National Office
250 City Centre Avenue, Suite 400
Ottawa, Ontario, Canada K1R 6K7
613-237-5236; Fax 613-237-0524
www.oxfam.ca

Oxfam Canada

January 24, 2007

Oxfam Canada Submission to Consultation on Canada's Access to Medicines Regime

Disease and ill health continue to ravage poor people worldwide. In 2005 there were approximately four million new HIV infections. Non-communicable diseases (NCDs) have unleashed a new epidemic of suffering across the developing world. And poor countries are unprepared for a pandemic, such as avian influenza.

Access to affordable, quality medicines is critical for patients in poor countries who suffer a disproportionately high burden of disease. Most poor people pay for medicines out-of-pocket, so even slight price increases can make life-saving medicines unaffordable. The cost of medicines represents the greatest share of health care expenditures for people in poor countries, and most developing countries provide little health insurance or public sector coverage for medicines.

Oxfam Canada has been deeply involved in efforts reduce the price of medicines, especially through the introduction of generic competition, the main mechanism proven to achieve lower prices over time. We have worked to reinforce the public health safeguards in the TRIPS agreement and to encourage countries to make use of them. We are, therefore, very pleased that this consultation has been launched, and are delighted to take part.

Canada's Access to Medicines Regime, introduced with much fanfare two years ago, seeks to increase access to affordable medicines in poor countries by facilitating the export of generic versions of patented products. Sadly, the law has not worked as its framers envisioned. In fact, no medical products have been exported under the law to date.

Oxfam Canada believes the failure of CAMR to provide affordable medicines lies in the unnecessarily long and expensive process mandated in the law. The request for a single licence by Médécins sans frontières has dragged on for years, with no licence granted. Incredibly, the current rules require companies to repeat the entire cumbersome process for every batch of medicines to be exported. We believe the process can be simplified greatly by removing a number of steps and restrictions, by removing invitations to litigation, and especially by allowing licences to cover multiple orders and multiple countries for the duration of the patent. Oxfam's full recommendations can be found at the end of this submission.

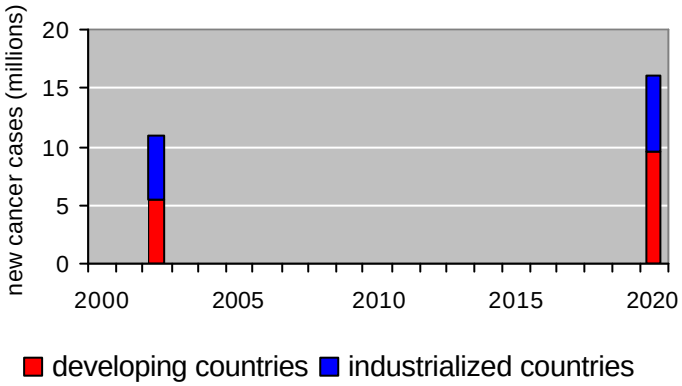
The urgent need for affordable medicines

In 2000, world leaders made health a priority of the Millennium Development Goals,[i] recognizing that significant investments in health were essential for human development. Yet the health crisis that has devastated the developing world has shown no signs of

abating. Infectious disease continues to kill millions of children and young adults.[ii] Since the adoption of the Doha Declaration in November 2001, more than 20 million people have been infected with HIV, bringing the total number of people living with HIV and AIDS to 38.6 million people.[iii] Other infectious diseases, such as tuberculosis and Hepatitis C, are a severe burden in many developing countries, while avian influenza threatens the lives of millions. Neglected diseases such as sleeping sickness are still endemic in poor countries.

Furthermore, non-communicable diseases (NCDs), once considered a burden of the rich, are increasingly affecting people in developing countries. In fact, over 80 per cent of deaths from NCDs occur in the developing world.[iv] Cancer rates are expected to double between 2002 and 2020, with 60 per cent of these occurring in developing countries (Figure 1).[v] Additionally, diabetes cases have risen from 30 million to 230 million over the last two decades, with most new cases occurring in the developing world.[vi]

Figure 1: Projected new cases of cancer by 2020



Source: WHO

Besides causing illness and death, NCDs cripple poor people economically and socially because treatment means a lifetime of expenditures for medicines, with the burden of care most often falling upon women.

Improving health conditions in developing countries requires actions on many fronts by the international community and national governments. Insufficient funding and capacity, user fees for health services, and the lack of health services and health workers remain major impediments for poor people to access the services they need. The international community and national governments need urgently to improve health service delivery.[vii]

However, the international community will not be able to reach its goals if it fails to tackle the problems caused by the high price of patented medicines, which keeps millions of people from receiving any treatment in developing countries.

