



Campaign for Access to Essential Medicines
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**NEITHER EXPEDITIOUS, NOR A SOLUTION:
THE WTO AUGUST 30TH DECISION IS UNWORKABLE**

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An illustration through Canada's Jean Chrétien Pledge to Africa

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CANADA WAS THE FIRST G8 COUNTRY TO AMEND ITS NATIONAL LAWS TO IMPLEMENT THE WORLD TRADE ORGANIZATION'S AUGUST 30TH DECISION, ALLOWING GENERIC VERSIONS OF PATENTED DRUGS TO BE MANUFACTURED AND EXPORTED UNDER COMPULSORY LICENSE.

MÉDECINS SANS FRONTIÈRES DECIDED TO PLACE AN ORDER UNDER THE *JEAN CHRÉTIEN PLEDGE TO AFRICA* FOR A TRIPLE FIXED-DOSE COMBINATION ANTIRETROVIRAL DRUG FOR PATIENTS IN ITS HIV/AIDS PROJECTS. THAT WAS IN 2004, OVER TWO YEARS AGO.

NOT ONE PILL HAS BEEN EXPORTED, AND NOT ONE PATIENT HAS YET BENEFITED FROM THE CANADIAN LAW.

THE WTO AUGUST 30TH DECISION DOES NOT ADDRESS THE PROBLEMS FACED BY DEVELOPING COUNTRIES IN ACCESSING MEDICINES AT AFFORDABLE PRICES. THE WORLD STILL LACKS AN EXPEDITIOUS SOLUTION TO EXPORTING PATENTED LIFE-SAVING MEDICINES.

BACKGROUND

What is the August 30th Decision?

The minimum standards for intellectual property protection, including pharmaceutical patents, are set out in the 1995 World Trade Organization (WTO)'s Agreement on Trade-Related Aspects of Intellectual Property (TRIPS).

The TRIPS Agreement does not allow for differentiation between products that are merely consumer goods and those that are life-saving medicines. Its aim is to harmonise intellectual property standards globally. This has led to patent practices that maintain drugs at artificially high prices even in the poorest countries.

In November 2001, members of the WTO sought to restore a balance by adopting the Doha Declaration on TRIPS and Public Health. Paragraph 4 of the Doha Declaration states that the TRIPS 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 reaffirm the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose."

These flexibilities include, for example, compulsory licensing, whereby a government allows the production, import and sale of a drug still under patent. This can be done without the permission of the patent holder, who must nevertheless be paid royalties.

But Article 31 of the TRIPS Agreement limits the use of compulsory licenses "predominantly for the domestic market" and puts restrictions on the quantities of drugs that can be exported. This poses huge problems for countries that have little or no drug manufacturing capacity. Indeed in Paragraph 6, the Doha Declaration recognises that such countries "could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an **expeditious solution** to this problem."¹

Almost two years later, on August 30th 2003, the WTO adopted a temporary decision in an attempt to address this issue. The proposed solution allows for the exportation of a drug under compulsory license and waives the requirement that production has to be predominantly for

the domestic market. The August 30th Decision establishes the conditions under which a compulsory license can be granted for export. But MSF's experience trying to buy drugs under the new rules shows that they are prohibitively complex.

The Jean Chrétien Pledge to Africa

In September 2003, Canada became the first country to announce its intention to implement the August 30th Decision into its national law. Bill C-9, more commonly referred to as the Jean Chrétien Pledge to Africa (JCPA)² was eventually passed in May 2004. The JCPA permits the granting of "export only" compulsory licenses to Canadian generic pharmaceutical companies that wish to supply countries having inadequate or no pharmaceutical capabilities with lower cost versions of pharmaceutical products patented in Canada.

According to the JCPA, the purpose of the legislation is to "give effect to Canada's and Jean Chrétien's pledge to Africa by facilitating access to pharmaceutical products to address public health problems afflicting many developing and least developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics."³

In May 2004, the month the law was passed, MSF publicly committed to test the expediency and efficacy of the JCPA by placing an order for medicines needed for its field projects.

