



## Data Exclusivity & Access to Medicines in Guatemala

Doctors Without Borders/Médecins Sans Frontières  
Campaign for Access to Essential Medicines

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### HIV/AIDS AND GUATEMALA

According to the World Health Organization (WHO) and UNAIDS, more than 78,000 Guatemalans live with HIV/AIDS, and annual AIDS-related deaths totaled 5,800 in 2003. Approximately 13,500 of all those living with HIV/AIDS now are in urgent need of antiretroviral (ARV) treatment. Yet only 3,600 Guatemalans were receiving it in December 2004.<sup>1</sup>

Doctors Without Borders/Médecins Sans Frontières (MSF) has been providing ARVs to Guatemalans since 2001 and is currently treating more than 1,600 people (approximately half of all those on ARV treatment in the country) in one clinic and one hospital in Guatemala City as well as clinics in Coatepeque and Puerto Barrios. Most of the patients in MSF's treatment programs are receiving generic medicines, which allows MSF to treat the largest possible number of people. Our clinical outcomes parallel those found in the United States and other industrialized countries.

MSF currently pays as little as \$350 per person per year for the most commonly prescribed WHO-recommended first-line regimens. Most ARVs are not patent protected in Guatemala, and generic competition has been effective in bringing down prices of originator products despite the fact that the Guatemalan government is only beginning to open its national drug procurement system to tenders from generic producers. **Access to affordable medicines is key in making life-extending treatment available to more people who need it.**

### ACCESS TO MEDICINES AT RISK

Unfortunately, this access is now being threatened. In country after country, the US is negotiating "free trade agreements" (FTAs) containing intellectual property provisions that limit generic competition and the ability of countries to make use of safeguards in their patent laws to protect public health and ensure access to medicines. These provisions go far beyond what is required in the World Trade Organization (WTO) Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS), and directly contradict the November 2001 WTO Ministerial Declaration on the TRIPS Agreement and Public Health (Doha Declaration).<sup>2</sup> By pressuring countries to accept these provisions, the US is in effect creating a new "TRIPS-plus" norm that will undermine the right of countries to protect public health.

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<sup>1</sup> "3 by 5" Progress Report, December 2004, WHO/UNAIDS. Available at <http://www.who.int/3by5/progressreport05/en/> (accessed February 20, 2005).

<sup>2</sup> Paragraph 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."

The many troubling provisions in US FTAs include extensions of patent terms, rules that would turn national drug regulatory authorities (NDRAs) into “enforcers” of patents on medicines, granting of patents for “new uses” of known compounds, and restrictions on compulsory licensing. But of particular concern is the US Administration’s attempt to push countries to accept new obstacles related to pharmaceutical test data (so called “data exclusivity”), which will delay the availability of generic medicines. Guatemala is a case in point.

Under extreme pressure from the US, Guatemala has been going back and forth between proposed legislation that guarantees multinational pharmaceutical companies monopoly-like exclusivity on the Guatemalan market and amendments that maintain some degree of public health protection (see Annex 1 for a full chronology of events). The latest development in this process is the proposed text for a law (*initiative for the amendment of the Industrial Property Law, Decree 57-2000 of the Congress and its amendments*) presented to the Guatemalan Congress by President Oscar Berger in January 2005.

### **DATA EXCLUSIVITY: PRACTICAL CONSEQUENCES FOR GUATEMALANS**

MSF is concerned that the new draft law will, if enacted, prevent the Department of Regulation and Control of Pharmaceutical Products from granting marketing approval to generic medicines in Guatemala for five to 10 years,<sup>3</sup> thereby giving a market monopoly to originator drug manufacturers and preventing access to affordable medicines for five to 10 years in the country.

In a worst case scenario, the new legislation will prevent generic medicines from entering the Guatemalan market during the period of exclusivity *even if the originator medicine is not marketed in Guatemala*. This means that patients may have no access at all to some medicines for five years - even exorbitantly priced originator versions.

If these data exclusivity provisions had been in effect prior to 2001, generic ARVs would not have been marketed in Guatemala and MSF would not have been able to access generics. This would have limited our ability to expand access to treatment and demonstrate the feasibility of delivering ART.

