ACCESS AND INNOVATION

Position Paper on ensuring affordable anti-retroviral drugs, sustainable universal access to treatment, as well as continued innovation in research and development

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## Contents

Executive Summary .......................................................................................................................... 3

1. Introduction and Purpose ........................................................................................................... 5

2. Access in Europe and Central Asia .......................................................................................... 5

3. Affordability of Universal Access ............................................................................................ 6
   3.1. Limited Generic Competition .............................................................................................. 6
   3.2. Anticompetitive Use of Patents .......................................................................................... 7
   3.3. Deep and Comprehensive Trade Agreements (DCFTA) .................................................... 8
   3.4. Test Data Exclusivity Requirements .................................................................................. 8
   3.5. Intellectual Property Enforcement, Counterfeits and Generic Competition ...................... 8
   3.6. Differential Pricing ............................................................................................................ 9
   3.7. Medicines Patent Pool ...................................................................................................... 10
   3.8. Pooled Pricing Negotiations ............................................................................................ 10
   3.9. Cooperation and Commitment ........................................................................................... 10

4. Intellectual Property Rights and Innovation ............................................................................. 10

5. Alternative Incentive Strategies and Models to Enhance Innovation and Access .................... 11

Glossary of Terms .......................................................................................................................... 13
Executive Summary

The European AIDS Treatment Group (EATG) is a network of expert patients and treatment advocates from 54 countries in Europe and Central Asia with a mission to achieve the fastest possible universal and equitable access to state of the art medical products that prevent or treat HIV infection, and to improve the quality of life of people living with HIV/AIDS (PLHIV). This paper outlines EATG’s positions on issues related to the affordability and sustainability of universal access and continued innovation.

Research and development has yielded state of the art medical products and devices that many people still do not benefit from, as access remains limited. For example, while access to antiretroviral treatment (ART) in the high income countries of EATG’s region is nearly universal, it is extremely low among many of the middle and lower income countries in the region and for many most-at-risk populations throughout it. The prices of ART in most countries in the region are among the highest in the world.

The financial crisis has led to increasing pressure to make treatment more cost-effective while maintaining high levels of quality of care and improving levels of access. There is opportunity to improve the affordability and sustainability of equitable and universal access by reducing the costs of medicines. To take advantage of this opportunity, while maintaining adequate and rational investment in research and development, cooperation and leadership from civil society, governments and industry on a number of issues concerning intellectual property is needed.

WHO pre-qualified generic versions of medicines for HIV and TB treatment as well as medicines approved by the United States Food and Drug Administration and the European Medicines Agency are bio-equivalent to the originator medicines and have the same therapeutic effect. Competition among the generics market has resulted in a reduction in drug prices and improved access to affordable anti-retroviral drugs (ARVs) around the world. Patents and the extensions thereof are protecting monopolies and preventing the entrance of generics to pharmaceutical markets. Trade negotiations are pressuring countries to adopt provisions limiting generic competition in various ways. Data exclusivity provisions, which prohibit use of the originator’s data for registration of generic equivalents, promote wasteful spending, delays and the unethical practice re-researching medicines already proven safe and effective. Anti-counterfeit regulation developed to target trademark and copyright infringements have been applied to legitimate, high quality generic medicines leading to their seizure and countries are being pressured to adopt legislation that would exacerbate this problem. EATG supports measures to counter these problems and lower medicine prices through increased generic competition.

EATG also supports other means of reducing prices, such as differential pricing schemes that would offer lower prices on brand name drugs to countries in need. EATG also supports the Medicines Patent Pool (MPP) and encourages companies to license their patents to the Pool, including for use by middle-income countries. EATG supports the expansion of the MPP to medicines for hepatitis C, tuberculosis and possibly other diseases. Countries should be supported to engage in pooled pricing negotiations as lower prices can be agreed upon for larger volume purchases.

Continued innovation is necessary to further improve quality of life, reduce the risk of transmission, counter resistance to existing medicines, and develop other biomedical preventive and therapeutic and or curative products as well as develop vaccines. EATG supports
increased investment especially from the public sector in research and development and transparency and involvement of civil society in setting the research agenda.

