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Advancing Therapeutics.
Improving Lives.

January 24, 2007

Brigitte Zirger
Director, Bureau of Policy, Science, and International Programs
Health Canada
1600 Scott Street
Ottawa, Ontario K1A 0K9

Douglas Clark
Director, Patent Policy
Industry Canada
235 Queen Street
Ottawa, Ontario K1A 0H5

Dear Ms. Zirger and Mr. Clark:

On behalf of Gilead Sciences, I'd like to thank you for the opportunity to submit comments as part of the legislative review of the Canadian Access to Medicines Regime (CAMR).

Gilead Sciences, Inc.

Gilead Sciences is a biopharmaceutical company that focuses on the discovery, development and commercialization of innovative therapeutics in areas of unmet medical need. Headquartered in Foster City, California, Gilead has operations and approximately 2500 employees in North America, Europe and Australia. In Canada, Gilead has a manufacturing operation in Edmonton, Alberta and a sales and marketing organization based in Mississauga, Ontario.

Since the company's foundation nearly 20 years ago, Gilead's mission has been to advance the care of patients suffering from life-threatening diseases worldwide. Gilead's scientists and clinicians have contributed significantly to the world's ability to treat HIV, influenza, hepatitis and other infectious diseases by inventing and developing novel therapeutics that address the unmet medical needs of patients. These therapeutics include Viread (tenofovir disoproxil fumarate), Emtriva (emtricitabine), Truvada (emtricitabine and tenofovir disoproxil fumarate), and Atripla (efavirenz/ emtricitabine/ tenofovir disoproxil fumarate) for the treatment of HIV, Hepsera (adefovir dipivoxil) for the treatment of hepatitis B and Tamiflu (oseltamavir) for the treatment and prophylaxis of influenza (a product commercialized by Gilead's partner F. Hoffmann-La Roche).

Gilead fully recognizes the significant need for access to our medications, particularly in areas of the world where the HIV epidemic has hit the hardest. For this reason, over the past several years, Gilead has developed and continues to refine a program that seeks to remove barriers to access to our HIV therapies worldwide. We originally launched this program four years ago and have made substantial modifications to it based on our

experiences. With respect to Tamiflu and influenza, Gilead and our partner Roche, have taken significant steps to ensure the available supply and affordability of Tamiflu. Based on our international experiences in HIV and influenza, we would like to offer useful perspective and recommendations during the CAMR review process.

Gilead's Investment in Canada

In addition to Gilead's Alberta and Ontario locations, we have partnered with Canadian companies to expand our manufacturing and R&D capabilities, investing approximately $50 million (USD) in 2006. For that same time period, Gilead's total revenue in Canada was approximately $30 million (USD).

Gilead also initiated Early Access Programs (EAP) in Canada for Viread and Hepsera, to provide free product to patients who had failed other treatment regimens prior to Viread and Hepsera being available commercially. For example, the EAP for Viread was initiated in October 2001. As of April 2003, approximately 1310 patients were enrolled on Viread, representing nearly 10 percent of the HIV patient population receiving treatment in Canada. Through the Hepsera EAP, Gilead provided approximately $9 million (USD) of free drug between 2004 and 2006. The EAPs are officially discontinued one year after the products receive formulary approval in every province.

Gilead Access Principles and the Developing World

Our comprehensive approach to access to therapies, particularly in resource-limited parts of the world, relies on partnerships with governments, rational and consistent tiered pricing strategies, innovative voluntary licensing agreements with multiple leading Indian generic drug manufacturers and an access program that offers our products at no-profit pricing in nearly 100 developing countries, and at substantially reduced prices in middle income countries. Attachment 1 contains "Gilead HIV Access Principles," an overview of our approach to global access.

Gilead has developed a transparent system of tiered pricing, based primarily on a country's economic status as well as HIV prevalence. With this approach we significantly reduce, and in many cases eliminate, profits in resource-limited countries. We work with governments, the medical community and non-governmental organizations (NGOs) on an ongoing basis to gather feedback that helps shape our overall approach to access in the developing world. Our overall transparency with respect to pricing, specifically regarding our system of tiered pricing, was encouraged and supported by many of these groups. Their input contributes to our ability to address roadblocks and make continuous improvements to the program.