The cost of medicine represents the greatest share of health-care expenditures for people in poor countries. Expenditure on pharmaceuticals ranges from 10–20 per cent of expenditure on health in the richest countries and 20–60 per cent in poorer countries.[viii] Unlike many rich countries, most developing countries lack universal health insurance. Across Asia, medicines comprise 20-80 per cent of out-of-pocket health-care costs.[ix] In Peru, where 70 per cent of expenditures on medicines are paid for out of pocket, only 52

per cent of the population has health insurance, and coverage mostly excludes those living under the poverty line.[x]

The Doha Declaration

Millions of women and men in developing countries make great sacrifices to buy the medicines needed for themselves and their families. The cost of health care, especially medicines, often drives them into poverty. The main proven mechanism to reduce the price of medicines is generic competition. In Colombia, where generics supply two-thirds of the national market, the cost of generic medicines is, on average, a quarter of the cost of brand-name equivalents.[xi] Yet intellectual property rules included in the WTO's TRIPS Agreement restrict generic competition, thus keeping new medicines out of reach for all but a small elite in developing countries.

The enormous difficulties faced by developing-country governments trying to provide life-saving medicines to their citizens have raised serious questions about the appropriateness of high levels of intellectual property protection in developing countries. The WTO responded in 2001 with the Doha Declaration, which unequivocally recognizes and clarifies that the TRIPS Agreement should not prevent WTO member countries from taking measures to protect public health.

Doha Declaration on the TRIPS Agreement and Public Health
Article 4 of the Declaration states: "We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health, and, in particular, to promote access to medicines for all. In this connection, we affirm the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose."

Specifically, the Declaration recognizes the legitimate need of countries to take measures to reduce the price of medicines, such as using TRIPS safeguards. The Declaration also acknowledges the need for WTO members to identify a mechanism that developing countries with insufficient or no drug manufacturing capacities could use to import generic versions of patented medicines under compulsory licences. This is because TRIPS stated that compulsory licencing must be predominantly for the domestic market, which meant that poor countries without the necessary manufacturing capacity could not rely upon other countries to provide medicines. Finally, the Declaration extended the 'transition period' for least-developed countries to 2016, with each least-developed country retaining the right to apply for additional deferments.

Although the Declaration is a promising mechanism to mitigate the harmful effects of intellectual property rules, rich countries and pharmaceutical companies have undermined its potential over the last five years.

The record of wealthy countries

Since 2001, the behaviour of rich countries has ranged from apathy and inaction to sheer determination to undermine the Doha Declaration. The USA is uniquely guilty of imposing higher standards of intellectual property protection (TRIPS-plus rules). These

rules violate US commitments under the Doha Declaration and prevent developing countries from using safeguards to protect public health. The USA has accomplished this agenda through bilateral and regional trade agreements, WTO accession negotiations, and other forms of unilateral pressure. Other rich countries, Canada included, have not provided sufficient political, economic, or technical support needed for developing countries to enact and actively apply TRIPS safeguards. Furthermore, rich countries have collectively failed to make compulsory licencing workable on behalf of countries with insufficient manufacturing capacity.

The WTO Waiver

One objective of the Doha Declaration was to find an appropriate solution to ensure that countries with insufficient or no domestic manufacturing capacity could import generic medicines under a compulsory licence. Rich-country intransigence during negotiations created barriers and bureaucratic hurdles that made the solution almost unworkable.[xii] Although the Director-General of the WTO called the Paragraph 6 solution 'a historic agreement' that 'proves once and for all that the [WTO] can handle humanitarian as well as trade concerns',[xiii] NGOs, including Oxfam, derided it as a solution 'wrapped in red tape'.[xiv]

To date, the solution has not produced the desired results. According to a recent TRIPS Council report, no qualifying member has notified the WTO to use the system created to implement the solution.[xv] For potential importing countries, this is probably because of the complexity of the process, lack of technical capacity, and fear of reprisal. Instead, such countries seem to have relied so far on ad hoc donations, non-notified imports or other safeguards, such as parallel importation.

Rich countries, for their part, seem to be in no hurry to make it work. Many have been slow to implement the deal, and no country has successfully used the mechanism to export medicines to countries with insufficient manufacturing capacity. The USA has not enacted legislation to implement the solution,[xvi] while the European Union only approved regulations implementing the public health solution in mid-2006.[xvii]

Rich countries that did implement the law made it more complicated. The legislation which Canada enacted contained numerous additional restrictions and complications not required by the WTO waiver. Canada's Access to Medicines Regime has proved unworkable, and not a single licence has been granted in the two years since it came into effect.

