Roche

Pharmaceuticals

January 24th, 2007

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Dear Mr. Clark and Ms. Zirger:

On behalf of Hoffmann-La Roche Limited (Roche), please find attached our submission for your consultation regarding *Canada's Access to Medicines Regime.*

As you will note from our submission, Roche supports the principles and intent of Bill C-9, now referred to as *Canada's Access to Medicines Regime.* The purpose of this document is to provide the federal government with some information on initiatives presently underway by Roche in the developing world, offer suggestions to the federal government for an overarching approach to encourage more humanitarian aid from Canada, along with specific answers to the questions posed in the consultation document.

If you require any further information or have any questions regarding this submission, please call Brigitte Nolet, our Director of Federal Health Policy and Government Relations at (613) 741-4446.

Sincerely,

Hoffmann-La Roche Limited

Ilona Torontali

Ilona Torontali
Vice-President, Public Affairs

Response to the consultation paper re:

CANADA'S ACCESS TO MEDICINES REGIME

January 24th 2007

Hoffmann-La Roche Limited

EXECUTIVE SUMMARY

"The critical lack of medical care in the world's poorest countries is a problem that can only be resolved by a joint effort. That's why we're working with governments and competent, dedicated, locally based partners who are willing to do their part to make a difference. This is the only way of developing sustainable solutions for today's many unmet or inadequately met healthcare needs and extending the benefits to the world's poorest populations."[1]

- Hoffmann – La Roche Limited (Roche Canada) supports the principles and intent of *Canada's Access to Medicines Regime* (CAMR) which is to supply developing nations and Least-Developed Countries with medicines to address existing public health crises in those countries.
- Roche believes it has a unique perspective in terms of program care and delivery given its efforts around the world with non-governmental organizations (NGOs) and the World Health Organization (WHO).
- Medicines are only one part of the solution. Elements such as infrastructure, technology transfer and education are equally important.
  - Roche has supported expanded access programs for medicine and capacity building partnerships such as:
    - the HIV Care Program, in collaboration with PharmAccess International, in the Ivory Coast, Senegal, Kenya and Uganda;
    - the Cambodian Treatment Access Program in collaboration with the University of New South Wales Australia and the Cambodian Government;
    - the HIVNAT treatment centre in Bangkok; and
    - the establishment and operation of orphanages in Malawi.
- Roche has long-term experience in supporting developing and Least-Developed Countries, including the decision to <u>not enforce any of its patents</u> for any products within Least-Developed Countries as defined by the United Nations.
- In terms of pricing policies, Roche offers its HIV protease inhibitors, Invirase® and Viracept®, and Tamiflu® (oseltamivir phosphate) at prices that are similar or lower than generic versions of those products already available for Least Developed Countries and sub-Saharan Africa.
- Our patent and pricing policies are not barriers to accessing Roche products in the world's Least Developed Countries.
- Roche has donated five million courses of Tamiflu treatment to the World Health Organization (WHO) for rapid response/containment of a pandemic and for regional use in Asia.
- Roche does have specific views for CAMR:
  - There should be no abuse of this Act in Canada;
  - The Government of Canada must ensure that all anti-diversion measures remain and are strengthened by measures such as greater transparency in product shipment and exact amounts produced;
  - Schedule 1 is an important element of CAMR although it should be subject to reviews that would both add and remove listed products, and the Expert Advisory Committee should be established as soon as possible;
  - The Health Canada review process should be an important element to ensure the continued reputation of the country and of the products;

[1] *Access to HealthCare: Helping Where Help Adds the Most Value*, www.roche.com/home/sustainability/sus_csoc-med.htm

- Stronger termination provisions should be in place where diversion has occurred; and
- The legislation should continue to reflect the provisions of the Doha Decision, the Chairperson's Statement and the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) overall.

- Further, Roche supports Health Partners International Canada's (HPIC) recommendation for a medical aid incentive to encourage more product donation, in addition to current CAMR legislation, in addressing the Government of Canada's response to the access to medicines issue.

INTRODUCTION

For more than a century Hoffmann – La Roche Limited (Roche) has focused on innovation — on developing innovative solutions for unmet medical needs and turning these innovations into products and services that save lives or ease the burden of disease for people around the world.

Over and above our primary role as an innovative healthcare business, the company has a long heritage of community involvement – in humanitarian and social projects centered mainly in Least Developed Countries, and through our support of scientific research, development opportunities for young scientists and community initiatives. We also encourage our employees to play a part in the community, and support their efforts to do this.

We focus our energies on areas in which we can add unique value. Experience shows that jointly developed industry–community partnerships can often achieve greater and more lasting effects than many showcase projects.

In 2005, 63 per cent of all Roche global donations were made to support humanitarian and social projects, 28 per cent of donated funds were used to support basic science and education beyond business considerations, and 8 per cent was devoted to community and environmental initiatives.

Hoffmann-La Roche Limited

Hoffmann-La Roche Limited (Roche) was founded in 1896 in Basel, Switzerland. The company currently employs 65,000 employees in 150 countries. Roche Canada, founded in 1931 and headquartered in Mississauga, Ontario, currently employs 850 employees nationally, inclusive of our Diagnostics Division, headquartered in Laval, Quebec.

Roche products and services address a continuum of care for patients from prevention, through diagnosis and treatment of disease. We are a world leader in diagnostics and in-vitro diagnostics in all fields of medical testing with a specialty-based product focus: pioneering and leading in the areas of virology, transplantation and cancer. Further, of the four classes of HIV antivirals available today, the protease inhibitor class was pioneered by Roche, as was the fusion inhibitor class in collaboration with Trimeris Inc.

Roche's biotechnology focus is demonstrated through our strategic alliances with majority ownership of Genentech and Chugai. Five of our 10 top-selling medicines are biotech products with biopharmaceuticals accounting for 40 per cent of Roche Pharma sales.

Canada's Access to Medicines Regime

Roche is responding to the Government of Canada's consultation paper on *Canada's Access to Medicines Regime* which was posted on November 24th, 2006. The purpose of this document is to provide the federal government with information on initiatives presently underway by Roche in the developing world, offer suggestions to the federal government for an overarching approach to encourage more humanitarian aid from Canada, along with specific answers to the questions posed in the consultation document. Further, Roche supports the submissions provided by Canada's Research-Based Pharmaceutical Companies and BIOTECanada.