At a meeting convened by Health Canada⁴ and the Canadian Generic Pharmaceutical Association (CGPA) in August 2004, MSF was asked to identify which drugs were most urgently needed. Despite MSF's identifying five drugs, and engaging repeatedly with the CGPA and generic companies, seven months after the law had passed not a single generic manufacturer had expressed a concrete interest in producing a drug under the terms of the JCPA.

Finally, in December 2004, Apotex Inc, a Canadian privately-held company, agreed to produce a three-in-one antiretroviral combination of zidovudine / lamivudine / nevirapine (AZT/3TC/NVP). At that time, these drugs, part of the World Health Organization (WHO) guidelines for the first-line treatment of HIV, were not available in the form of an approved fixed-dose combination (FDC). An FDC, combining several drugs in one pill, makes treatment much simpler for patients, and improves adherence and capacity to scale-up

treatment. In short, producing such a three-in-one combination could have a significant impact on improving access to treatment.

After receiving the specifications for the FDC in January 2005, Apotex had an active prototype ready by April 2005. But despite the speed at which the drug was developed, it is still not available for export under the JCPA.

MSF's involvement in testing the practicalities of the JCPA has been considerable. MSF provided technical input and critiques to the Canadian authorities in the drafting stages of the legislation, suggested which drugs with the greatest potential therapeutic benefit could be produced, and identified an MSF field project prepared to engage with national authorities to encourage them to take up the JCPA.⁵ As a result, MSF is now in a key position to document the problems associated with trying to place an order under this legislation.

But the blame for the JCPA's lack of efficacy cannot be laid solely at the door of the Canadian government. The August 30th Decision, presented by the WTO as a 'solution', is unworkable; this paper will first examine the flaws inherent in the Decision. The JCPA is merely an implementation of this Decision, albeit one that introduces hurdles beyond those erected by the WTO's decision; these will be detailed in the second part of this report.

THE AUGUST 30TH DECISION

To date, a limited number of countries including Canada, Norway, China, India and the European Union, have adopted legislation to implement the August 30th Decision. Even so, not a single importing country has notified the TRIPS Council that they intend to use the mechanism to import cheaper life-saving medicines.

This lack of uptake is a stark illustration of the hurdles within the Decision which make it difficult for countries with little or no manufacturing capacity to import a generic under compulsory license, and difficult for generic manufacturers to export a drug under compulsory license.

MSF's experience highlighted the following key problems:

(1) **Prior negotiation necessary before compulsory license granted**

Before a generic company can apply to a government to issue a compulsory license allowing the firm to begin exporting a drug under the August 30th Decision, it has to engage in negotiations with the patent holder for a voluntary license.⁶ A voluntary license serves to set the terms under which the patent holder allows the generic company to manufacture and export its patented product.

Negotiations for a voluntary license are protracted and complex, and a source of considerable delays.

In Canada, the JCPA requires that a potential exporter engage in prior negotiations with the patent holders for at least 30 days. In practice however, it remains unclear when voluntary negotiations can be considered to have ended in failure, a necessary step before

an application for a compulsory license can be submitted - on this point the JCPA provides no further guidance. No compulsory license application has yet been filed in Canada.

Prolonged prior negotiations severely limit the ability to use the August 30th Decision and act as a disincentive to manufacturers to participate in the process.

(2) **Anti-diversion measures kill incentives for generic production**

The August 30th Decision imposes conditions that the drugs be clearly identified through specific labelling and marketing, to ensure that they will only be exported to the destination stated in the compulsory license.

The anti-diversion measures in the August 30th Decision include:

- products produced under the compulsory license must be clearly identified as being produced under the August 30th Decision, through specific labelling or marking
- the product must be distinguishable from the branded product through special packaging and/or shape or colour of the product
- the generic manufacturer must post on a website information pertaining to the quantity of the product, its destination, and the distinguishing features of the product

Anti-diversion measures that generic companies must comply with are onerous and are further disincentives to their participation in the process.

(3) **Notification of intention to use the August 30th Decision**

Under the terms of the Decision, a potential importing country must send a notification in writing to the WTO TRIPS Council, declaring its intention to import pharmaceutical products according to the provisions set out in the Decision. The notification must include the specific names and expected quantities of the product needed.