### **GENERICS: TREATING MORE PEOPLE WITH THE SAME AMOUNT OF MONEY**

Generic competition on the Guatemalan market has brought down the prices of originator ARVs, and the Guatemalan government is slowly moving from purchasing only originator ARVs to including generic suppliers in the national tender. Still, Guatemala’s social security system spends significantly more on ARVs - in some cases more than 20 times more than MSF - because it procures mostly originator drugs. For example, whereas MSF pays \$216 per person per year for a generic version of the “back-bone” double combination of AZT+3TC, Guatemala’s social security system paid \$4,818 (open tender 2004) for the same combination from the originator, GlaxoSmithKline. This is 22 times more than what MSF pays.

Guatemala has the opportunity to expand access to ARV treatment significantly, particularly because of a \$ 40 million grant from the Global Fund to Fight AIDS, Tuberculosis and Malaria. In fact, there is no reason that Guatemalan authorities should not be able to ensure universal access to ARV treatment. To treat all 13,500 Guatemalans in urgent clinical need with the first-line ARVs MSF uses, Guatemalan authorities could spend \$ 5 to 9 million per year. But if the government is paying 20 times more - or even two times more - for ARVs, only a small fraction of those in need will be treated. Treating fewer people means condemning others to premature death.

In order for the Guatemalan government to expand access to ARV treatment for all those in need, it will need to retain the right to procure affordable generic AIDS medicines.

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<sup>3</sup> Because the originator has five years of data exclusivity from the first date of approval in another country, and then receives another five years of protection from the date of approval in Guatemala, for a total of up to 10 years.

Guatemala, along with other WTO members, signed the Doha Declaration and thereby committed to putting the health needs of its people before commercial and trade interests. Guatemalan authorities must not give in to US pressure. Instead, they should make full use of the flexibilities of the TRIPS Agreement to protect public health and promote access to medicines, as acknowledged by the Doha Declaration.

### **HOW DATA EXCLUSIVITY WILL AFFECT AN IMPORTANT ARV: THE EXAMPLE OF ATAZANAVIR**

In November 2004, the Congress of Guatemala repealed Decree 9-2003 (see Annex 2), which provided for five-year data exclusivity. In December, the Congress replaced Decree 9-2003 with Decree 34-2004, which passed by an important majority and was seen by Guatemalan civil society groups, MSF, and others as a positive step forward, and a critical moment for the government to commit to ensuring treatment for greater numbers of people with HIV/AIDS in Guatemala. In the roughly 18 months during which Decree 9-2003 was in effect in Guatemala, 25 medicines received “data exclusivity” protection under the law. Among those medicines affected is the ARV atazanavir. Atazanavir is a protease inhibitor, which is a key part of second-line therapy for people with HIV/AIDS once they experience treatment failure on their first-line regimen, and is used widely, in the US, Europe, and Brazil.

Today, the US price of atazanavir is more than US\$10,000 per person per year - there is no differential price for developing countries and it must be combined with at least two additional ARVs. There is no generic version of atazanavir available on the world market because it is a relatively new drug, but based on experience with other ARVs, it is possible that the price could drop by approximately 95% with robust generic competition.<sup>4</sup>

If a more affordable generic version of atazanavir is developed, however, it will not be able to enter the Guatemalan market until 2009 (given that the original atazanavir of Bristol-Myers Squibb was registered in Guatemala in February 2004). This means that BMS will have a monopoly during the entire period of exclusivity (at least five years) and, free from competition, will be able to charge whatever the market will bear - far more than what the average Guatemalan will be able to afford. It is therefore unlikely that the vast majority of Guatemalans who will need this medicine will be able to access it.

This is just one example of what could happen to all new medicines entering the Guatemalan market - not only AIDS drugs - if Decree 34-2004 is repealed and a US-style data exclusivity law is implemented, either through new national legislation or enactment of DR-CAFTA. And newer medicines will be crucial to the longer-term survival of people with HIV/AIDS and other illnesses.

### **CONCLUSION**

Guatemala has the opportunity and capacity to guarantee universal access to ARV treatment for Guatemalans with HIV/AIDS and to make other improvements in public health. However, this will not be possible if Guatemalan authorities give in to US pressure to relinquish the right to take all necessary measures to protect public health and promote access to medicines. The Guatemalan government must not trade away the health of its citizens in FTAs or any related legislation. Instead, it should uphold its obligation to put the health needs of its people before commercial and trade interests by defending Decree 34-2004, which is based on the Doha Declaration and is in full conformity with the TRIPS Agreement.