EATG also supports the exploration of alternatives to the current model for promoting innovation which links the costs of research and development (R&D) with the cost of producing essential medical products as innovation is rewarded with patents which give pharmaceutical companies market exclusivity enabling them to charge monopoly prices for their products. There is ongoing debate in the international community about the appropriateness of this linkage. Prior to the 1970s, most countries excluded medicines and food (and processes of producing them) from patentability to avoid creating barriers to these essential public goods. Since 1995, the TRIPS agreement made the current model in which innovation is rewarded by patents global. In the current model, tension exists between economic exploitation of the reward for innovation and the need to provide affordable universal and equitable access to high quality medicines and medical products. Moreover a market-led research agenda leads to the inadequate investment in R&D for products that may not be profitable. EATG supports the exploration of alternative models and strategies to promote innovation and provide universal access, including models that would de-link the price of essential medical products from the costs of R&D.
1. Introduction and Purpose

Founded in 1992, the European AIDS Treatment Group (EATG) is a network of expert patients and treatment advocates from the 54 countries in Europe and Central Asia. EATG’s mission is to achieve the fastest possible universal and equitable access to state of the art medical products, devices and diagnostic tests that prevent or treat HIV infection, and to improve the quality of life of people living with HIV/AIDS (PLHIV) in Europe and Central Asia. EATG’s members and constituency are directly affected by the policies regarding access to HIV/AIDS and related treatments.

Innovation has provided medical products, devices and diagnostic tests that prevent or treat HIV infection, and improve the quality of life of people living with HIV/AIDS (PLHIV), some of which have turned HIV infection from a fatal disease (through its progression to AIDS) to a chronic health condition. In Europe and Central Asia, while many countries have achieved universal access to many of these products, the region’s low and middle-income countries have among the lowest levels of access to antiretroviral therapy in the world and access is not yet equitable in many countries as vulnerable populations continue to face significant barriers.

Considerable investment of resources is necessary to achieve equitable and universal access to high quality medical products and services. Likewise considerable investment of resources is necessary to guarantee continued innovation. It is essential that resources are used rationally and that affordability of both access and innovation be improved in order to make access to needed state-of-the-art medical products and services equitable, universal and sustainable. This paper outlines the European AIDS Treatment Group’s positions on issues related to the affordability and sustainability of universal access and continued innovation.

2. Access in Europe and Central Asia

In Europe and Central Asia, the rate of newly diagnosed HIV cases reported has more than doubled from 44 per million in 2000 to 89 per million in 2008. While access to ARV treatment in the high-income countries is nearly universal, among many of the middle and lower income countries, access is extremely low. Furthermore, there are vulnerable groups like undocumented migrants and people who use drugs, for example, in both categories of countries who lack access to prevention, treatment and care services. Tuberculosis (TB) remains the leading cause of death of PLHIV in most countries and access to treatment for many remains limited. Multidrug-resistant tuberculosis (MDR-TB) has reached the highest levels ever recorded, particularly in the Eastern European countries. Hepatitis C (HCV) is a common co-morbidity and the high cost of its treatment is contributing to a treatment crisis in Eastern

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3 Idem.
Europe and Central Asia as neither governments’ nor insurance schemes adequately cover HCV treatment.5

There are many barriers to access in the region including: lack of commitment (and adequate financing) from governments; stigma and discrimination towards PLHIV and key affected populations; inadequate access to voluntary HIV counselling and testing; inadequate programs to support uptake and adherence to ARV and non-integrated health services for PLHIV especially for most-at-risk populations like people who inject drugs, lack of adequate programs to provide care (in addition to ARV treatment), such as treatment of drug dependency and mental health support programs; problems with procurement and supply management; as well as unique barriers in low prevalence countries of South Eastern Europe where small numbers of people in need of treatment face a host of problems ranging from heightened stigma to reduced price negotiation leverage and difficulty maintaining uninterrupted medicine supplies due to the small quantities of drugs procured. There is considerable work to be done to build political commitment, coordination and investments by governments, industry and civil society to address these barriers.