In the least developed countries that are included in Gilead's Access Program, which includes all of Africa and 43 other countries, the antiretroviral therapies Viread and Truvada are available at a no-profit price of $17.00 (USD) and $26.25 (USD) per month,

respectively. Gilead continually strives to lower these no-profit prices through manufacturing process improvements and efficiencies. Gilead does not enforce patents in least developed countries. Our no-profit prices represent only our cost of manufacturing, and do not include recovery of any past or current research and development expenses.

In addition to no-profit pricing in least developed countries, in 2006 Gilead launched an unprecedented initiative to establish partnerships with multiple Indian generic manufacturers to produce generic versions of Gilead's HIV drugs (both active pharmaceutical ingredient and finished product), and distribute those generic versions in all access program countries, India and Thailand. We choose our partners in India based on their expertise in high quality manufacturing and in breaking down in-country barriers, navigating healthcare systems and distributing HIV products in these countries most affected by the HIV/AIDS epidemic. To date, we have reached agreements with 11 companies, including Hetero Drugs Ltd., Matrix, Ranbaxy and Aurobindo. Under the arrangement, our partners are free to establish pricing for their products. Our expectation is that multiple manufacturers will create a competitive environment, resulting in lower prices and increased access for patients. All agreements include a full technology transfer to enable our partners to quickly ramp up production and begin to distribute high-quality product.

Gilead understands that access to essential medicines is also an issue for middle income countries. These middle income countries, such as Brazil and China, have significantly greater resources than the least developed countries of the world such as those of sub-Saharan Africa. We believe these countries can and should contribute to the cost of medical innovation. At the same time, we recognize that their contribution must be aligned with their economic realities. Within our pricing tiers, we have categorized countries based on economic status, including gross national income (GNI) per capita. In the "lower middle income tier" (e.g., China, India, Thailand and Peru), our price is $1.00 (USD) per day for Viread and $1.50 (USD) per day for Truvada. In the "upper middle income tier" (e.g., Brazil, Mexico and Chile), Gilead works in partnership with governments to establish pricing based on an individual country's ability to pay. While we do not specifically list these prices, they represent discounts of approximately 70 percent of our prices in Canada, Europe and the United States. In 2006, Gilead reached agreements with the Ministries of Health in Brazil, Mexico and Thailand that reward Gilead for its innovation and at the same time meet the individual countries' needs of affordability and accessibility.

In addition to our experience in HIV, Gilead, along with our partner Roche, has established multiple mechanisms to manufacture and distribute the drug Tamiflu for seasonal and pandemic influenza worldwide. The Gilead and Roche collaboration to ensure access to Tamiflu includes a transparent tiered pricing structure that incorporates a steep discount for pandemic purchases, and further reduced pricing for purchases by low and lower middle income countries as defined by the World Bank. Additionally, five

million treatment courses of Tamiflu have been donated to the World Health Organization (WHO) – three million to contain a pandemic at the site of outbreak and two million for regional stockpiling in developing countries.

In an effort to secure a reliable and high-capacity supply chain, the Tamiflu supply chain network includes 18 external partners on 3 continents. Sub-licenses have also been provided for the local production of oseltamivir in Africa, India and China. The reinforced production capacity greatly exceeds the number of Tamiflu treatment courses ordered to date by governments around the world.

At Gilead, our rational and inventive approaches to access rely on consistent patent regimes that protect and enforce intellectual property (IP) rights, and our ability to collaborate and partner with governments, regulators and funders to achieve the broadest access possible. We understand that price and affordability are significant issues to access, and that patents have and can continue to make price a barrier. However, we believe that patents are important to viability of ongoing drug development, and that when they are used responsibly and appropriately, and when they are not creating barriers to access, should be enforced.