It should be noted at the outset that Roche supports the principles and intent of Bill C-9, now referred to as *Canada's Access to Medicines Regime* (CAMR). Roche supports the objective of the legislation - to facilitate "access to pharmaceutical products to address public health problems afflicting many developing and Least Developed Countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics."[2]

This legislation was enacted - after agreement at the World Trade Organization (WTO) in August 2003 - to facilitate access for a specified country (generally a "least developed" or "developing" country), to lower-cost versions of patented pharmaceutical products to respond to a public demand addressing "public health problems", most notably HIV/AIDS, malaria and tuberculosis. Under the Doha Decision, where alternatives are available and indeed less expensive than the patented medicine, member countries may allow patented products to be manufactured under license by someone other than the patent holder for a limited period of time and in response to a public demand by a country for humanitarian purposes with insufficient pharmaceutical manufacturing capacity.

This is indeed an important and responsible humanitarian initiative for the Government of Canada to have undertaken – and the federal government should be applauded for its efforts in being the first country to have announced its intention to apply the Doha Decision.

Given the lack of use of the CAMR legislation since its coming into force date in May 2005, it is important for the federal government to undertake a discussion on the reasons for this gap. While Roche appreciates the reasons for this review, it sincerely hopes that the federal government will review this legislation within the broader context of all Canadian efforts to help the developing world – including work done by patent holders globally, in Canada and through HPIC.

Further, it is important for the federal government to note that this lack of uptake is not Canadian specific. It is also mirrored in other developed countries. Since Canada's adoption of the Doha Decision into domestic legislation, Norway, China, India and the European Union have adopted similar legislation. Still, not one developing country has notified the TRIPS Council that they intend to use the program to import a generic drug.

In our view, Canada has an opportunity to demonstrate leadership in the development of a more comprehensive approach to humanitarian aid and, to that end, the Government of Canada should consider looking at the access regime in the context of delivery of affordable medicines more broadly in order to ensure that its humanitarian goals are reached.

PATENTS AND PRICING

[2]Section 21.01 of Bill C-9, also known as Jean Chrétien Pledge to Africa, which amends the Patent Act and the Food and Drugs Act.

Given Roche's extensive experience in health care delivery, we understand that the development of a functioning infrastructure is an essential requirement for any medical therapy, no matter how simple. Medicines, after all, are just one element in a highly complex system involving diagnosis, treatment and treatment monitoring.

As a healthcare company, Roche has made an active contribution — particularly by sharing its know-how both in terms of "on the ground support" and "policy development". We believe that for CAMR to be able to have a fundamental impact, the Government of Canada must also be aware of the need to spearhead program/infrastructure development, public/private partnerships, technology transfer, and basic education.

Roche is also aware that patents — and the level of drug prices required to sustain economic development in the industrialized world — can present one of the many barriers to providing basic medical care in the world's poorest countries. That is why we have adopted patent policies for the Least Developed Countries that are designed to give their populations better access to our medicines. Patents do not impede access to Roche medications in the world's Least Developed Countries. Fundamentally, government initiatives along with individual company policies can work together to help reduce barriers to local development/manufacturing capacity and access to medicines.

In 2003, Roche introduced the following policy in an effort to ensure that patents do not prevent access to its medicines for those living in the poorest countries of the world:

Roche will not file new patents on ANY Roche medicines – across all disease areas – in the Least Developed Countries as defined by the United Nations. Nor will Roche enforce existing patents it holds in these countries.

Patents for HIV Antiretrovirals

Roche has developed a specific patent policy for its HIV antiretroviral medicines, which commits that:

- In addition to not filing or enforcing patents on any Roche medicines in the Least Developed Countries (as defined by the UN), Roche will not file patents on new antiretrovirals (ARVs) in sub-Saharan Africa, the poorest and hardest hit region.

- Roche will also not take any action against generic manufacturers of its ARVs in these countries.

By making such commitments, Roche provides generic manufacturers with simple and clear parameters on what is legally permitted. As a result, generic versions of any Roche medicine can be produced in Least Developed Countries without consultation or the need to apply for a voluntary or compulsory licence to grant permission. Upon request, Roche also provides letters granting immunity from lawsuits to manufacturers interested in producing generic versions of HIV medicines for Least Developed Countries and sub-Saharan Africa.

This policy enables local manufacturers to produce generic antiretroviral medicines, without prior consent. Roche hopes to encourage those with the necessary skills and resources to produce competitively priced HIV treatments.

To help strengthen the manufacturing capability and capacity within these countries, Roche also launched a new initiative in January 2006 - the AIDS Technology Transfer Initiative – to provide local manufacturers with the technical expertise to produce their own generic version of saquinavir (Invirase) (*see below*).

"We are encouraged that Roche has recently committed itself not to take action against bioequivalent generic versions of its HIV drugs in sub-Saharan Africa."
Médecins Sans Frontières (MSF), Campaign for Access to Essential Medicines, November 2002

Patents for Tamiflu (oseltamivir phosphate)

Roche and the patent holder Gilead have taken significant measures to ensure that intellectual property rights do not present a barrier to global availability of Tamiflu and will continue these efforts to meet all requests for Tamiflu:

- Tamiflu is not patent protected in any African countries or countries on the UN list of Least Developed Countries;
- Tamiflu does not have patent protection in the world's poorest countries;
- Where there is no patent protection, governments are free to purchase or manufacture oseltamivir phosphate at their discretion.

Given its work with Tamiflu for many years now, Roche is very proud of the significant measures the company has put in place to help make oseltamivir phosphate available to Least Developed Countries in the face of a pending influenza pandemic, including:

- The donation of over five million treatment courses of Tamiflu to the WHO for pandemic use;
- Work with the WHO to facilitate emergency shipments to manage outbreaks of avian influenza;
- The expansion of Roche manufacturing capacity to four hundred million courses of therapy per year;
- Increased global availability by granting sub-licenses to manufacturers in China and India (including a facility to supply to defined developing nations); and
- Knowledge and technology transfer to Aspen Pharmaceuticals in Africa for supply to the African continent.

Pricing for HIV/AIDS Products

Roche offers its HIV protease inhibitors, Invirase and Viracept, at no profit prices for direct supplies from the headquarters in Basel to Least Developed Countries and sub-Saharan Africa.

The "no profit prices" do not reflect research or development costs, marketing costs, distribution costs or company overheads. Roche reviews its no profit prices on an annual basis, and will continue to do so for as long as the company supplies these medicines.

Following a cost analysis by Médecins Sans Frontières, the no profit prices available from Roche for Invirase and Viracept have been calculated to be similar or lower than the generic versions of these medicines.[3] No profit prices apply to all presentation of Roche protease inhibitors, including Viracept paediatric powder and the Invirase 500 mg.

[3] Médecins Sans Frontières (MSF), Eighth edition of "Untangling the web of price reductions: A pricing guide for the purchase of ARVs for developing countries". June 2005.

Roche also offers significantly reduced pricing for direct supplies of Invirase and Viracept from the headquarters in Basel to low and lower middle income countries, where there is a need for access to HIV/AIDS treatment, but where local governments are able to play a greater role and make a more significant contribution towards the provision of public healthcare and treatment.

