to licensee or through an entity set up specifically to administer the pool" (Merges, 2001).

The concept of patent pools has been around for quite some time, the most recent example being the proposed SARS patent pool. Ms. Rius noted several examples over the past 150 years of patent pooling. KEI has proposed patent pools for essential medical technologies to the WHO IGWG. Their proposal involves the creation of voluntary and non-voluntary patent pools focused on patents required for the production and distribution of generic versions of essential medical technologies in the developing world. Models include the EMILA (Essential Medical Inventions Licensing Agency), the UNITAID proposal for HIV/AIDS drugs, and regional or disease-specific proposals (e.g., Human Papillomavirus [HPV]), all which could be arranged by either governments or the WHO as non-profit undertakings.

Pools would be created to promote access to essential medical technologies. Licences would be offered on a non-discriminatory basis to any person to make, sell, import or export. Royalty payments should be reasonable and affordable, and adjusted by country capacity. There are many benefits to patent pools. They make both voluntary licensing negotiations and compulsory licensing processes more efficient, they provide one-stop licensing, and they facilitate the management of multiple patent-owners and staking of royalties. Economic benefits include economies of scale through multi-country pools and the potential to facilitate technology transfer. Patent pools can be arranged to promote R&D and medical innovation. Patent pools and pull mechanisms such as financing incentives can be combined (e.g. through the use of the Global Fund).

(3) Research and development: alternatives to the patent system

In his presentation, Rob Weissman of Essential Action argued that we must break the link between R&D and the marketing monopoly created by the patent system. The frameworks for alternatives are based upon the premise that market-driven mechanisms are not working in important respects. He suggested that the patent system was not delivering "much bang for the buck", and indeed was not leading to much in the way of either bucks or bang.

He pointed out that global pharmaceutical sales in 2002 were approximately US$400.6 billion (according to IMS Health data), while spending globally on R&D by "Big Pharma" was only US$45 billion (according to the International Federation of Pharmaceutical Manufacturers Associations), representing an R&D-to-sales ratio of merely 11 percent. The total spending remains low (i.e. not much "buck"): in 2006, global pharmaceutical sales had risen to US$643 billion (IMS), while the Pharmaceutical Research & Manufacturers of America (PhRMA) reported only US$55.2 billion in spending on R&D by the entire industry and that R&D amounted to but 17.5 percent of global sales revenue. Furthermore, that spending is not producing much "bang": consider, for example, that only about one-third of U.S. FDA approvals of new drugs are designated as "priority review" (which is given to drugs that offer "major advances in treatment, or provide a treatment where no adequate therapy exists"), whereas the majority receive standard review because they offer "at most, only minor improvement over existing marketed therapies". He suggested that even this analysis was overly generous to the existing system, pointing out that reported figures for spending on R&D are inflated by characterizing marketing efforts as R&D, by conducting extra-large Phase III clinical trials for marketing purposes, and by characterizing post-approval surveillance for marketing (including promotional activities with physicians) as R&D.

Mr. Weissman also identified other harmful outcomes of creating market monopolies in medicines, such as:

- the misdirection of research, including an overemphasis on "me-too" drugs and follow-on research, a greater focus on long-term treatments rather than cures, and the phenomenon of neglected diseases that had been referred to earlier;
- extreme investment in marketing;
- secrecy in the research field, including concealment by companies of data about health risks and adverse effects of their products;
- the pressure on private and public payers from high prices of patented pharmaceuticals, and consequent limits on access for patients, especially those who cannot pay; and
- waste of resources.

All of this suggests that we need to break the link between health R&D and the granting of market monopolies. (Mr. Weissman noted that some models being proposed to stimulate R&D represent heightened or intensified exclusivity — that is, more of the same current approach — which has been the approach taken with things like "orphan drugs", including additional exclusivity incentives for testing of drugs in pediatric formulations, and the Project BioShield initiative in the U.S. to encourage medical countermeasures against chemical, biological,

radiological or nuclear attack.) We need alternative frameworks, and in designing those, attention will need to be paid to the following considerations:

- money on the table, because R&D is a real expense
- the institutional arrangements
- the processes of R&D
- the reward system — what will be rewarded, and how?

Mr. Weissman described five different alternatives to the current patent system for stimulating R&D in the pharmaceutical sector:

- **Advance market commitments (AMCs):** This has recently been seen in the vaccines field, in an effort to create a market for new vaccines that are needed in poor countries. Donors commit money upfront according to a specified market size, price and product specifications. The pharmaceutical industry does the R&D, and an expert committee would assess candidate products to determine whether they meet the specified criteria of the AMC. There would be little change in existing research processes, although it could also be undertaken through public-private partnerships. The delivery of a targeted product will be rewarded if it meets the specified criteria of what donors agreed in advance to pay for. AMCs operate as complements to the existing patent system. Some of the concerns with AMCs are: the "winner takes all" approach, the challenge of calibrating the right financial incentives, and controlling the price.

- **Prize funds:** Governments establish and manage funds to reward R&D, and distributions from the fund ("prizes") constitute the payment to innovators. Drugs developed under prize funds could then be made immediately available as generics. Money for such funds could come from governments' general budgets or could be generated through specific fees or taxes. Committees would be required to adjudicate the allocation of prize funds. A variety of R&D actors could be incentivized through prize funds, and the research process could be diversified, operating either entirely within the status quo or being structured to support new and open research models. As for rewards, payment would be based on medical benefits from the innovation, not market opportunity. This is a change in the incentive structure and could revamp the industry. Such an approach can create incentives for favoured research outcomes (e.g., neglected diseases, vaccines) or approaches (e.g., open R&D). The size of the prize is a policy choice, but more could be made available for health R&D than the current system is delivering. Challenges with the prize fund approach include the creation of new institutions and questions about feasibility. But note that the U.S. National Institutes of Health (NIH) already operates an award system of about US$28 billion in medical R&D, and that 80 percent of the NIH's funding is awarded through almost 50 000 competitive grants to more than 325 000 researchers at over 3000 research institutions, while about 10 percent of the NIH budget supports projects conducted by nearly 6000 scientists in NIH laboratories. Furthermore, Australia and other countries already conduct assessments of pharmaceutical medical benefits in determining price regulation and reimbursement for products.

- **Government-based R&D:** Government funding bodies could condition initial grants on medical merit and make policy choices to favour certain investments over others. But governments also need to think further about managing IP differently from current practices. At the moment, inventions from U.S. Government-funded research are often licensed to private pharmaceutical companies to undertake development and commercialization. Royalties received range from nothing to medium-level royalties, depending on the institution. The development model remains reliant on private pharmaceutical industry, even though the government has funded much of the research, and exercises little control over prices and virtually no influence over ensuring access, when efforts fail in the use of so-called safeguards such as "march-in" rights (i.e., compulsory licensing). Government could consider investing to carry drugs through development and maintaining IP rights, instead of licensing the rights to the pharmaceutical industry for development and commercialization. One proposal is to create a series of competing development centres to carry out development; this could include contracting with the private sector in some instances. Such an approach would likely produce greater openness and sharing in the research process. Drugs developed under this system could then be made immediately available generically. Mr. Weissman suggested the government could double what the private pharmaceutical industry is investing in R&D and still make drugs available more cheaply. Even in the context of current arrangements, governments could manage IP differently. Governments that do not currently exercise price controls (of which the U.S. is the only one among major industrialized countries) could introduce measures aimed at ensuring "reasonable pricing". Non-exclusive licensing of government research to other entities could be favoured, and provisions on ensuring access at reasonable prices required as a condition of licensing. Government could also legislate a lower threshold for exercising "march-in" rights, and use it more robustly. Legitimate concerns with respect to this approach are whether government can do the job, whether this would reduce competition, and again, the challenge of creating new institutions.

- **Public-private partnerships (PPPs) or non-profit initiatives:** There is already a diverse array of undertakings along these lines, such as the Global Alliance for Vaccines and Immunisation (GAVI), the Medicines for Malaria Venture (MMV), and the Global Alliance for TB Drug Development. The IFMPA references over 60 PPPs, although mostly they focus on access to existing products rather than R&D needs. Key funds for these initiatives have come from the public sector and foundations, often for specific health goals. The amount of funding varies across initiatives, as do structures for collaboration. The research process is one of directed research, and application of the usual patent system is often the reward. But these approaches can be complementary to the patent system.

- **The DNDi model:** This was described previously in detail, as a collaborative initiative between non-profits and public sector with a specific R&D focus on the most neglected diseases. The emphasis is on incremental R&D to meet field-driven health needs. Funding comes from donations, the research is undertaken collaboratively through a network of researchers, the rewards are "push-driven" (i.e., not drive by the "pull" of

some sort of financial reward), and IP in the public goods created through this model is in the public domain so as to maximize access.

Mr. Weissman emphasized the importance of developing country contributions to R&D, recognizing that capacity varies. Outside of the larger, middle-income countries (e.g., India, Brazil, China, Cuba), significant investment in researching and developing new chemical entities may be unrealistic. There is a need for alternatives to the patent-driven system because, as recognized by the WHO Commission on Intellectual Property, Innovation and Public Health (CIPIH), weak intellectual property actually facilitates learning through access to information and technology. Research and institutional capacity needs to be increased in developing countries and this needs to be explored through various alternative R&D frameworks. Mr. Weissman concluded with the vision of a new international treaty that focuses on R&D contribution and not protection of IP. The agreement could be calibrated by development level, support diverse methods of R&D, favour open research, and use IP only as a tool for R&D where useful and appropriate, with regard to managing IP for access to medical products.

(4) Global access to essential medicines: the role of universities

Caroline Gallant, of Universities Allied for Essential Medicines (UAEM) and McGill University, provided an overview of the role of universities in R&D and IP protection. Universities are major contributors to health-related innovations, including drugs, vaccines, diagnostics, monitoring tools, and know-how and technical expertise. Of 63 neglected disease drug projects, universities are involved in 26, according to a recent report in *PLoS Medicine*. A U.S. congressional committee recently reported that 15 of the 21 drugs with the most therapeutic impact were derived from academic centres receiving funding from the U.S. federal government. A number of U.S. universities hold patent rights in key HIV/AIDS drugs on the market.

