# CANADA'S ACCESS TO MEDICINES REGIME

# CONSULTATION PAPER

**Response from:**

***Canada's Research-Based Pharmaceutical Companies***


**January 24th, 2007**

## EXECUTIVE SUMMARY

In August 2003, the World Trade Organization (WTO) reached a decision (the Doha Decision) on implementing the Declaration relating to the Trade-Related Aspects of Intellectual Property Rights Agreement and Public Health (Doha Declaration). Canada was the first country to take steps to provide domestic legislation to implement the Doha Decision and allow Canadian generic pharmaceutical manufacturers to export their products to developing and least developed countries with insufficient pharmaceutical manufacturing capacity.

Rx&D continues to support the principles behind CAMR. For many years, Rx&D member companies have been at the forefront of helping those in need. Since 2000, global innovative pharmaceutical companies have provided enough health interventions to help up to 539 million people, or more than two-thirds the population of sub-Saharan Africa, with a conservatively calculated value of USD $4.4 billion[1]. Preferential and no-profit pricing have been key initiatives used by Rx&D member companies to increase access to medicines in developing countries.

Similarly, since 1990, Rx&D member companies have assisted Health Partners International of Canada (HPIC) on hundreds of humanitarian efforts around the globe, contributing $145 million in medicines and financial assistance to HPIC humanitarian missions, and signing a 3 year partnership agreement with HPIC to provide secure funding for humanitarian aid into the future.

This document draws on the experiences of Rx&D member companies to suggest ways to strengthen the access regime. Specifically, we suggest that:

- The existing legislation should be viewed as only one step in an overall effort to increase access to medicines in developing countries. Rather than amending the legislation, Canada should consider developing and executing a holistic strategy to address the underlying humanitarian crisis in least developed and developing nations;
- Canada should 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;
- Canada should consider whether it can play a stronger role in facilitating partnerships between organizations wishing to purchase affordable medicines for least developed countries and organizations that have the products to offer. Tax incentives and other policies could form an integral part of Canada's overall humanitarian strategy; and,
- Canada should ensure that anti-diversionary safeguards remain in the legislation in order to help ensure that patients in developing countries do not receive counterfeit versions of important drugs.

[1] The survey methodology and data were validated by the London School of Economics and Political Science.

## CONTEXTUAL CONSIDERATIONS

### Doha Declaration – International Support for National Access to Medicines Regimes

The World Trade Organisation (WTO)'s Agreement on Trade-Related Aspects of Intellectual Property (TRIPS) sets the minimum standards for intellectual property protection, including pharmaceutical patents. One of the flexibilities contemplated by the TRIPS Agreement includes compulsory licensing – the ability of governments to allow the production, import and sale of a drug still under patent. Article 31 of the TRIPS Agreement limited the use of compulsory licences "predominantly for the domestic market" and put restrictions on the quantities of drugs that could be exported.

In November 2001, members of the WTO adopted the Doha Declaration on TRIPS and Public Health as a measure designed to recognize critics' concerns that health products be valued differently from other consumer goods. Paragraph 4 of the Doha Declaration states that the TRIPS Agreement:

> …can and should be interpreted and implemented in a manner supportive of the WTO Members' right to protect public health and, in particular, to promote access to medicines for all. In this connection, we reaffirm the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.

Two years after the Doha Declaration, the WTO General Council adopted a solution to address the fact that many developing countries lack the domestic infrastructure and manufacturing capacity to make use of Article 31. The Doha Decision waives the requirement that production of the product be predominantly for the domestic market and allows for the exportation of a drug under compulsory licence. The Decision establishes the conditions under which a compulsory licence can be granted for export, and is the basis of Canada's access to medicines legislation.

The WTO has since made this a permanent measure, adopted as a proposed amendment to the TRIPS Agreement in December 2005. The Amendment requires ratification by WTO Members.

### Canadian Legislative Context

In September 2003, Canada became the first country in the world to announce its intention to implement the Doha Decision into national law. The intent became law with the passage of Bill C-9 in May 2004. The legislation allows the granting of "export only" compulsory licences to Canadian generic pharmaceutical companies that wish to supply countries that have inadequate or no pharmaceutical capabilities with lower cost versions of pharmaceutical products patented in Canada. The law came into force in May 2005.

The objective of the legislation is 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]

[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.

Health Canada took steps to implement the legislation by holding a meeting with the Canadian Generic Pharmaceutical Association in August 2004 together with Médecins Sans Frontières (MSF) regarding the health needs of developing countries[3]. At that meeting, MSF offered advice regarding drugs it would be interested in purchasing through Canadian Generic Pharmaceutical Association member companies as an intermediary for developing countries where the organisation works. Nearly two years after the passage of the legislation in May 2005, no generic drugs have been exported. The lack of uptake under the Canadian legislation is mirrored in other developed countries that have tried to implement similar legislation. Since Canada's adoption of the Doha Decision into domestic legislation, Norway, China, India and the European Union have adopted similar legislation.

There are many potential reasons for the apparent lack of interest in this legislation so far. One is that the success of preferential pricing policies in developing countries makes offers from generic producers under the legislation less enticing than expected. Prices from the generic producers in developing countries are cheaper than those available from domestic/developed world manufacturers. For example, MSF data suggests that the prices of existing fixed-dose combination anti-retro viral (ARV) drugs are lower than the price proposed by Apotex to produce a generic form for export under CAMR[4].

