



## WORLD HEALTH ORGANIZATION (WHO)

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### Description of the Committee

The World Health Organization (WHO) is a specialized agency of the United Nations that provides leadership on all global health matters. Within the United Nations, WHO is the authority for the “health research agenda, setting norms and standards, articulating evidence-based policy options, providing technical support to countries and monitoring and assessing health trends.”<sup>1</sup> It was founded in 1948 and was preceded by the Health Organization of the League of Nations. The World Health Organization has 194 member nations and provides support and information on issues such as food safety, HIV/AIDS, maternal health and scientific research.



**World Health Organization**

### Topic: Generic Drugs

#### Introduction

With the help of innovation and scientific advances in the medical field, many life-threatening diseases such as HIV/AIDS and various forms of cancer can be treated with effective drugs. Major pharmaceutical companies spend millions, even billions, on the research and development (R&D) of these novel drugs. Once the drug meets all the standards of national and international drug regulation agencies, the companies can obtain a patent for that drug. A patent is essentially a claim given by a government or international authority to inventors on a specific idea or product. It gives inventors full ownership of their invention and forbids others from producing or using the invention without the inventors' permission. Drug patents are usually in effect for 17 to 20 years.<sup>2</sup> After this period expires, other companies can produce and sell the drug without the permission of the pharmaceutical company that patented the drug. These drugs are called generic drugs; they have the same chemical formula as the expensive major pharmaceutical brand, but are sold at much cheaper prices.<sup>3</sup>



Child receiving generic drug.

Source: UNICEF.org

Generic drugs are vital to those who cannot afford high-priced brand-name prices. Usually these are the people who need these drugs the most. Major pharmaceutical (“Big Pharma”) companies charge high rates for their drugs because they put in so much money into R&D initially. Generic drug producers do not have to worry about developing a drug because the chemical formula is available to them. They also do not have to worry about completing all the regulatory testing because the originating company has already done it. This allows generic drug producers to charge so little.

Eight million people in low- and middle-income countries currently receive drug treatment for HIV/AIDS.<sup>4</sup> Without reduced generic drug prices, this would not be possible. However, it is Big Pharma that is inventing these lifesaving drugs. R&D is very costly, and if Big Pharma can't profit, the development of better, more effective drugs may be in danger.

## Background

Prior to the 1800s, medicine was primitive. Drugs were not mass-produced, and many “medicines” were rudimentary concoctions produced at home that often did not have any benefits—some were even harmful or poisonous. Fortunately, medical advances have paved the road for creation of more effective drugs that can be mass-produced efficiently. However, with the emergence of numerous drugs and therapies, governments began regulating the pharmaceutical industry to ensure the safety of their citizens. In any nation, a new drug must pass clinical trials to prove its effectiveness and safety. After the drug passes these tests, a patent is granted, and the drugs can be sold to consumers.

Because a large initial investment is necessary to getting a new drug into the market, the pharmaceutical industry is made up of a few, very large companies. It has become increasingly difficult for new companies to compete, and consequently, prices of vital drugs were too high for developing nations to afford. As a result, some nations began to produce generic versions of patented drugs. For example, Brazil produced many generic HIV/AIDS treatments without the permission of pharmaceutical companies.<sup>1</sup> This was illegal because the patents for these drugs were not yet expired.

### *TRIPS and Compulsory Licenses*

In 1994, Big Pharma was given protection by the World Trade Organization. The Uruguay rounds of multilateral trade talks led to the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).<sup>5</sup> Intellectual property (IP) is “the overall term for property in the creation of the mind,” including novel drug development.<sup>6</sup> This agreement required the signatories to improve intellectual property laws, including increasing the patent period by 20 years. If the member nations wanted the benefits of being part of the WTO, they would have to respect the Big Pharma patents.

However, there was a loophole. The agreement stated that members are allowed to override the patents when the nation is in a state of emergency. States can issue a “compulsory license” that allows them to produce a drug nationally in the midst of an epidemic even if the patent has not expired. The agreement was very ambiguous and confusing as to when the compulsory licenses are applicable. States were now able to use compulsory licensing as a bargaining chip with Big Pharma to get lower prices on drugs for diseases such as malaria, tuberculosis and HIV/AIDS. Countries such as India, Brazil and Thailand issued compulsory licenses on many antiretroviral drugs (ARV) to treat those infected with HIV. India in particular emerged as one of the leaders in producing cheap, generic ARVs. In 1996, the price of treating a patient with ARVs was about \$10,000-\$15,000 a year, and only 2 percent of those in developing countries were receiving these drugs. Pressure from non-government and governmental organizations on Big Pharma and increased production of generic ARVs dropped the cost of treating a patient to only \$295 per year.<sup>3</sup>

