NEITHER EXPEDITIOUS, NOR A SOLUTION:
THE WTO AUGUST 30TH DECISION IS UNWORKABLE

An illustration through Canada’s Jean Chrétien Pledge to Africa
Prepared for the XVI International AIDS Conference, Toronto, August 2006
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, Gabon, Gaines, India, Kenya, Laos, Lesotho, Liberia, Malawi, Mozambique, Myanmar, Nepal, Nigeria, Peru, Rwanda, Sierra Leone, South Africa, Sudan, Thailand, Uganda, Zambia and Zimbabwe.

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. 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 unsuitable: 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, 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. 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 exportor 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 manufac

turers 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 participa

tion 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’s TRIPS Council, declaring its intention to import a drug under the August 30th Decision, and providing the specific quantities and prices of the drug.

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 unsuitable: 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.

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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.

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 authorization of a compulsory license and generic production. Bayer for example, successfully challenged the inclusion of mosfloxacin, 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 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.

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.

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.
An increasing number of developing countries and donor agencies require imported drugs to be WHO-prequalified. 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 expert

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".

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.

The WHO 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 WHO 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 R&D 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 wake-up 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.

**CONCLUSIONS**

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**2005**

**FEBRUARY:** Apotex agrees to develop 3-in-1 ARV of AZT/3TC/NVP. Health Canada regulators state they will not accept approval for issuing on healthy subjects due to concerns about nevirapine toxicity.

**MARCH:** MSF prepares analysis of drug for Health Canada. "Testing Canada's Resolve with Bill C-9: The case for a triple fixed-dose combination with nevirapine." International meeting on HIV/AIDS protocols in Boston where nevirapine use discussed.

**APRIL:** MSF presents case for 3FDC at drug pre-submission meeting between Apotex and Health Canada. Drug submission accepted.

**MAY:** JCPA comes into force. At one year anniversary of legislation, Canadian media headline "Drug aid for Africa a fixed-dose combination with nevirapine." MSF presents case for 3FDC at drug pre-submission meeting between Apotex and Health Canada. Drug submission accepted.

**JUNE:** MSF submits comments supporting amendment of Schedule 1 to include the 3FDC on the list.

**SEPTEMBER:** AZT/3TC/NVP FDC is added to Schedule 1 of JCPA. Pre-clinical trials application at Health Canada.

**NOVEMBER:** MSF begins discussing JCPA with potential importing country authorities.

**DECEMBER:** WTO Members make August 30th Decision permanent.

**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 $1.36 per tablet. MSF field begins ordering.

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

**US FDA approves 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.**

**2007**

**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.