The no profit prices for Least Developed Countries and sub-Saharan Africa, together with the reduced prices for low and lower middle income countries, apply to more than 33 million people, representing over 87 per cent of all people living with HIV/AIDS worldwide. *(See Annex 1)*

Reduced Price for Tamiflu in the Developing World

Roche also has a tiered approach to pricing for pandemic preparedness with a significant reduction for all developing governments -12 euros/pack (US$14.50).

This price for developing governments to stockpile for pandemic use is considerably discounted compared to the regular price for seasonal influenza use.

The following countries have contracts in place with Roche that reflect this pricing for developing countries: Syria, Georgia, Brazil, India, Algeria, Egypt, Jordan, Kazakhstan, Morocco, Philippines, Serbia and Sudan.

It should be noted that the pandemic price for developing countries is similar to or lower than prices offered by a number of generic manufacturers of the medicine recently cited in international media reports as follows:

- The price for one pack of generic oseltamivir phosphate from Cipla is US$23 (quoted by Cipla's Joint Managing Director in Mumbai, Amar Lulla, in *The Wall Street Journal Europe* of February 22, 2006)
- The Thai Government Pharmaceutical Organization announced they will be selling their generic version for US$17.50 (Xinhua News Agency, February 9, 2006)
- Hetero Drugs Limited of India is said to be selling their generic version to India and other developing countries in Africa for US$14.55 (Dow Jones).

ROCHE'S HUMANITARIAN AID PROJECTS

From our long experience, we know that delivering medicines to patients in developing countries addresses only one part of the health system challenges these countries face. The health systems of resource-poor countries face many obstacles. That is why Roche has taken a multifaceted approach to its humanitarian aid which also includes:

- Promoting education, training and knowledge-sharing;
- Technology transfer and not enforcing its patents;
- Working in partnership with committed government, NGOs and other parties;
- Continuing its research into new HIV/AIDS medicines and improving existing ones; and
- Donating expertise in technical development.

When it comes to humanitarian aid projects, Roche did not wait for the WTO to come to an agreement in 2003. Having been at the pioneering forefront of HIV/AIDS treatment since 1986, Roche has focused much of its efforts on increasing access to medicines in this area, as this is where we believe our resources and expertise will have the greatest impact. Roche has concentrated its efforts on two main areas of concern: the existing HIV/AIDS epidemic in Least Developed Countries; and the pending influenza pandemic that would have global impact; but where Least Developed Countries are the least able to prepare.

Roche focuses its efforts on the poorest and hardest hit countries: Least Developed Countries as defined by the United Nations.

Roche's Efforts Regarding HIV/AIDS

Roche has developed a number of humanitarian aid projects for people living with HIV/AIDS. Some of these projects include:

HIV/AIDS treatment programs in Africa

CARE, the *Cohort to evaluate Access to antiRetroviral treatment and Education*, was established by Roche and PharmAccess Initiative in 2001. The program was set-up in four major urban treatment centers across Africa: Côte d'Ivoire, Kenya, Senegal and Uganda.

The aim of CARE was to provide a structured program through which antiretroviral medicines could be provided to those infected with HIV/AIDS, and from which the learnings and results could be used as a model for providing HIV healthcare in any resource-limited country across the world.

CARE has generated positive results. Data from the four sites show that HIV treatment success rates for people living with HIV/AIDS in Africa can be as high as those achieved in Western settings; something which many thought would not be possible due to the numerous challenges faced in delivering treatment.

In addition, as a result of the education forums that have been held as part of the CARE program, hundreds of health care professionals from more than 14 African countries, as well as delegates from USA and Europe, have met to discuss HIV/AIDS and shared knowledge with the aim of helping to improve the care and treatment offered in each of these countries and to develop strategies to overcome some of the challenges.

"At the time, Roche and PharmAccess were the only ones investing in the kind of programme that CARE represented. CARE is a very important project because we learnt how to implement treatment scale-up programmes and so could immediately expand when the funds became available. JCRC is now the largest treater of HIV/AIDS in Uganda".
Principal CARE Investigator, Kampala

Cambodian Treatment Access Program

The *Cambodian Treatment Access Program*, known as CTAP, was established in September, 2003 as a unique three-way partnership between the Cambodian Ministry of Health, the National Centre in HIV Epidemiology and Clinical Research at the University of New South Wales in Australia and Roche.

The aim of CTAP was to establish and launch a local treatment centre, to provide a range of services including counseling, clinical care and HIV treatment. It was also designed to provide a framework for a comprehensive education program for healthcare professionals. In addition to meeting these aims, Cambodian and expatriate staff supported by CTAP played a role in the development and publication of Cambodian National HIV Treatment Guidelines and Policies and National HIV Care Training Program to help further expand access to quality HIV care throughout the country.

Cambodia has taken major steps in both the prevention and care of HIV/AIDS, which have seen reduction in transmission rates and expanding uptake of treatment.

AmpliCare and the Clinton Foundation

In 2004, Roche was chosen by the William J Clinton Presidential Foundation to support its HIV/AIDS initiatives by providing access to its HIV/AIDS related diagnostic products, representing an additional component in Roche's global effort to provide healthcare for people in areas where access is limited. The agreement between the Clinton Foundation and five medical technologies companies will cut the costs of key tests by up to 80 percent for people with HIV/AIDS. The tests will initially be available in 16 countries and territories where the Foundation is working with governments and organizations to set up country-wide integrated care, treatment and prevention programmes.

About the Global Roche Employee AIDS Walk

The first Roche Employee AIDS Walk took place in 2003 as a pilot project involving three large sites. Immensely successful in its first year, the event was subsequently extended to include Roche sites globally. Since 2003 over 21,000 Roche employees have taken part in the annual walk, raising a total sum of 2.8 million Swiss Francs for children impacted by AIDS in Malawi and worldwide.

Roche Canada matches the amount raised by staff and donates it, along with the other Roche affiliates, to UNICEF and the European Coalition of Positive People (ECPP) an organization that creates and supports orphan centres in Malawi. In Malawi, one million people -- one in 12 -- have HIV/AIDS, and more than 500,000 children have lost one or both parents to AIDS.

Roche's Partnership with UNICEF

On October 12, 2006, Roche announced a new partnership with UNICEF. The partnership, designed to improve the lives of children orphaned by AIDS in Africa, focuses on education for children in Malawi. Roche will provide funding to UNICEF Switzerland to supply desks, school uniforms, textbooks and other educational material to schools attended by children orphaned by AIDS.