Unless the importing country is classified as a least-developed country (LDC), it must also specify whether the product is under patent, and provide information that establishes that it lacks sufficient manufacturing capacity in the pharmaceutical sector to develop the drug being ordered.

The requirement that importing countries notify in advance their intention to use the August 30th Decision also opens them up to pressure from countries whose policy and practice it is to discourage the granting of compulsory licenses.

Although the notification is supposed to be solely for the purpose of providing transparent information, the conditions may deter importing countries from doing so.

2001

NOVEMBER: Doha Declaration on TRIPS and Public Health

¹ Emphasis added

² The Jean Chrétien Pledge to Africa Act amends the Patent Act and the Food and Drugs Act. The JCPA is now commonly referred to by the Canadian government as the Canadian Access to Medicines Regime (CAMR).

³ Jean Chrétien Pledge to Africa Act, Section 21.01

⁴ Health Canada is Canada's federal Department of Health. The Canadian drug regulatory authority (the Therapeutic Products Directorate) falls under this department, and is referred to in this report as Health Canada.

⁵ As of March 2006, MSF provides antiretroviral therapy to over 60,000 patients in 65 projects in over 32 countries: Benin, Burkina Faso, Burundi, Cambodia, Cameroon, China, Congo Brazzaville, Côte d'Ivoire, DR Congo, Ecuador, Ethiopia, Guatemala, Guinea, India, Kenya, Laos, Lesotho, Liberia, Malawi, Mozambique, Myanmar, Nigeria, Peru, Rwanda, Sierra Leone, South Africa, Sudan, Tanzania, Thailand, Uganda, Zambia and Zimbabwe.

⁶ Providing the national law permits, the requirement for negotiations for a voluntary license may be waived in the case of 'national emergency' or other urgent circumstances, or in cases of public non-commercial use.

(4) The Decision is unrealistic

The August 30th mechanism is based on a drug-by-drug, country-by-country and case-by-case decision-making process. Indeed, the compulsory license application must stipulate the destination and the quantity of drugs that are to be purchased and exported under the license.

Drug needs must therefore be determined with extreme precision beforehand, and are binding. If medical needs increase, and more patients are included in a programme than forecasted in the compulsory license application, the only way to purchase more drugs is to begin the process again, starting with the voluntary license negotiations between brand and generic manufacturers detailed above. If on the contrary, needs have been overestimated, and a quantity of drugs is unused, but are desperately needed in a third country, the entire process must also start again from scratch.

From a manufacturer's perspective, it means the whole process must be undertaken each time it fills an order for a drug destined for export.

The Decision flies in the face of the practical reality of managing a health programme, where flexibility and rapidity of response to ever-changing circumstances are vital. It also ignores the fact that economies of scale are needed to attract interest from producers: without the pull of a viable market for drugs, generic manufacturers will not seek to produce for export.



Kenya © Sebastien Le Clezio

(5) The Decision is not automatic, but a succession of complex procedural steps

Let us assume a potential purchaser, under the terms of the Decision, has forecasted needs and identified a generic producer willing to participate in the process and fill the drug order, and the manufacturer has completed negotiations with the patent holder, and the terms for a voluntary license have been rejected.

The generic firm must then apply for two compulsory licenses – one in its home country, from which the drugs will be exported, and one in the country where the drugs are destined if the drugs are under patent there. This requires considerable human and financial resources on the part of the generic, particularly when seeking to file a compulsory license in the country of destination, where the generic may have no prior contacts or experience.

Each of these steps is time-consuming and holds no guarantee of success. The authorisation to export life-saving drugs can be delayed (if negotiations for a voluntary license are prolonged), or even denied.

A compulsory license for export can only be granted once the heavy procedural steps described in this report have been completed successfully. It did not have to be this way; in fact the WTO chose to stay away from designing an automatic procedure which would have been possible under WTO law.

The Decision introduces intricate, time-consuming and burdensome procedures for the exportation of medicines, when what is needed is a simple, fast, and automatic mechanism.

CANADA'S IMPLEMENTATION OF THE AUGUST 30TH DECISION

The August 30th Decision is overly cumbersome. As a result, the legislation that implements the Decision into national law, as in Canada with the JCPA, is bound to be cumbersome too. Given the nature of the WTO rules, it is incomprehensible that the Canadian Government included additional requirements in the JCPA that increase the complexity of the process.