### Non-communicable Diseases

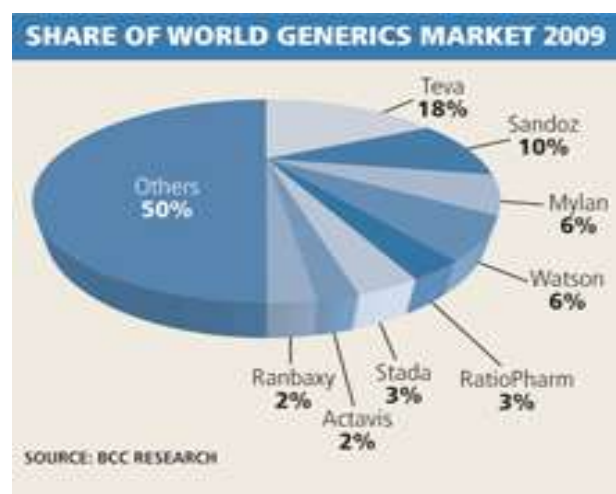
#### CRITICAL THINKING

How do you think the international community should deal with non-communicable diseases? Are they as dangerous as HIV/AIDS and malaria? How should the WHO prioritize their importance?

Big Pharma has argued that member states are keen to abuse the right to issue compulsory licenses when there is no emergency. Many nations might simply rather not spend their money if there was a way out. This is particularly important when dealing with middle-income nations and non-communicable diseases. A non-communicable disease, “also known as chronic diseases, are not passed from person to person.” In 2006, Thailand issued compulsory licenses for several cancer drugs after it was not able to negotiate a low enough price with Big Pharma.<sup>1</sup> According to a report from the Secretary-General in 2011, non-communicable disease such as cancer, diabetes and heart disease accounts for more than 60 percent of deaths globally (80 percent in the developing world). Big Pharma relies on profits from the sale of drugs for these diseases to fund R&D for new drugs, so the actions of countries like Thailand is very troublesome for these companies.

### Current Situation

There has been a major increase in generic drug production in recent years. PhRMA, an international lobbyist group, concluded that the percentage of the market that relies on generic drugs rose from 49 percent in 2000 to 78 percent in 2011. The top generic manufacturers include Ratiopharm (Germany), Teva Pharmaceutical Industries (Israel) and Ranbaxy (India). About 80 percent of all generic ARVs are produced in India.<sup>7</sup> PhRMA also concluded that R&D costs have steadily increased by about



This graph represents the way generic drug brands are divided as of 2009.

Source: BBC Research.

\$20 billion over this decade. With a smaller market and rising R&D costs, Big Pharma is in an uncomfortable position. In 2012, many patents for essential ARVs expired, and another wave of expirations will take place in 2014 for a number of other important drugs. Additionally, this September, Indonesia issued compulsory licenses for seven HIV and hepatitis B medicines.<sup>8</sup> All this will mean a major loss in profits for many Big Pharma companies.

Big Pharma has taken a few drastic measures to cope with the changing nature of the industry. One is the adoption of “tiered pricing.”<sup>3</sup> In this system, the price of the branded drug is calculated by a formula that takes into account the income per person in each nation. This will allow developing nations to buy from the big companies directly at lower prices and reduce the need for compulsory licenses. The problem with this approach is that middle-income countries often don’t benefit from this arrangement.

In 2009, the UN initiative that deals with the purchase of drugs, UNITAID, worked with the Clinton Foundation to create a “Medicines Patent Pool” program to tackle AIDS, malaria and tuberculosis.<sup>3</sup> In this program, a pool of nations would manufacture generic versions of patented drugs and combine them into a single treatment for developing nations. Gilead Sciences became the first major pharmaceutical company to allow four of its patented drugs to be produced under this agreement.<sup>9</sup> Several other Big Pharma companies have since followed. Additionally, a comprehensive web-based database called “The Global Price Reporting Mechanism” was created for ARVs. Founded by the AIDS Medicines and Diagnosis Service (AMDS), this database made it easier for national and international authorities to get the best price for the best drugs. This also put more pressure on Big Pharma to lower prices because it created more competition.

Even with this progress, there remains a dark cloud on the horizon, particularly for HIV/AIDS drugs. The patents for many first-line AIDS drugs have expired, and countries such as India are ferociously producing them at low prices. However, the new second-line medicines are still under tight patents. These new drugs are often better and less toxic than old first-line drugs, making them about six times as expensive. When patients experience resistance or toxicity, second-line treatment options are necessary to better fight the virus. Patients in developing nations are unable to get these drugs and are forced to stick to older treatment options.<sup>3</sup>



Students in Capetown, South Africa, march to increase distribution of cheap ARVs.