The agreement builds on an existing project between Roche and the European Coalition of Positive People (ECPP) to establish day care centres for children in Malawi orphaned by HIV/AIDS, and on the project "Schools for Africa", established by UNICEF in collaboration with the Nelson Mandela Foundation to promote education in 6 African countries, including Malawi. To achieve these

educational goals, Roche will provide UNICEF Switzerland with a portion of funds raised through its annual Global Roche Employee AIDS Walk.

Currently, only 26 per cent of the girls and 32 per cent of the boys are in secondary school in Malawi. Evidence has shown that getting and keeping young people in school, particularly girls, can dramatically decrease their vulnerability to HIV/AIDS and that HIV infection rates are at least twice as high among young people who do not finish at least primary school compared to those who do.

"We welcome the steps taken by Roche to support children whose lives have been devastated by AIDS and are pleased - to use our local expertise to increase the quality and availability of education for these orphaned children. Access to primary education is a basic need and right of every child. It provides children them with emotional support and life skills, as well as the perspective of a better future."
Elsbeth Müller, Executive Director of UNICEF Switzerland, October 2006

Technology Transfer Initiative

As part of its ongoing commitment to increase access to HIV medicine and to address the growing need for second-line treatment in sub-Saharan Africa, in 2006, Roche committed to a new 'AIDS Technology Transfer Initiative'.

The aim of this initiative is to share the knowledge Roche has developed to manufacture second-line HIV medicine and provide hands-on guidance to local manufacturers from countries within sub-Saharan Africa or those defined by the United Nations as 'Least Developed.'

A new Roche team has been established, based in part on the ground in Africa, as much of the knowledge and skill sharing will be undertaken onsite at the local manufacturer's production facilities, and also at the global headquarters in Basel, Switzerland.

Recent Developments

On September 22, 2006, Roche announced a transfer of technology to three African companies; South Africa's Aspen Pharmacare, Kenya's Cosmos Limited and Universal Corporation Limited. Roche will provide these companies free of charge with the technical expertise to manufacture generic HIV medicine, based upon the processes to produce saquinavir, Roche's second line HIV medicine. The companies will be able to produce saquinavir for supply throughout Kenya and South Africa in addition to any country within sub-Saharan Africa or defined as Least Developed by the United Nations, encompassing 64 per cent of all people living with HIV globally. These agreements are the first in a series of planned Technology Transfers, announced in January 2006.

Paediatric Formulations

The need to increase access to antiretroviral therapy for the millions of children living worldwide with HIV/AIDS is vital. Currently, nine out of ten children needing antiretroviral treatment worldwide live in sub-Saharan Africa.[4]

[4] World Health Organization. *Progress on Global Access to HIV antiretroviral therapy – a report on '3 by 5' and beyond.* March 2006.

A paediatric formulation of Viracept has been developed for children aged three years above and is available at no profit within Least Developed Countries and sub-Saharan Africa. Roche continues to research and develop new and improved formulations of its HIV medicines for paediatric use.

Additional Roche Canada Initiatives:

At a local level, Roche has been donating medicine to Health Partners International of Canada (HPIC), a Canadian charitable organization that sends donated medicines, vaccines and medical supplies to people in need in developing countries, since 1995. Over the years the partnership has grown and has also included financial support for the mission of HPIC. Since Roche began partnering with HPIC, the company has donated over $1 million in needed medicine.

Influenza Antiviral Drugs to Support Least Developed Countries

In the case of Tamiflu and pandemic influenza preparedness, Roche has taken significant measures to fulfill all demand from developing countries for Tamiflu to date.

Roche has already voluntarily granted sublicenses to generic companies that are able to produce significant quantities of oseltamivir phosphate to developing and Least Developed Countries in need.

Roche has increased its global production capacity to an annual level of 400 million treatment packs – at this rate Roche can manufacture enough Tamiflu to cover twenty percent of the world's population in less than three years. This is unprecedented compared to any other pharmaceutical. It is also worth noting that this is in excess of the 200 million treatment courses ordered to date by governments around the world.

Through Roche donations of Tamiflu to developing countries via the WHO and established sub-licenses for production of Tamiflu in those countries, no unmet need for Tamiflu currently exists within developing countries. Indeed, Roche is not aware of any developing country having indicated such need to the Government of Canada to date.

Roche has been actively engaged in a series of collaborations aimed at increasing the availability of its influenza antiviral Tamiflu since 1997. The company has put measures in place that include:

- a tiered pricing system;
- increasing manufacturing capacity;
- involvement of more than 15 other companies in the Tamiflu production network to accelerate the pace of capacity expansion;
- granting of sub-licenses to three generic manufacturers in India and China;
- providing technical know-how to help an African company expedite their production and registration of oseltamivir phosphate.

Global Production Capacity of Tamiflu: Double the Current Worldwide Government Demand

Roche has significantly increased annual production capacity to be in a position to manufacture over four hundred million treatment courses (four billion capsules) annually. This production capacity of Tamiflu is more than double the 200 million treatment courses ordered to date by governments around the world and is more than a ten-fold increase over the capacity in 2004.

Roche is able to supply the necessary commercial quantities of oseltamivir phosphate with quality, technical ability, capacity and the speed to bring that capacity on stream.

Donations of Tamiflu to the World Health Organization (WHO) to Ensure International and Regional Rapid Response

Roche has been a collaborative and responsible partner with governments and the WHO since 1997 to assist in preparing countries in the developing world, including Africa, for a potential influenza pandemic, including the stockpiling of Tamiflu.

This collaboration includes the Roche donation of 5.125 million treatment courses (51 million capsules) of Tamiflu treatment to the WHO for international rapid response and regional response to a pandemic influenza strain:

- three million treatments (30 million capsules) for "Fire Blanket" containment of pandemic at site of outbreak
- two million treatments (20 million capsules) for "Regional Stockpiles" to manage outbreaks of avian influenza or to mount regional responses in the event of a pandemic.

While Roche operates on a first come, first served basis for fulfilling government pandemic orders, these urgent demands require rapid response and Roche has worked closely with the WHO to make urgent deliveries to countries hit by H5N1:

Delivered	Country	Packs	Delivery Time	Special
23.01.06	Turkey	100,000	36 hrs	Government pandemic purchase
17.02.06	Nigeria	10,000	24 hrs	Donation
03.02.06	Iraq	7,000	24 hrs	Pandemic purchase through WHO
22.02.06	Egypt	64,000	4 days	Government pandemic purchase
17.03.06	Azerbaijan	10,000	38 hrs	Donation; delivery through WHO

Tamiflu Global Pandemic Orders for Developing Countries on Schedule

Worldwide, 80 countries have received their Tamiflu, ordered or provided letters of intent to purchase Tamiflu for pandemic stockpiling. Roche has met all orders in a timely manner, either on time or ahead of schedule. The following developing or Least Developed Countries have been supported:

- 13 African countries
  Algeria, Egypt, Ghana, Ivory Coast, Libya, Mauritius, Morocco, Niger, Senegal, Seychelles, South Africa, Sudan, Tunisia

- 13 countries from the Middle East
  Bahrain, Georgia, Iran, Israel, Jordan, Kazakhstan, Kuwait, Lebanon, Qatar, Saudi Arabia, Syrian Arab Republic, United Arab Emirates, Uzbekistan

- 10 countries from Asia
  Hong Kong, India, Indonesia, Republic Of Korea, Malaysia, Philippines, Singapore, Sri Lanka, Taiwan, Thailand.