Canada would do well to address the problems described below during the parliamentary review of the legislation scheduled for May 2007, while keeping its positive aspects, such as the royalty provisions. The problems identified by MSF include:

(1) The JCPA is unnecessarily onerous

The JCPA, contains 19 sections and over 100 clauses and sub-clauses. Simply understanding the legislation requires legal training or support. Significant financial and human resources are necessary for a government to analyse and use this legislation – resources which are limited in many developing and least-developed countries.

As Tanzania's High Commissioner to Canada, His Excellency Ombeni Sefue, noted in May 2006:⁷

"It's not that we don't want to do it. It's just that we haven't because... **all the bureaucratic, administrative, and legal requirements take a lot of time...The system is too complicated...**"⁸

(2) The JCPA restricts medicines

The scope of the JCPA is limited to a list of specific medicines, in specific formulations, included as Schedule 1 in the legislation. In other words, if a drug is not included in Schedule 1, a Canadian generic manufacturer cannot apply for a compulsory license under the JCPA to manufacture and export the drug where it is needed.

This is significant because the restricted list of medicines was the subject of extensive discussions at the WTO TRIPS Council, and was rejected by WTO Member States, including Canada, at that time. Yet, only a few months later, the list was introduced into Canadian national legislation. This amounts to imposing the very same restrictions rejected by the WTO.

Schedule 1 is tantamount to placing certain drugs beyond the scope of the JCPA. Indeed, during the drafting stages of the legislation, the pharmaceutical industry lobbied to keep their products off a list that might one day facilitate the authorisation of a compulsory license and generic production. Bayer for example, successfully challenged the inclusion of moxifloxacin, its treatment for pneumonia.

Furthermore, Schedule 1 did not include fixed-dose combinations (FDC), despite the presence on the list of the individual drugs that make up certain combinations. The government justified this decision by claiming that the list was intended as a guide and support for companies, and that adding drugs to it would be a simple and

2004

JANUARY: Canadian public letter-writing campaign to challenge fundamentally flawed legislation.

FEBRUARY: Parliamentary Standing Committee Hearings on legislation to discuss fundamental flaws in legislation raised by NGOs and civil society actors.

APRIL: Government of Canada press release regarding amendments to the legislation, hailing legislation "as a model to the world."

MAY: Jean Chrétien Pledge to Africa (JCPA) is passed by Parliament and receives Royal Assent

MSF commits publicly to testing the legislation in practice by attempting to make a drug order.

AUGUST: Canadian government, generic companies and MSF meet to discuss the process under the JCPA and the steps to making an actual drug order. MSF proposes five possible drugs to generic companies.

DECEMBER: Apotex expresses interest.

rapid process. However, even with the commitment of individuals in the Canadian bureaucracy, it took five months of efforts before the government published a proposed amendment to JCPA Schedule 1 to add the anti-influenza drug oseltamivir (Tamiflu®) to the list of drugs eligible for compulsory licensing.

Schedule 1 unnecessarily limits the scope of the JCPA to products included in the list, and it seems likely that the industry will oppose future proposed extensions of Schedule 1 should other drugs be considered for inclusion.

(3) The JCPA requires unnecessary Health Canada approval

Although domestic approvals are not required by the August 30th Decision, all products to be exported under the JCPA must be approved by Health Canada. The inclusion of this requirement in the JCPA is surprising given that Canada's regulatory regime does not require that non-JCPA drugs that are manufactured "for export only" meet the same safety, quality and efficacy standards as the drugs destined for consumption in the Canadian market.

Although the decision *seems* praiseworthy, by showing that Canada is exporting drugs of a quality equivalent to those approved at home, in reality, the requirement means duplicating the work of the WHO Prequalification Project. This project evaluates pharmaceutical manufacturers and products according to internationally agreed standards for quality, safety and efficacy.

2003

AUGUST: WTO August 30th Decision

SEPTEMBER: Stephen Lewis, UN Secretary General's Special Envoy for HIV/AIDS in Africa, calls on Canada to lead the way on the WTO Decision.

