

# **Submission**

**New Zealand Ministry of Economic Development**

**Acceptance of the Protocol Amending the TRIPS Agreement to  
Implement the Doha Declaration on TRIPS and Public Health**

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## **Doha TRIPS Protocol Submissions**

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14 December 2007

*“We believe that the central challenge we face today is to ensure that globalization becomes a positive force for all the world’s people... only through broad and sustained efforts to create a shared future, based upon our common humanity in all its diversity, can globalization be made fully inclusive and equitable..”<sup>1</sup>*

### **1.0 Declaration of interests**

I am an independent submitter with no political or commercial interests or affiliations.

### **2.0 Submission ‘lens’**

This submission considers the questions from the perspective of developing countries. Their preference will be for the most streamlined, un-onerous pathway possible. Although a moral imperative existed, the Rwandan CL for ARVs with Canada resulted in frustrating delays caused by Canada’s bureaucratic procedures, or in some instances lack of, that served to delay much needed drugs from reaching suffering people and to deter other developing countries from using this mechanism, which is the only one available to them.

I also use a ‘*public health sector*’ perspective, as distinct from a purely economic, or ‘*trade sector*’, perspective, to respond to the questions.

### **3.0 Submission Questions**

#### **3.1 Acceptance of the Protocol**

Given the WTO membership's unanimous support for the Doha Declaration and New Zealand's role in drafting the waiver that later became the Protocol, there appears to be no reason why New Zealand should not accept the Protocol.

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<sup>1</sup> WHO (2007). *Public health, innovation and intellectual property rights*. Report by the Commission on intellectual property rights, innovation and public health (CIPRH). Available at <http://www.who.int/entity/intellectualproperty/documents/thereport/ENPublicHealthReport.pdf>, last accessed 13/12/07

1. Do you agree with this proposition? **YES**
2. If your answer to this question is no, what benefits would New Zealand gain (or what disadvantages would be avoided) by non-acceptance?

While the moral imperative and potential economic benefit to NZ generic manufacturers were noted in the comments section, two further compelling reason for this relates to New Zealand's human rights obligations under the International Covenant of Economic, Social and Cultural Rights (ICESCR) and the momentum this creates introduces scales of economy to the global (generic) pharmaceutical industry.

- **New Zealand's international human rights obligations**

The moral obligation is backed by a *legal* imperative. Most governments have committed to take steps ensuring that various fundamental human rights are fulfilled. Human rights have an authority that is not trivial; most countries have already acknowledged the primacy of human rights by signing and ratifying the international agreements in which they are enshrined, and many have further made provision in national constitutions and legislation. In this context, the relevant human right agreed in the International Covenant on Economic, Social and Cultural Rights (article 12.1) is “the right of everyone to the enjoyment of the highest attainable standard of physical and mental health”<sup>2</sup>.

This language reflects the overarching objective in WHO's Constitution, which is “the attainment by all peoples of the highest possible level of health”<sup>3</sup>.

At a minimum, human rights, and the right to health in particular, prescribe that States have an obligation to give consideration to the health implications of their policies. Health policies, as well as inter alia those addressing trade, the environment and commerce, should be equally subject to assessments as to their impact on the right to health.

Moreover, the ICESCR Committee emphasizes that it is incumbent on States and “other actors in a position to assist” to provide international assistance and cooperation, especially economic and technical, to enable developing countries to fulfill their obligations under the Covenant. Although the General Comments of the Committee do not have legally binding effect, they are considered authoritative guidance on clarifying the contents of rights and obligations enshrined in the Covenant. They therefore constitute an important foundation for arguments that treat access to essential treatments, preventives and diagnostics as a right, and entail particular obligations on States. Access to these products is, therefore, a legitimate and core component of the right to health, as is the right to benefit from the fruits of scientific progress.

New Zealand is strongly committed to the protection and promotion of international human rights, as embodied in the Universal Declaration on Human Rights, and in the key human rights treaties. As a member of the United Nations, New Zealand supports the human rights provisions of the United Nations Charter and the Universal Declaration of

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<sup>2</sup> ICESCR, entry into force, 197,6 <http://www.unchr.ch/html/menu3/b/a-cescr.htm>, accessed 12/12/07

<sup>3</sup> Constitution of the WHO. In : *Basic documents*, 45<sup>th</sup> ed. Geneva, World Health Organisation, 2005

Human Rights. We are also a party to the six core international human rights instruments:

- International Covenant on Civil and Political Rights (ICCPR)
- International Covenant on Economic, Social and Cultural Rights (ICESCR)
- International Convention on the Elimination of All Forms of Racial Discrimination (CERD)
- Convention on the Elimination of All Forms of Discrimination Against Women (CEDAW)
- Convention Against Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment (CAT)
- UN Convention on the Rights of the Child (UNCRC) <sup>4</sup>

- **Simplifying CL procedures will contribute to scales of economy in the generics industry, in turn improving the supply of cheaper drugs to developing countries**

While CL's are not an ideal mechanism (see below for drawbacks eg. local market distortion), they nevertheless are the only instrument available to developing countries to overcome market failure in access to essential medicines. Streamlining CL Protocols and administration in Exporting Member countries not only assists individual countries that raise the CL, but also contributes to improving the scales of economy for the global generic manufacturing industry, resulting in enhanced supply of cheaper drugs to developing countries as a whole. This is described in the following excerpt:

#### ***2007 Victories - Fewer Patents, More Compulsory Licenses*** <sup>5</sup>

*Most of the licenses thus far have been issued for government use. This form of licensing has certain advantages because it is widely practiced in rich countries, including the U.S., because it obviates the need for prior negotiations with the drug company, and because it reserves the private sector to the patent holder's monopoly control, undermining claims that all profits are foregone and that research and development will be undermined.*

*However, there are also some drawbacks to government use licenses, especially when one considers how much pressure has been brought to bear on Thailand even though it carved out a private-sector monopoly reserve for Big Pharma. The first drawback, not so apparent in Thailand as perhaps in other countries, is that many poor people cannot access medicines in public sector pharmacies, which often experience stock-outs or*

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<sup>4</sup> Refer to MFAT website: <http://www.mfat.govt.nz/Foreign-Relations/1-Global-Issues/Human-Rights/0-overview.php>

<sup>5</sup> *2007 Victories - Fewer Patents, More Compulsory Licenses* sourced from : [ip-health@lists.essential.org](mailto:ip-health@lists.essential.org), on Tue, 11 Dec 2007 11:30:23 -0500

*otherwise fail to carry essential medicines. These patients must therefore rely on private sector pharmacies where monopoly pricing prevails. Thus, in countries where high disease burdens persist and where major portions of the population are de facto dependent on private-sector pharmacies, government use licenses may be an imperfect solution to access on the ground. The second drawback is that having two pricing regimes in the same country, high private-sector prices and low public-sector prices, encourages "arbitrage," or more accurately theft and resale of public sector medicines to private sector consumers. Third, avoiding negotiations may be overrated since governments can set short time limits for such negotiations and insist on strict pro-access terms whether by regulation or negotiation demands.*

*The impact of Thailand's compulsory licensing victories will be lessened if other developing countries do not follow suit. In fact, a better scenario will arise when developing countries cooperate more vigorously in the selection and timing of compulsory licenses. Generic producers are most likely to invest the \$1-\$1.5 million dollars needed to formulate a generic equivalent if they can see a sizeable market in developing countries that aggregate their collective demand. In addition, with larger, more secure, and more predictable markets, more producers will enter the market and more producers will manufacture at efficient economies of scale. The combination of competition and efficiency will result in lower prices and more secure and redundant sources of supply.*

*The strongest way for countries to cooperate may well be through creation of patent pools that allow the collective management of both compulsory and voluntary licenses (negotiations on both in- and out-licenses). Alternatively, developing countries could form regional "buying groups" and/or work intensively with the Clinton Foundation (at least for ARVs). However, in order to be able to take advantage of their South-South strength, countries will need to be more proactive both in amending their patent legislation to allow maximum use of TRIPS-compliant flexibilities and in utilizing those flexibilities to actually issue compulsory licenses.*

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### **3.2 New Zealand as an Exporting Member**

Acceptance of the Protocol by New Zealand without legislative amendment to become an Exporting Member would appear to render acceptance meaningless. Acceptance without such amendments does not seem a viable option.

1. Do you disagree with this proposition? **NO**
2. If your answer to the preceding question is yes, why do you disagree?

### **3.3 Legislative Changes**

If New Zealand accepts the Protocol and becomes an exporting Member, legislative changes will be required. The following questions deal with issues surrounding these changes. In answering these questions, submitters should consider the likely impact on applicants for compulsory licenses of the options suggested.

### 3.3.1 Purpose of the License

1. Should New Zealand's legislation specifically list the public health problems for which licenses can be granted under the Protocol? **NO**
2. If you think New Zealand's legislation should list the public health problems, which ones should be specified?