There exists great potential for alternative R&D arrangements. Even the WHO CIPIH explicitly states: "Public research institutions and universities in developed countries should seriously consider initiatives designed to ensure that access to R&D outputs relevant to the health concerns of developing countries and to products derived there from, are facilitated through appropriate licensing policies and practices." Universities need to measure their research and technology transfer success according to impact on human welfare.

UAEM's mission is two-fold:

- to ensure that biomedical innovations, such as drugs, developed in campus labs are accessible in developing countries; and
- to facilitate and promote research on neglected diseases, or those diseases predominantly affecting people who are too poor to constitute a market attractive to private-sector R&D investment.

There are many ways that universities can promote access to essential medicines, including the Equitable Access License (EAL), which allows generic companies to manufacture and export university innovations to eligible countries. Ms. Gallant suggested that the failure to date of measures such as Canada's Access to Medicines Regime has revealed flaws in the legislation and

the limitations of the underlying TRIPS compulsory licensing framework; we need to consider approaches that go beyond the 2003 WTO Decision. The EAL framework for universities offers one such approach.

The research and development pipeline has an increasing reliance on university biomedical discoveries, meaning that universities have leverage to set licensing terms for innovation. They can include provisions allowing generics to manufacture and export to eligible countries. Universities can leverage their rights in life-saving innovations to lift patent, data and production barriers to generics. EAL works through the following mechanism. First, the university develops and transfers rights to the pharmaceutical company for development. In exchange, the company transfers back those rights and any associated rights (including downstream development) to the university. This "flow back" of rights would be solely for use to produce generics for eligible countries. Those who want to make the medicine and export it to a country need only notify the university and the pharmaceutical company, following which the university will immediately transfer the rights to the manufacturing company, which can go straight into production. Any additional improvements made by the notifier would flow back to the university. The benefit of this arrangement is that it requires no prior negotiation between the supplier and the manufacturer and patent holder. This model is the basis for the U.S. *Public Research in the Public Interest Act of 2006*, which conditions federal research funding on an institution's adoption of EAL.

Ms. Gallant suggested that universities can also promote R&D for neglected diseases, by promoting in-house research, engaging with non-traditional partners to create new opportunities for developing drugs for neglected disease, and carving out a neglected diseases exemption for any patents held or licences executed by the university. UAEM is undertaking various initiatives, such as:

- bringing together funders, universities, and PPPs to develop a policy on neglected diseases;
- pursuing alternative, access-minded licensing policies (e.g., at Harvard);
- developing more progressive technology transfer "metrics" (e.g., at Johns Hopkins and McGill);
- expanding the WHO Essential Medicines List (e.g., the successful application to add a statin drug in April 2007); and
- bringing together university presidents and other stakeholders.

Discussion points

Denis Matwa of the Treatment Action Campaign (TAC) in South Africa raised the issue of extensively drug-resistant tuberculosis (XDR-TB) and the lack of effective drugs to treat TB. Ms. 't Hoen from MSF noted a shift in thinking that TB is under control to a recognition that we haven't got the tools we need. In general, new diseases are arriving very fast and we are unprepared. This is a new area that acknowledges a radically different approach to R&D is needed, and it provides an opportunity to bring the partners together to develop new products and provide treatment today. Even pharmaceutical companies are recognizing that the current system is not adequate for that.

Ms. Gallant of UAEM emphasized that the role of universities is significant because they can gain considerable income from licensing. However, the access provisions discussed should not affect either universities' or companies' bottom lines. Most funding universities receive is from government. It is possible that universities need not license at all and could instead just permit public use.

Mr. Weissman of Essential Action noted that the U.S. *Bayh–Dole Act*, which gave universities the right to license innovations exclusively, is an important part of the history of this policy debate. Universities have a strong lobby, and are currently trying to export the U.S. R&D model to developing countries. Ms. Dentico mentioned that DNDi negotiations with U.S. universities are longer (nine months) than those with European universities (four to six months). She suggested that in some instances universities are actually more aggressive than pharmaceutical companies.

Senator Ungphakorn emphasized the importance of increasing collaboration between universities in developed and developing countries to increase research capacity.

Finally, Ms. Rius spoke of the feedback KEI has received from the industry and universities on the concept of patent pools. She said that generally, feedback on the licensing term is positive but the problem area is the incentive for them to license. There is a need for both sticks (compulsory licensing and civil society pressure) and carrots (the rule of law, R&D incentives, etc.). Some pharmaceutical companies want to give access to their inventions but want to ensure that it does not affect profits in markets of the global north.

Friday, 20 April 2007

The objective of the second day of the meeting was to review Canada's Access to Medicines Regime (CAMR) and to elicit commentary on and recommendations for reform, if necessary, of that regime and of similar legislation on compulsory licensing of pharmaceuticals for export in other jurisdictions. Before delving into a discussion of the specifics of CAMR and the underlying 2003 WTO Decision, participants were welcomed by a keynote address.

(1) Keynote address: "Making it work for those who need it"

Stephen Lewis, former UN Special Envoy on HIV/AIDS in Africa for over five years, delivered a keynote address to participants, in which he outlined a number of points regarding CAMR and the broader dimensions of the global crisis in access to medicines for HIV/AIDS.

First, **the members of the Canadian parliamentary committee reviewing CAMR are not serious about the necessary amendments to this legislation**. Having appeared as witness earlier in the week before the House of Commons committee reviewing CAMR, Mr. Lewis was disappointed by the level of the committee's deliberations. He does not believe that they are taking CAMR seriously and gave a sense of the political landscape. The Conservative Party, currently governing with a minority in Parliament, appears content to have CAMR seen as a failed legacy of the former Liberal Party government and wants nothing to do with it. The Liberal Party that brought forward the legislation creating CAMR in 2003–2004, and named it after a previous Liberal Prime Minister, would like to distance itself as far as possible from it since it is not working. Liberal MPs are trying to intervene by looking at diversions and by 'grandstanding'. The Bloc Québécois grasps very little of what is happening and the New Democratic Party (NDP) appears to be the lone voice advocating for some kind of meaningful change along the lines of what expert NGOs have proposed. Mr. Lewis doubted that the political constellation will be in place to get a majority together to agree on amendments, but that should not stop advocates from changing the situation. It is possible to make the necessary amendments plausible and valuable enough that parliamentarians embrace their key features, because in its current form, the legislation is deeply embarrassing for Canada. These circumstances make the work done during these meetings and the immediate future that much more important.

Second, **UN agencies are distancing themselves from the responsibilities of ensuring treatment access**. Recently, the WHO, UNAIDS and UNICEF released a report on progress on scaling up ARV treatment access: approximately 2 million people are in treatment and 1.3 million of them are in Africa. There has been a lot of "glad-handing" but the fact is that more than 5 million are still without treatment, which is an appalling consideration. Only 11 percent of HIV positive pregnant women are receiving either nevirapine or anything else for preventing mother-to-child transmission (MTCT) of HIV, and only 15 percent of children who need ARV treatment are receiving it. Mr. Lewis noted that it is important to emphasize the fact that the recovery rate once patients are on these medications is 93 percent — politicians need to be constantly reminded of the benefits that are at stake and that are currently being denied. He was struck by how UN agencies distance themselves from the fray. They frame the situation as an epidemiological review as if they take no responsibility and all fault lies with the governments of

affected countries. How is it possible that only 11 percent of HIV-positive women are receiving some kind of treatment when even Dr. Peter Piot, the Executive Director of UNAIDS, says that this is one of the easiest things to achieve? Why was it necessary for the Clinton Foundation to negotiate lower prices for ARV treatment for children, rather than UNICEF? We must recognize that UN agencies have a real responsibility and cannot be let off the hook. These agencies have tremendous influence on the ground and yet they are not doing nearly enough.

Third, **the cost of the second-line drugs is extremely high**. Governments know the severity of the future costs that lie ahead. The Clinton Foundation is now in tense negotiations on second-line drugs. Nothing is in place yet but the price reductions will not be anything like current first-line prices, so this prospect remains a source of great anxiety for various governments. These developments give the intellectual property issue a tremendous significance, meaning that breaking through on CAMR or similar regimes in other countries that have implemented the 2003 WTO 2003 Decision is important. These governments cannot submit to the pressure of the pharmaceutical industry and the United States in refusing to take steps that would help supply medicines at lower cost.

Fourth, **developing countries face a looming financial crisis**. The figures on international official development assistance (ODA) remain appalling. How do we get the world to understand? Countries make these amazing commitments at the G8 and they are falling apart. Despite the last commitments at the 2005 G8 meeting in Gleneagles, Scotland, we have witnessed a decline in ODA from 2005 to 2006, and even those numbers were inflated by debt cancellations in Iraq and elsewhere such as Nigeria. The developing world is facing a serious financial crisis. It is estimated that the global AIDS response requires US$18 billion in 2007, and the world will be lucky if even US$10 billion is mobilized. How do we get these countries to recognize that obligations must be honoured? They must keep their promises. A related question is the renewal of the U.S. PEPFAR, and the level of that renewal. Even would-be Democratic presidential candidate Barack Obama says he would commit only $US 1 billion more per year, when the U.S. must renew PEPFAR at US$8–9 billion per year or else the financial needs for the response will not be met. There is a widespread perception that there is a flood of money being poured into addressing AIDS globally, but this is far from being the case.

Fifth, **there is a new belligerence on the part of Big Pharma**. It seems that the industry feels collectively like it is coming back into play after some retreats following the debacle of the court case against South Africa and the resistance from developing countries that led to the Doha Declaration. What Abbott has done in response to Thailand's use of compulsory licensing, and what Novartis is doing in India to challenge measures that limit the scope of patents and patent rights, are good examples of this new approach, as is the push for TRIPS-plus bilateral trade agreements. The power of Big Pharma will have to be contended with again. They are in an aggressive mood.