Recommendations

Oxfam Canada concurs with our colleagues in the Global Treatment Access Group that the single most important step to make the CAMR effective is to provide for licences which are not limited to a single drug-order for a single country. Single-issue licences which cover all amounts of a given medical product for all eligible countries for the length of the remaining patent would encourage manufacturers to invest in producing a generic version based on potential future sales. Allowing NGOs, private foundations like the Clinton Foundation and multi-lateral initiatives such as UNITAID to purchase medicines from such a single-issue compulsory licence would constitute a further incentive to encourage production of generic medicines and increase economies of scale.

Our recommendations:

1. Provide authorizations to export which are not limited to a single drug-order for a single country. There are a number of options for achieving this:

a. Create a standing statutory authorization permitting export of generic medicines to eligible countries: Parliament could enact legislation that authorizes the manufacture of generic versions of any drug patented in Canada for export to any eligible country specified in the legislation. The law could require any generic manufacturer exporting under this statutory authorization periodically to disclose the dollar value of the contracts it has negotiated with various importing countries and remit to the patent-holder the required royalties, following the formula in the existing Canadian law. This approach complies with Canada's WTO obligations would be compliant with the WTO Decision of 2003.

The WTO waiver specifies that "only the amount necessary to meet the needs of the eligible importing Member(s) may be manufactured under the licence and the entirety of this production shall be exported to the Member(s) which has notified its needs to the Council for TRIPS." Therefore a licence could be issued for an open amount with the stipulation that production cannot exceed the amounts requested by developing countries. In other words, as countries request a particular medical product, the generic company can fill those requests without seeking additional licences.

b. On any given drug, grant a single, open-ended licence to a given manufacturer: Instead of requiring a generic manufacturer to apply for a separate licence to satisfy each order of a medicine, the law could grant that manufacturer one initial compulsory licence authorizing the company to export that medical product to any eligible country, on the condition that the generic company pay royalties to the patent-holder, following the formula in the existing law. This approach would also be more streamlined than Canada's current law and, just like option "a," would comply with WTO rules.

c. Introduce a simple, fast process for additional licences: Even if the law were still to require a separate licence for every single drug order, it should at minimum provide for a simple, rapid process for amending or supplementing the original licence to authorize the export of additional quantities of the drug, to additional eligible countries, or for an extended period of time. This would be a more streamlined implementation of the WTO Decision of 2003 on which Canada's current legislation is based.

In this regard, there should be no need for requiring a copy of the importing country's notification to comply with the WTO waiver. The WTO waiver only requires the importing country to notify the quantities. The exporting country may grant an open licence, as long as all exports go to an eligible country for an eligible purpose.

In addition, there are other unnecessarily restrictive and time-consuming steps in the licencing process, not required by the WTO Decision or prior Canadian law that should be removed from the legislation. The following changes would address this:

2. Remove the time limit on licences granted: Licences should cover the duration of the remaining patent term on the drug to be exported. The current time-limit of 2 years is arbitrary and not required by the WTO Decision of 2003. This measure constitutes a major barrier to the participation of generic companies, since they must re-initiate the

long approval process to continue exporting the product beyond a 2-year period. This also prevents generic companies from guaranteeing to purchasers that they will be able to continue supplying after two years. Medical products are needed over the long term. Until developing countries achieve sufficient wealth to no longer be considered developing countries, we should continue to export generic medicines to them. The procedure must be simplified by removing the arbitrary time limitation on licences.

3. Limit the requirement of negotiating with a patent-holder before seeking a compulsory licence: These negotiations involve high costs and considerable delays. Canada's legislation should provide clear limits on the negotiations required. The WTO waiver specifically says that an effort to negotiate a voluntary licence is not required in cases of public non-commercial use. Following WTO rules, where the importing country wants to import the drug to address a national emergency or similar circumstance, or for public non-commercial use, there should be no requirement that the generic manufacturer try to negotiate a voluntary licence.

4. Eliminate the list of eligible drugs: The WTO Decision does not require any limitation to specific medical products; this type of provision was debated and rejected at the WTO level. The list of drugs in CAMR (Schedule 1 of the Patent Act) has resulted in months of unnecessary delays. The sole limitation is their use: they must be employed for public non-commercial use. All patented products ought to be eligible, and there should be no need for bureaucratic steps, such as Orders-in-Council and an expert committee to ensure that is the case. Who could predict five years ago that Tamiflu would become so important? We disagree that having such a list will limit the degree to which licences may be challenged in court. Patent-holders always retain the option of exporting their product at a lower rate, and have no need to go to court to retain their business. Schedule 1 should be removed. Regarding ingredients, all medical products means all medical products, including active pharmaceutical ingredients.