Source: Guardian.co.uk



## International Action

The international community has taken significant steps both to ensure accessibility of lifesaving drugs to the sick and to protect intellectual property. The World Trade Organization's TRIPS agreement in 1994 encouraged signatories to respect patents; the 20-year patent period was made law in this agreement. The agreement also gave nations the option of issuing compulsory patents in times of severe emergencies. Significantly, a member state cannot simply issue as many compulsory patents as it wishes without suffering political backlash from the international community.

During the 1999 WTO Ministerial Conference, the issues of intellectual property and generic drugs were intensely debated. In this conference, the United States made a very important policy change with regard to intellectual property. President Clinton stated in his speech, "The United States will henceforth implement its health care and trade policies in a manner that ensures that people in the poorest countries won't have to go without medicine they so desperately need."<sup>10</sup> President George W. Bush created the President's Emergency Plan for AIDS Relief (PEPFAR) in 2003, which pledged billions for AIDS relief. President Barak Obama expanded the program during his presidency. However, many developed nations, including the United States and several Western European nations, have enforced strict patent protection laws, especially when dealing with non-communicable diseases. They argue that diseases such as cancer and diabetes are less of an emergency than HIV/AIDS, malaria and tuberculosis.<sup>11</sup>



This graph represents inflation rates in generic and brand drugs, emphasizing the price difference between the two types.

Source: Express Scripts.

The Doha Declaration in 2001 made special provisions on the TRIPS agreement on matters that deal with public health.<sup>9</sup> It stated that not only are member states allowed to issue compulsory licenses in times of emergencies, but they can also export generic drugs to other nations. This means that if one nation issues a license and produces the cheap generic option, other nations can simply buy the drugs from that nation.

The sixth Millennium Development Goal aims to “combat HIV/AIDS, malaria and other diseases.” Access to cheap generic drugs is vital to achieving this goal, and the international community recognizes this. In 2012, WHO took a step further to protect the use of generic drugs. According to WHO, “counterfeit medicine is one which is deliberately and fraudulently mislabeled with respect to identity and/or source.” Many in the Big Pharma sector have tried to classify generic drugs in this category to stop the growing generic manufacturing industry. It was not uncommon for generic drug shipments from India and Brazil to be held at European Union Ports on grounds of breaking intellectual property laws. However, in June 2012, WHO adopted a resolution that clearly distinguishes counterfeit drugs from generic drugs.<sup>12</sup> This made it easier for generic drug manufacturers to get their products to patients who desperately need them.

### CRITICAL THINKING

Using income per person to create a tiered pricing system is not the only option. What other factors could be used to create a more efficient pricing system that benefits both low- and middle-income nations?

### Recommendations for Creating a Resolution

When delegates are drafting a resolution, it is important to find a balance between the financial needs of multinational pharmaceutical companies that spend billions on R&D to invent lifesaving drugs with the needs of the poor who can only afford generic drugs for treatment. An ideal resolution would increase accessibility to these drugs without hindering innovation and research.

The patent pool program implemented by UNITAID proved a great success and was effective in lowering the cost of essential drugs. It also ensured that major pharmaceutical companies would be compensated for allowing the production of patented drugs. The problem with this method is that companies and nations would have to voluntarily sign up to be a part of the pool agreement. This can limit the amount of generic drugs that can be produced and which countries can buy them.

Another option is “tiered pricing.” Nations with a lower income per person can buy branded drugs at lower prices. Usually nations with higher rates of poverty have sicker populations and a greater need for cheap drugs. Unfortunately millions of people reside in middle-income nations that cannot afford even the tiered prices.



Delegates are encouraged to look at the needs of their specific nation and gain a full understanding of the jurisdiction of the World Health Organization when formulating a resolution. Intellectual property has mainly been a matter related to WTO but has gained significance in WHO in relationship to health-care access. Delegates should examine specifically the implication of patent laws on access to generic drugs.

### Questions To Consider

1. How many years do patents need to remain in effect to ensure that multinational pharmaceutical companies make enough money to pay for the R&D of drugs and still have enough resources left over for future research, paying employees and profit?
2. How can we bring down the price of name-brand drugs so that they can become available to the world's ill before the patent expires and cheaper, off-brand drugs enter the market?
3. How should generic drugs be regulated once the patent on the original drug expires 20 years after its original production? What role should name-brand drugs continue to play after this point?
4. Is it fundamentally unfair for generic drugs to be produced at all? In other words, is it right that smaller companies can make money off the R&D of large pharmaceutical companies? Does the fact that it makes lifesaving drugs more accessible make a difference?
5. Since lifesaving drugs are generally inaccessible to the world's poor during the patent period, critics charge that major drug companies are simply profiting at the expense of the lives of the world's poor. Given that patents make drugs less accessible, is it right to patent them at all?

### Research Aid

This is the official website of the World Health Organization.

- **WHO website,** <http://www.who.int>

This summary of European Union legislation explains the role of TRIPS and discusses some of its key provisions.