Global Production Further Enhanced through Production Partnerships and Sub-Licensees

Following the assessment of more than 200 company and government applications to become involved in the production/sub-licensing opportunities for oseltamivir phosphate, Roche initiated a number of sub-licensing agreements with generic drug companies in India and China for the production of generic oseltamivir phosphate as part of continued efforts to increase and speed up availability of the medicine for pandemic planning in Africa and Asia.

- In May 2006, Roche entered into an agreement with South Africa-based Aspen for the production of a generic version of oseltamivir phosphate for Africa, as part of continued efforts to increase and speed up availability of the medicine for influenza pandemic planning world wide. Roche is providing technical know-how, including pre-clinical and clinical data, to assist Aspen in expediting production and registration.
- In addition, Roche has sub-licensing agreements in place with India-based Hetero Drugs Limited to manufacture oseltamivir phosphate for India and developing countries in Africa.
- Roche also has sub-licensing agreements with HEC Pharma and Shanghai Pharmaceutical Group for oseltamivir phosphate for pandemic use in China.

As an example of how these agreements are working to supply developing countries, Algeria's leading drug maker Saidal is currently buying the active pharmaceutical ingredient from Hetero Drugs and is producing a local generic version of Tamiflu called Saiflu as part of Algeria's measures to plan for a possible influenza pandemic. This highlights that Roche's sublicensing agreements are working to ensure access to Tamiflu in the developing world.

In addition to sub-licensing agreements, Roche's global network for the manufacturing of Tamiflu includes several Roche sites and more than 15 external contractors located in 10 different countries around the world.

Roche and Gilead

Tamiflu was invented by Gilead Sciences and licensed to Roche in 1996. Roche and Gilead partnered on clinical development, with Roche leading efforts to produce, register and bring the product to market. Under the terms of the companies' agreement, amended in November 2005, Gilead participates with Roche in the consideration of sub-licenses for the pandemic supply of Tamiflu in resource-limited countries. To ensure broader access to Tamiflu for all patients in need, Gilead has agreed to waive its right to full royalty payments for product sold under these sub-licenses.

PROPOSALS FOR IMPROVING CAMR

In order to maximize the humanitarian benefits inherent in *Canada's Access to Medicines Regime,* the Government of Canada must develop a comprehensive strategy to address the underlying humanitarian crisis in least developed and developing nations, which should acknowledge that patented medicines are only one component of the overall humanitarian need requirements of these nations.

Roche fully supports the medical aid incentive model that HPIC has proposed to the Department of Finance as an innovative approach that Canada could undertake to increase Canada's capacity to deliver humanitarian medical aid – whether by the patent holder, generic manufacturer, health care

professionals, etc. Medical aid incentives and other policies should form an integral part of Canada's overall access to medicines strategy, in addition to the CAMR.

Canada could also consider whether there are opportunities to work towards strengthening the health delivery infrastructure in resource-poor settings, as well as increasing and retaining the number of health professionals in developing countries.

Further, the primary objective of the federal government should be to educate least developed and developing nations about this legislation. Representatives from Roche have participated in meetings with Rx&D where diplomats from countries across the African continent had little or no knowledge of this humanitarian program, but were interested in learning more.

Finally, patients should not be exposed to counterfeit or unsafe versions of life saving drugs, nor should products under CAMR become available in the general stream of commerce in Canada or elsewhere. Roche fully supports government efforts and is committed to cooperating with the authorities whenever Roche products are concerned. Roche's policy ensures an action plan for rapid information, possible detection, coordination, analysis of suspect products, reporting and timely interaction with authorities. Recently, Roche has worked in cooperation with the WHO regarding counterfeit Tamiflu. Examples of counterfeit product include:

- The Dutch Healthcare Inspectorate warned consumers in early 2006 not to buy Tamiflu through the Internet, after counterfeit capsules were found in the Netherlands containing lactose and vitamin C, and no active substance.
- In the United Kingdom, officials seized 5000 packets of counterfeit Tamiflu in early 2006, estimated to be worth £500 000.

To that end, Canada must continue to preserve and strengthen anti-diversion measures for the pharmaceutical supply chain as well as preserve product testing and approval.

ELIGIBLE IMPORTERS

1. NGOs may purchase products "permitted by" an eligible importing country. Should CAMR provide guidance on the meaning of "permitted by" in this context?

While the reason that an NGO may purchase products "permitted by" an eligible importing country is clear – the WTO waiver is a country to country agreement, there is room for clarity in terms of the language of section 21.04(f) of the *Patent Act*. The legislation should be more specific: the name to be provided is the name of the person or entity permitted by the government of the importing country "to purchase products on its behalf", or some such language.

2. The WTO waiver also allows the export and distribution of licensed products to developing and least-developed countries that are party to a regional trade agreement. Does CAMR accommodate the purchase and distribution of licensed products by and amongst regional trade groups?

At present, the system does not contemplate a country making a request on behalf of others. There would be technical difficulties if one country of a regional trade group agrees to be the purchaser and the country of import, due to the termination provisions. Re-exportation is a ground for termination. Further, anti-diversion efforts would be much more problematic if product flows among regional trade

groups because it would be more difficult to track how much was given to each country. This type of arrangement also goes beyond the intent of direct transfer between donating and receiving country, and could be seen as entering the general stream of commerce – which is not a goal of this legislation.

ELIGIBLE PHARMACEUTICAL PRODUCTS

3. Is Schedule 1 an appropriate mechanism to define the products that are eligible for export under CAMR?

Yes. Roche strongly believes that a schedule of eligible products for export is necessary. The Doha Decision is meant to address serious public health problems being experienced in developing and Least Developed Countries. Further, pharmaceutical products are very valuable, and can be commoditized, making them at risk for sale in unauthorized channels. Roche would be very concerned if there were no limits on the potential drugs that could be exported under the regime, given that the risk of diversion of products is very high.

Roche further believes that the Expert Advisory Committee, a key and mandatory part of the legislation/regulation, to review new product additions to the list should be established as soon as possible to ensure the proper, adequate and timely review of any additions or deletions as well as the ability for industry representatives to appear.