**Table 1: Pricing comparison of existing fixed-dose combinations and Apotex price**

| | **Aurobindo** | **Cipla** | **Hetero** | **Ranbaxy** | **Apotex** |
|---|---|---|---|---|---|
| **Price in $US per year (per pill)** | 257 (0.352) | 231 (0.317) | 263 (0.360) | 255 (0.350) | 278.90 (0.382) |

In fact, the prices of generic medicines in Canada are as much as 49% higher than the prices in other G7 countries, which means that Canada's program may not offer a complete solution to the lack of access to affordable medicines in poor countries. It is unclear why developing nations seeking products would avail themselves of CAMR when preferentially priced products or cheaper non-Canadian generics may already be available in their countries.

Despite the challenges, we believe that Canada has an opportunity to strengthen the effect of CAMR by moving beyond the current legislation to institute a more broad based approach to reaching Canada's humanitarian goals.

**Innovative Industry's Experience: Fostering Access to Treatment**

Rx&D member companies have a history of humanitarian contributions in Canada and internationally[5]. For decades, the global research-based pharmaceutical industry has been on the ground working to prevent, treat and eradicate disease. As a result, we know first-hand the positive impact that medicines can have, and we understand the real challenges and obstacles that exist for delivering medicine into the hands of the people who need it. Rx&D and Government officials

[3] *"Neither Expeditious Nor a Solution," MSF briefing note at AIDS 2006: http://www.msf.ca/aids2006/files/REP_JCPA_en.pdf*
*4 "Untangling the Web of Price Reductions, a pricing guide for the purchase of ARVs for developing countries,"* MSF briefing note at AIDS 2006 and *Ottawa Citizen* page C1, August 13, 2006 article by Ann Silversides.
[5] *Please see Appendix 1 for a detailed list of Rx&D member company contributions.*

share a common objective – to provide safe, affordable medicines to countries in need as quickly as possible.

In the fight against HIV/AIDS, Rx&D member companies and their global affiliates have already provided:

- More than 100 million antiretroviral treatments (tablets and injections etc) and rapid testing kits;
- Hundreds of millions of preferentially priced and no-profit priced treatment regimens;
- Training for more than 25,000 health workers in the safe detection, treatment and monitoring of HIV/AIDS;
- More than 350 HIV/AIDS patient care programs in the developing world;
- HIV/AIDS clinics, including three clinical centres in Africa for children with HIV/AIDS; and
- Technology and voluntary licences to generic companies enabling them to manufacture drugs overseas for developing and least developed countries.

In the fight against tuberculosis, Rx&D member companies and their global affiliates have:

- Donated more than 8 million treatments, including 500,000 single dose treatments that permit the simultaneous intake of several medicines, reducing the risk of resistance and dramatically reducing the number of tablets patients need to take;
- Strengthened district health systems;
- Trained healthcare workers in effective diagnostic, treatment and control measures;
- Encouraged TB testing and adherence to treatment; and
- Transferred medicine-manufacturing know-how.

In the fight against malaria, Rx&D member companies and their global affiliates have:

- Identified and analyzed the obstacles to effective treatment;
- Improved access to care for people spending months away from home during cultivation periods;
- Trained healthcare workers to better advise, diagnose and treat malaria in public health facilities;
- Encouraged effective prevention and prompt treatment for children and pregnant women; and
- Donated 600,000 treatments for anti-malarial bednets.

Our members are also key drivers in research into improved treatments in all major disease areas as is demonstrated by the numerous examples set-out in Appendix 1. Our member companies and their global affiliates are making a real difference though the developing world with their programs, initiatives and contributions.

Our experiences have provided us with a good understanding of the opportunities for innovative approaches to strengthening access to health services in least developed countries and the challenges inherent in any project that delivers therapeutic products overseas.

Canada has an opportunity to expand its access to medicines regime to include a range of programs beyond the CAMR legislation – to include initiatives that facilitate access through non-legislative means. For example, Health Canada or the Canadian International Development Agency could bring together potential buyers with potential donors in both the innovative and generic pharmaceutical industry to partner in the delivery of humanitarian aid.

One example of such a partnership is Rx&D's work with Health Partners International of Canada (HPIC). On November 14, 2006, HPIC and Rx&D signed a formal partnership agreement to help speed the delivery of medicines, vaccines and other supplies to people in need across the developing world. The signed agreement formalized a history of collaboration.

HPIC is a Canadian medical aid agency that provides donated medicines, vaccines, medical supplies and devices to Canadian doctors and NGOs working internationally, and to developing countries in need of medical aid. Rx&D member companies contributed to the very first HPIC shipment in 1990 and since then have provided $145 million in medicines and vaccines to HPIC humanitarian missions. In addition, Rx&D and its global affiliates have provided billions of dollars in donated medicines and vaccines to people in the developing world while working in partnership with development agencies to build clinics, train health professionals and promote health, especially among women and children.