I support the statements in the comments section. Furthermore, a prescriptive system, eg. Canadian version, suggests that developing countries lack the ability to judge for themselves what diseases qualify for CLs which undermines their right to self determination. Using specific drug categories, eg similar to the WHO <sup>6</sup> (see Annex 1 for a description), would be inappropriate and over-restrictive as well because increasingly diseases in Category I are taking on the characteristics of Category II <sup>7</sup>. In addition there is a large range of conditions, in particular, maternal and child health, and to reproductive health, that deserves special consideration for developing countries because they are major causes of morbidity and mortality for women and children. As a consequence I am in favour of a broad definition.

3. If you think that New Zealand's legislation should not list the public health problems, what broader definition of "public health problem" could be used?

The definition used by Norway (under 3.3.2.1 – NZ as an Exporting Member) would be appropriate.

### 3.3.2 Products for Which a License Should be Granted

1. The Protocol contains a definition of "pharmaceutical product". Should this definition be adopted "as is" by New Zealand? **NO**
2. If your answer to the preceding question is "no", and bearing in mind that any alternative definition may differ from, but must not be inconsistent with the definition in the Protocol, what alternative definition should be adopted?

I support the comments. In which case the Swiss legislation would be an improvement. I am aware of the political pressure at the WTO to restrict the definition to a sub group of diseases. However I support broadening this definition even further, if it is not inconsistent with the definition of the Protocol. I note that Thailand has discussed raising CLs for up to 20 drugs that include 'western-type' diseases:

*"The proactive Ministry of Health in Thailand is also continuing to weigh additional government use C.L.s on four cancer medicines and up to 20 additional products for treating hypertension, diabetes, and hyperlipideamia."*<sup>8</sup>

### 3.3.3 Eligible Countries of Importation

1. Should non-WTO Members be included as eligible countries of importation? **YES**

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<sup>6</sup> See [www.WHO.int](http://www.WHO.int), for diseases categories: Category I,II (neglected diseases), III (very neglected diseases)

<sup>7</sup> WHO (2007) *ibid* pp. 13

<sup>8</sup> 2007 *Victories - Fewer Patents, More Compulsory Licenses*. *ibid*

2. If your answer to this question is "no", why should non-WTO Member countries be excluded? I support the reasons given in the comment section
3. Should any or all of the countries that have indicated that they will not use the Protocol as importing Members be excluded as eligible countries of importation?

**NO**

If your answer to this question is "yes", why? I support the reasons provided in the comments section. In addition there are a variety of complex reasons why some developing countries may not have indicated they will use the Protocol as importing Members. These include factors that indirectly impact on the health sector, such as: political coercion, lack of coherent policymaking, resource limitations, and poor governance and corruption. These are not reasons to place obstacles in the way of relieving people's suffering or to discharge the responsibility of developed country's from taking concrete, targeted steps towards the realisation of human rights and greater sharing of technology to reduce inequality.

### 3.3.4 Voluntary Licenses

The requirement, in s46 of the Patents Act 1953, for applicants for compulsory licenses to take "all reasonable steps" to obtain a voluntary license may be stricter than the "make efforts" requirement of Article 31(b) of the TRIPS Agreement.

1. Should New Zealand amend its legislation to require applicants for compulsory licenses to "make efforts" to obtain a voluntary license? **YES**
2. If your answer to this question is "no", why?

### Annex 1

The Commission on Macroeconomics and Health (CMH) in its report distinguished among three types of diseases:

**Type I diseases** are incident in both rich and poor countries, with large numbers of vulnerable population in each. Examples of communicable diseases include measles, hepatitis B, and *Haemophilus influenzae* type b (Hib), and examples of non communicable diseases abound (e.g. diabetes, cardiovascular diseases, and tobacco-related illnesses). Many vaccines for Type I diseases have been developed in the past 20 years but have not been widely introduced into the poor countries because of cost.

**Type II diseases** are incident in both rich and poor countries, but with a substantial proportion of the cases in the poor countries...HIV/AIDS and tuberculosis are examples: both diseases are present in both rich and poor countries, but more than 90 percent of cases are in the poor countries.

**Type III diseases** are those that are overwhelmingly or exclusively incident in the developing countries, such as African sleeping sickness (trypanosomiasis) and African river blindness (onchocerciasis). Such diseases receive extremely little R&D, and essentially no commercially based R&D in the rich countries. When new technologies are developed, they are usually serendipitous, as when a veterinary medicine developed by Merck (ivermectin) proved to be effective in control of onchocerciasis in humans...

Type II diseases are often termed *neglected diseases* and Type III diseases *very neglected diseases*.