Canada announces it is willing to amend the Canada Patent Act to give generic companies permission to produce some patented drugs for export to developing countries. Five government departments are involved, plus the Prime Minister's Office.

International drug companies call the initiative a "negative black eye for Canada" that might very well "affect the investment climate."^{*}

OCTOBER: Government consults with pharmaceutical industry, generic manufacturers and civil society groups, including MSF, on draft legislation of implementation of August 30th Decision.

^{*}Harvey Bale, International Federation of Pharmaceutical Manufacturing Associations, Chase S and Fagan D. 27 September 2003. "Drug companies balk at Ottawa's AIDS plan." The Globe and Mail.

⁷ "No Drugs Yet Approved by Former Pledge to Africa", Sarah McGregor, Embassy Magazine, 17th May 2006

⁸ Note that the Government of Canada launched a new website explaining how the legislation can be used, on 28th July 2006. http://www.hc-sc.gc.ca/ahc-asc/media/nr-cp/2006/2006_64_e.html

An increasing number of developing countries and donor agencies require imported drugs to be WHO pre-qualified. This was the case for the country identified by MSF for importation of the Apotex FDC. The Health Canada approval process is therefore superfluous.

The requirement of a double approval process is a source of unnecessary delays - in the case of MSF's order, it cost seven months.

(4) The JCPA limits drug quantity and export

Even after all the hurdles have been navigated, and a compulsory license has been granted, the license will only be valid for two years. The original application for a compulsory license can be renewed for another two years, provided the full shipment, as indicated on the original application, has not yet been delivered.

The significance of limiting the period of a compulsory license should not be underestimated: it acts as a further disincentive for a generic manufacturer to participate in the JCPA. Indeed, on expiration of the compulsory license, the generic manufacturer wishing to continue exporting (even if it is the same product to be exported to the same country as named in the original application for a compulsory license), would have to begin the whole process all over again.



The JCPA also requires that, in the application for a compulsory license, the exporter stipulate the **maximum quantity** of the product that will be exported during the two year license. This is inconsistent with the August 30th Decision, where the importing country is only required to notify the TRIPS Council of “**expected quantities** of the product(s) needed”.⁹

This is all the more significant considering that the JCPA does not allow for increasing the quantity of drugs that figure in the application for a compulsory license. If needs increase and more drugs need to be produced and exported, the whole process must be undertaken again from the beginning.

Canada's inclusion of limitations to the duration of a compulsory license and to the quantities that can be exported under it are unnecessary and unsustainable in a world of dynamically changing health needs and contexts.

(5) The JCPA compromise

The flaws in the Canadian legislation are self-evident. Many of these stemmed from the Canadian government's attempt to balance competing interests. The goal was to include all stakeholders in the discussions. However, by trying to balance the needs of patients against the business interests of the pharmaceutical industry, the Canadian government committed itself to developing a compromise that did not put humanitarian needs first. In so doing, the government diluted the potential impact of the JCPA and made the August 30th mechanism even more unworkable.

The stated aim of the JCPA is “facilitating access to pharmaceutical products to address public health problems.” Instead of fulfilling its promise, the law includes a number of significant restrictions that limit its impact - some of which were rejected by Canada in international negotiations - and effectively make the JCPA an empty promise.

“When we order medicines normally, all we need to do is type up a form, send it to the supplier and pay the bill - then we receive the shipment. With this system we have to persuade a government to notify the WTO, find a company willing to produce, push to get a drug on the list of eligible medicines, wait for voluntary license negotiations to be completed, wait for the compulsory license application to be made, and then granted For a disease that kills 8,000 people a day, not only is this is not a solution, it's unacceptable”

Dr. Felipe Garcia de la Vega, AIDS Doctor, MSF

CONCLUSIONS

The WTO August 30th Decision was supposed to be an ‘expeditious solution’ to the crisis in access to medicines faced by developing countries with little manufacturing capacity. The WTO has since made it a permanent solution, adopted as an amendment to the TRIPS Agreement in December 2005. This amendment to TRIPS disregards the fact that there is no proof of the Decision's efficacy. In fact proof to the contrary exists: nearly three years on from the August 30th Decision, not a single drug has reached a single patient under the WTO mechanism.