5. Eliminate the requirement of Health Canada approval: This measure is not required by the WTO Decision of 2003 or prior Canadian law. No other drugs require Health Canada approval for export. As with all other drugs, the importing country can determine what quality standards it will apply. Many developing countries will require "pre-qualification" of both the generic manufacturer and the drug in question by the World Health Organization before purchasing it. Canada should accept WHO pre-qualification as sufficient to permit export of a generic drug produced under a compulsory licence. Requiring Health Canada approval can lead to duplication of effort and add months of unnecessary delay. That said, after a licence is issued, Health Canada should undertake to register the medicine, enter into a reciprocal agreement with WHO to pre-qualify these medicines, and provide assistance to importing developing countries to register the medicine if requested.

6. Eliminate patent-holders' extra litigation rights: In three separate provisions, the legislation underpinning the CAMR includes eleven separate grounds on which a patent-holder can start legal proceedings against the generic manufacturer at different stages (ss. 21.08(5), 21.14, 21.17). These are unnecessary additions to existing legal recourses under the *Patent Act*. For example, there is the invitation to the patent-holders to litigate for a higher royalty. The CAMR should expressly prohibit such litigation. Similarly, the Good Faith Clause is an invitation to extended litigation, which is a major disincentive to generic manufacturers and thus an obstacle to the effective use of CAMR. It is not required by the WTO waiver and should be struck from the legislation. Note that the

WTO Chairperson's Statement is not part of the WTO waiver. Finally, the language regarding termination explicitly encourages litigation and constitutes a clear disincentive to CAMR being used. This should be removed.

7. Eliminate the requirement that NGOs get the 'permission' of the importing country government: Under Canada's current law, an NGO providing humanitarian relief in an eligible developing country has to get the "permission" of that country's government to import under CAMR. (This is in addition to the existing, sensible requirement that the medicine be approved for use by the importing country's drug regulatory authority.) Requiring this extra permission for NGOs to do their jobs is not required by any WTO rules, and creates an additional, unnecessary barrier to patients getting the medicines they need. What's more, countries suffering conflict may not have a functioning government, or may wish to deny access to medicines for political reasons.

8. Eliminate double-standards that apply to some importing countries: Under the current law, if a developing country does not belong to the WTO, it faces additional barriers to importing generic medicines from a Canadian producer, such as the requirement to declare a national emergency or similar situation. These additional hurdles are not required under WTO rules of WTO member countries. Patients' access to more affordable medicines should not depend on whether their country belongs to the WTO. The WTO waiver does not require countries to declare a national emergency or other circumstance of extreme urgency. Canada should remove this additional burden which CAMR places on non-WTO members. WTO members need only confirm that medical products are needed for public non-commercial use. That should be sufficient for all. What's more, the WTO waiver does not require any list of countries. We recommend removing Schedules 2, 3 and 4 and declaring that all developing countries, WTO members and non-members alike will be eligible without having to be added on a case-by-case basis.

9. Eliminate additional anti-diversion measures: A smaller point, worth noting is regarding the anti-diversion measures. The stringent standards on importing countries established in the WTO waiver are more than sufficient to prevent re-export. Beyond requiring the product to be distinguishable and posting information on a website, no other requirements are necessary. The additional anti-diversionary measures contained in CAMR should be eliminated. Please note as well that the WTO waiver requires special packaging and/or special colouring/shaping "provided that such distinction is feasible and does not have a significant impact on price."

10. Reaffirm the intended scope of the CAMR: A final note to correct the background presented in the consultation paper. The WTO waiver was not intended to facilitate access to medicines to treat epidemics. It was explicitly created to facilitate access to medicines for any public non-commercial use, including epidemics and emergencies. Raising epidemics and emergencies as the justification for the CAMR undermines its intended scope. Non-communicable diseases and other public health problems are equally valid public health concerns for poor countries and are eligible under the WTO CAMR. The WTO waiver may provide the only way they can obtain medicines such as new drugs to treat Hepatitis C.

11. Assist developing countries to make use of the CAM R: Besides amending the CAMR, Canada should consider ways to assist developing countries to make use of it, as well as to fully implement TRIPS safeguards, to ensure that the Paragraph 6 solution

is both workable and used, and to review whether the TRIPS Agreement requires further modification to ensure that public health can truly be protected.