The Canadian Access to Medicines Regime

The World Trade Organization's (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) is intended to "balance the long term social objective of providing incentives for future inventions, and the short term objective of allowing people to use existing inventions and creations." (WTO, 2006)

For pharmaceutical patents, the balance outlined in TRIPS has been further clarified by the General Council Decision of August 30, 2003, "Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health," which was further reinforced by the recommended December 6, 2005, "Amendment of the TRIPS Agreement," permitting countries with pharmaceutical manufacturing capabilities to export drugs made under a compulsory license to countries without manufacturing capacity in cases of "national emergency or other circumstances of extreme urgency" [TRIPS Article 31(b)]. While TRIPS fundamentally respects IP, it has built in flexibilities to allow a company, other than the patent holder, to manufacture and export a drug in cases where IP stands in the way of access to medicines.

Gilead supports the goals and intent of Canada's legislation to implement the 2003 Decision on Public Health – Canada's Access to Medicines Regime (CAMR) – to fulfill a legitimate humanitarian need for an innovative medicine when there are no other options for access. For the current review process, we believe that CAMR should be realistically evaluated in the context of what it can and cannot accomplish. We understand that there has been some criticism of CAMR based on the fact that it has not yet been used. However, based on our experience, we do not believe CAMR is fundamentally flawed,

but rather believe it has not been used because (*1*) responsible IP strategies such as Gilead's access program and that of our partner Roche, and the availability of generic version of many antiretrovirals in most of the developing world, have for many drugs removed prices and patents as a true barrier to access, and (*2*) the same in-country barriers to access that have blunted the use of Gilead's access program, stockpiling of Tamiflu and the use of generics are also an obstacle to the use of CAMR. These in-country barriers include lack of healthcare infrastructure, lack of general infrastructure, corruption, lack of healthcare professionals, taxes and tariffs and lack of political will. Until these barriers are addressed by the governments of the countries most affected by diseases such as HIV/AIDS, actions taken by Canada, NGOs, the generic industry, and companies like Gilead and Roche will meet with limited success.

The intended goal of TRIPS and its flexibilities taken together is to enforce IP as an asset and reward those who innovate while at the same time ensuring that those who innovate act responsibly to provide access to medicines. We do understand that patent abuses can and have resulted in prices that serve as a barrier to access and in these cases the flexibilities of TRIPS and CAMR should be available. On the other hand, TRIPS (and CAMR) should protect innovative companies that have acted responsibly and proactively to ensure that patents are not barriers. Can access and IP coexist? We firmly believe it can. We also believe companies that have distinguished themselves through voluntary licensing and responsible use of IP should be recognized and protected through CAMR.

Canada is a widely respected authority on strategies that enable access to healthcare in the developing world, balanced with a respect for IP rights. As a leader in the global economy and the first country to take steps to operationalize the 2003 WTO Decision on Public Health, Gilead welcomes the opportunity to formally engage in the dialogue between the Canadian Government and the public about the current administration of CAMR and the review of this legislation.

Statutory Review of CAMR

I would like to offer several comments on the CAMR legislative framework based on our practical experiences to support access to medicines in the developing world and our mission to advance patient care by developing therapeutics to treat life-threatening diseases.

Eligible Pharmaceutical Products
Gilead believes that the true humanitarian intent of CAMR can be better carried out if amendments to Schedule 1 were vetted through a more transparent and clearly defined process. In doing so, CAMR can be strengthened to ensure that *(1)* a timely response to the healthcare needs of eligible importing countries takes place, and *(2)* international respect for IP rights are appropriately upheld. Innovative pharmaceutical companies that

use their IP responsibly should not be penalized, and instead should be rewarded for proactively addressing the health care needs of developing world countries.

Eligible Importers
The request for Canada to issue a compulsory license should originate from the country that intends to import drugs under CAMR. By doing so, the evaluation to issue a compulsory license under CAMR will be made on a country-by-country basis and appropriately consider the humanitarian need for a medication. Negotiations and partnerships between innovative pharmaceutical companies and importing countries should be encouraged. In our experience, direct negotiations are respectful of a country's sovereignty, and result in timely and mutually agreeable solutions.

Evaluation of Legitimate Need
As Gilead fosters collaborations to ensure access to essential medicines around the world, we remain concerned that the CAMR process has not clearly defined the linkage between determination of need and the compulsory licensing process. The lack of safeguards in the CAMR process could lead to the issuance of a compulsory license where patents and pricing are not impeding access, potentially disrupting fair and rational pricing structures that are designed to create access and, where appropriate, respect IP rights.