MSF devoted considerable energy and resources to trying to get a drug exported under the Canadian implementation of the Decision. Three years after initial discussions on the draft legislation began, only the preparatory work of getting the legislation in place, identifying a drug and an interested generic company, and seeking regulatory approval and inclusion in Schedule 1 for the drug has been achieved. In effect, we are still just at the beginning of the process.

For the time being, Indian producers provide a relief to the stalemate. Two Indian generic firms have since succeeded in getting their zidovudine / lamivudine / nevirapine FDCs approved either by the WHO or the US FDA. Ordering these generic versions is much easier for MSF or any other potential purchaser or importing country. It requires filling in an order sheet and faxing it to the company. There are no strings attached nor any extraordinary labelling, colouring or tracking requirements. Purchasing from Apotex, on the other hand, means overcoming all of the hurdles laid down in the JCPA.

But Indian generic companies, which have been essential in supplying life-saving quality medicines at affordable prices, may not be able to provide that relief in the future. In accordance with the TRIPS Agreement, as of 2005 India is obliged to grant patents on pharmaceutical products, thereby threatening generic production and export of newer essential drugs. In the future, generic production may therefore largely depend on compulsory licenses.

If the August 30th Decision could have shown its effectiveness, it would have been in Canada. All conditions for success were present: Canadian authorities stated their commitment to making it work, a generic company was interested in producing, and an NGO ready to place and pay for the order of the medicines was involved. Despite these conditions, no drug has yet left the country.

This should be a wakeup call to all. In the future, generic competition will depend on compulsory licenses since drug patenting will become a global reality. If these medicines cannot be exported to countries where they are needed, generic production of newer medicines will cease to exist. And millions will have no option but to wait out the 20 year patent terms before they can have access to essential medicines. This is an unacceptable situation that urgently needs to be addressed at the global level.

All WTO Members should draw conclusions from this: tinkering in the margins of a basically flawed framework is simply not going to deliver. Canada, which has committed to a public review of the legislation in April 2007, and the WTO, responsible for the new TRIPS rules, need to act on these conclusions.

2006

MARCH: MSF agrees to purchase the first competitively priced batch of FDC from Apotex subject to conditions. Despite Health Canada letter explaining the process for approval of a pharmaceutical product under the JCPA, potential importing countries require drug to be prequalified by WHO.

MAY: Hetero version of 3FDC approved by WHO prequalification project, reasonably priced at US \$0.36 per tablet. MSF field begins ordering.

MSF provides comments on Canadian CD-ROM to be incorporated in new version of Canadian government website on JCPA.

US FDA approve Aurobindo version of 3FDC for US funded HIV/AIDS projects.

JULY: Apotex drug passes Canadian review process. Apotex submit dossiers to WHO prequalification project. Canadian government launches website and CD-ROM explaining how to use the JCPA.

TO DATE, NO NOTIFICATIONS HAVE BEEN MADE TO THE WTO TRIPS COUNCIL BY IMPORTING COUNTRIES THAT THEY PLAN TO USE THE AUGUST 30TH DECISION. NOT A SINGLE APPLICATION HAS BEEN SUBMITTED TO CANADIAN AUTHORITIES OR WTO TRIPS COUNCIL, TO MAKE USE OF THE JCPA.

RECOMMENDATIONS

The World Trade Organization:

- Must review the implementation of the TRIPS flexibilities, and in particular assess the efficacy of recent TRIPS amendments based on the August 30th Decision, with a view to proposing alternative mechanisms that meet health needs, are expeditious and take into account the economic reality of global drug procurement. In particular, the WTO should explore automatic solutions that do not necessitate complex time-consuming procedural steps.

The Canadian government:

- Must assure a rigorous and transparent parliamentary review of the Jean Chrétien Pledge to Africa in May 2007, one that seriously addresses the fundamental flaws in the legislation; and
- Must use its experience trying to implement the Decision as the basis to act at the WTO in order to remedy the constraints of the WTO rules governing the delivery of generic medicines to those in need.

⁹ WTO Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health Decision of 30 August 2003, Paragraph 2(a)(i), WT/L/540