In addition to partnering with Rx&D, HPIC has proposed a novel approach to encouraging increased donations of medicines to developing countries. HPIC's proposal invites the Government to include in its next budget an innovative donation incentive that encourages the private sector to provide and, if necessary, manufacture medical aid products that are most urgently required, perhaps with the inclusion of desperately needed antiretroviral drugs for Africa. The proposal seeks to address the fact that there is currently no economic incentive for companies to give gift-in-kind donations out of inventory. Specifically, HPIC has proposed to the Department of Finance that a deduction from taxable income of the cost of the inventory or cost basis, plus one half of the gain that would have been realised if the inventory had been sold at its fair market value on the date of the contribution, up to a maximum of twice the donated inventory's cost basis. This is similar to a tax incentive presently provided in the U.S.[6] and would provide an additional incentive to both Canadian research-based pharmaceutical companies and the generic drug industry.

**Medicines Only One Part of the Solution**

From our industry's long experience, we know that delivering medicines - whether innovative/'brand name' or generic - 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. Insufficient access to medicines is one component of poor access to health services generally, but the twin challenges of insufficient infrastructure and broad-reaching corruption of the of the pharmaceutical supply chain contribute equally to the problem. Together, these barriers make it more difficult to ensure that the drugs of any kind supplied will actually reach the intended patients. As Dr. Margaret Chan, the Director General of the World Health Organization (WHO) noted in her acceptance speech on November 9th, 2006, "[H]ealth systems are the tap root for better health. All the donated drugs in the world won't do any good without an infrastructure for their delivery."

[6] www.pqmd.org

Our experience also shows that it is necessary to provide and distribute affordable medicines to developing countries while ensuring proper support infrastructure including physician supervision.

A more holistic approach to increasing access to medicines would offer more success in meeting the health needs of patients in developing countries. Legislation in Canada allowing for the provision of generic pharmaceuticals is only one step in addressing the public health needs and challenges of the world's poorest countries. CAMR must be combined with initiatives that help to ensure:

- Patients have access to clean drinking water (the most basic human need);
- Patients receive appropriate diagnosis;
- Patients have access to proper and adequate medical facilities;
- Medicines are properly administered;
- Patient compliance is adequately monitored; and
- That there are adequate health human resources in order to provide proper follow-up care.

Dr. Kevin de Cock, head of the WHO HIV program emphasized this point in an interview with Reuters[7], saying "if you work in these countries it is very obvious, very quickly, that the elephant in the room is not the current price of drugs. The real obstacle is the fragility of the health systems, particularly in Africa."

Kofi Annan, the 7th UN Secretary General, echoed this view following his meeting with pharmaceutical executives on July 24, 2006, saying, "all participants agreed that strengthening health-care systems at the country level is essential to expanding treatment access and advancing prevention efforts. While this is the primary responsibility of national Governments, I look forward to greater collaboration between the private sector and the United Nations to expand existing efforts."

Leading global health researchers have made similar comments. Dr. Amir Attaran, a lawyer and immunologist who writes on public health and global development issues, has been vocal about the need to fight poverty in the quest for increased access to medicines. Dr. Attaran's research has found that "poverty, not patents, imposes the greater limitation on access."[8]

> [B]y any objective measure of success — such as the number of generic medicines manufactured under compulsory licences, the number of patients treated using those medicines, or the dollars of pharmaceutical sales lost to compulsory licences - the effort has been fruitless…Pragmatism and greater flexibility are urged, so that policy may better concentrate on the greater causes of epidemic mortality, which now pose unprecedented threats to global peace and security.[9]

Finally, it must be emphasized that only approximately 5% of the products on the WHO's List of Essential Drugs are protected by patents. In essence, many of the conditions that have been and

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[7] Published July 21, 2006

[8] *"How Do Patents And Economic Policies Affect Access To Essential Medicines In Developing Countries?"* Health Affairs, Policy Journal of the Health Sphere, *23, no. 3 (2004): 155-166 and "What Patent Problem?"* National Review *by Roger Bates, May 17, 2004*

[9] *"How Do Patents And Economic Policies Affect Access To Essential Medicines In Developing Countries?"* Health Affairs, Policy Journal of the Health Sphere, *23, no. 3 (2004): 155-166 and "What Patent Problem?"* National Review *by Roger Bates, May 17, 2004*

continue to be treated with medicines are already off-patent, something that the Government of Canada should carefully consider before entertaining any amendments to CAMR.

**Additional Challenges: Corruption, Counterfeiting and Diversion of Medicines**

At the same time, we cannot ignore other challenges in the medicine delivery system which need to be addressed in order to boost the availability of affordable drugs.

Corruption of the pharmaceutical supply chain also poses challenges for developing countries. The Global Corruption Report 2006[10] cites several sources of corruption in the pharmaceutical supply chain. From procurement, to distribution, to counterfeit medicines, each provides an opportunity for unscrupulous individuals to tamper with the therapeutic products delivered overseas.

The Report states that procurement transactions are often poorly documented and processed, which makes them a far easier target for supply chain corruption than contracting in other sectors. Specifically, the Report gives several reasons for the potential for corruption during procurement:

- The method to determine the volume of drugs needed is often subjective;
- There are difficulties in monitoring the quality standards in drug provision;
- Suppliers use different prices for the same pharmaceutical products; and
- Emergency situations may call for rapid intervention.

