

# The Global Campaign on Access to Medicines: Re-shaping intellectual property rules at the World Trade Organisation

## The problem

Modern medicines and technology have the potential to provide solutions to some of the most pressing public health problems around the globe. However, huge disparities in health remain. Many of the diseases causing loss of life and health are preventable or treatable, yet the poor and vulnerable populations continue to suffer a high burden of disease. Many factors contribute to the persistence of the health gap; including the lack of research and development (R&D) for diseases that disproportionately affect the poor and lack of access to safe, affordable and effective medical treatments for all. Research suggests that approximately 90% of medical R&D efforts only seek to address 10% of the global burden of disease.<sup>1</sup> Moreover, over two billion people lack access to essential medicines.<sup>2</sup>

For over a decade, several NGOs have been campaigning at the international level to increase R&D and secure availability and access to medicines to address priority health needs of those in most need.<sup>3</sup> International trade rules and practices have been one of the focuses of NGO campaigns. In particular, ensuring international agreements relating to the protection of intellectual property do not hinder access to essential medicines. NGOs have been pressuring States to fulfil their international obligations to enable access to essential medicines, including adopting trade practices and using trade flexibilities and safeguards to protect public health, and implementing national legislation that prioritises the right to essential medicines. They have also been pushing States to abstain from measures that hamper the implementation of flexibilities and safeguards available under current international trade agreements.

## The international campaign to strengthen access to medicines

At the time the Uruguay Round of multilateral trade negotiations was completed and the agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) came into force in 1995, there was little awareness of the relation between intellectual property rights and public health. In particular, it was unclear how the issue of patent protection for pharmaceuticals would impact on access to medicines. The World Trade Organisation (WTO) TRIPS Agreement was meant to help achieve a balance between two related public health goals; to enhance incentives for R&D into new drugs and to ensure affordable access to existing drugs.<sup>4</sup> However, by the mid 1990s public health activists and NGOs were voicing concerns that patent protection and the new TRIPS rules would lead to

higher drug prices and guard large pharmaceutical companies against cheaper generic drug competition. If developing countries were proscribed from promoting the use of cheap generic medicines, most would be unable to provide access to medicines to their populations if high prices made patented medicines unaffordable.

On October 4, 1996, an event organised by Health Action International (HAI)<sup>5</sup> in Bielefeld, Germany, marked the beginning of sustained NGO engagement in the international debate on patents and access to medicines.<sup>6</sup> The HAI seminar brought together for the first time a large group of health, intellectual property experts, academics, and activists to discuss the impact of WTO agreements on pharmaceutical patents, prices and availability of medicines and national public health policies. Among those present were Ellen t'Hoen<sup>7</sup>, James Love<sup>8</sup> and Dr. Kumariah Balasubramaniam<sup>9</sup> and NGOs such as Consumers International (CI), CPTech<sup>10</sup> and HAI. The result of the HAI 1996 meeting was a common stance that intellectual property agreements could have negative implications for public health and limit or deny access to essential medicines.<sup>11</sup> Importantly, it identified the targets of the access to medicines campaign and paved the way for more NGOs to join.

***“NGOs have been pressuring States to fulfil their international obligations to enable access to essential medicines, including adopting trade practices and using trade flexibilities and safeguards to protect public health, and implementing national legislation that prioritises the right to essential medicines.”***

Once a core coalition of health activists and NGOs had been built, they began to raise the awareness of the public on the magnitude of the problem of access to medicines in the developing world and the impact of trade rules and pushed to place the issue on the international policy agenda. NGOs such as CPTech and the HAI network organised workshops and conferences to increase the understanding of the issues and strongly lobbied policy makers domestically in the United States and Europe, as well as developing country delegates in Geneva. CPTech, which had been involved in disputes involving health care, intellectual property and trade policy since in 1994, brought ample technical expertise to the campaign. HAI united many NGOs in one large network. Several US-based AIDS advocacy groups such as Act Up and the Health Global Access Project (Health GAP) were also important early on in raising public awareness and putting pressure on the US government to change its trade and public

health policy. National NGO coalitions in South Africa and other developing countries were also starting to take shape, which would come to play a crucial role in informing the international access to medicines debate.