Since the goal of TRIPS is to ensure that innovative pharmaceutical companies act responsibly to provide access to medicines where no other avenues for access exist, countries should have a responsibility to step forward and have an open, need-based discussion with innovative pharmaceutical companies before a compulsory license is considered. Compulsory licenses should be issued as a last resort, when innovative pharmaceutical companies insist on enforcing IP rights where IP is truly a barrier to access.

Health Canada's Drug Review
Drugs that don't meet minimum quality standards are dangerous for treatment and prevention of many diseases, as they could increase drug resistance and mortality for patients and populations. It is important that generic products demonstrate bioequivalence to the patented drug, are appropriately labeled and safely manufactured. In our licenses with Indian generic manufacturers, we require that products receive WHO prequalification. Beyond that, we respect the authority of countries that import the generic product to establish their own quality standards. Canada will need to decide whether or not to export drugs that are Health Canada approved, and whether or not to impose a different quality standard on the developing world than it currently imposes on its own citizens.

Duration of the License and Quantities Exported Under License
Provided that the intent of CAMR is being fulfilled and the necessary safeguards exist (e.g. a clear process has been outlined to evaluate need, a need-based discussion has

taken place between the eligible importing country and the patent holder, and a legitimate need for a patented product has been identified), Gilead recommends that compulsory licenses be granted indefinitely, commensurate on need, to ensure the success of CAMR in addressing a country's healthcare need. Countries should not be limited to fixed quantities, nor should they be limited on duration of a license, as estimates of quantities and license duration are likely arbitrary and might, if incorrect, disrupt the supply of essential medicines where they are needed the most. In our experience, forecasting quantities of drug, and the duration of time for which the drug needs to be available, is extremely difficult in resource-limited parts of the world.

Anti-Diversion Measures
If CAMR is used to address a legitimate need, a formal government mechanism will help to ensure that drugs exported through CAMR reach the intended country and in the quantities that were exported. Gilead acknowledges the challenges associated with regulating corruption of the pharmaceutical supply chain. However, oversight by the Canadian government will improve the integrity and accountability of the generic drug distribution process set in motion by CAMR.

At Gilead, we are proud of our strong commitment and innovative approaches to increasing access to life-saving medications. We will continue to challenge ourselves and our collective industry to find new ways to address the complex challenges associated with improving global public health. The intent of the 2003 WTO Decision on Public Health and of CAMR is consistent with Gilead's commitment to access in the developing world. While Gilead does not use IP protection to profit in the world's least developed countries, we rely on IP protection in markets where we believe the company should realize a return on our R&D investments. This will ensure ongoing innovation in and beyond the field of HIV medicine.

We thank the Government of Canada for the opportunity to comment and look forward to working together to help ensure that healthcare needs in the developing world continue to be addressed.

Sincerely,

Gregg Alton
Senior Vice President and General Counsel
Gilead Sciences, Inc.

Attachment – Gilead HIV Access Principles

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Gilead HIV Access Principles

Overview

- Gilead recognizes the need for access to HIV medications worldwide, particularly in resource-limited parts of the world where the epidemic has hit the hardest.

- We are proud of the progress we have made thus far, and we look forward to continuing to address the worldwide need for antiretroviral medications through our development of new products and through our efforts to expand access to our products.

    - For example, we have entered into a partnership with South Africa's Aspen Pharmacare and are offering non-exclusive licenses to multiple Indian generic manufacturers for access program countries.

- Gilead is committed to seeking registration of our HIV products in all countries where HIV is taking the greatest toll, working independently or in partnership with other organizations to do so.

- We have developed a system of tiered pricing, based on a country's economic status and HIV prevalence. This approach allows us to price our products based on a country's ability to pay and helps to ensure we can continue our research and development of new therapies for HIV and for other diseases that represent significant unmet medical needs.

    - To achieve these goals, we rely on intellectual property protection, and on our ability to collaborate with funders, regulators and governments to achieve the broadest access possible.

Gilead Access Program

- We have had in place since early 2003 an access program to provide our products at substantially reduced prices in developing countries.