Finally, **the uncertain future of India is of great concern**. Ominously, no one seems quite able to predict what will happen in India. We must plan on the assumption that we will require interventions elsewhere if the outcome there restricts access to Indian-made generics. Mr. Lewis said that "it is time to take the gloves off" and struggle with even greater determination for access, or else the concept of "universal access", endorsed by the G8 and the UN, will come to

rot and millions will die. He is inclined to be more vigorous about the situation and identify the "bad guys" and go after them with no holds barred. The UN, Big Pharma, Canada and even NGOs that undermine the effort for access — take the gloves off! There is no time for undue respect any longer. It is time for substance, analysis and the concrete work done today to rescue this legislation. The World Bank is mired in a leadership that is corrupt. The IMF has been reduced to the margins except when it comes to harassing countries. "This world is relying on the activists to bring sanity. It is time to be really, really tough."

Discussion points

WHO developments and the need to hold UN agencies accountable

Ms. 't Hoen of MSF noted that developments at the WHO are distressing. Recently, the new Director-General, Dr. Margaret Chan, held a meeting with the brand-name pharmaceutical industry to tackle the issue of neglected diseases. Ms. 't Hoen noted that the primary response from the WHO appears to be "ignore the hard questions, especially with IP and celebrate the achievements in neglected diseases (that do not exist), and accept drug donations as a response to the crisis." At times donations can be useful, but this is a distressing solution coming from the WHO. She raised the question of what to do in the context of these developments and what the role of countries like Canada should be to influence policies at the WHO, particularly in light of the fact that Canada is chairing the IGWG.

Mr. Lewis agreed with these concerns. Through a WHO colleague, he learned that the issue of intellectual property has been infusing its way into most WHO Executive Board Meetings, a development which is particularly distressing. This is likely due to the fact that the U.S. is on the board. Dr. Chan's criticism of Thailand's compulsory licence occurred shortly after these meetings. These developments suggest that the industry is really calling the shots and the WHO is becoming more deferential. Mr. Lewis suggested that this should be handled by going after the WHO on these issues. It is important to understand that UN agencies get very anxious when they are criticized and attacked. With the power of MSF in particular, there is potential to make the WHO draw back somewhat from being the "handmaiden of pharma".

Lack of political leadership

Counsellor Mboya described a meeting that he recently attended where French President Jacques Chirac observed that globalization had generated much profit but that it is mostly shared in developed countries. Only 5 percent of the profit (100 billion euros) is sufficient to ensure effective health programs in developing countries; this is where the investment is needed and it is entirely feasible. Counsellor Mboya believes Chirac will bring this issue before the next G8 meeting. It is clearly not a question of lack of resources but about powerful leadership. He questioned what prevents these politicians from following through on their commitments. Mr. Lewis agreed with Mboya's reflections by highlighting that the airline tax France recently spearheaded to increase funds for treatment, through UNITAID, is not enough. The money is there to be had, and Jeffrey Sachs has documented these arguments well in the report for the WHO Commission on Macroeconomics and Health in 2001. It is clearly an issue of lack of political leadership. Mr. Lewis hopes we will see greater leadership on this front from the

incoming British Prime Minister, Gordon Brown, who he sees as having been the one consistent voice on poverty and disease. If the U.K. can meet its target for ODA of 0.7 percent of GNI by 2013, and then accelerate withdrawal from Iraq, they will be a more formidable voice giving leadership on the G8. This leadership is not likely to come from Canada in the immediate future.

V. Exporting and Importing Generics: Implementing the 2003 WTO Decision — The Canadian Case

(1) Canada's Access to Medicines Regime (CAMR): an overview

As both the Department of Industry and the Department of Health have responsibilities related to the implementation of CAMR, participants heard presentations explaining the basics of the regime from both Douglas Clark, Director of Industry Canada's Patent Policy Directorate, and Brigitte Zirger, Director of the Bureau of Policy, Science and International Programs within Health Canada's Therapeutic Products Directorate.

Mr. Clark summarized the main aspects of the CAMR and how they relate to the 2003 WTO Decision.[3] He noted that among the Decision's main terms and conditions were the following:

- The importing country must notify the WTO of its intent prior to using the waiver, and of the amount of a product needed and its patent status in the importing country.
- The quantity of the drug produced under the compulsory licence cannot exceed the amount notified by the importing country.
- The waiver must be used in 'good faith' and not for commercial or industrial objectives.

Mr. Clark compared CAMR to other countries' implementation of the 2003 WTO Decision. He noted that most countries waive the voluntary licensing requirement in situations of national emergency or extreme urgency without specifying whether these situations must exist in the importing or exporting country, and this was an area of uncertainty.

In reaction, Prof. Abbott suggested that in effect, Canada was making the unique contribution to international law of undermining the WTO process by suggesting that the public health emergency has to be in Canada instead of the developing country that is the intended beneficiary. Prof. Abbott mentioned that Canada is making this argument formally at the WTO TRIPS Council and that the Canadian government should be entirely embarrassed, since it is clear that it is an emergency or similar situation in the importing developing country that would be the relevant consideration. Mr. Clark stated that this was not clear to him and he has taken the advice of counsel from the Department of Justice on this point, but he was "leaving the door open".

Mr. Clark noted that the federal government's review of CAMR is underway, and that Parliamentary committee hearings are also in progress.[4] Based on submissions received, the

[3] For complete details about CAMR, see the website maintained by the Government of Canada at www.camr.gc.ca.
[4] For details, see: Government of Canada, *Canada's Access to Medicines Regime — Consultation Paper* (November 24, 2006), on-line: http://camr-rcam.hc-sc.gc.ca/review-reviser/camr_rcam_consult_e.html

positions of various stakeholders on CAMR were largely unchanged from 2003–2004 when the legislation was drafted and enacted. The brand-name industry wanted little or no change to the legislation and would like to focus on other ways of improving access to medicines. Generic manufacturers have expressed minimal interest in using CAMR unless there are greater incentives for them. NGOs would like immediate liberalization of the regime. Notably, developing country representatives — the intended beneficiaries of the legislation — were not among the stakeholders listed or consulted. Ms. Zirger of Health Canada suggested that having a formal contribution from developing countries would be invaluable.

Ms. Zirger then briefly described Health Canada's role in CAMR, which is three-fold:

- To undertake review of a generic product intended for export to ensure it meets the requirements of the *Food and Drug Regulations* in the same manner as a product intended for sale in Canada.
- To ensure that the product is distinguishable from the patented version in Canada.
- To perform a pre-export inspection.

Health Canada has had some experience with the first two aspects of the process, in relation to the product developed by Apotex, Inc., a fixed-dose combination (FDC) of the already-approved ARVs zidovudine (AZT), lamivudine (3TC), and nevirapine (NVP). As no compulsory licence has yet been issued under CAMR, the third element, the pre-export inspection, has not yet occurred.

There are two application processes for a generic manufacturer wishing to export under CAMR, one under the *Patent Act* (for a compulsory licence) and one under the *Food and Drugs Act* (for review by the drug regulator). Under the *Food and Drugs Act*, after conducting relevant reviews, Health Canada issues a "patent hold" letter, which essentially indicates that the drug could be released onto the Canadian market were there not still a patent on the originator product(s). This allows Health Canada to certify that the product has met the regulatory requirements of safety, efficacy and quality, while avoiding issuing a Notice of Compliance (NOC), which is the marketing authorization that it is prohibited from issuing, under Canada's separate "linkage" regulations that link marketing approval to patent status, until there is no patent barrier to the generic product going to market. As of July 2006, the Health Canada review has been recognized by the WHO Prequalification Programme (to be discussed in more detail below). No application for a compulsory licence has yet been filed under CAMR, but Health Canada continues various outreach activities to publicize the regime to developing countries.

Discussion points

Cailin Morrison, a consultant and former legal advisor to MSF's Access to Essential Medicines Campaign, noted that CAMR requires importing countries to indicate the maximum quantity requested for production and import, whereas the 2003 WTO Decision states "expected quantities". Mr. Clark agreed with her interpretation but emphasized that there was no attempt in the WTO waiver to minimize the quantity and that is not CAMR's intent. The importing country has all the freedom to determine the quantity.

Mr. Weissman of Essential Action suggested that it was misleading to look at the details without thinking about the larger framework, and that the intent of the 2003 WTO Decision is to place importing countries in the same position as if they had the manufacturing capacity to use compulsory licensing to produce generics domestically. The exporting country should therefore create this situation. CAMR needs to facilitate economies of scale and generic competition. Furthermore, the pressure and intimidation that developing countries face in issuing compulsory licences must be recognized in how the legislation is written and implemented. This step must be facilitated by CAMR as easily as possible. Mr. Clark agreed with Mr. Weissman's observations but stated that this was a problem of the WTO framework and not the CAMR *per se*. Mr. Clark stated that they are investigating increasing economies of scale through the regional trade provision of the 2003 WTO Decision, allowing licences to apply to many countries at a time.

Counsellor Mboya of the Kenyan Mission in Geneva spoke to the trust that the African Group at the WTO has in Canada, hence advocating for the Canadian chair of the WHO IGWG. CAMR's purpose as set out in the legislation is to "give effect to Canada's pledge to Africa". Canada has the opportunity to try to fix the regime which has not delivered on this pledge. The African Group is putting their faith in Canada to fix the problems of the legislation which include the administrative complexities, the lack of incentives for generic manufacturers, and finally, creating a policy framework for all actors to be included. Counsellor Mboya's last point speaks to a greater and more formal involvement of developing countries in such policy processes, given that this is a long-term issue which will require future policy interventions.

Mr. Clark stressed that each feature of the legislation had a clear rationale for inclusion but that the problems ultimately reflect the overarching complexity of the WTO regime. Mr. Lewis emphasized that the problems with the legislation are inherently political. While each feature of the legislation has a rationale and technically-based justification, the choices were inherently political. Mr. Lewis was privy to the political machinations behind the development of the legislation and was astonished by how anxious politicians were to appease the brand-name companies.

(2) Using Canada's Access to Medicines Regime: a case study

NGO purchaser perspective: MSF's experience

Rachel Kiddell-Monroe summarized MSF Canada's experience with trying to request an order for drugs under the legislation.[5] MSF's request for drugs started in August 2004 and until now, the process has yet to reach fruition. Ms. Kiddell-Monroe outlined the various components of the legislation that were problematic, which included its "case-by-case" approach.