The first joint success of NGOs and developing countries in the access to medicines debate was the adoption of a Revised Drug Strategy (RDS) at the 52<sup>nd</sup> session of the World Health Assembly (WHA) in May 1999. Throughout 1998 and up to mid 1999, developing countries and NGOs fiercely fought the US, several European governments and pharmaceutical transnationals who strongly opposed any reference in the resolution to the impact of trade agreements on access and prices to medicines. The RDS gave a new mandate to the World Health Organisation (WHO) to ensure improved access to essential medicines and to assist countries in their efforts to safeguard public health while implementing trade agreements.<sup>12</sup>

Once the issues had been raised at the WHO, NGO attention turned to the WTO. The access to medicines issues were first raised by NGOs in the WTO context in late 1999 during the Seattle trade negotiations. The coalition of NGOs made public their demands on access to medicines in the Amsterdam Statement.<sup>13</sup> NGOs could not participate in the negotiations but they were able to influence these through media work, side-events and back-door lobbying of negotiators. Though the overall trade negotiations in Seattle failed, NGOs had helped place the issue in the international trade agenda and at that point influenced the change in US government trade and intellectual property policy in regards to access to medicines.<sup>14</sup>

***“The Doha Declaration is a clear example of how NGOs and developing countries can work together in a functioning coalition to achieve common goals.”***

The momentum and size of the global campaign on access to medicines increased when two leading NGOs; Medicines Sans Frontiers (MSF) and OXFAM, joined the coalition. MSF had been participating in the debate since 1998. In September 1999, MSF launched its own Access to Medicines campaign,<sup>15</sup> bringing in added strength, resources and credibility to the global campaign. MSF, working on the ground in developing countries to provide emergency aid for over 30 years and a large buyer of essential medicines, systematically provided information about the extent and development of the public health crisis. Moreover, having just won the Nobel Peace Prize in 1999, MSF was highly respected by the both governments and the public. Oxfam, a large and experienced advocacy organisation, also played a crucial role in expanding the reach of the campaign. In February 2001 Oxfam launched its Cut the Cost campaign, which was critical in mobilizing mass public opinion through popular campaigning and extensive media work to press developed country governments and pharmaceuticals

to change their policies and practice.<sup>16</sup> By 2001 other important NGOs had joined the campaign, including the Third World Network (TWN)<sup>17</sup> and the Quakers United Nations office (QUNO)<sup>18</sup> in Geneva. Both NGOs had a long history of working with developing countries and thus helped strengthen the relationship with national and Geneva based delegates.

The growing NGO coalition regularly exchanged information and coordinated their research, advocacy, campaigning, litigation and technical activities. Through 1999 to 2001 the NGO campaign had a double focus; building increased public support and awareness and providing research and technical support to developing country policy-makers and negotiators related to access to medicines. NGOs exposed how developing countries were being pressured domestically by the US and pharmaceutical firms not to make use of the available mechanisms and flexibilities under TRIPS. They also showed that while countries could use TRIPS flexibilities and safeguards, including provisions on compulsory licensing and parallel imports to broaden access to essential medicines, their use was being opposed by the US, other developed country governments and pharmaceutical companies.<sup>19</sup>

A crucial factor to the success of the global coalition was coordinating action and developing concerted positions among North and South NGOs and social movements working either at the grass-roots level or focusing on international processes. National coalitions in developing countries such as Brazil and South Africa were to pressure their governments to implement TRIPS compliant legislation to protect public health and promote access to medicines, while international NGO and public support helped ease the pressure from developed countries and pharmaceutical transnationals on developing country trade negotiators.

The main victory NGOs have achieved so far in the access to medicines campaign has been the WTO Doha Declaration on TRIPS and Public Health in 2001.<sup>20</sup> The Doha Declaration is a clear example of how NGOs and developing countries can work together in a functioning coalition to achieve common goals. NGOs played a crucial role in supporting developing countries in the run up to the Doha Declaration, which permanently established the primacy of public health over intellectual property rights and trade rules. The Doha Declaration also reaffirmed the flexibilities and safeguards contained under TRIPS to protect public health and specified how these could be used. However, it did not offer a solution for countries without production capacity that wanted to make use of compulsory licensing. The Doha Declaration also did not resolve the problem of TRIPS limitations on exports of generic medicines made under compulsory license. However, Paragraph 6 of the Declaration did call on the TRIPS Council to find an expeditious solution to the problem that would be made into a permanent amendment to the TRIPS Agreement.

Over the next two years, international NGOs and experts continued to support developing countries, particularly the African group, in developing negotiating proposals on implementing Paragraph 6 of the Doha Declaration. The technical nature of the work and differences in the positions between NGOs as well as developing countries on what could be the best solution changed the dynamics of global access to medicines campaign. NGOs were able to work with developing countries in the elaboration of the text of the Doha Declaration because of their similarity of agendas and trustful relationship. During the Paragraph 6 negotiations, NGOs and developing countries were unable to reach the same level of trust and consensus.

On August 30, 2003, WTO members finally agreed on a mechanism in the form of a temporary waiver to TRIPS to allow the export and import of medicines under compulsory licenses.<sup>21</sup> The waiver was to terminate when a final amendment to TRIPS incorporating the new solution would be made. Many NGOs and some developing countries were unsatisfied with the result; the procedures were considered too burdensome and unworkable in practice. Most NGOs were highly critical of the decision.<sup>22</sup> Some took the position that the mechanism was seriously flawed and needed to be redrawn; while others emphasised that it needed to be tested and shown to work before it could be turned into a permanent TRIPS amendment. There were also divided positions among developing countries regarding the best way to proceed; both on the timing and form the amendment should take.