4. Is Schedule 1 necessary to avoid delays due to litigation?

Schedule 1 is necessary to ensure that the system is used for the humanitarian purposes of the Regime – products truly needed in the developing world.

5. Should the government review Schedule 1 at regularly scheduled intervals to consider amendments that are in addition to requests received from interested manufacturers, importing countries and NGOs?

No. An Expert Advisory Committee must be established immediately to provide advice to the relevant Ministers who decide which drugs should be added or deleted. There is no reason to alter this process, although, we urge the federal government to establish this advisory body as soon as possible for consistency in recommendations, process, and to give patent holders and others an opportunity to also present their views.

6. What criteria should be considered when amending Schedule 1?

Schedule 1 should be amended when:

- There is a demonstrated need for a particular drug to resolve a public health issue; and
- It is on the WHO's List of Essential Medicines; and
- There is a significant gap in the patent holder's ability to supply the product to a requesting country; and
- An importing country is asking for a particular product that is not on the list.

Amendments should also only be made after consideration/recommendation by the Expert Advisory Committee. Further, Roche also believes that the list should not only be reviewed for the addition of products but also for the removal from the list (i.e. if there is a Canadian recall or withdrawal of a product, a change in the benefit – risk of the product no longer making it a product of choice, if the product is no longer patented in Canada, if there no longer is a need, etc).

7. Schedule 1 does not currently contain any active pharmaceutical ingredients (API). Should CAMR allow for the export of APIs?

The Doha Decision envisions that developed countries will assist lesser developed countries by providing pharmaceutical products where needed and where no manufacturing capacity exists. Further, CAMR calls for a review of all products by Health Canada. Health Canada, however, cannot make an evaluation of safety and efficacy for an API as it is not in final dosage form for administration to humans. How will the potential manufacturer be able to use bioequivalency studies as a substitute for clinical studies for the product being offered for humanitarian export if it is an API? Could there be any liability issue for Health Canada regarding the approval of an API? If the foreseeable scenario is that the API would be offered at the request of another country's generic manufacturer's use - in a formulation other than one that is approved in Canada - this falls beyond the scope of this Act.

N O T I F I C A T I O N

8. Is the requirement that a certified copy of the importing country's notification be included in the application for a compulsory licence necessary to comply with the WTO waiver?

Yes. This will ensure that the importing country does believe it has a need - which is particularly important when it is an agent of the importing country who is applying, as per the requirements of the legislation. Further, it is important in a system such as Canada's where there are minimal evidentiary requirements needed in order to obtain a compulsory licence.

Other countries similarly require some form of documentation evidencing a request from an importing country. In Canada, the requirement to provide the certification fits well within the scheme which envisages that the importing country first indicates its need. It is only at that time that a licence applicant, after observing the voluntary licence phase, may be in a position to file a compulsory licence application. It should be noted that it is possible for a potential licence applicant in Canada to get in the queue for approval at any time at Health Canada, and even before there is a specific request from any country.

9. CAMR requires non-WTO Member developing countries (those listed on Schedule 4) to: declare a national emergency or other circumstance of extreme urgency; agree that the imported product will not be used for commercial purposes; and undertake to adopt anti-diversionary measures. Are these requirements unduly burdensome on non-WTO developing member countries that wish to participate in CAMR?

The WTO agreement calls for only developing countries that are members of the WTO to participate. Canada has been extremely sensitive to the needs of all nations by including non-WTO member countries. These are fundamental elements of the Doha Decision and are fundamental elements that ensure the system is not abused. They are not too cumbersome and must remain.

In respect of the declaration of national emergency/circumstance of extreme urgency, this is not burdensome because it is a "declaration" in no particular form. In respect of the agreement not to use the product for "commercial" purposes, it goes without saying that this is a significant element of the Decision. To object to such a requirement is to say that the system should be able to be used for commercial purposes; this clearly is not the intention of the Doha Decision.

In respect of the requirement on importing countries to adopt "anti-diversionary measures", Roche notes the system simply requires a compulsory licence applicant to provide in its application a copy of a notice in writing that it undertakes to adopt the measures set out in Article 4 of the General Council Decision.

HEALTH CANADA'S DRUG REVIEW

10. Does the requirement that pharmaceutical products be reviewed for safety, efficacy and quality promote or discourage Canadian pharmaceutical manufacturers and eligible importing countries from participating in CAMR?

It is not appropriate to relax the standards by which a product is reviewed for safety and efficacy. Importing countries should be entitled to the same level of safe and reliable medicine that Canadian citizens can rely on. It is our understanding that countries would want to order from Canada because of our reputation for safe and efficacious products. If the review is removed, and something unfortunate should happen with the quality of the products, it is Canada's reputation that is tarnished. Further, given that these products would be part of an expedited approval, there seems to be little disadvantage to requiring its review. However, Health Canada must also ensure that the domestic review process continues to meet existing national standards and time lines.

11. Would manufacturers and countries be more or less likely to participate in CAMR if this review were optional?

Canada should not offer drugs to developing countries in a manner that it would not allow for its own citizens. The safety of citizens who live in importing countries is equally important and deserves the same level of care, and product safety as Canadians receive. Making the review optional would not be good public policy.

12. Are there alternatives to a mandatory/optional Health Canada review process that would be acceptable to Canadian pharmaceutical manufacturers while providing safety, efficacy and quality assurance to eligible importing countries?

No. Canada should not send unapproved products to the developing world, nor should it compromise its standard of review. The exporter should also be held responsible for pharmacovigilence obligations associated with the form of the drug they are supplying in all importing countries which includes the collection and reporting of spontaneous adverse reactions and the dissemination of such information to relevant authorities including those countries in which the reports have arisen, those in the country of origin of the drug and those dictated by other applicable laws and regulations.

THE APPLICATION PROCESS

13. Does the type of information that must be provided to the patentee in the request for a voluntary licence pose a barrier for the licence applicant?

No. Given that the voluntary licence timeframe is only 30 days long, and the generic manufacturer is free to go directly to a compulsory licence application, it is in no way a barrier. The type of information requested is actually less onerous than a domestic application. Further, the generic manufacturer can start the Health Canada review at any time – even before the voluntary licence application.

It is also important to know the destination of the product and understand its differentiating features to ensure that the potential for diversion is minimized. Given that the product is being manufactured for humanitarian aid, there should be absolute transparency, as there should be nothing to hide.

Finally, it aims to meet the TRIPS requirement that **prior to seeking a compulsory licence, a voluntary licence must be sought.**

14. How might the application process be simplified?

Roche believes the system can work as it has been designed and would work well if there were occasion to use it. The application process is already as simple as possible.