[5] For more detail, see: Médecins Sans Frontières, *Neither Expeditious, Nor a Solution: The WTO August 30th Decision is Unworkable — An illustration through Canada's Jean Chrétien Pledge to Africa*, Briefing Paper for the XVI International AIDS Conference, Toronto, August 2006, on-line at: http://msf.ch/fileadmin/user_upload/uploads/communiques/images_2006/pdf/came_Neither_expeditious_nor_a_solution_-_August_30_and_the_JCPA_single_page.pdf.

MSF's operations require stockpiling drugs at a warehouse in France and then distributing to their various projects and missions. CAMR is entirely incongruent with this process. She highlighted the lack of interest from generic companies and cites Apotex's involvement and commitment to developing a product, at MSF's request, as being a unique case. She noted a lack of interest on the side of developing countries in using the legislation. Meanwhile, in June 2006, Apotex's fixed-dose combination product produced for possible export under CAMR was produced by a number of Indian generic companies, and some of those products have been approved by the U.S. FDA and the WHO PQP and are now available without the constraints of the 2003 WTO Decision or associated legislation such as Canada's.

Ms. Kiddell-Monroe emphasized that CAMR issues were inherently based in the conflict between corporate and humanitarian interests. She also noted the difficulty encountered by MSF in its efforts to get a country to come forward and make the requisite notification to the WTO and be the first to attempt to use the 2003 WTO Decision, via Canada's implementation of it in the form of CAMR. Noting the political reality facing countries considering using compulsory licensing, she also raised the question of why the Canadian government is not supporting Thailand's issuance of a compulsory licence, given that CAMR represents Canada's recognition that countries need to be able to make use of this tool to obtain affordable medicines. During the discussion, Ms. Kiddell-Monroe also stressed that the list of drugs under CAMR (Schedule 1 of the *Patent Act*) is problematic, since developing country needs are dynamic. Finally, she stated that Canada should go to the WTO and say that the 2003 Decision does not work and show why from its own experience as one of the first countries to implement it.

<u>Generic producer's perspective: Apotex, Inc.</u>

Bruce Clark, Vice-President (Medical & Regulatory Affairs) of Apotex, Inc. reviewed his company's involvement in CAMR. Apotex, a privately-held Canadian company, is the largest generic manufacturer in Canada. Its involvement in attempting to use CAMR began in August 2004 through a meeting with MSF and government representatives to discuss options. In response to MSF's request, in December 2004 Apotex agreed to produce a three-in-one fixed-dose combination of zidovudine (AZT), lamivudine (3TC), and nevirapine (NVP). Apotex has invested more than CAN$2 million to date. The product has satisfied all of the requirements of Canada's *Food and Drug Regulations*, but is currently on "patent hold" since an application for a compulsory licence under CAMR requires identification of the importing country. The country must initiate this notification, to the WTO (or to the Canadian government in the event of a non-WTO Member), and the compulsory licence application must conform to the information in that notification. Apotex is unlikely to attempt using CAMR again if the process remains the same.

Mr. Clark had three main recommendations for CAMR. First, he suggested streamlining the process and moving directly to the compulsory licence after regulatory approval. Second, the Canadian government must move from the passive role of facilitator to the active role of implementer, by putting in place mechanisms to engage generic manufacturers, which are profit-based companies. They are constrained by costs and while Apotex was able to engage because of its latitude in being a privately-held company, industrial priorities and global competition will not allow them to participate in such a regime in a long-term way. Finally, Clark recommends

using existing government-sponsored, university-based facilities to engage in non-profit development of these products under compulsory licensing agreements.

Mr. Clark suggested that Apotex would participate again if CAMR is improved and has the possibility of working. He stated that Apotex can currently sell its FDC product (Apo-TriAvir), at $0.39 per tablet, which is comparable to the equivalent generic FDC produced by Aurobindo in India, which sells at $0.34–0.36 per tablet.

In response to the presentations about MSF's experience and that of Apotex, Tenu Avafia, Intellectual Property Policy Advisor with the UN Development Programme (Regional Service Centre) in South Africa, highlighted the point that government tendering to procure medicines is usually across numerous categories of drugs, not for single products, and that this legislation fails to account for that procurement reality.

(3) CAMR and the 2003 WTO Decision: comparative analysis, possible alternatives

Richard Elliott, Deputy Director of the Canadian HIV/AIDS Legal Network, outlined a number of problems with CAMR, compared the features of CAMR with other countries' implementation of the 2003 WTO Decision and outlined some proposed amendments put forward by the Global Treatment Access Group (GTAG) and the Canadian HIV/AIDS Legal Network.[6] His review presented ideas for consideration in the subsequent discussion by participants regarding features of Canada's regime and those of other jurisdictions, and the underlying WTO framework.

VI. Canada's Access to Medicines Regime: Existing Features and Options for Reform

Informed by (i) the presentations from Industry Canada and Health Canada regarding the basics of CAMR, (ii) the lessons learned from the experience of MSF and Apotex as would-be purchaser and supplier in attempting to use CAMR, and (iii) a comparative analysis of CAMR and other countries' similar regimes and proposed alternatives, participants then discussed various features of CAMR in order and considered possible directions for reform, with a view to contributing to the review of CAMR currently underway and discussions in other fora regarding IP and access to medicines.

Richard Elliott facilitated an examination of each of the major areas of concern regarding the existing legislation.

[6] For a short summary of proposed amendments, see: Global Treatment Access Group, "Delivering on the Pledge: Reforming Canada's Access to Medicines Regime", Submission to the Government of Canada (January 2007), on-line via: www.aidslaw.ca/gtag. For a more detailed analysis, including specific statutory amendments proposed for streamlining CAMR and implementing a mechanism freed of the limitations of the 2003 WTO Decision, see: Canadian HIV/AIDS Legal Network, *Getting the Regime Right: Compulsory Licensing of Pharmaceuticals for Export*, Brief to the House of Commons Standing Committee on Industry, Science and Technology regarding Canada's Access to Medicines Regime (April 18, 2007), on-line via www.aidslaw.ca/gtag.

(1) Health Canada approval and relationship to WHO's Prequalification Programme (PQP)

Mr. Elliott recommended eliminating the requirement of getting Health Canada approval on the product for export and making it optional instead. He noted that this requirement was introduced with the legislation that created CAMR and only applies to products produced for export under compulsory licence per CAMR; the pre-existing section 37(1) of the *Food and Drugs Act* expressly says, in relation to all other products, that no Health Canada approval is required for products that are exported. It is sensible that Canada's technical capacity for such review be made available to assist countries in guaranteeing access to a quality product, but it should not be mandated as the only such acceptable mechanism if there are other avenues for approval, including the PQP. Ms. Zirger from Health Canada mentioned that Health Canada has been criticized for allowing exports of vaccines under section 37(1) of the *Food and Drugs Act*, the section stating that no review is required; therefore, they see a need for approval.

Discussion followed on whether WHO prequalification is dependent upon Health Canada approval. The general consensus was that Health Canada approval did not mean automatic WHO PQP approval. A company must make a formal request to be placed on the WHO's list of prequalified products and manufacturers. Then, the WHO can refer to the approving country (Health Canada) for additional information that they might need to complete their dossier. Bill Haddad of Cipla suggested this was a formality and emphasized that the WHO PQP was the global standard. While a country like Canada may not find WHO PQP sufficient, many recipient developing countries require it. Using Nigeria as one example, Mr. Avafia of UNDP also stated that WHO prequalification is most often required in various countries.

Ms. 't Hoen of MSF noted that the WHO PQP is meant to help national drug regulatory authorities make decisions. Despite the Health Canada approval, the appropriate national body of the importing country will have to make the decision of whether or not to register the product. Many like to rely on the WHO as a multilateral mechanism that they participate in and support, and it is particularly important with respect to the products specifically produced for developing countries. But there are also many national drug regulators that deal with these dossiers themselves, such as in Thailand. Billy Mweetwa of the CIDRZ in Zambia said that Health Canada approval was valuable because they have experienced some quality issues with the WHO PQP.

Ms. Kiddell-Monroe noted that, in MSF's experience of trying to get Health Canada to approve a combination product containing nevirapine, they found that many regulators in Health Canada at the time were not versed in the developing country context and the fact that the risk-benefit assessment can be much different. Health Canada was extremely reluctant to approve nevirapine because of concerns about toxicity and getting this approved took a lot of effort and convincing on the part of MSF and expert consultation.

Jim Keon of the CGPA noted that Health Canada approval is something that generic companies support and that they would be concerned if it was made only optional. Their companies like the fact that it is mandatory. Mr. Clark of Apotex supported this statement by adding that Health

Canada approval gives them a "patent hold" letter, which is a guarantee that once the patent expires they can immediately enter the Canadian market.

(2) Compulsory licensing procedures under CAMR

Mr. Elliott highlighted a number of problems with respect to the compulsory licensing procedure under CAMR and the 2003 WTO Decision, including:

- The generic company requires the essentials of a contract as the basis for seeking a voluntary licence or compulsory licence to export but has no guarantee that it can actually supply without a licence.
- The precondition of negotiation for voluntary licence means potential importing countries can be exposed earlier — and for a greater time, even before a compulsory licence is issued — to pressure and retaliation to dissuade them from proceeding.
- The compulsory licence imposes a limitation on a specific contract to supply a set quantity of a product to just one country.

Ms. 't Hoen suggested some useful resources to find solutions to these problems, including (i) the WHO's submission to the WTO TRIPS Council, in which WHO strongly supported an Article 30 approach of creating "limited exceptions" to patent rights to enable compulsory licensing for export and warned against an Article 31 solution, and (ii) the WHO CIPIH report which goes into the economic viability of these solutions.

Mr. Elliott recommended waiving the requirement for voluntary licence negotiations entirely, moving automatically to compulsory licensing. Ms. Kiddell-Monroe mentioned that there was an issue with respect to the duration of negotiations, and that the 30 days should be a maximum amount of time. Ms. Morrison mentioned that then the dispute becomes a question of when the 30 days actually started. Mr. Elliott responded by agreeing with this issue in part; however, he sees the major stumbling block as the patent-holder being able to claim that the generic company did not fulfill all of the information requirements as long as, for example, the intended importing country is not identified to the patent-holder. Indeed, Mr. Clark of Apotex agreed and said that the current stumbling block facing Apotex is that no country is named. Once the country is named, in theory, the 30 day clock should start ticking.