3. Affordability of Universal Access

In South Eastern Europe, Eastern Europe and Central Asia, significant portions of both state and donor financed HIV budgets are spent on antiretroviral medicines6 and the prices of medicines in most of these mostly middle and high-income countries are among the highest in the world. The financial crisis has led to increasing pressure to make treatment more cost-effective while maintaining high levels of quality of treatment throughout the EATG region. There is an opportunity to make our response to the epidemic more effective and more sustainable by reducing the costs of drugs and thus improving the affordability of equitable and universal access. To take advantage of this opportunity, cooperation and leadership from civil society, governments and industry on a number of issues related to intellectual property (IP) is needed.

3.1. Limited Generic Competition

WHO pre-qualified generic versions of medicines for HIV and TB treatment as well as medicines approved by the European Medicines Agency and the United States Food and Drug Administration are bio-equivalent to the originator medicines and have the same therapeutic effect. Competition among the generics market has resulted in reduced drug prices and improved access to affordable ARVs around the world.7 Many patients and health systems have access to lower priced medicines due to intellectual property barriers varying across countries.

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5 Idem.
➢ EATG supports adherence to commitments expressed in the Doha Declaration on TRIPS and Public Health which affirmed that TRIPS “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.”

➢ EATG supports adherence to EU commitments on Equity in Health and Health in all Policies, and that the recommendations in the Final Report of the European Commission’s Inquiry in the Pharmaceutical Sector be carried out. Specifically, EATG supports the elimination of unnecessary obstacles and delays before generic applicants to register their products, settlements between the originator and generic producers which delay entry of generics to the market. EATG also supports the elimination of patent-registration linkages which require applicants to submit evidence that no patents are infringed an activity that is not within the competencies of the drug regulatory authorities. Linkages often delay or hinder the registration of generics. EATG supports the full use of TRIPS flexibilities to increase access including, when justified, the use of compulsory licenses.

➢ EATG supports the extension of the waiver for least developed countries under the TRIPS Agreement beyond 2016.

➢ EATG supports a revision of paragraph 6 of the Doha Declaration, so that a workable solution can be found to ensure that countries with insufficient or no domestic manufacturing capacity could import generic medicines under a compulsory license.

➢ EATG calls upon the pharmaceutical industry to grant voluntary licenses in middle and low income country markets without restrictive conditions to generic manufacturers to optimize competition and reduce prices.

➢ EATG encourages pharmaceutical companies including generic companies to register their products in countries in need and supports countries in need to adopt simplified registration of medicines, diagnostic tools, and vaccines which are prequalified by WHO or approved by adequately stringent other agencies.

### 3.2. Anticompetitive Use of Patents

The EU Commission’s Pharmaceutical sector inquiry highlighted anticompetitive use of patents. Patents and the extensions thereof are protecting monopolies which are preventing the entrance of generics available outside Europe and Central Asia.

➢ EATG calls on the competition agencies and the European Commission (the Commission) Directorate-General for Competition to ensure fair competition among manufacturers. Both

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10 TRIPS flexibilities are health safeguards in the Agreement on Trade Related Aspects of Intellectual Property (TRIPS), to improve access to medicines. Debate on the interpretation and scope of the flexibilities culminated in the adoption of the Doha Declaration on the TRIPS agreement and Public Health, reconfirming the policy space for WTO members to protect and prioritize public health over intellectual property rights. [www.wto.org](http://www.wto.org).

11 In 2003 an amendment was added to the Doha Declaration in paragraph 6 intended to find an appropriate solution to ensure that countries with insufficient or no domestic manufacturing capacity could import generic medicines under a compulsory license. This has been deemed mostly unworkable, and a ‘solution wrapped in red tape’. In fact, the Paragraph 6 Amendment, despite its implementation in the EU since 2006, has not been used once in the EU, and has only been used once through Canadian legislation, to export anti-retroviral medicines to Rwanda. It is now under review in the TRIPS Council.