There are also several opportunities for corruption at the distribution stage. Stocks of products may be oversupplied if individuals can collect commissions for orders. Medicines may be over or under-prescribed depending on whether health professionals are paid per patient diagnosed or per treatment dose given.

Finally, counterfeit medicines continue to be a serious developing world health problem. Regulators may receive funds to ignore counterfeit manufacturers and customs agents may also be paid to ignore imports and exports of these products. The Report found that in 2001, China had roughly 500 illegal medicine manufacturers and an estimated 192,000 people died last year due to fake pharmaceuticals. Laos had approximately 2,100 illegal medicine sellers, and in Thailand, sub-standard medicines make up approximately 8.5 per cent of those on the market.[11]

According to a joint study by the WHO, the Organisation for Economic Cooperation and Development (OECD) and the Pharmaceutical Security Institute, more than 30 per cent of medicines in some areas of Latin America, Southeast Asia and sub-Saharan Africa are counterfeit. As a contrast, in Western industrialised nations with strong regulatory mechanisms, counterfeits account for less than one percent of the market value.[12]

In light of these statistics, it is essential to ensure that the anti-diversion provisions of the CAMR remain in place. As underlined in The Report:

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[10] *The Global Corruption Report is published by Transparency International annually, and provides examples of abuse of entrusted power for private gain in different industry sectors and in different countries.*

[11] *The Corruption Report 2006, Pharma Sector section*

[12] *http://www.ipsnews.net/news.asp?idnews=35799*

> Corruption in any one of the critical decision points in the pharmaceutical system can be harmful to a country's ability to improve the health of its population by limiting access to high-quality medicines and reducing the gains associated with their proper usage. While corruption affects the entire population, it is typically the poor who are most susceptible when officials hoard drugs, or waste resources on the wrong kind of medicines. Good governance is therefore a sine qua non for ensuring better access to essential medicines.[13]

## PROPOSALS FOR IMPROVING CAMR

### General Recommendation

Rx&D encourages the Government of Canada to reach beyond current legislation and consider adding initiatives that will contribute to building health infrastructure. These could include ensuring appropriate warehousing facilities for storage of the medicines supplied, trained healthcare personnel who will ensure that the drugs supplied will be taken as needed for safety and efficacy, and building clinics and other healthcare facilities that will reach out to those in need through a broader access to medicines regime.

### Specific Recommendations

1. In order to maximise the humanitarian benefits inherent in CAMR, the Government of Canada must recognise that the existing legislation that permits generic companies to export versions of patented medicines is only, at most, one step in a comprehensive access program. Rather than amending existing legislation, the Canadian Government should develop and execute a comprehensive strategy to address the underlying humanitarian crisis in least developed and developing nations, which should acknowledge that providing affordable medicines are only one component of the overall humanitarian need requirements of developing nations.

2. Canada should move quickly to fully implement all aspects of this legislation, and specifically should initiate the expert panel as referenced in the original legislation.

3. In addition to existing export-related legislation, Canada should consider whether it can play a stronger role in facilitating partnerships between organizations wishing to purchase affordable medicines for least developed countries and organizations that have the products to offer. A tax incentive model is one example of an innovative approach the Government could take to increase Canada's capacity to deliver humanitarian medical aid. Tax incentives and other policies should form an integral part of Canada's overall humanitarian strategy.

4. Another objective of the Government should be to educate least developed and developing nations about this legislation. Rx&D does not believe that, at present, representatives of these nations most in need are fully aware of CAMR.

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[13] *As above*

5. Key to any access regime are measures to ensure that patients are not exposed to counterfeit versions of life saving drugs. To that end, Canada must continue to preserve anti-diversion measures for the pharmaceutical supply chain.

6. Canada should 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.

## SPECIFIC QUESTIONS RAISED BY THE GOVERNMENT

### 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?**

The current provisions of the CAMR under the Patent Act permit an NGO to be the purchaser on behalf of an eligible country. There is no ability for an NGO to contract directly with a supplier in an exporting country. The reason for this is clear – the WTO waiver is a country to country agreement. The Doha Decision contemplates that countries will give notice of the need for product and countries are responsible for having the appropriate laws in place to ensure that the system is not abused. The provisions are required to be put in place by participating countries so that, in the event that the rules are not observed, the country itself will be held accountable.

There is perhaps room for clarity in the terms of the language of section 21.04(f) of the *Patent Act*, which sets out that an application must set out:

> The name of the governmental person or entity, or the person or entity permitted by the government of the importing country, to which the product is to be sold, and prescribed information, if any, concerning that person or entity.

The legislation could be more specific to set out that 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 licenced products to developing and least-developed countries that are party to a regional trade agreement. Does CAMR accommodate the purchase and distribution of licenced products by and amongst regional trade groups?**

The CAMR as it is currently drafted permits licensing of products destined for a particular country. There may 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 under which re-exportation is a ground for termination (if with knowledge of the licence holder). As well, the system contemplates a country making a request for supply for that country – not for others. Accordingly, there may be difficulties for regional trade groups to participate in the Canadian system as purchasers and re-exporters.