(3) Procurement practices and CAMR

One of the major barriers to the use of this legislation is its incongruence with standard international procurement practices. As Mr. Buluma of KEMSA and Sarah Perkins of the University of Toronto Access to Drugs Initiative both noted, governments and public institutions have domestic laws they must follow in the interests of transparency and this includes issuing a bid for an international tender. Potential suppliers then make a bid. It is unclear how a generic company complying with CAMR's licensing procedure will be able to have a contract upfront as the basis for seeking a licence.

Mr. Clark of Apotex proposed the option of simply having a letter of intent on a certain quantity, while the actual procurement would be done on an invoice basis. However, Ms. Perkins

described the experience of attempting to arrange a meeting between Ghanaian regulatory authorities and Apotex to explore options through CAMR. The delegates refused to meet with Apotex because it would be in violation of their domestic procurement laws. Even engaging in discussions about letters of intent outside of their rules was considered entirely inappropriate. Mr. Keon of the CGPA agreed, stating that it is very difficult to be considered a serious bidder without a licence already in hand, since there is no certainty that such a company could in fact deliver. In the end, it is unknown whether, under CAMR, a statement of "intent to purchase" would be considered sufficient to issue a compulsory licence.

Ms. 't Hoen capped off this discussion by describing the core problem of CAMR as trying to make the importing countries fit the mechanism, rather than the other way around. The reality of drug purchase for and by developing countries or international agencies is not taken into account. MSF buys some of its product through IDA and UNICEF. UNICEF does not know how much is distributed and to what countries by MSF, which stores it in warehouses, stockpiling it and then shipping it as necessary to various projects in the field. Normally, MSF does not have product shipped directly from a manufacturer to specific projects. Given this complexity, CAMR and similar regimes need to be as automatic as possible. The focus should be on the procedure of fulfilling the importing countries' needs and, after that, the rest must be automatic. Prof. Abbott supported this view, stressing that the voluntary licence negotiations have rarely been positive and the process needs automaticity.

(4) Two-year limit on duration of compulsory licence under CAMR

Mr. Elliott noted that CAMR included a provision that limits the length of any compulsory licence to a maximum of two years. There is a provision that allows for simpler administrative extension of this timeframe for up to two more years, but only for the purposes of completing production and delivery to the named importing country of the original quantity of the product authorized by the licence; it is not a renewal that permits the manufacture of additional quantities of the product. If the country and generic manufacturer want to extend the contract or expand the product quantity, then a new process of seeking a licence, including first attempting to negotiate a voluntary licence with the patent-holder(s), must be undertaken. Mr. Elliott noted the two-year limit was not a feature of the 2003 WTO Decision. He suggested the two-year limit was not only an unnecessary restriction that is a disincentive to generic producers and potential purchasers, but was also arbitrary. He suggested that the term of any compulsory licence issued under CAMR should last for the remaining term of the patent(s) on the product(s), or at least for the duration of the contract negotiated between the generic producer and the purchaser, which could exceed two years. In addition, extending an existing licence easier was also advisable.

Meeting participants generally viewed the two-year limit on compulsory licences as a negative feature of CAMR. Most generic company representatives suggested this was entirely economically unattractive and unfeasible. Mr. Clark of Apotex commented that his company must schedule the production of drugs well in advance (3 years), and cannot afford to have this uncertainty in planning its production process. Several participants also pointed out that a two-year period was not nearly enough, especially given the long-term timeframe of AIDS treatment. Dr. Hoos of Columbia University's ICATP noted that usually contracts for sourcing generics need not lock the purchaser into a sole source, so there is no advantage to this arrangement.

(5) List of products eligible for compulsory licensing (*Patent Act,* Schedule 1)

It had been observed that CAMR includes a list of products that are subject to compulsory licensing for export. A product must be on the list before a generic producer can obtain a licence. The list consists primarily of products that are under patent in Canada and that are on the WHO's Model List of Essential Medicines or ARVs approved in Canada for treatment of people living with HIV. Mr. Elliott noted that, during the passage of the legislation, NGOs' concerns about such a limited scope of a list, as well as it creating delay and opportunities for patent-holders to lobby against additions, were borne out. During final reading of the legislation in Parliament, lobbying from the brand-name pharmaceutical sector led to the defeat of a motion to add two drugs to the Schedule, notwithstanding an earlier agreement by all parties at the stage of committee hearings (and the concurrence of Health Canada) to add these two products. In its recent consultation paper regarding CAMR, the Government of Canada has noted that few other countries that have implemented the 2003 WTO Decision have included a limited list of this sort.

The legislation includes provisions that allow for a federal Cabinet decision to add new products to the list, following a recommendation from each of the ministers of Health and Industry. The list has been amended twice; the first instance was to add the AZT/3TC/NVP combination product developed by Apotex, the second was to add the antiviral drug oseltamivir phosphate, marketed under the brand-name Roche for prophylaxis and treatment of viral influenza.

Mona Frendo, Acting Senior Project Leader with Industry Canada's Patent Policy Directorate, explained the rationale behind including the list of eligible products in the legislation. She said that to ensure the licence process is as automatic and certain as possible, and given the litigious nature of the industry, the inclusion of the list was to minimize the discretion applied by the Commissioner of Patents in issuing a compulsory licence. The concern is that the greater the discretion on the part of the Commissioner, the more grounds or greater opportunity for patentees to litigate and hold up the process.

Prof. Abbott pointed out that Schedule 1 reflects an initial response by the Canadian government a few days after the call by Stephen Lewis and NGOs to enact legislation implementing the 2003 WTO Decision, and the widely-reported comment by IFPMA Director-General Harvey Bale's that the move would be a "black eye" for Canada. Canada's opening response was that there is uncertainty about the Decision, and therefore we should make a restriction on the drugs eligible for compulsory licensing. The negotiating history on this point is well-documented: the U.S. held up negotiations on the Article 31(f) waiver based upon the issue of restricting it to a scope of diseases, but ultimately abandoned this request, and the final text adopted by consensus on 30 August 2003 does not include such a restriction. This would clearly inform the interpretation of CAMR, and in any event the 2003 WTO Decision and, for example, the European implementing regulation are both clear that they extend to "any pharmaceutical product". To suggest that Schedule 1 was included as a positive mechanism to reduce the discretion of the patents commissioner so as to avoid litigation is not supported by the record of events in Canada.

John Fulton of Biolyse Pharma was concerned about the delays experienced in getting his company's generic oseltamivir phosphate onto the list (seven months), and that it took much

lobbying and advocacy on their part and by NGOs to get it added. He would like to see the process sped up and more resources dedicated to it. He suggested that if avian flu had hit Canada, the addition would have likely been made much more quickly. Ms. Zirger of Health Canada suggested that in the event of an avian flu outbreak, they could fast-track the process. Mr. Elliott mentioned that during negotiations over the legislation, government officials stated that obtaining a federal Cabinet order adding a drug to the list could be done within a matter of days, which has not proved to be the case.

Jim Keon would like to see the list removed completely. To think that it would have an impact on litigation is naïve. He has further concerns about the delay in establishing the expert committee promised by the Canadian government.

(6) Eligible purchasers and importers: restrictions on NGOs

Mr. Elliott recommended eliminating the requirement under CAMR for NGOs to obtain "permission" from the government of the importing country. This requirement does not arise out of the 2003 WTO Decision. The term "permission" is undefined. No participants voiced any disagreement with this recommendation.

(7) List of eligible importing countries: Schedule 3

Mr. Elliott explained that CAMR largely replicates the classification of countries as potential importers that is set out in the 2003 WTO Decision and accompanying Chairperson's Statement of the same date. Schedule 2 to the *Patent Act* lists all countries recognized by the UN as "least-developed countries" (LDC), and sets a positive precedent of including those LDCs that are not WTO Members. Schedule 3 lists other developing countries, but only those that are WTO Members. Non-LDC developing countries that do not belong to the WTO are not currently included on this schedule as countries that are eligible to import generics made in Canada under CAMR. If they are certified by the Organisation for Economic Co-operation and Development (OECD) as eligible to receive development assistance, they can be added to the Schedule, but in order to qualify, they must declare a "national emergency or other circumstance of extreme urgency" and pledge to not permit "commercial use" of the product (which term is undefined). Mr. Elliott suggested these additional requirements were unjustified and set a double standard between developing countries based on WTO Member or non-Member status. He recommended removing these additional requirements.

Prof. Abbott saw adequate scope in the 2003 WTO Decision to permit WTO Members to allow non-Members to take advantage of the system. He remembers this point being raised during Parliamentary committee hearings into the draft legislation in early 2004. One mechanism for allowing non-WTO Members to take advantage of the mechanism is to request a letter from the relevant country stating that they would abide by the rules of the 2003 WTO Decision, but CAMR has more restrictions than that. Prof. Abbott also took the view that generally declaring a national emergency is often a bad idea because it can involve suspension of constitutional rights, and can have other kinds of negative consequences, especially because these countries are the poorest of the poor. In general, he does not support putting in restrictions that are TRIPS-plus, which this feature of CAMR certainly is.