12 As opposed to a compulsory license, when a company is forced to license by a government.


national and regional patent organizations both should carefully scrutinize patent applications and extensions and appropriately limit patents including, for example, for fixed dose combinations and when multiple patents are sought for the same substance.

3.3. Deep and Comprehensive Trade Agreements (DGFTA)

The European Commission requires provisions that go way beyond the TRIPS standard in their trade negotiations. Of particular concern are test data exclusivity and excessive enforcement requirements as well as patent extensions and supplementary protection certificates (which limit the opportunity for countries to use the TRIPS flexibilities.

- EATG opposes the inclusion of IP requirements in EU trade agreements with developing and neighbouring countries that exceed minimum requirements contained in the WTO TRIPS agreement as well as pressure to include measures to enforce prevention of import of counterfeits which would inhibit access to generics in the agreements.15

3.4. Test Data Exclusivity Requirements

Data exclusivity provisions (which prohibit use of the originator's data for registration of generic equivalents) promote wasteful spending and the unethical practice re-researching medicines already proven safe and effective.16 The application of data exclusivity provisions is already limiting access to life-saving second-line treatment for patients in Eastern Europe for example, in Ukraine. Recently, the Republic of Moldova, one of the poorest countries in Europe, with its public healthcare dependent on foreign aid, was requested to introduce EU-levels of test data exclusivity and IP enforcement in the process of the negotiations of a DCFTA.

- EATG calls on the EU to refrain from including data exclusivity requirements (which are not required by TRIPS) and which can delay registration of effective generic medicines in trade agreements.
- EATG calls on countries to refrain from adopting data exclusivity provisions.

3.5. Intellectual Property Enforcement, Counterfeits and Generic Competition

Anti-counterfeit regulation developed to target trademark and copyright infringements have been applied to legitimate, quality generic medicines leading to their seizure. The IP enforcement

15 EU Council Conclusions on Global Health, 16. a., “the EU should support third countries, in particular LDCs, in the access to effective implementation of flexibilities for the protection of public health provided for in TRIPS agreements, in order to promote medicines for all, and ensure that EU bilateral trade agreements are fully supportive of this objective”, Foreign Affairs Council meeting, Brussels, May 2010, http://www.consilium.europa.eu/uedocs/cms_Data/docs/pressdata/EN/foraff/114352.pdf

16 Data exclusivity prevents competitors from obtaining registration on a product, prohibiting a generic supplier from relying on efficacy & safety data submitted by an originator medicine to register a generic product. The alternative would be for generic manufacturers to repeat clinical trials of medicines to prove their safety and efficacy. However, as the safety and clinical validity of the medicine being tested is already established, having patients undergo these experiments would be in conflict with medical ethics. Data exclusivity is not always subject to the flexibilities and exceptions that have been established for patents. The provisions on data exclusivity overlap with and complement patent protection and may extend beyond it. Furthermore, data exclusivity will apply to all medicines, regardless if they are patented or not. This creates a very strong kind of monopoly, which is ‘TRIPS-plus’, as TRIPS does not require WTO member states to integrate data exclusivity into its national laws.
agenda spearheaded by the EU and the US could hamper competition by delaying or limiting generic market entry. Anti-counterfeit measures conflate intellectual property protection with quality, safety and efficacy of medicines. While there is no proof that such measures are effective in stopping the spread of substandard, falsified and spurious medicines, there is growing evidence that they are misused to block access to generics and to promote private proprietary interests. Nevertheless, such measures continue to be supported, for instance through the recently signed Medicrime Convention. This document foresees criminal sanctions for “counterfeiting” while failing to adequately include intent in its definitions among other problematic provisions. The Convention was negotiated under the auspices of the Council of Europe with heavy involvement of the WHO-based enforcement taskforce, IMPACT, and at least one big pharmaceutical company. Medicrime has never been subjected to a public debate. In late October 2011, 15 countries signed Medicrime, including Russia and Ukraine. So far it has not been ratified but, after 5 ratifications, this document will enter into force.