15. Should "reasonable terms" be defined? If so, how?

Roche is of the view that defining reasonable terms would be beneficial to all involved as it would provide more certainty in the process and facilitate planning by all involved including generic manufacturers. Roche submits that prices charged by the patentee in the developing world and royalty rates granted and accepted by licensees supplying the developing world should be presumptively reasonable. The legislation should set out this presumption.

DURATION OF THE LICENCE

16. Is a two-year, once-renewable licence term an appropriate duration for a compulsory licence issued under CAMR?

Yes, given that the effective licence is renewable, thereby making it a four year licence. Further, the Health Canada review does not have to be repeated, making future applications much faster to approve. And finally, the duration ensures that if something goes wrong within the licence timeframe, there is a defined end period by which it can be corrected – and it allows the terms of the licence to be revisited, as circumstances can change over the course of four years.

17. Should CAMR provide for a simplified procedure for the renewal of a compulsory licence where the conditions that gave rise to the original licence persist?

There is no need for a simplified procedure – the procedure for renewal is already simple, in that, at the end of (or potentially even before) a licence, a further licence with the same country could be sought by providing the same requirements to the Commissioner of Patents. Regulatory approval has already

been sought and obtained on the earlier licence. Therefore, there is no additional burden if a company seeks a further licence. It is also important to consider the domestic progressive licensing framework to ensure eventual consistency between this process and the domestic process of tracking the entire lifecycle of a drug. Therefore, it is important to ensure a specific duration and clear conditions for renewal to ensure the manufacturer complies with the same standards both domestically and for humanitarian export – particularly in a world of potential recalls, storage conditions, etc. Some of these conditions will change over time and it is important that they be reviewed at key moments in time, thereby supporting the notion of a specified licence duration.

ROYALTIES

18. Is there an alternative to the CAMR formula for calculating remuneration that would better encourage uptake of the regime while remaining compliant with the WTO waiver and TRIPS?

The issue is ensuring that the royalty continues to meet the WTO waiver, without being onerous for the developing or least developed country. Uncertainty as to the royalty cannot be a real impediment to participating in the system, given that the maximum royalty is so low. Further, there is no evidence that the royalty is the reason for the system not being used.

THE GOOD FAITH CLAUSE

19. Does the prospect of litigation under the good faith clause discourage Canadian pharmaceutical manufacturers from participating in CAMR?

The good faith clause ensures that no one gains large profits through this humanitarian exercise. We are supposed to be working together to ease the burden on developing and/or Least Developed Countries. Given that the system is designed for lesser and Least Developed Countries, the price limitation is a reasonable limit. The good faith clause also is not an absolute bar and permits the licence holder, if challenged, to justify its price if the price is not higher than 15 per cent over the direct supply cost. There is a fair amount of flexibility, and as such, the clause should not discourage those wishing to legitimately participate in the system for humanitarian purposes.

20. Is the good faith clause necessary to implement the Chairperson's Statement?

The good faith clause does adhere to the Doha Decision to ensure the system is not used for commercial gain.

21. What alternative measures might be employed to ensure that CAMR is not used for commercial purposes?

As stated above, product diversion is the issue of most concern to Roche. It is important to ensure that the CAMR legislation undertakes all possible measures to limit diversion of product, and ensure it gets to those who need it. It is imperative that licensees take responsibility for the drugs being exported, and that requests to add products to Schedule 1 come from the importing countries.

Further, Roche believes that there is a strong need to maintain the current safeguards for patentees' rights including: a limited scope of drugs for export; procedural steps including notice of a request from a particular country; notice of an application for a compulsory licence; product differentiation and transparency requirements including website notices.

QUANTITIES EXPORTED UNDER LICENCE

22. How does the limit on authorized quantity impact participation in CAMR?

It does not limit participation – it ensures that if diversion occurs, there is only a certain amount that is diverted. It is, in fact, an important anti-diversion measure. Further, until full infrastructures are available, certain amounts will sadly expire without ever having been delivered from the clinics to those in need. Further, if a company truly wants to participate, it will follow the rules to ensure it gets to those who need it. To suggest that a compulsory licence holder should be able to manufacture and export more than the authorized quantity (which equates with the quantity requested by a particular country) raises the question of why that would be necessary. The importing country has indicated its needs; the exporter has responded and has obtained a licence to export that amount.

23. Should CAMR include a simplified procedure for amending the authorized quantity of a compulsory licence after it has been granted?

Roche submits that there could be a simplified procedure to amend the authorized quantity if there is agreement that the original need requires a lesser amount than the original licence application. However, if there is a need for more quantity – which could be at risk for diversion – one can apply for a new compulsory licence or can amend at the renewal stage, given that the Health Canada review will not have to be redone.

ANTI-DIVERSION MEASURES

24. Are the safeguards in CAMR sufficient to prevent the diversion of exported pharmaceutical products?

No, unfortunately they are not. It is concerning that there is no official tracking done by the Government of Canada once the product leaves the Canadian border. Therefore, there is no appropriate tracking to ensure that the products are getting to those in need; to ensure the proper amount was produced; and to monitor shelf life at time of shipping. If the federal government is not able to do so, the patentee and/or a third party should have access to federal government reports as they relate to the product shipments to ensure absolute transparency and protect the integrity of both the system and product reputation.

Further, there is also no effort to ensure that the product is distinguishable from all other versions of the product in the developed world – thereby increasing opportunity for diversion, even though patentees would be willing to offer details on the distinguishing elements of all versions. If the federal government is not able to confirm product differentiation, the patentee should be allowed to do so.

Finally, the required labelling for a given drug needs only to set out that the product is for export under the decision; the specific country of export is not named. This is sub-optimal and Roche would prefer if the system required specific labelling for the products relating to the country of export.

25. Do the anti-diversion provisions extend beyond the requirements of the WTO waiver in a manner that negatively impacts participation in CAMR? If so, what alternatives should be considered?

They do not extend beyond the requirements. In fact, the General Council Chairperson stated; "[…] *Members recognize that the purpose of the Decision would be defeated if products supplied under this Decision are diverted from the markets for which they are intended. Therefore, all reasonable measures should be taken to prevent such diversion in accordance with the relevant paragraphs of the Decision.*"

If any change should be required, the federal government should consider making the anti-diversion measures more stringent, particularly given that there is no tracking of product shipments once they leave Canada. Perhaps the federal government would consider better tracking on quantities shipped, distinguishing features and labeling requirements – or allow the patentee to track this information to ensure the integrity of the system.

Further, it is important to remember that this Decision is also part of the overarching TRIPS agreement within which basic patent rights are still recognized. Therefore, anti-diversion measures are crucial to ensuring that this system both respects patent rights within the developed world, while ensuring that the needs of those in developing and Least Developed Countries are met through this humanitarian initiative.