Ms. Frendo of Industry Canada explained that these additional requirements were included because of the requirements of the 2003 WTO Decision — this is where the language in Canada's legislation came from. Paragraph 1(b) of the WTO Decision states (with emphasis added):

> 'eligible importing Member' means any least-developed country Member, and any other Member that has made a notification to the Council for TRIPS of its intention to use the system as an importer, it being understood that a Member may notify at any time that it will use the system in whole or in a limited way, for example only in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. It is noted that some Members will not use the system set out in this Decision as importing Members and that some other Members have stated that, if they use the system, it would be in no more than situations of national emergency or other circumstances of extreme urgency;

Bill Haddad mentioned that he had monitored those discussions at the WTO and that this amendment was called the "Pfizer amendment", given its origin. To think that these are logical negotiations is wrong; these are political arguments presented as arguments of science and rationality. It was noted that the language referred to in the 2003 WTO Decision did not warrant or justify the inclusion of this particular limitation in CAMR, because (i) it merely refers to the possibility that a WTO Member may voluntarily notify that it will use the 2003 WTO Decision mechanism only in limited circumstances such as emergencies; (ii) the WTO Members that stated on the record that they intended to use the system to import only in such circumstances are not primarily developing countries, meaning it is misleading to equate non-WTO developing countries with this group of WTO Members; and (iii) the comparable developing countries that are WTO Members are not required to declare emergencies or give additional undertakings in order to be eligible importers under either the 2003 WTO Decision or CAMR.

(8) "Anti-diversion" measures under 2003 WTO Decision and CAMR

There was insufficient time to discuss this item.

(9) "Good faith" clause and CAMR provisions on termination of a licence

There was insufficient time to discuss this item.

Saturday, 21 April 2007

The objective of the third and final half-day was to examine additional areas, beyond questions of intellectual property, for international action supporting access to treatment.

VII. Role of Drug Regulatory Authorities in Exporting and Importing Generics

Brigitte Zirger of Health Canada's Therapeutic Products Directorate (TPD) reviewed the drug regulatory process in Canada and explained the process of regulatory review for the first — and so far only — product under CAMR. In this case, there was no reference product for Apo-TriAvir already approved for use in Canada, because the product combines three drugs (AZT/3TC/NVP) that had not previously been manufactured as a combination product. Therefore, Health Canada's TPD compared bioequivalence of the combination product to the component parts. A new product monograph also had to be created.

Ms. Zirger also described the TPD's international program which includes three pillars:

- bilateral international regulatory cooperation;
- multilateral international harmonization; and
- capacity-building and technical assistance.

Health Canada undertakes bilateral initiatives with other regulatory authorities on specific initiatives, such as memoranda of understanding (MOU) to share information, or joint initiatives on reviewing drugs or medical devices. With respect to multilateral engagement, Health Canada contributes to the International Conference on Harmonization (ICH), the Global Harmonization Task Force (with respect to medical devices), and expert committees and networks of the WHO and the Pan-American Health Organization.

Health Canada's TPD also undertakes initiatives to help strengthen drug regulatory capacity through mechanisms that assist developing countries, such as the WHO Prequalification Programme. Ms. Zirger described the WHO PQP process and explained its purpose. As part of the UN action to increase access to medicines, the WHO PQP aims to address many problems that regulators may face in the developing world. The PQP attempts to address issues with respect to inadequate quality assurance procedures, counterfeit drugs and quality problems. Health Canada sends its best regulators to participate in the assessment of product dossiers for the PQP, as technical assistance to the UN. The assessments occur every few months and the work requires intense efforts over a one-week time frame.

Health Canada also works directly with developing countries that have identified the need for such things as direct technical assistance, and also hosts foreign delegations and a regular study session on drug regulatory issues. Ms. Zirger noted that of 192 member states of the WHO, about 20 percent have well developed drug regulatory capacity, half are of variable capacity, and about 30 percent have quite limited or no capacity in this area.

Discussion points

Denis Matwa from the TAC spoke about the registration problems that they are experiencing in South Africa, especially with respect to the failure of the government to register tenofovir. It was seen as an issue of political will. Options to fast-track registration were discussed. Tenu Avafia of the UNDP explained that the normal registration process is 18 months and the fast-track process is 6 months. TAC eventually decided to write a letter demanding that the South African Medicines Control Council register the product or face litigation.

Ms. Zirger described "best practices" to address such delays including priority reviews. Discussants questioned the role of regulatory authorities such as Health Canada in influencing the MCC to register the product. Ms. Zirger viewed the issue as primarily domestic.

Ms. 't Hoen of MSF suggested that the WHO should be more proactive and take a greater role in moving products into the PQP, going after certain priority products. She provided more context to the establishment of the PQP, suggesting it was largely a political move at a time when regulatory agencies in developing countries had little capacity or experience in dealing with new drugs. The PQP played a major role in opening the market for fixed-dose combination products and it also raised confidence by providing the information necessary to help countries make their own regulatory decisions. She emphasized that it was not set up to combat counterfeit medicines and that we must be wary of the industry's counter-campaign against generics that tries to confuse the issue of counterfeit products with generic products. In some cases, this creates unfounded anxiety about the use of generic drugs, and another hurdle toward using generics as a critical component of scaling up access to medicines.

With respect to the issue of multilateral harmonization of regulatory systems, Ms. 't Hoen clarified that the International Conference on Harmonization was an initiative brought forward by Europe, Japan, the U.S. and its industries. The role of developing countries' national drug regulatory authorities in the process was very small and she urged caution against applying standards that are not sensitive to the context in developing countries. She used the AIDS epidemic in the U.S. as an example: the U.S. took huge risks with respect to patient consent where patients could not be adequately informed at the time because of a lack of evidence about the first generation of ARVs, and accelerated drug development in light of the urgency of the situation, but in the present day we see an insistence of being perhaps overly cautious with developing countries, even though it is also clearly a situation of even greater urgency. The risk-benefit analysis is much different in these countries given the context. One remedy to this is to help developing countries increase capacity and involve these countries in the debates.

Ms. Rius and others raised questions about recent changes in Canada to data exclusivity rules and their relationship to CAMR. Mr. Elliott of the Legal Network explained that CAMR was established before the changes to data exclusivity regulations. There was an explicit provision in the new regulations that exempts products produced under CAMR from the data exclusivity rules. However, as Ms. Morrison mentioned, problems may still exist on the side of the developing country if it has signed or signs a bilateral or regional trade agreement that includes data exclusivity provisions that will restrict its use of compulsory licensing because it cannot register the drug under its domestic rules.

Ms. Cepuch of HAI-Africa raised the issue of patent linkage/patent policing. Mr. Elliott agreed that the link between patent status and regulatory approval is of great concern and, in the Canadian context, is a major source of litigation between patentees and generic manufacturers. The Supreme Court of Canada has described the "linkage" regulations as "draconian". He suggested that we consider the inverse model that exists in Brazil, where they police the patent system from the health side: health authorities can intervene in the patent system when they see that patent law or regulation interferes with health needs.

The issue of increasing developing countries' regulatory capacity was discussed. Ms. Zirger of Health Canada suggested that in the context of scarce human resources, the priority should be placed upon monitoring the supply chain to ensure that the products imported or produced are stable. Counsellor Mboya of Kenya emphasized the need to strengthen local systems and argued that countries like Canada, with stringent mechanisms, have an obligation to transfer this technology or capacity. Substandard medications increase drug resistance, which then becomes a global problem — the lack of capacity in developing countries is, therefore, everyone's problem. The need to increase capacity is even more pressing in the context of the international health regulations coming into force in June 2007.

VIII. Ways Forward: Concluding Observations

Final discussion centered upon the IGWG. Matt Sanger of Health Canada's International Affairs Directorate described the mandate and the process. He emphasized that the period between now and November 2007 is crucial and others emphasized the fact that increased input from all stakeholders must be made. Counsellor Tom Mboya encouraged Canada to take a leading role in advancing ideas that would benefit developing countries, particularly since Canada is chairing the working group. Importantly, inputs should be made before the end of May 2007, to incorporate them into the first draft of the Global Plan and Strategy of Action. Developing countries in particular need to step up and provide inputs beyond the WHO regional consultation that will take place. Ms. 't Hoen supported these calls and emphasized that we need a more substantial debate; Canadian and other NGOs should organize their own inter-sessional meetings to provide more substantive input. The informal session held in Geneva with pharmaceutical companies was very encouraging, as many people showed willingness to cooperate and bring solutions to the table.

Mr. Elliott of the Legal Network noted that in recent debates over reforming CAMR, some parliamentarians and pharmaceutical companies were suggesting that, instead of amending the regime, Canada should put up funds to purchase Canadian-made pharmaceuticals (brand-name or generic). Rather than pursue yet another instance of "tied aid" as an excuse for not fixing CAMR, Mr. Elliott suggested that such resources be put toward technology transfer, the "poor cousin" of TRIPS obligations that has never received much uptake by countries with technology to transfer or much attention at the WTO. He asked whether there is a role for the Canadian International Development Agency (CIDA) to engage with the generic sector to bring technology and know-how for domestic production, where desired and economically sensible, to developing countries. Chris Armstrong, Acting Team Leader (HIV/AIDS) at CIDA, was open to this idea,

but noted that it takes the willingness of the industry to do that. Bill Haddad stated that if any developing countries are interested, that they should simply approach companies such as Cipla and not wait for government action. Ms. Logez of the Global Fund suggested that there are ways to leverage Global Fund money towards technology transfer and suggested that applications should relate to technical assistance and capacity building. She recited a clause in the GFATM policy to that effect and urged countries and partners to investigate these opportunities.

Ms. Zirger of Health Canada's TPD emphasized the importance of having the alternative viewpoint that the discussions at this meeting brought to the CAMR review. Developing country perspectives and inputs are critical and must be made through a formal process. Ms. Masiga of MEDS warned the group about the lack of awareness in Kenya and other developing countries about the impending access issues. They are bogged down with other concerns. She urged everyone to raise awareness among their governments about the realities of what could happen once these intellectual property laws begin to have even more impact on access to generics. Senator Ungphakorn from Thailand offered the last observation, saying that access to medicines was an important part, but just one part, of a bigger vision of global, universal health insurance.

Conclusions and acknowledgments

Richard Elliott of the Canadian HIV/AIDS Legal Network and John Foster of The North-South Institute thanked participants for their enthusiasm and perseverance in contributing to an intense and rich discussion. Particular thanks to all those who prepared presentations and those who had traveled long distances to attend. They also thanked Michael Carty-Arbour and Aniket Bhushan for assistance with meeting logistics. Thanks are also due to the Canadian International Development Agency (CIDA) and Health Canada's International Affairs Directorate for collaboration and financial support in planning the meeting, and to Industry Canada and Foreign Affairs and International Trade Canada for their support and involvement.