### ELIGIBLE PHARMACEUTICAL PRODUCTS

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

Rx&D believes strongly that a schedule of eligible products for export is necessary. The Doha Decision is concerned with addressing serious public health problems that may be experienced in developing and least developed countries. The agreement was not intended to provide access to any drug. Unfortunately, pharmaceutical products are very valuable products, and can be commoditized, making them at risk for sale in unauthorized channels. Rx&D 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. The greater the opportunity to export products, the greater risk there is that there will be abuses of a system which was, we must recall, put in place to assist countries experiencing serious public health problems.

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

The schedule of drugs was, in our view, put in place for the precise reason of offsetting the automatic nature of the system. Under the regime, there is no discretion on the Commissioner of Patents to decide not to issue a licence; once the technical requirements on paper have been met, there is no provision for the Commissioner to go behind the licence application to question whether there is a need in the country for a particular drug, whether the quantity is as necessary, whether the applicant has diverted products in the past, etc. Accordingly, the list of eligible drugs was restricted. Rx&D strongly supports maintaining a list of eligible products.

**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?**

In Rx&D's view, manufacturers' requests should not factor into a decision of whether to list products on the Schedule of eligible drugs – only requests from countries and NGO's should be relevant.

In addition, a process is envisioned by the legislation to deal with the addition of drugs to Schedule 1 – namely, an advisory committee is to be set up to provide advice to the relevant Ministers who decide which drugs should be added. Rx&D sees no reason to alter this process, although, Rx&D questions why the advisory body has not yet been set up. It is recommended that the advisory body should be set up as soon as possible for consistency in recommendations and process. In addition, patentees should be permitted to appear before the Advisory Committee to make representations.

**6. That criteria should be considered when amending Schedule 1?**

Rx&D is of the view that the Schedule of eligible drugs should reflect the current and acute healthcare needs of recipient countries. Schedule 1 should be amended where there is a demonstrated need for a particular drug product to resolve a public health issue.

**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. The Decision includes active pharmaceutical ingredients (APIs) within the scope of "pharmaceutical products" that may be exported under the

regime. Some jurisdictions, such as the EU, have included APIs as being eligible for export under their regime to implement the Doha Decision.

In the event that APIs are included as part of the regime, other adjustments will need to be made. For example, provisions would need to be put in place to ensure appropriate packaging and labelling of any products exported.

## NOTIFICATION

**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?**

The WTO Doha Decision is far from a complete code as to how to implement the waiver of certain obligations. Strictly speaking, the Decision itself does not formally require that there be such notification by way of a certification contained in a compulsory licence application. Nonetheless, there is, under the Decision, a requirement for importing countries who wish to avail themselves of the benefits of the decision to notify the WTO TRIPS Council of the expected quantities of the products needed. The requirement to provide a "certified copy" of the notification appears to be a rather minimal obligation; indeed the legislation does not specify by whom the request must be "certified". As such, it would seem to be quite an easy task for a licence applicant to provide this kind of documentation. The documentation is essential, as it serves a valuable purpose by providing evidence of the importing country's request. This is very important, particularly 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 attempting to negotiate for a volountary licence with a patentee, 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?**

Rx&D does not believe the requirements are too burdensome. In respect of the declaration of national emergency/circumstance of extreme urgency, this is clearly not burdensome; 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 system, which incorporates the Doha Decision as well as the accompanying Chairperson's Statement. To object to such a requirement is to say that the

system should be able to be used for commercial purposes; which is clearly not the intention of the Doha Decision.

In respect of the requirement on importing countries to adopt "anti-diversionary measures", Rx&D notes the specific requirement in section 21.03(1)(d)(ii)(D), 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.

Article 4 merely requires importing members to take reasonable measures "within their means, proportionate to their administrative capacities and to the risk of trade diversion to prevent re-exportation of the products". Accordingly, it appears that this is a reasonable expectation to place on non-WTO members who wish to take part in the system. Furthermore, the requirements are clearly geared to the ability of these countries to put in place such measures, and as such, cannot be construed as overly onerous.

## 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?**

Rx&D is not aware whether the requirement for approval of products prior to export either promotes or discourages participation in CAMR, given that no countries have indicated a need. However, this appears to be a matter of public policy for the federal government. Rx&D strongly supports this element of the regime. It is good policy for Canada to ensure that the products exported are safe and efficacious, particularly given that many of the importing countries will not have the capacity to review and approve pharmaceutical products. Dilution of standards in respect of medicines to be exported under CAMR would represent an unethical double standard. Given such products would be on an expedited time line for approval, and the approval can be used for many countries once obtained, there seems to be little disadvantage to requiring such approval.

Rx&D also is supportive of Health Canada's stated intent concerning the allocation of resources for product approvals.

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

It appears to us that the requirement to seek regulatory approval should not be an onerous one for companies seeking to export; the products that have the potential for export are generally expected to be Canadian approved products with a suitable Canadian Reference Product. To say that regulatory approval should not be required suggests that Canada would support sending unreviewed and potentially substandard products to other countries. We submit this is not good 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?**

Rx&D is aware that the WHO has a prequalification process which may be relied upon by Health Canada in respect of products sought for export. Rx&D agrees that the standards set by the pre-qualification process may be appropriate, if Health Canada ultimately reviews the information and agrees with the pre-qualification process, and provided that such standards are consistent with those applied domestically.