    - We have worked to proactively address roadblocks and make improvements to the program. Many of the changes we have implemented are the result of suggestions and recommendations we have received about the program from a variety of constituents, including governments, physicians and community groups.

    - Through partnerships with other research-based companies and generic manufacturers, we believe that we can expand access to HIV therapy in the developing world.

Licensing to Indian Generic Manufacturers

- Gilead also has offered non-exclusive licenses to multiple generic manufacturers in India. Under these license agreements, a generic manufacturer is granted rights to produce and distribute generic versions of Gilead's HIV drugs in access program countries. Generic companies are free to establish pricing for those products.

- We expect that multiple manufacturers will ensure competitive pricing and the broadest access possible for patients with HIV/AIDS.

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Gilead HIV Access Principles

- We have reached agreements with 11 companies: Alkem Laboratories, Aurobindo Pharma, Emcure Pharmaceuticals, FDC, Hetero Drugs Ltd., J.B. Chemicals, Matrix, Medchem, Ranbaxy, Shasun and Strides Arcolab.
    - These agreements include a technology transfer, to enable faster ramp-up for production of high-quality product.

Aspen Agreement

- In 2005 Gilead entered into a non-exclusive partnership with South Africa-based Aspen Pharmacare, under which Aspen manufactures finished product for access program countries and distributes product in sub-Saharan Africa. Under this agreement, Aspen may source API from other manufacturers, ensuring the lowest price possible.

Eastern Europe and Russia

- The European Union operates as a single-market economy, and we have priced our products according to that dynamic.
- Planned and potential accession countries will receive pricing similar to that established in countries of the European Union.
- Where permissible and consistent with EU law, we will work with governments in less affluent nations to provide contractual rebates to the EU price on government purchases.

Intellectual Property

- Intellectual property is important to the viability of ongoing drug development, and we believe it should be used responsibly and appropriately. While Gilead does not pursue IP protection to block generic manufacturing or distribution in the world's least developed countries, we rely on IP protection to protect markets where we believe the company should realize a return on our R&D investments.
- Recognition of intellectual property, along with responsible pricing based on a country's relative ability to pay for medications, will ensure ongoing innovation in and beyond the field of HIV medicine.

Tiered Pricing and Country Segmentation

- We have categorized countries based on their economic status, including gross national income per capita:
    - Low income: $825 or less GNI per capita
    - Lower middle income: $826 - $2,999 GNI per capita
    - Upper middle income: $3,000 - $10,065 GNI per capita
    - High income: $10,066 or more GNI per capita

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Gilead HIV Access Principles

- With these pricing tiers as guidelines, we will work independently or in collaboration with potential pharmaceutical partners to establish fair pricing. Actual pricing may differ among countries based on specific factors, including HIV prevalence, common markets/cross border trade and reference pricing.

Low Income Country Pricing

- In the access program countries, Truvada and Viread are available at $26.25 and $17.00 per month, respectively. These prices are based on Gilead's cost of goods and production volumes, and may change accordingly.

Lower Middle Income Country Pricing

- For lower middle income countries, we have set a target price of approximately $45.00 per month for Truvada and $30.00 per month for Viread.
    - Examples of countries in this category include: Belarus, China, Ecuador, Peru, Thailand

Upper Middle Income Country Pricing

- For upper middle income countries, we will establish pricing based on a country's economic status and their ability to pay. Prices in these countries represent approximately 30 percent the cost of Gilead's products in high income regions of the world (an approximate 70 percent discount).
    - Examples of countries in this category include: Brazil (where we recently reached a new pricing agreement with the government), Chile, Malaysia, Mexico, Venezuela

High Income Country Pricing

- We establish pricing in the United States and Europe that we believe is fair and reflective of the innovation represented by our products.

- We also work with government purchasers to establish appropriate discounts, as allowed by regulations.

- In the United States, Gilead has a patient assistance program that provides a bridge for many patients who are uninsured or underinsured or have been wait-listed for state AIDS Drug Assistance Program support.
    - To date, approximately 10,000 patients have received drug through Gilead's Advancing Access patient assistance program.