ANNEX 1:

MEETING AGENDA

Access to Medicines and Intellectual Property:
An International Expert Consultation on Canada's Access to Medicines Regime, Global Developments, and New Strategies

Courtyard Marriott Hotel
350 Dalhousie Street
Ottawa, Ontario, Canada

19–21 April 2007

AGENDA

DAY 1: Thursday, 19 April 2007

Objectives:

- *To place legislation on compulsory licensing of pharmaceuticals for export (e.g., Canada's Access to Medicines Regime) in the context of broader global debates and developments over intellectual property and access to medicines.*
- *To provide orientation as to issues facilitating access to medicines in developing countries, including practical considerations regarding procurement and scale-up, so as to inform recommendations.*

9:00 – 9:45 a.m. **Welcome and introductions**
Joanne Csete, Executive Director, Canadian HIV/AIDS Legal Network
Roy Culpeper, President, The North-South Institute

Review of the agenda and objectives of the meeting
Richard Elliott, Deputy Director, Canadian HIV/AIDS Legal Network
John W. Foster, Principal Researcher, The North-South Institute

The organizers of the consultation welcome the support and collaboration of the Canadian International Development Agency (CIDA), Health Canada, Industry Canada and Foreign Affairs and International Trade Canada.

9:45 – 11:00 a.m. **Intellectual Property and Access to Medicines: Recent Developments, Current Concerns and Initiatives**

- Doha Declaration, WTO Decision of Aug 30, 2003 and compulsory licensing: Prof. Fred Abbott, Florida State University
- The U.S.–Morocco FTA: Nadia Rafif, Association lutte contre le sida — Maroc
- The U.S.–DR–CAFTA: Eugene Schiff, Agua Buena Human Rights Association
- Questions and discussion

11:00 – 11:15 a.m. Break

11:15 – 12:30 p.m. **TRIPS and Access to Generic Drugs Post-2005: India, Thailand and generics**

- Ellen 't Hoen, MSF Access to Essential Medicines Campaign
- Chan Park, Lawyers Collective HIV/AIDS Unit, India
- Dr. Vithaya Kulsomboon, Chulalongkorn University,Thailand
- Questions & discussion

12:30 – 1:45 p.m. Lunch

1:45 – 3:15 p.m. **Medicines Procurement: Importing and Compulsory Licensing**
Case Studies: A focus on practical considerations including the use of generics, imports and other issues in developing country contexts.

- Various speakers from Africa, Asia and Latin America
- Questions and discussion

3:30 – 3:45 p.m. Break

3:45 – 4:45 p.m. **Managing Intellectual Property for Access, and Alternatives to Patents for Health R&D**

- Intergovernmental Working Group on Public Health, Innovation and Intellectual Property, and initiatives on neglected diseases: Nicoletta Dentico, Drugs for Neglected Diseases Initiative
- Patent pools as a policy tool for access: Judit Rius Sanjuan, Knowledge Ecology International
- Alternatives to patents for stimulating health R&D: Rob Weissman, Essential Action

4:45 – 5:00 p.m. **Conclusions**
A brief statement of key findings of the day and segue to the theme of Day two

"The Other War on Drugs: Access to Medicines in Developing Countries"
Canadian and international advocates speak at a public forum on recent developments in the struggle for access to affordable medicines. Open to the public, parliamentarians, and the media.

7:00 p.m. at the National Press Club
150 Wellington Street (or South Entrance, 165 Sparks St.), 2nd floor

Co-sponsored by the Interagency Coalition on HIV/AIDS and Development (ICAD), the Canadian HIV/AIDS Legal Network, and The North-South Institute

DAY 2: Friday, 20 April 2007

Objective: *To elicit commentary and recommendations for reform of Canada's Access to Medicines Regime and similar legislation on compulsory licensing of pharmaceuticals for export.*

9:30 – 9:45 a.m. **Welcome and review of objectives and the agenda for Day 2**
- Joanne Csete, Canadian HIV/AIDS Legal Network

9:45 – 10:15 a.m. **Keynote Address: "Making it work for those who need it"**
- Stephen Lewis, former UN Special Envoy on HIV/AIDS in Africa

10:15 – 10:45 a.m. **Exporting and Importing Generics: Implementing the 2003 WTO Decision — The Canadian Case**
- Canada's Access to Medicines Regime (CAMR): An Overview
  - Brigitte Zirger, Health Canada
  - Douglas Clark, Industry Canada
- Questions & answers

10:45 – 11:00 a.m. Break

11:00 – 11:45 a.m. **Using Canada's Access to Medicines Regime: Case Study**
- NGO purchaser perspective: Rachel Kiddell-Monroe, (formerly of) MSF Canada
- Generic producer perspective: Bruce Clark, Apotex Inc.
- Questions & discussion (15 mins)

11:45 – 12:15 p.m. **Assessment of CAMR and August 30, 2003 WTO Decision**
- Comparative analysis of regimes implementing WTO Decision of August 30, 2003, and alternative(s) to Aug 30, 2003 model: Richard Elliott, Canadian HIV/AIDS Legal Network

12:15 – 1:15 p.m. Lunch

Canada's Access to Medicines Regime: Existing Features and Options for Reform

1:15 – 1:30 p.m.

- Developing country and purchaser perspectives: Short opening commentaries on current Canadian regime and alternatives by developing country representatives and international foundations/agencies engaged in procurement
- Questions and general discussion

- Discussion of particular CAMR features and reform options

1:30 – 3:00 p.m.

- Eligible products and eligible purchasers and importers
- Process for obtaining compulsory licence
  - notification requirements
  - voluntary licence negotiations

3:00 – 3:15 p.m. Break

3:15 – 5:00 p.m.

- Conditions of licence
  - quantity of product authorized for export
  - duration of licence
- Anti-diversion measures
- "Good faith" clause and termination of licence

5:00 – 5:15 p.m. **Conclusions**

Summary of main recommendations and/or debates emerging, and preview objectives for Day 3.

- John Foster, The North-South Institute

DAY 3: Saturday, 21 April 2007

Objective: *To examine related areas for international action supporting access to treatment.*

9:00 – 9:15 a.m.	**Welcome and review of objectives and the agenda for Day 3** ➢ John Foster, The North-South Institute
9:15 – 10:30 a.m.	**Role of Drug Regulatory Authorities in Exporting and Importing Generics** ➢ Health Canada review of generics exported under compulsory licence and coordination with WHO review: Brigitte Zirger, Health Canada ➢ Strengthening WHO Prequalification Programme (TBD) ➢ Strengthening drug regulatory authorities (TBD)
10:30 – 10:45 a.m.	Break
10:45 – 11:45 a.m.	**Ways Forward: Concluding Observations** *Participants are encouraged to share any conclusions, recommendations to the Canadian government, for proposals to the Intergovernmental Working Group, WHO, etc.*
11:45 – 12:15 p.m.	**Concluding remarks and appreciation** ➢ Richard Elliott, Canadian HIV/AIDS Legal Network ➢ John Foster, The North-South Institute
12:15 p.m.	Concluding lunch

ANNEX 2

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ANNEX 3

BACKGROUND MATERIALS

1. Compulsory licensing for export: Canada's legislation

Canada's Access to Medicines Regime — Consultation Paper (November 2006)
As a first step in the Government's accelerated statutory review of Canada's Access to Medicines Regime (CAMR), the purpose of this paper is to solicit comments as to how CAMR can better deliver on Canada's commitment to improve access to less expensive medicines that are urgently needed to treat HIV/AIDS, malaria, tuberculosis, and other epidemics in developing and least-developed countries, while remaining compliant with World Trade Organization (WTO) rules. See:
http://camr-rcam.hc-sc.gc.ca/review-reviser/camr_rcam_consult_e.html.

Neither Expeditious, Nor a Solution: The WTO August 30th Decision is Unworkable — An illustration through Canada's Jean Chrétien Pledge to Africa
Briefing paper by Médecins Sans Frontières, prepared for the XVI International AIDS Conference, Toronto, August 2006. On-line at:
http://msf.ch/fileadmin/user_upload/uploads/communiques/images_2006/pdf/came_Neither_expeditious_nor_a_solution_-_August_30_and_the_JCPA_single_page.pdf

"Delivering on the Pledge: Reforming Canada's Access to Medicines Regime" — Submission to the Government of Canada by the Global Treatment Access Group (January 2007). This short submission by a working group of civil society organizations proposes a number of reforms to Canada's legislation on compulsory licensing of pharmaceuticals for export. On-line via: www.aidslaw.ca/gtag.

2. Selected key recent developments on patents and access to medicines

Thailand

Thiru Balasubramaniam. **Notes from Knowledge Ecology International's "Q&A Session on Thai White Paper (Facts and Evidences on the 10 Burning Issues Related to the Government Use of Patents on Three Patented Essential Drugs in Thailand)"**, Geneva, 8 March 2007. On-line via www.keionline.org. (The full White Paper from the Thai government, over 100 pages, is available on-line at: http://www.cptech.org/ip/health/c/thailand/thai-cl-white-paper.pdf.)

India

Médecins Sans Frontères. **"Examples of the importance of India as the 'pharmacy for the developing world'"** (January 2007). On-line via:
http://www.accessmed-msf.org/documents/Overview%20Jan%202007%20FINAL.doc.

3. Managing IP for access

WHO Intergovernmental Working Group on Public Health, Innovation and Intellectual Property. **"Elements of a global strategy and plan of action"** (8 December 2006). Discussion of various ideas and actions to be implemented to improve both health R&D and access to medical technologies. On-line:
http://www.who.int/gb/phi/PDF/phi_igwg1_5-en.pdf.

ANNEX 4

LETTER TO GOVERNMENT OF CANADA

July 25, 2007

The Honourable Maxime Bernier
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The Honourable Tony Clement
Minister of Health
Minister's Office — Health Canada
Brooke Claxton Building, Tunney's Pasture
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Ottawa, ON K1A 0K9

Dear Ministers,

Re: Canada's Access to Medicines Regime:
highlights from an international expert consultation

We write with regard to the government's review of Canada's Access to Medicines Regime (CAMR), currently underway, and to share you with some highlights of findings from a recent international consultation our organizations co-hosted to examine CAMR and related issues.