## 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?**

Rx&D does not believe that the voluntary licence process presents a barrier to effective use of the system. The idea that this process is overly cumbersome or bureaucratic is simply incorrect. In fact, the system is very easy to use:

- A generic may apply for Health Canada approval at any time, on the basis that it "intends" to seek regulatory approval for export;
- The submission requirements for an approval for export are minimal over and above the typical requirements of a domestic approval;
- Once health regulatory approval is obtained, the approval can be used in respect of ANY licence actually granted - i.e., no new safety and efficacy approval is necessary for a different country;
- Before filing for a compulsory licence, a voluntary licence must be sought;
- The voluntary licence must identify the country, the quantity, and other salient information to the patentee; it is not necessary that the applicant have actually concluded an agreement with the country in order to ask for a voluntary licence or to seek a compulsory licence; and
- The voluntary licence period equates to a period of 30 days notice to a patentee that a compulsory licence will be sought; it also 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?**

Rx&D firmly believes the system is designed to work and would work well if there were occasion to use it. The system is already as simple as possible – the grant of a compulsory licence (aside from the health and safety regulatory requirements) is essentially automatic once the simple formalities have been complied with and the paperwork has been submitted. The process is already simplified to the extent of stripping the rights of due process that a patentee would typically have under a request for a compulsory licence of its patents in Canada. The requirements placed on exporting companies are meant to compensate to some extent for the fact that the process is, indeed, so simple. If amendments are made to take away some of the minimal safeguards that already exist, patentees' rights would be further encroached upon and compensating measures would need to be put in place.

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

Rx&D is of the view that the language of the current legislation tracks, to a large extent, the WTO TRIPs requirement in Article 31 for compulsory licence applicants to seek a voluntary licence, "on

reasonable terms" prior to seeking a compulsory licence. It is difficult to imagine how one would define "reasonable terms" as what is reasonable in any case will be a function of the circumstances.

Rx&D is of the view that defining "reasonable terms" is an unnecessary exercise.

## DURATION OF THE LICENCE

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

In effect, the current legislation permits a licence duration of 4 years, since there is the potential to renew the licence if the amounts authorized for export were not exported as of the end of the licence period. Re-application for another licence is possible at any time. We thus assume that the duration cannot be really seen as a limitation on use of the CAMR system.

**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?**

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, minimal requirements to the Commissioner of Patents. Health regulatory approval has already been sought and obtained on the earlier licence, so there is no additional burden if a company seeks a further licence; all that needs be done is to engage in a further voluntary licence negotiation, and to submit the necessary paperwork to the Commissioner. The process is already simplified.

## 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?**

Rx&D is of the view there is no demonstrated problem with the remuneration currently required to be paid in accordance with the legislation. Uncertainty as to royalty cannot be a real impediment to participating in the system, given that the maximum royalty is calculated on a non-commercial basis. R&D notes the premise of this question is that there is insufficient "uptake" of the regime – yet there is absolutely no evidence that the levels of remuneration or any other requirement of CAMR is responsible for lack of "uptake". The fact is that simply no developing or least developed country has requested importation of any drug, despite the fact that all 25 countries of the EU as well as other countries now have a similar system of access**.**

## THE GOOD FAITH CLAUSE

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

Similar to our responses to previous questions, the question assumes there is a problem with the statutory regime. It has not yet been tested, as no country has publicly declared an interest in importing under the Doha Decision. It is thus impossible to know whether the good faith clause is an impediment. However, Rx&D is strongly of the view that the clause is necessary and should be maintained as a safeguard against commercial use of the regime. The pricing standard in the clause is set very high, allowing prices of up to 25% of the domestic Canadian price. Given that the system is designed for developing 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% over the direct supply cost. There is a fair amount of flexibility, and as such, the clause should not pose a discouragement to those wishing to legitimately participate in the system for humanitarian purposes.

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

Given the aim of the clause is to ensure that the system is not used for commercial purposes, the aim of the section accords with the principles of the Doha Decision and Chairperson's Statement.

Rx&D notes that this clause is a worthwhile and necessary safeguard to ensure that the system is not used for commercial purposes. Rx&D is of the view that the good faith clause must be maintained as an essential element of the system.

## QUANTITIES EXPORTED UNDER LICENCE

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

As stated above, Rx&D believes that there is a strong need to maintain the current safeguards for patentees rights, including a clearly specified amount of drugs for export, procedural steps including notice of a request from a particular country, notice of an application for a compulsory licence, and transparency requirements including website notices.

For Rx&D, diversion remains the issue of most concern. It is virtually impossible to stop diversion once a product has left Canada's borders. For that reason, it is imperative that licences take responsibility for the drugs which are being exported. The anti-diversionary measures in the legislation and regulations go some way towards this goal, by requiring the licence holder to name all known parties in the distribution chain. However, these measures could be improved upon to ensure responsibility of the product by the licence holder from Canada and through to the importing country.

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

Rx&D is unsure of what is meant by this question and asks if the issue to be addressed is whether there should be a limit on the quantity to be authorized. The only limit on the authorized quantity is that a compulsory licence holder is only permitted to manufacture the amount of drug that is authorized under the licence. This appears quite sensible and reasonable; 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. There appears to be little room for debate that the current provision is appropriate, and assist in preventing the possible diversion of medicines.