- EATG condemns the seizures of legitimate, quality generic ARVs and other medicines resulting from the application of anti-counterfeiting regulation to generic medicines in transit as well as legislation and investment in enforcement which does not prevent such seizures.
- EATG calls for countries not to ratify Medicrime and for signatories to withdraw from the Convention.
- EATG calls for transparency and public accountability when documents that directly impact public health and patient’s rights are negotiated.
- EATG calls for developing a public health driven agenda to address the legitimate problem of quality safety and efficacy, through empowerment of drug regulatory authorities and not through inefficient enforcement measures.

3.6. Differential Pricing

The new European Union member states (2004 and 2007), as well as candidate and potential candidate countries to EU accession, which have limited health budgets and increasing patient co-payment requirements for both treatment and diagnostics, must adhere to the same intellectual property regulation and are subject to the same level of reference pricing for brand name medicines as the wealthier old member states.

- EATG calls for reconsideration of the reference pricing scheme for brand name medicines and for greater transparency of pricing.
- EATG calls for differential pricing in low and middle-income country markets.
- EATG calls for measures to be taken to prevent harmful parallel exporting, incentive for which is created by differential pricing and has led to shortages of medicines in the countries of origin.


3.7. Medicines Patent Pool

- EATG supports the Medicines Patent Pool (MPP)\(^{19}\) and encourages companies to license their patents to the Pool, allowing for broad geographical scope for both use and production that ensures middle-income countries will benefit from the license. EATG supports the expansion of the MPP to medicines for Hepatitis C, TB and possibly other diseases.

3.8. Pooled Pricing Negotiations

Pooled pricing negotiations can lead to lower prices.

- EATG also supports transparent and regional price negotiations to ensure the affordability of ARVs and other medicines needed by PLHIV through mechanisms like the Baltic countries agreement or use of services like those offered by UNICEF.

3.9. Cooperation and Commitment

- EATG calls upon governments to uphold their commitments to provide universal access and for pharmaceutical companies (both originator and generic), civil society to cooperate to ensure affordable, sustainable, equitable, universal access to HIV and HIV co-morbidity prevention, diagnostics treatment and care. EATG calls for renewing of the Bremen Initiative.
- EATG calls for patient groups to get involved in finding solutions to increase affordability at national, regional and global levels.
- EATG calls for technical support to be provided to countries which are transitioning from funding procurement of medicines for HIV and co-morbidities with international funds to national funds in order to limit the increase in price (which has often been seen) after such transitions.

4. Intellectual Property Rights and Innovation

Innovation has been crucial to providing medicines and medical tools which have turned HIV infection from a fatal disease (through its progression to AIDS) to a chronic health condition. Continued innovation is necessary to further improve the quality of life, reduce the risk of transmission, counter resistance to existing medicines, and develop other biomedical preventive and therapeutic and or curative products as well as develop vaccines.

- The European Commission should increase budgetary allocation to promote innovation for medicines to treat HIV, TB, HCV as well as diseases for which there is a lack of innovation.
- Russia too should follow up on its commitment cooperate for enhanced pharmaceutical innovation as expressed in the BRICS (Brazil, Russia, India, China and South Africa) Summit 2011 Beijing Declaration.

Data produced by research should be shared for greater and more efficient innovation. Public investments into medical research should lead to shared public knowledge and broad access to resulting medical products.

Civil society organisations including expert patient organisations like EATG should be given a more direct role in defining research priorities and where and how countries and regional intergovernmental bodies invest budgets for innovation and share knowledge on innovation.

EATG encourages greater transparency about the costs of R&D as well as production of medical products so that informed decisions can be made about investments and pricing.

EATG commits to support increased knowledge, skills and cooperation around access and innovation issues among civil society organisations.