As you know, both the North-South Institute and the Canadian HIV/AIDS Legal Network have been actively engaged in consultations with government and discussions with parliamentarians over several years in the drafting, enactment and review of the 2004 legislation that created CAMR. You may be aware that, during the drafting of that legislation, it was recognized that the perspective of developing countries was not adequately represented in the policy-making process. This was recognized again more recently during hearings in April of this year by the House of Commons Standing Committee on Industry, Science and Technology into the experience to date with CAMR. While several Canadian civil society groups active in providing input to the Government of Canada in 2003/04 brought to those discussions

their many years of experience working in developing countries to provide humanitarian aid, this was an imperfect substitute.

In light of this, and in order to contribute to the review of CAMR, on April 19–21, our organizations co-hosted in Ottawa an ***International Expert Consultation on Canada's Access to Medicines Regime, Global Developments, and New Strategies for Access to Medicines***, an initiative aimed at ensuring that CAMR and related issues could benefit from analysis by an expert group that specifically included the perspectives of developing country representatives.

This pertinent meeting was attended a wide range of participants, including numerous representatives from developing countries such as Kenya, Ghana, Zambia, South Africa, Thailand, India, Morocco, Costa Rica and Brazil. A number of the participants work in the area of pharmaceutical procurement and related policy issues for government agencies or for private care providers (e.g., Kenya Medical Supplies Agency, Mission for Essential Drugs and Supplies, Centre for Infectious Diseases Research Zambia, Health Consumer Protection Project at Thailand's Chulalongkorn University), as did a number of participants working for international organizations (e.g. International Dispensary Association, the Global Fund to Fight AIDS, Tuberculosis & Malaria) or projects engaged in scaling up access to AIDS treatment (e.g., Columbia University's International Center for AIDS Care and Treatment Programs). Other meeting participants included some of the world's leading policy experts in the area of intellectual property and pharmaceuticals from civil society (including from developing countries), academia and international organizations (e.g., the World Trade Organization). Finally, the meeting enjoyed the participation of officials from Health Canada, Industry Canada, Foreign Affairs and the Canadian International Development Agency. The event was organized with partial financial support from CIDA and Health Canada, and with the support and advice of the other departments.

In total, some 60 participants attended two and a half days of intensive discussion that not only examined CAMR in detail but also explored related global developments regarding intellectual property policy and access to medicines, as well as new strategies that could be pursued to advance both research into global public goods for health such as medicines and access to those goods particularly for the developing world. The motivation of the Expert Consultation was founded in the desire to contribute effectively to the internationally-agreed objective of universal access to HIV/AIDS treatment by 2010 (e.g., G8 2005 Summit Communiqué, UN General Assembly's 2006 Political Declaration on AIDS). The overall intent and result of the debates in the Expert Consultation was to facilitate and simplify the process of licensing, procurement and sale under the Canadian legislation.

The full report of the Expert Consultation will follow in due course, but we wish to share with you highlights of the consultation, as a way of further informing and contributing to the government's review of CAMR.

The objective of responding to urgent health needs, and to the requirements of purchasing governments or agencies, must be the predominant objective. As one expert commented, at present CAMR seeks to make importing countries fit the mechanism, rather than making the mechanism or procedure fit the needs of the prospective importers and their patients. It was also noted that the current legislation does not adequately take into account the practical considerations facing generic drug manufacturers who are the intended suppliers of lower-cost medicines to these prospective purchasers.

For example, it was noted that *the current legislation is incongruent with standard international procurement practice*. If Canada wishes to facilitate generic manufacturers issuing a bid for an international tender, CAMR must serve rather than restrict the ability of a generic company to make such a bid and be ready to undertake a contract. In other words, such a company must have a licence permitting manufacture for export already in hand, authorizing supply to any of the countries eligible

under CAMR to benefit as importers of Canadian-made generics, and without restriction on the quantity of the product permissibly exported. The Canadian licensing process should be made as automatic as possible.

To achieve this, participants considered the requirement of a *Health Canada approval* for the product for export, and its relationship to the WHO's Prequalification Programme. Health Canada approval does not guarantee automatic WHO approval, although it is encouraging that Health Canada and WHO have taken steps to streamline WHO prequalification following Health Canada approval. It should be borne in mind that national regulatory agencies of importing countries must further make the effective decision of whether or not to register the product. In doing so, the WHO Prequalification Programme is the most common reference standard for those products to which WHO's programme applies, including antiretroviral for treatment people living with HIV. There was some expert support for a continuation of Health Canada approval, and it may well be that Canadian generic manufacturers in some instances will prefer to pursue this route, but increased expertise on and sensitivity to the circumstances and requirements of product use in developing country contexts was advised. It was also suggested by some participants that Canada create alternative streams for product approval, allowing WHO prequalification to suffice as an alternative to Health Canada approval should a generic manufacturer and an importing country determine this suits them better.

Further, the *voluntary licensing requirements* have proven complicating, delaying and limited in terms of product, firm and contract. There was considerable support for waiving the voluntary licence procedure, and creating instead a more automatic and direct compulsory licensing process. The current legislation leaves too many doors open for delay and complication. Should such a procedure remain in CAMR, a strict time limit of 30 days should be applied.

The current *time-limit of two years on the compulsory licence*, and the *limit of any given licence to a specific, pre-determined quantity* of the product, were viewed as negative features of CAMR, economically unattractive and difficult given producers' needs to schedule production well in advance, confirm market demand, and reduce uncertainty. Furthermore, given the long-term aspect of the need for sustained treatment, the limit adds an additional unpredictability for importing countries, and limits flexibility in adjusting and extending purchase quantities over time.

The CAMR *list of eligible products (Schedule 1 of the Patent Act)* has proven an additional cause for delay, and an opportunity for patentees to lobby, successfully in some instances, against the addition of new products that address developing countries' public health needs. No such list is required under the 2003 WTO decision that CAMR implements, and indeed it runs counter to the spirit of the WTO negotiations, during which proposals to restrict the scope of the WTO decision to specific products or diseases were ultimately rejected in the text adopted by consensus. There was considerable support for removing the list completely.

The current requirement that potential *NGO purchasers* seek approval of the importing country should also be removed, as this is an additional feature of CAMR that is unnecessary under the WTO decision and creates additional barriers for humanitarian organizations in seeking to deliver treatment.

The *list of eligible importing countries (Schedule 3 of the Patent Act)* was a matter of significant debate, including its relationship to the 2003 WTO decision and the requirements under CAMR to satisfy additional requirements in order to be included, such as declaring a "national emergency" or situation of "extreme urgency", etc. The declaration of a "national emergency" has negative constitutional and other negative consequences, and is not required of importing developing countries that are WTO Members. A number of experts felt these requirements, and other provisions which could be considered "TRIPS-plus", should be avoided.

A further observation was the need for *incentives* for potential manufacturers that would encourage them to participate in the regime. A number of the simplifications recommended above can contribute to this end.

Participants in the Expert Consultation also considered policies and approaches which could facilitate production of needed pharmaceuticals and their availability at more affordable prices, including a number of proposals that Canada should explore further as Chair of the WHO's Intergovernmental Working Group on Public Health, Innovation and Intellectual Property. These included:

- the development of patent pools, on both a voluntary and non-voluntary basis, with a view to maximizing access to technologies for both further research and development and for treatment of patients;
- advance market commitments (AMCs) to encourage research into, and eventual access to, products needed for public health — both positive and negative aspects of AMCs were noted;
- prize funds leading to the development of pharmaceutical products addressing public health needs (rather than profit-driven priorities);
- merit-based, public investment by governments in research and development based on public health needs;
- various not-for-profit alliances between private and public sector actors with clear rules governing licensing of any products developed and accessible prices for developing countries (e.g., the Drugs for Neglected Diseases Initiative); and
- adoption by universities and/or through legislation of public-interest policies regarding the use of university-held patents.

Cost factors impeding the provision of universal access to HIV/AIDS treatment were in mind throughout the Consultation, although financing the scale-up of the AIDS response was not its focus. The importance of generic production and competition, the strategic usefulness of compulsory licences and the urgency of action in the light of the international pandemic were all recurrent themes.

One of the additional benefits of the consultation was the opportunity for generic manufacturers — and in particular the only Canadian company that has yet developed a product for potential export under CAMR — to meet with colleagues involved in drug purchasing from a number of countries, particularly in Africa. A number of conversations occurred at the meeting, and subsequently, regarding possible use of CAMR to secure the existing generic product, but many concerns remain about the feasibility of doing so.

In recent days, we have witnessed the historic step of Rwanda becoming the first country to notify the WTO of its intention to import the generic ARV drug from a Canadian manufacturer, setting the stage for what may prove to be the first use of CAMR to export lower-cost medicines to a country in need. We are very pleased at this news, but we caution that a number of steps are still required of both Rwanda and the Canadian manufacturer, under both the strictures of the 2003 WTO decision and CAMR, and the benefits to patients have not yet been realized. Given the unanimous support in Parliament for CAMR when it was created, and the considerable support and interest of the Canadian public that has been demonstrated over the years in seeing the pledge of affordable medicines fulfilled, we trust that in the coming weeks and months your government will take the necessary steps to ensure that this possible first use of CAMR comes to fruition.

We also stress that it has taken more than three years, and an extraordinary amount of time and work by NGOs and the Canadian manufacturer, to arrive at this stage. It is unrealistic to expect that such effort can or is likely to be repeated. Indeed, the sole Canadian manufacturer that has attempted to use CAMR

has publicly indicated that it is not likely to undertake such an initiative again, given the hurdles experienced with the regime to date. A recurrent theme throughout the Expert Consultation was the need to amend Canada's regime to make it more straightforward and easier to use for potential beneficiary countries in the developing world and generic suppliers able to assist in addressing their public health needs. We look forward to the government's report on its review of CAMR, which we understand you expect to table in Parliament when it resumes in September of this year, as well as to ongoing engagement with your offices in making the necessary reforms to the regime that will encourage its use in future to benefit patients in the developing world.

Sincerely,

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