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<sup>4</sup> In some countries, a WHO-recommended first-line fixed-dose combination (e.g. d4T/3TC/NVP) is now available for as little as \$140 per patient per year (Clinton Foundation price) because of robust international generic competition. The same combination is available in Western countries as originator companies' separate products at \$8,773 per patient per year (the only country for which prices are publicly available is Australia and this price was calculated based on the schedule of Pharmaceutical Benefits for Approved Pharmacists and Medical Practitioners, May 2004; exchange rate used for conversion 1Australian \$=0.72213 US\$). This means that the price in developing countries for WHO-recommended first-line therapy is 98% lower than what the same combination costs in Western countries.

## ANNEX 1:

### WHAT EXACTLY IS “DATA EXCLUSIVITY” AND HOW CAN IT IMPACT ACCESS TO MEDICINES?

“Data exclusivity” refers to a practice whereby, for a fixed period of time, national drug regulatory authorities (NDRAs) cannot use the pharmaceutical test data from an originator company to register a therapeutically equivalent (“bioequivalent”) generic version of that medicine. Data exclusivity is distinct from patents. In fact, the biggest impact of data exclusivity may be felt on medicines that are not patented, as competition will be blocked and a patent-like monopoly will be created. Whereas patent barriers can be overcome through compulsory licensing or government use, there is no legal “remedy” for data exclusivity. Even if a generic company is authorized to produce a medicine under compulsory license, the generic medicine cannot be registered during the period of exclusivity, and therefore cannot be used.

In order for a medicine to be sold in any country it must first be registered (in other words, it must get “marketing approval” or “authorization”) by the NDRA, and in order for an NDRA to approve a medicine, it must review safety and efficacy data and ensure that the medicine meets certain quality standards.

Typically, the originator of a drug submits the needed pharmaceutical test data to NDRAs. When a generic competitor seeks to enter the market, it must simply prove that its product is of quality and is therapeutically equivalent to the originator drug. The NDRA can rely on the test data on safety and efficacy submitted by the originator company to register the generic medicine, and in this way, generic entry to the market is facilitated and accelerated.

However, the US Administration and the multinational pharmaceutical industry are pushing strongly to impose “exclusive rights” over pharmaceutical test data for a specific period of time, usually a minimum of five years. In some agreements, such as “DR-CAFTA” - the US free trade agreement with the Dominican Republic and five Central American countries (Costa Rica, El Salvador, Guatemala, Honduras and Nicaragua) - the US is even seeking what could be described as “data exclusivity-plus.” If an original manufacturer of a drug has not been registered for use in a given country, then the data exclusivity period can start running from the date of approval in another country that is party to the agreement (in this case usually the US). Neither five nor 10 years of data exclusivity is required in the TRIPS Agreement.

The concrete practical outcome of data exclusivity, whether it is implemented through specific national legislation or enactment of FTAs such as DR-CAFTA, is that originator companies have a patent-like monopoly for at least five years and can determine the price, which invariably leads to artificially high prices that are unaffordable to most. A five- to 10-year delay in access to affordable medicines for Guatemalans with HIV/AIDS and other illnesses can be a death sentence.

## ANNEX 2:

### CHRONOLOGY OF EVENTS IN GUATEMALA: ONE STEP FORWARD, TWO STEPS BACK ON DATA EXCLUSIVITY

In April 2003, the Guatemalan government, which was under pressure to adopt US standards for protection of pharmaceutical test data, modified its national intellectual property (IP) bill by passing a national decree (Decree 9-2003) that gave originator pharmaceutical companies five years of data exclusivity. Civil society groups in Guatemala mobilized to urge the government to repeal the Decree and abolish data exclusivity in order to promote generic competition and improve access to affordable quality medicines. In November 2004, the Congress finally repealed Decree 9-2003, and replaced it with Decree 34-2004, which was approved by a large majority.

This was seen by Guatemalan civil society groups, MSF, and others as a positive step forward, and a critical moment for the government to commit to ensuring treatment for greater numbers of people with HIV/AIDS in Guatemala.