- **European Union,** [http://europa.eu/legislation\\_summaries/internal\\_market/single\\_market\\_for\\_goods/pharmaceutical\\_and\\_cosmetic\\_products/121168\\_en.htm](http://europa.eu/legislation_summaries/internal_market/single_market_for_goods/pharmaceutical_and_cosmetic_products/121168_en.htm)

See these articles to get a good grasp of the fundamental debate regarding generic drugs and why they are so controversial.

- **Diplomat Magazine,** [http://www.diplomatmagazine.com/index.php?option=com\\_content&view=article&id=135&Itemid=](http://www.diplomatmagazine.com/index.php?option=com_content&view=article&id=135&Itemid=)
- **Council on Foreign Relations,** <http://www.cfr.org/drugs/debate-over-generic-drug-trade/p18055>

## Terms and Concepts

**Clinical Trials:** For the purposes of registration, a clinical trial is any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes.

**Determinants of Health:** Factors that influence health status and determine health differentials or health inequalities. They are many and varied and include, for example, natural and biological factors such as age, gender and ethnicity.

**Generic Drugs:** A pharmaceutical product usually intended to be interchangeable with an innovative product that is manufactured without a license from the innovator company and marketed after the expiration date of the patent or other exclusive rights."

**Patent:** A title granted by public authorities that confers a temporary monopoly for the exploitation of an invention on the person who registers it, furnishes a sufficiently clear and full description of it and claims this monopoly.

**Research and Development:** Scientific investigation and invention. Applied research and development has a commercial objective and includes the invention and design of production systems. In the pharmaceutical sector, research and development (R&D) costs are often very high, so the industry is likely to invest only in drugs with profit potential.

## References

<sup>1</sup>"About WHO," World Health Organization, United Nations, 2013, accessed January 16, 2013, <<http://www.who.int/about/en/>>.

<sup>2</sup>Toni Johnson, Council on Foreign Relations, August 3, 2011, accessed December 30, 2012, <<http://www.cfr.org/drugs/debate-over-generic-drug-trade/p18055/>>.

<sup>3</sup>"Generic Drugs," WHO, December 30, 2012, <<http://www.who.int/trade/glossary/story034/en/index.html>>.

<sup>4</sup>"AIDS, Drug Prices and Generic Drugs," Avert, December 21, 2012, <<http://www.avert.org/generic.htm>>.

<sup>5</sup>"Agreement on Intellectual Property Rights Relating To Trade and Pharmaceutical Patents," *Europa*, 2008, accessed October 18, 2012, <[http://europa.eu/legislation\\_summaries/internal\\_market/single\\_market\\_for\\_goods/pharmaceutical\\_and\\_cosmetic\\_products/121168\\_en.htm](http://europa.eu/legislation_summaries/internal_market/single_market_for_goods/pharmaceutical_and_cosmetic_products/121168_en.htm)>

<sup>6</sup>"Intellectual Property," WHO, December 27, 2012, <[http://www.who.int/topics/intellectual\\_property/en/](http://www.who.int/topics/intellectual_property/en/)>.

<sup>7</sup>Simon Reid-Henry, and Hans Lofgren, "Pharmaceutical Companies Putting Health of World's Poor at Risk," *The Guardian*, Guardian News and Media, July 26, 2012, accessed December 30, 2012, <<http://www.guardian.co.uk/global-development/poverty-matters/2012/jul/26/pharmaceutical-companies-health-worlds-poor-risk>>.

<sup>8</sup>"Indonesia Licenses Patents for Seven HIV & Hepatitis B Medicines," Public Citizen, September 30, 2012, accessed December 30, 2012, <<http://www.citizen.org/PC-statement-on-compulsory-licensing-in-Indonesia>>.



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<sup>9</sup>"Medicines Patent Pool Signs Licence Agreement with Gilead to Increase Access to HIV/AIDS Medicines," Unitaid, December 30, 2012, <<http://www.unitaid.eu/resources/news/348-medicines-patent-pool-signs-licence-agreement-with-gilead-to-increase-access-to-hiv-aids-medicines>>.

<sup>10</sup>Ellen T. Hoen, "TRIPS, Pharmaceutical Patents, and Access to Essential Medicines: A Long Way From Seattle to Doha," *Chi. J. Int'l L* 3: 27.

<sup>11</sup>Elizabeth Whitman, "Rich Nations Step Up Assault on Generic AIDS Drugs," *Guardian Development Network*, June 10, 2011, accessed October 19, 2012, <http://www.guardian.co.uk/global-development/2011/jun/10/rich-nations-generic-aids-drugs>.

<sup>12</sup>Vineta Panday, "WHO Will Set Generics Apart from Counterfeits," *Daily News and Analysis*, June 4, 2012, accessed December 29, 2012, <<http://www.dnaindia.co>>.