26. Are the grounds for the termination of a licence in CAMR sufficiently clear?

The grounds for termination are clear, although Roche requests that there be more robust termination provisions where diversion has occurred. Termination provisions should exist for any diversion - without having to show licensee knowledge. Further, should a product be diverted from its intended destination, the exporting company should not only have its license terminated, but should also be prevented from applying for any other license until it has demonstrated to the federal government that is can meet the anti-diversion requirements of the CAMR.

27. Are they fair?

There are serious inequities in the system that work against patentees. For example, if a licence is terminated by reason that the products authorized for export have been diverted to another country, there is nothing to stop the licensee company from seeking another licence to manufacture for export to the same or a different country. In that sense, the termination provisions are ineffective as they do not deter misuse of the system. There is also inequity in that the patentee must seek the court's termination of a licence – until such time as the licence is terminated the activity can continue.

28. Does the possibility of having a licence terminated in this manner deter pharmaceutical manufacturers from participating in CAMR?

There should be little concern that licence termination rules will deter participation in the program. There are minimal requirements for participation in the program. The licence would be terminated because the terms of the licence have not been fulfilled and/or diversion has occurred. These measures cannot be removed. Otherwise, the federal government is indirectly signaling that it is amenable to breaking terms of licences and diversion of product, which is not the intent of the legislation.

CONCLUSION

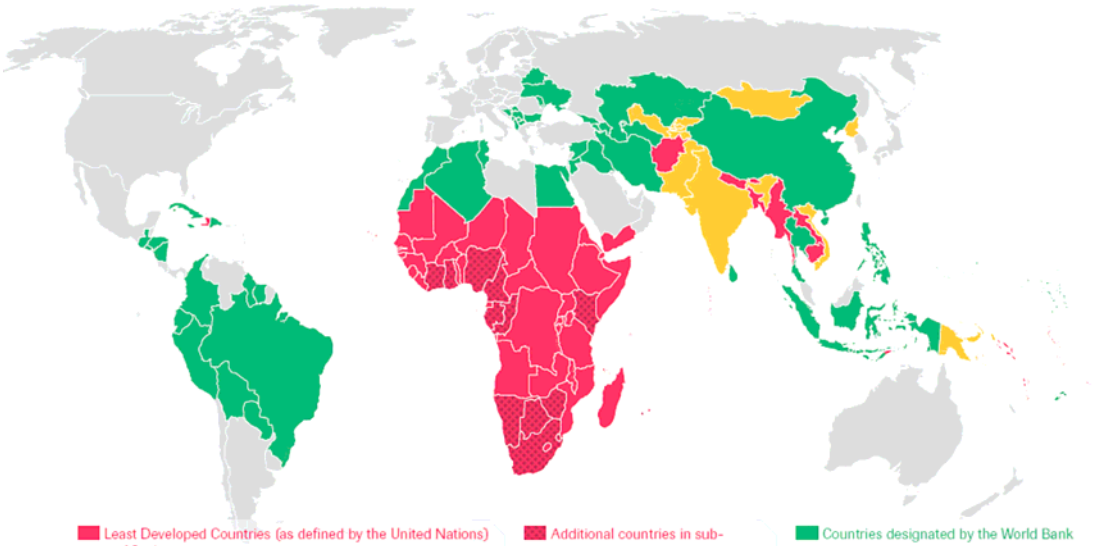
As stated throughout this document, Roche does support the principles of *Canada's Access to Medicines Regime*. The Government of Canada has been a leader in establishing this legislation and it should be applauded for being one of the first countries to implement it.

It is absolutely imperative to ensure that this system is not abused and that the most effective anti-diversion measures are put in place to ensure that products get to those who need them. Therefore, Roche hopes that the Government of Canada will not weaken any of the anti-diversion measures and will, in fact, strengthen them by: adding more transparency to ensure better tracking of product once it leaves Canada; ensuring the exported products are differentiated from all products available around the world; and establishing stronger termination provisions, just to name a few.

Further, Roche wants to highlight through this submission that it has been undertaking and will continue to undertake programs of support in the developing world and transferring its technology to companies in Africa and elsewhere to help create local manufacturing capacity. Roche would also be interested in partnering with the Government of Canada on any initiatives that it would like to develop to continue supporting Least-Developed Countries.

Country Classifications

Countries eligible to purchase Roche no profit (red) and reduced price (green/yellow) HIV protease inhibitor medicines October 2006



Least Developed Countries (as defined by the United Nations) as of October 2006

Afghanistan
Angola
Bangladesh
Benin
Bhutan
Burkina Faso
Burundi
Cambodia
Cape Verde
Central African Republic
Chad
Comoros
Congo, Democratic Republic
Djibouti
Equatorial Guinea
Eritrea
Ethiopia
Gambia
Guinea
Guinea-Bissau
Haiti
Kiribati
Lao People's Democratic Republic
Lesotho
Liberia
Madagascar
Malawi
Maldives
Mali
Mauritania
Mozambique
Myanmar
Nepal
Niger
Rwanda
Samoa
São Tomé and Principe
Senegal
Sierra Leone
Solomon Islands
Somalia
Sudan
Timor-Leste
Togo
Tuvalu
Uganda
United Republic of Tanzania
Vanuatu
Yemen
Zambia

Additional countries in sub-Saharan Africa not covered by the UN list of Least Developed

Botswana
Cameroon
Congo, Rep
Cote d'Ivoire
Gabon
Ghana
Kenya
Mauritius
Namibia
Nigeria
Seychelles
South Africa
Swaziland
Zimbabwe

Countries designated by the World Bank classification of economies as low income economies (Those not otherwise classified as "Least Developed" by the UN) as of October 2006

India
Korea, Dem Rep.
Kyrgyz Republic
Mongolia
Pakistan
Papua New Guinea
Tajikistan
Uzbekistan
Vietnam

Countries designated by the World Bank classification of economies as lower middle income (Those not otherwise classified as "Least Developed" by the UN or within sub-Saharan Africa) as of October 2006

Albania
Algeria
Armenia
Azerbaijan
Belarus
Bolivia
Bosnia and Herzegovina
Brazil
Bulgaria
China
Colombia
Cuba
Dominican Republic
Ecuador
Egypt, Arab Rep.
El Salvador
Fiji
Georgia
Guatemala
Guyana
Honduras
Indonesia
Iran, Islamic Rep.
Iraq
Jamaica
Jordan
Kazakhstan
Macedonia, FYR
Marshall Islands
Micronesia, Fed. Sts
Moldova
Morocco
Nicaragua
Paraguay
Peru
Philippines
Serbia and Montenegro
Sri Lanka
Suriname
Syrian Arab Republic
Thailand
Tonga
Tunisia
Turkmenistan
Ukraine
West Bank and Gaza