On December 6, 2005, after a long negotiating process, developed and developing countries came to an agreement at the WTO the TRIPS Council on a permanent amendment based on the initial 30 August waiver.<sup>23</sup> Most NGOs, who had advised developing countries to reject the deal,<sup>24</sup> reacted against the amendment, pointing that developing countries had been bullied and too quick to agree to the text.<sup>25</sup> Some pointed out that delaying the amendment would have been a far better option, as it would have ensured the possibility of testing and improving the mechanism in practice.<sup>26</sup>

NGOs have now turned their attention on new trade agreements. A pressing concern today is that new international, as well as bilateral and regional trade agreements, that include additional requirements to those set forth in the TRIPS Agreement as they relate to access to medicines are currently being negotiated and concluded. Such agreements are undermining the Doha Declaration on TRIPS and Public Health that the NGO and developing country coalition worked so hard to achieve.<sup>27</sup>

## Successes and lessons learned

NGOs have been able to effectively pressure Western governments and pharmaceutical companies to reevaluate their policy on trade and intellectual property as regards to access to medicines and have raised the public profile of the issues. A number of other achievements have been made by NGOs in the global campaign on access to medicines.<sup>28</sup>

There are multiple internal and external factors that accounted for the successes, and drawbacks, of the campaign. Strong internal coordination helped sustain the NGO coalition and NGO and developing country alliance; both which weakened during times of disagreement. The diversity of NGOs brought a combination of strengths to the coalition and a natural division of tasks.

The combined expertise of the NGO coalition included:

- Effective advocacy and campaigning, including use of media, development of campaign slogans and presenting the issues in ways people could understand and relate to the problems;
- Strong research and policy analysis;
- Strategy development and knowledge of negotiating dynamics;
- Legal and technical expertise;
- Presence on the ground and in Geneva where the negotiations were taking place;
- Targeting and monitoring pharmaceutical companies;
- Access to key information and individuals;
- Close relationships with developing country government officials and delegations.

The political atmosphere and developing countries' multiple and at times competing interests and changing priorities accounted for varied degrees of trust and political feasibility of the NGO and developing coalition during different moments in the campaign. Nonetheless, the Doha Declaration on TRIPS and Public Health is a clear example that NGOs can work in an effective coalition with developing countries to withstand pressure to undertake unfavourable policies and pro-actively advance their agenda.

As long as the public health problems remain, the global campaign of access to medicines is likely to continue. Although current developments may present a murky picture for the future, NGOs now have a decade of experience to look back on and draw lessons from, in order to work in partnership with governments towards new successes.

*Viviana Munoz Tellez*

---

<sup>1</sup> See Drug for Neglected Diseases Working Group, *Fatal Imbalance: The Crisis in Research and Development for Neglected Diseases*, MSF, September 2001.

<sup>2</sup> See UN Millenium Project, 2005, *Prescription for Healthy Development: Increasing Access to Medicines*, Report of the Task Force on HIV/AIDS, Malaria and Access to Essential Medicines, Working Group on Access to Essential Medicines, Sterling, VA: Earthscan.

<sup>3</sup> See for example Bernard Pécoul, Pierre Chirac, Patrice Trouiller, Jacques Pinel, "Access to Essential Drugs in Poor Countries - A Lost Battle?", *Journal of American Medicine Association*, Vol 281, No. 4, 1999.

<sup>4</sup> See "WTO Agreements and Public Health", Joint study by the WHO and WTO Secretariat, 2002, pp. 2, para 8.

<sup>5</sup> HAI is a global network of health, development, consumer and other public interest groups. See <http://www.haiweb.org>

<sup>6</sup> See "Seminar on WTO, Pharmaceutical Policies and Essential Drugs", dated 14 August 1996.

<http://www.essentialdrugs.org/edrug/archive/199608/msg00001.php>. (last accessed 18.04.06)

<sup>7</sup> Director for Policy Advocacy, Campaign for Access to Essential Medicines, Medics Sans Frontieres (MSF).

<sup>8</sup> Director of the Consumer Project on Technology (CPTech).

<sup>9</sup> Co-ordinator, Health Action International (HAI) Asia, Sri Lanka.

<sup>10</sup> CPTech is a US - based NGO, currently focusing on issues concerning the production of and access to knowledge, including medical inventions, information and cultural goods, and other knowledge goods. See <http://www.cptech.org>.