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

Rx&D submits that it would be appropriate to reduce the quantity authorized if it turns out that a contract is negotiated for a lesser amount than the original licence application. Rx&D supports a process that ensures that any licence that is issued is amended in the event the contract is concluded – after licence issuance – for a lesser amount. If a contract issues for a greater quantity, then a further application can be made seeking a licence for that further amount.

## ANTI-DIVERSION MEASURES

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

The safeguards in the system to prevent diversion are still rather weak. For example, 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 it would be preferred if the system required specific labelling for the products relating to the country of export. In addition, consideration should be given to including a provision permitting an audit of records to ensure integrity of the regime, as exists in the EU regime.

**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?**

It is again not possible to measure a negative impact in participation due to the fact no country has asked for product. It cannot be said that the anti-diversion provisions extend beyond the requirements of the WTO waiver. Anti-diversion requirements appear in paragraph 2(b)(ii) and (iii). In addition, the Chairperson's Statement accompanying the Doha Decision, members are to take "all reasonable measures" to prevent diversion. The measures contained in the CAMR legislation and regulations represent a minimal and reasonable baseline standard, and do not extend beyond the WTO waiver.

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

There are limited grounds for termination of a licence. These include:

- The application contained material information that is inaccurate;
- The holder of the authorization did not establish the website as required;
- The holder of the authorization failed to provide pre-export notice;
- The holder of the authorization has failed to pay the royalty as required;

- The product was exported to another country with knowledge of the holder of the authorization;
- The product was exported to a country, other than in transit, to a country other than that named in the authorization;
- The authorization holder failed to provide a copy of the agreement to the holder;
- The product was exported in a quantity greater than the quantity authorized; and
- A non-WTO country has permitted the product to be used for commercial purposes.

The grounds for termination are quite clear. As such, and since we are not aware of any problems with these provisions, we do not believe any changes are necessary to make the termination provisions less stringent. We reiterate the concern expressed during consultations on the legislation, in that the provision that permits a patentee to seek termination if product is exported to another country other than the importing country, with knowledge of the licence-holder, presents a very high standard from an evidentiary point of view.

**27. Are they fair?**

There are still 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 licencee 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. Furthermore, no meaningful damages or other compensation are available to a patentee.

**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 termination rules, as regards diversion, require manufacturers to take responsibility for the transport of the product, and to encourage efforts to be made to ensure safe passage to the countries to which they are intended. This is obviously fair, as well as necessary, given that it is such an important feature of the regime – ensuring that patients get the products destined for them. It is not within patentees' power to ensure against the diversion of products manufactured and delivered by generic companies under CAMR.

# The Global Research-Based Pharmaceutical Industry:

# Part of the Global Solution

**Health Partners International of Canada (HPIC)**

HPIC is a Canadian charitable humanitarian organization that provides free medical aid without discrimination for the world's most needy. HPIC also works in tandem with several key Canadian government departments, such as the Canadian International Development Agency (CIDA), which is committed to providing aid on behalf of all Canadians.

Health Partners International of Canada (HPIC) reached a major milestone in its history on August 15, 2006 when a shipment of medical aid for Lebanon brought the total value of medical aid shipped to $200 million (wholesale value).
www.hpicanada.ca

The research-based pharmaceutical industry is developing 82 new treatments for HIV/AIDS and related conditions, including 18 vaccines. It is helping to make Antiretroviral (ARV's) more widely available through preferential pricing arrangements and donation programs. The industry also contributes to strengthening the health infrastructure in developing countries. The research-based pharmaceutical industry has been helping developing nations around the world since 1990

**International Federation of Pharmaceutical Manufacturers & Associations (IFPMA)**

IFPMA is a non-profit, non-governmental organization representing the pharmaceutical industry in both developed and developing countries. Member companies of the IFPMA are the major global research-based pharmaceutical and vaccine companies.

In 2005, the IFPMA conducted a Health Partnerships Survey to measure the industry's total contribution to the UN Millennium Development Goals (MDGs). The survey showed that, in the period 2000-2005, the industry provided enough health interventions to help up to 539 million people, or more than two-thirds the population of sub-Saharan Africa, with a conservatively calculated value of USD 4.4 billion *(1)*. Including but not limited to $421m in HIV/Aids funding, it helped train and educate over 28,000 professionals in HIV/Aids treatment and prevention, it operates in all 53 African countries, treating 2.6 million women, including 300,000 pregnant women.
www.ifpma.org

**Canada's Research-Based Pharmaceutical Industry (Rx&D)**

*Canada's Research-Based Pharmaceutical Companies* (Rx&D) is the national association representing over 22,000 men and women who work for more than 50 research-based pharmaceutical companies in Canada. Approximately 10,000 medical researchers are employed as a result of our member companies' investment in R&D. Of this total, about 4,000 work within Rx&D member companies and an estimated 6,000 work at universities, hospitals and research institutions. Member companies share a single primary objective: to discover new medicines that improve the quality of health care available for every Canadian.