5. Alternative Incentive Strategies and Models to Enhance Innovation and Access

The current model for promoting innovation links the costs of research and development (R&D) with the cost of producing essential medical products as innovation is rewarded with patents which give pharmaceutical companies market exclusivity enabling them to charge monopoly prices for their products. There is ongoing debate in the international community about the appropriateness of this linkage. Prior to the 1970s, most countries excluded medicines and food (and processes of producing them) from patentability to avoid creating barriers to these essential public goods. Since 1995, the TRIPS agreement made the current model in which innovation is rewarded by patents global. In the current model, tension exists between economic exploitation of the reward for innovation and the need to provide affordable universal and equitable access to high quality medicines and medical products. Moreover a market-led research agenda leads to the inadequate investment in R&D for products which may not be profitable. As the WHO report of the Commission on Intellectual Property Rights, Innovation and Public Health notes, IP rights are irrelevant for stimulating innovation in the absence of a profitable market, which often applies to products for use principally in developing countries. As a result, investment in research for new medicines for tuberculosis and an adequate diagnostics test, for example, is limited.

There is growing momentum behind calls for exploration of alternative models for R&D including ones which would de-link the costs and rewards of innovation from the costs of production of medical products, devices and diagnostic tests. In the EU Communication and Council Conclusions on Global Health of May 2010, Member States call for further exploration of innovation models that dissociate the cost of R&D from the price of medicines. The Innovation Union Communication, an EU flagship policy, states that EU innovation should be needs-driven, more efficient, cooperative, and calls for the creation of platforms for open innovation and citizen engagement, including the awarding of prizes for research. The Global Strategy on Public Health, Innovation and Intellectual Property calls upon stakeholders to “explore and promote a range of incentive schemes for R&D including addressing the de-linking of the cost of R&D and the price of health products.” (WHA 61.21) to ensure broad access once new products are available.

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developed. The World Health Assembly in May 2012, agreed on the need to follow up and further explore the recommendations of the Consultative Expert Working Group on Research and Development: Financing and Coordination which recommended exploring de-linking of R&D from production to ensure access to essential public goods.

- EATG supports increased public sector funding of R&D.
- EATG supports the exploration of alternative models and strategies to promote innovation and provide universal access, including models that would de-link the price of essential medical products from the costs of R&D. EATG supports the exploration of models such as: product development partnerships; prize funds to reward innovations; innovation inducement prizes;\(^\text{25}\) and the donor prize proposal for medicines and medical products for HIV as well as vaccines which would encourage inventors and companies to license their patents to the MPP on non-restrictive terms.\(^\text{26}\) EATG supports intergovernmental negotiations on an alternative global framework for R&D under the auspices of the WHO.\(^\text{27}\)
- EATG supports voluntary non-patent initiatives (which are done for neglected diseases).

\(^\text{25}\) Love & Hubbard, the big idea: prizes to stimulate R&D for new medicines, Chicago-Kent Law review, 2007.
\(^\text{27}\) A binding intergovernmental instrument regarding the coordination and financing of biomedical R&D is being considered at the WHO. This instrument would contain financial obligations for countries to contribute to R&D financing with incentives that deliver innovation and access. Since 2000, discussions on such an instrument have been taking place, and the need to coordinate and prioritize R&D has become increasingly obvious and pressing. Discussions at the WHO are becoming more concrete, most specifically in the establishment of the Consultative Expert Working Group on R&D Financing and Coordination, which is recommending for negotiations to start. Negotiations on such a binding intergovernmental instrument would take place under the auspices of the WHO. http://www.two3c.org/
Glossary of Terms


Voluntary license
As described by South African civil society legal experts, a voluntary license is “a license issued by the patent-holding company that allows another company to manufacture a patented product subject to the payment of an agreed royalty fee to the patent holder.”

Agreements on voluntary licenses typically are reached following significant (and often time-consuming) negotiations between drug firms. Governments are often involved in such negotiations as well. They have a vested interest in the success of such arrangements because in most countries the public sector purchases and dispenses at least a small amount of drugs through government health systems. In such cases the drugs are usually provided free of charge or at very low cost.