<sup>11</sup> See "New HAI report on WTO", dated 29 April 1997. <http://www.essentialdrugs.org/edrug/archive/199704/msg00076.php>

<sup>12</sup> See "Health: Assembly Adopts New Health Strategy", 24 May 1999, South-North Development Monitor (SUNS), <http://www.twinside.org.sg/title/assembly-cn.htm>. See also "Joint NGO release on WHA Revised Drug Strategy", HAI, MSF, CPTech, May 24, 1999, <http://lists.essential.org/pharm-policy/msg00095.html>

<sup>13</sup> See "Amsterdam Statement To WTO Member States on Access To Medicine", <http://www.cptech.org/ip/health/amsterdamstatement.html>.

<sup>14</sup> See Press Statement, "Major U.S. Policy Change Opens Door for Poor Countries To Produce Affordable Drugs", MSF, HAI, CPTech, <http://www.cptech.org/ip/health/seattle.html>.

<sup>15</sup> See MSF Access to Medicines Campaign webpage, <http://www.accessmed-msf.org>.

<sup>16</sup> See Ruth Mayne, "The Global Campaign on Patents and Access to Medicines: An Oxfam Perspective", in Peter Drahos and Ruth Mayne (Eds), *Global Intellectual Property Rights: Knowledge Access and Development*, MacMillan Press, UK, 2002, Chp. 15.

<sup>17</sup> The Third World Network is an international network of organizations and individuals that conduct research and advocacy activities on economic and social issues pertaining to the South, see [www.twinside.org.sg](http://www.twinside.org.sg).

<sup>18</sup> The Quakers United Nations Office in Geneva facilitates dialogue among delegations through informal and off-the-record meetings, see [www.quno.org](http://www.quno.org).

<sup>19</sup> For example, the US government was pressuring the South African Government since 1997 to abstain from introducing changes to its Medicines Act that to promote compulsory licenses and legalize parallel imports of pharmaceuticals. See for example, Statement of James Love (CPTech) before the Subcommittee on Criminal Justice, Human Resources and Drug Policy, Committee on Government Reform, "What is the United States' Role in Combating the Global HIV/AIDS Epidemic?", July 22, 1999, <http://legalminds.lp.findlaw.com/list/info-policy-notes/msg00093.html>. In March 2001, thirty-nine drug

pharmaceutical companies sued the South African government regarding the 1997 Medicines act, which after major NGO campaign efforts and wide public condemnation, ended with the companies' withdrawal from the case. See <http://www.cptech.org/ip/health/sa/pharma-v-sa.html>.

<sup>20</sup> See Doha Declaration on TRIPS and Public Health, adopted on November 14, 2001,

[http://www.wto.org/English/thewto\\_e/minist\\_e/min01\\_e/mindecl\\_trips\\_e.htm](http://www.wto.org/English/thewto_e/minist_e/min01_e/mindecl_trips_e.htm).

<sup>21</sup> See "Implementation of paragraph 6 of the Doha Declaration on TRIPS and Public Health",

[http://www.wto.org/english/tratop\\_e/trips\\_e/implem\\_para6\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm).

<sup>22</sup> See Joint NGO Statements on TRIPS and Public Health, "WTO Deal on Medicines: A "Gift" Bound in Red Tape", September 10, 2003,

<http://www.cptech.org/ip/wto/p6/ngos09102003.html>. and "WTO members should reject bad deal on medicines", December 3, 2003, <http://phm-india.org/issues/patents/ngostatement.html>.

<sup>23</sup> See Decision of the General Council of 6 December 2005 on an Amendment of the TRIPS Agreement, [http://www.wto.org/english/news\\_e/pres05\\_e/pr426\\_e.htm](http://www.wto.org/english/news_e/pres05_e/pr426_e.htm)

<sup>24</sup> See Joint statement by NGOs on TRIPS and Public Health, WTO members should reject bad deal on medicines, December 3, 2005,

<http://www.cptech.org/ip/wto/p6/ngos12032005.html>

<sup>25</sup> See for example, Statement of CPTech on TRIPS amendment, 6 December 2005,

<http://www.cptech.org/ip/wto/p6/cptech12062005.html>.

<sup>26</sup> See for example, MSF Press Release, Amendment to WTO TRIPS Agreement makes access to affordable medicines even more bleak, December 7, 2005, <http://www.accessmed-msf.org>.

<sup>27</sup> See Joint NGO Statement on Need for WTO Moratorium on Regional and Bilateral Trade Agreements and Policies Undermining Access to Health, December 17, 2005, <http://www.cptech.org/ip/wto/ngos12172005.html>.

<sup>28</sup> These include the reduction of the price for some drugs, particularly antiretroviral drugs to treat HIV/AIDS in the developing world; development of solid proposals for alternatives to the current innovation system based on patent protection and initiatives to increase funding and carry out R&D for neglected diseases (such as a proposal for an international R&D Treaty and the establishment of the Drug for Neglected Diseases Initiative, DNDi).