Perspectives for the future

Access to medicines is a basic human right. Poor people, particularly women, carry the burden of lack of access in terms of mortality, morbidity, socio-economic devastation, and caring for the sick. In 2001, the Doha Declaration was agreed upon by all WTO members to ensure that public health overrides commercial interests. Developing countries and civil society accepted the Declaration in good faith, believing that wealthy countries and the pharmaceutical industry had finally acknowledged the harm strict intellectual property rules caused in developing countries. Yet five years later, as the health crisis in developing countries grows unabated, rich countries and pharmaceutical companies continue undermining poor people's rights to medicines.

Canada can still become a leader in transforming this dark landscape. We look forward to working with the government to make CAMR an effective tool for realizing poor people's right to health.

Contact:
Mark Fried
Communications and Advocacy Coordinator
613-236-5236, ext. 231
markf@oxfam.ca

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[i] Of the eight MDGs, three address issues of health: reduction of child mortality; improvements in maternal health; and combating HIV and AIDS, malaria, and other diseases.

[ii] WHO Report on Infectious Diseases, 'Removing Obstacles to Healthy Development', 1999, http://www.who.int/infectious-disease-report/index-rpt99.html.

[iii] UNAIDS, Report on the Global AIDS Epidemic, 2003, 2004, 2005 and 2006.

[iv] WHO, 'Chronic diseases and their common risk factors', www.who.int/chp/chronic_disease_report/media/Factsheet1.pdf.

[v] WHO, *World Cancer Report*, 2006.

[vi] 'Poor nations struggle to cope with diabetes surge', *Detroit Free Press*, 11 June 2006.

[vii] Oxfam International and WaterAid (2006) *In the Public Interest: Health, Education, and Water and Sanitation for All*, http://www.oxfam.org.uk/what_we_do/issues/debt_aid/public_interest.htm?searchterm=In+the+public+interest.

[viii] WHO, 'The World Medicines Situation', Chapter 5, 2004. http://hinfo198.tempdomainname.com/medicinedocs/library.fcgi?e=d-0edmweb--00-1-0--010---4----0-0-10l--1en-5000---50-about-0---01131-00115ERnz+VC9ee84d6400000000436f372a-0utfZz-8-0-0&a=d&c=edmweb&cl=CL2.1.6&d=Js6160e.7.

[ix] E. Van Doorslaer et al., 'Paying out of pocket for health care in Asia: Catastrophic and poverty impact', Equitap Project: Working Paper #2, May 2005. In India, 80 percent of out of pocket expenditures on health are for medicines. See http://www.whoindia.org/LinkFiles/Commision_on_Macroeconomic_and_Health_Access_to_Essential_Drugs_and_Medicine.pdf

[x] G. Valladares Alcalde (coordinator), R. Cruzado Ubillús, J. Seclén Palacín, Z. J. Pichihua Serna, 'Evaluación de los potenciales efectos sobre acceso a medicamentos del Tratado de Libre Comercio que se negocia con los Estados Unidos de América', Lima: Health Ministry, April 2005. Also in: http://www.forosalud.org.pe/estudio_minsa_evaluacion_efectos_del_tlc_en_medicamentos.pdf.

[xi] Germán Holguín Zamorano, 'La Bolsa y la Vida: Impacto de la agenda norteamericana para el TLC sobre el acceso a medicamentos y la salud pública', Misión Salud, 2004. http://www.misionsalud.org/la-bolsa-y-la-vida-german-holguin.pdf

[xii] For a review of the major problems with the Paragraph 6 decision, see 'Neither expeditious, nor a solution: The WTO August 30th Decision is unworkable', Médecins Sans Frontières, August 2006, http://www.accessmed-msf.org/documents/WTOaugustreport.pdf.

[xiii] 'Decision removes final patent obstacle to cheap drug imports', www.wto.org/english/news_e/pres03_e/pr350_e.htm.

[xiv] This included an effort by the USA to limit the types of drugs which could be produced and exported under Paragraph 6, even though the TRIPS Agreement does not limit which drugs qualify for export. See http://www.cptech.org/ip/wto/p6/cptech03052003.html.

[xv] WTO, 'Annual review of the Decision on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health', 2006.

[xvi] However, a Senate bill was introduced by Senator Patrick Leahy in May 2006 to implement the Paragraph 6 public health solution, entitled 'The Life Saving Medicines Export Act'. See http://leahy.senate.gov/press/200605/052506a.html.

[xvii] 'EU accepts compulsory licencing of pharma patents for countries in need', 2 May 2005, http://www.euractiv.com/en/health/eu-accepts-compulsory-licencing-pharma-patents-countries-need/article-154874, accessed on 26 September 2006.