Many advocates consider voluntary licenses to be viable as an access to medicines strategy only when countries have demonstrated their will, ability, or inclination to take more aggressive action by issuing compulsory licenses. In their view, it is only in such cases that patent-holding firms will negotiate voluntary licenses in which they relinquish monopoly supply of a medicine. The companies negotiating voluntary licenses are aware that failure to reach such an agreement, in which they still retain significant control over their patented products, could prompt the issuing of a compulsory license that strips away even more of their influence.

TRIPS and patents
The WTO’s Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) establishes minimum standards for intellectual property rights and regulations. WTO members are obligated to pass and enforce laws that meet the standards.

The TRIPS agreement took effect one year after the WTO was officially founded in January 1995. Primarily developed countries keen to more thoroughly codify laws and expectations around the world spearheaded its drafting and passage. Not coincidentally, such countries are home to the vast majority of multinational companies, nearly all of which supported the pact.

Provisions of the TRIPS agreement cover a range of intellectual property issues including copyright, trademarks, and patents. They also specify that disputes between countries over these matters will be subject to WTO dispute-resolution mechanisms and procedures.

The provisions related to patents are the most relevant vis-à-vis medicines and other pharmaceutical products. The agreement aims to globally harmonize patent laws and protections to the fullest extent possible. Under the TRIPS agreement, “governments are required to recognize patents on products and processes in most areas of technology and

to confer rights to the patent holder for a given period of time." To that end, the agreement mandated that the majority of WTO member-states pass laws by 2005 providing patent protection to all new pharmaceuticals for a period of at least 20 years from the date of filing a patent application. That mandate applies to all new pharmaceuticals, regardless of the patent holders’ home country or type of product developed.

Subsequent revisions allowed important and notable exceptions to the 2005 deadline for the world’s poorest nations, which are classified as least developed countries (LDCs) by the United Nations. LDCs currently have until 2016 to pass and implement patent-protection laws for pharmaceuticals. Until they do so, LDCs need not (under WTO rules) recognize, protect, or enforce patents on pharmaceuticals. (Countries are also permitted to seek extensions beyond 2016.)

The TRIPS agreement also outlines numerous steps and measures, commonly referred to as “flexibilities,” that member-states may consider taking to improve access to patented pharmaceuticals. Among the specific flexibilities are compulsory licensing and parallel importing (both discussed elsewhere in this glossary). They are two of the most controversial flexibilities because, although legal under WTO rules, their use is often opposed by many pharmaceutical companies and national governments in developed nations. Opposition is usually based on the belief that such steps undermine patent-holders’ ability to profit fairly from the products they have developed.

**Doha Declaration**

In November 2001, WTO members adopted the Doha Declaration on the TRIPS Agreement and Public Health—named after the Qatari capital where member-state representatives unanimously agreed to it. Several developing countries, including many in Africa, refused to proceed further with the WTO’s ongoing Doha Round of global trade negotiations until after this initial declaration was agreed to. (Doha talks continue to this day.)

The Doha Declaration stemmed in part from developing countries’ desire to counter strong pressure from developed nations and the pharmaceutical industry to prevent poorer nations’ use of key “flexibilities” in the TRIPS agreement. These flexibilities are intended to help countries improve access to unobtainable or unaffordable medicines. Although the flexibilities are perfectly legal to exploit under WTO rules—and in fact they were created specifically to be utilized as needed—some governmental and industry opponents in the developed world consistently portrayed them as illegal.

The Doha Declaration did not formally alter the TRIPS agreement, although it did set in motion processes that were ultimately beneficial for developing countries, including some deadline extensions for LDCs. A key aim of the declaration was essentially to remind policymakers of the type and scope of flexibilities that member-states could potentially utilize—including the right to allow parallel importing and to grant compulsory licenses on the grounds determined by the original TRIPS agreement. The declaration also served to reinforce WTO members’ commitment to these flexibilities and to address the problem of

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using compulsory licensing for export purposes. (The case study on Rwanda refers specifically to the latter issue.)

The Doha Declaration stated: “We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health… We affirm that the Agreement can and should be interpreted in a manner supportive of WTO Members’ right to protect public health and in particular, to promote access to medicines for all.”