Decree 34-2004 regulates the protection of pharmaceutical test data and other undisclosed tests in a way that protects “public health and promotes access to medicines for all”<sup>5</sup> and is in full conformity with the TRIPS Agreement.

In particular, Decree 34-2004 establishes that Guatemala’s NDRA, the Department of Regulation and Control of Pharmaceutical Products, should protect these test data against “unfair commercial use,” as required by the TRIPS Agreement. The main paragraph of Decree 34-2004 is an exact copy of Article 39.3 of the TRIPS Agreement on “undisclosed tests and other data.”

However, since the passage of Decree 34-2004, the US Administration has exerted tremendous pressure on Guatemala to repeal the Decree and ensure passage of a new law that reverses Decree 34-2004 before ratification of DR-CAFTA. In a January 10, 2005, “Fact Sheet” on “CAFTA, Data Protection and Generic Drugs” the US Embassy to Guatemala stated that:

*“This law [Decree 34-2004] gives the U.S. Congress the impression that Guatemala is not serious about complying with commitments it made in the CAFTA. This could result in CAFTA not being ratified by the U.S. Congress, where a close vote is expected.”*

In response to US pressure, the Guatemalan government first enacted a regulation in January 2005,<sup>6</sup> which was originally supposed to regulate the implementation of Decree 34-2004, but in effect reintroduced data exclusivity, in contradiction with Decree 34-2004. It seems even this initiative was not good enough for the US. On February 1, 2005, the leading Guatemalan daily newspaper *Prensa Libre*, published an article saying:

*“In order to reduce the pressure [exerted by the U.S.], the regulation for 34-2004 was published explaining the protection, but this did not fully satisfy the U.S. Now, Oscar Berger’s government sent to Congress new legislation which has ‘saved’ the situation. ‘We no longer have any problem,’ assured Ryan Rowlands, U.S. Embassy spokesperson in Guatemala.”<sup>7</sup>*

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<sup>5</sup> The third introductory paragraph of the Decree states that “In conformity with Article 8 of the TRIPS Agreement and the Doha Declaration on TRIPS, member countries of the WTO may adopt measures necessary to protect public health and promote access to medicines at equitable and affordable prices for the population of Guatemala, using the flexibilities established in the said Agreement.”

<sup>6</sup> Government Agreement No. 3-2005 of 5 January 2005, published in the “Diario de Centro America” of 7 January 2005.

<sup>7</sup> “TLC a aprobacion al Congreso: Óscar Berger envía tratado comercial con EE.UU.; urge a ratificarlo,” *Prensa Libre*, February 1, 2005

The new draft law to completely repeal Decree 34-2004 will, if enacted, prevent the Department of Regulation and Control of Pharmaceutical Products from granting marketing approval to generic medicines in Guatemala for five to 10 years,<sup>8</sup> thereby giving a market monopoly to originator drug manufacturers and preventing access to affordable medicines for five to 10 years in the country (Article 1).

In a worst case scenario, this legislation will prevent generic medicines from entering the Guatemalan market for five years, *even if the originator medicine is not marketed in Guatemala*. This means that patients may have no access at all to some medicines for five years - even exorbitantly priced originator versions.

Moreover, the proposed law “clarifies” that no authorization or registration will be given to generic manufacturers for medicines containing a new chemical entity that are under patent in Guatemala. This dangerous detail inappropriately links regulatory approval with the patent status of a drug, and renders compulsory licensing useless.

In a supposed effort to balance the negative impact on access to medicines, the new proposed law includes a number of exceptions to data protection. However, only one of those may indeed have such an effect, and only if implemented in good faith.<sup>9</sup>

This proposed law protects the interests of owners of pharmaceutical test data to the detriment of public health and access to affordable medicines and should be strongly opposed.

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<sup>8</sup> Because the originator has five years of data exclusivity from the first date of approval in another country, and then receives another five years of protection from the date of approval in Guatemala, for a total of up to 10 years.

<sup>9</sup> The proposed law creates an exception for “new or second uses or indications of a product or chemical entity or new combinations of approved chemical entities,” for which data exclusivity should not be granted (Article 3(c)). Such an exception could mitigate sensibly the negative impact of data exclusivity since the majority of medicines are new uses, new indications or new combinations of known molecules.