*1. The survey methodology and data were validated by the London School of Economics and Political Science.*

**Abbott Access to HIV Care**
HIV/AIDS
Abbott
Since 2001
Access: medicines at no profit
Africa & least developed countries
www.accesstohivcare.org
Launched in 2001, Abbott Access to HIV Care provides the company's HIV products to Africa and least developed countries elsewhere. Through Abbott Access to HIV are the company offers two protease inhibitors, Kaletra® and Norvir®, at a loss to Abbott. Determine® HIV, a rapid test for HIV antibodies I/II, is also provided at no profit as part of the program. For more than 20 years, Abbott has made a significant contribution to the fight against HIV/AIDS through the development of innovative tests and medicines. Through Abbott Global AIDS Care programs, Abbott and the Abbott Fund also are investing more than $100 million to advance HIV testing, treatment and support services in developing countries. Abbott also provides a rapid HIV test at no profit to testing programs in these 69 countries, with more than 55 million rapid tests distributed to date. Abbott donates rapid HIV tests to enable pregnant women to know their HIV status in 69 countries, including all of Africa. To date, Abbott has donated more than 4.7 million rapid HIV tests. Through partnerships in developing countries, the Abbott Fund has helped more than 500,000 children and families.

Since 2001 Abbott has:

- Committed **$100 million** to Global Care Initiative;
- Provided 60 million rapid tests at no profit or free-of-charge to 69 Least developed countries (LCD's);
- Provided HIV products to 68 developing countries;
- Shipped 6.6 million testing kits; and
- The Abbott Fund is contributing a **$1.5 million** grant for the construction and operations of a new centre in Malawi dedicated to providing care and treatment for children with HIV/AIDS.

**Accelerating Access Initiative (AAI)**
HIV/AIDS
Abbott, Boehringer Ingelheim, Bristol-Myers Squibb, GlaxoSmithKline, Gilead, Merck & Co., Hoffmann-La Roche
Since 2000
Access: preferential pricing.
Developing countries
www.who.int / hiv /AAI_fs_4Q2005.pdf
The Accelerating Access Initiative (AAI), begun in 2000, is a cooperative endeavor by UNAIDS, the World Health Organization, UNICEF, the UN Population Fund, the World Bank and seven research-based pharmaceutical companies (Abbott, Boehringer Ingelheim, Bristol-Myers Squibb, GlaxoSmithKline, Gilead Sciences, Merck & Co., Inc. and Hoffmann-La Roche). Participants in AAI are committed to working with governments, international organizations and other stakeholders to find ways to broaden access, whilst ensuring rational, affordable, safe and effective use of medicines for HIV/AIDS-related illnesses. A report from the AAI indicated that, by

December 2005, more than 716,000 people living with HIV/AIDS in developing countries were receiving treatment with at least one antiretroviral supplied by the seven pharmaceutical companies in the AAI (compared with 403,000 people receiving treatment in developing countries at the end of 2004). The December 2005 total included 446,000 patients in Africa.

- By the end of September 2006, more than 738,000 people living with HIV/AIDS in developing countries were receiving treatment with at least one ARV medicine provided by the AAI companies.
- In the past two years, the total number of patients in developing countries receiving treatment from the AAI companies has more than doubled, with an increase of 104% since September 2004.
- In Africa alone, over 424,000 patients are being treated with at least one ARV supplied by the AAI companies, an increase of 11% over 12 months. This increase results in a 45-fold increase in the number of people being treated with medicines supplied by the AAI companies in Africa since the establishment of the AAI in May 2000.
- The estimated number of people on treatment is based on actual quarterly drug supply data from the seven companies. The drug unit data were converted into patient-equivalent numbers by quarter, based on dosage and indications. The data represent units supplied and actual sales, and the analysis is conducted independently.

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**African Comprehensive HIV/AIDS Partnerships (ACHAP)**
HIV/AIDS
Merck & Co.
Since 2000
Access: cash & medicine donations, capacity building & infrastructure
Botswana
www.achap.org
The African Comprehensive HIV/AIDS Partnerships (ACHAP), also known as The Merck/Gates/Botswana Partnership for HIV/AIDS, was established in 2000 by the Government of Botswana, the Merck Company Foundation, Merck & Co., Inc. and the Bill & Melinda Gates Foundation, to support and enhance Botswana's response to the HIV/AIDS epidemic through a comprehensive approach to HIV/AIDS prevention, care, treatment and support. The Merck Company Foundation and the Gates Foundation each are contributing $50 million over several years to the initiative. In addition, Merck is donating its antiretroviral (ARV) medicines to Botswana's national ARV treatment program – known as *Masa* (dawn) – for the partnership's duration. Results to-date are promising. As of December 2005, more than 56,500 patients were enrolled in the program, of which 50,000 patients were receiving medication. More than 1,000 new HIV+ patients are enrolled in the program each month. To expand its reach, the partnership has supported the construction of 32 regional treatment centers. It has also conducted disease awareness and de-stigmatization education for nearly 5,000 teachers in primary and secondary-level schools, and is helping to provide confidential pre- & post-HIV test counseling, disease information and support for people living with HIV/AIDS. The partnership makes available didactic HIV/AIDS clinical care training to all health care professionals in Botswana. To date, more than 3,200 health care workers have received hands-on, clinical training from HIV/AIDS experts.

**Astra Zeneca Canada Inc.**

AstraZeneca Canada, in partnership with Health Partners International Canada (HPIC), has provided over $ 14,252,000 in both financial support and product donations since 1994. Examples include $3.5 million to a CIDA-funded Cuba program, which helps to deliver medical aid, medical equipment and related services, and$20,000 in 2005/2006 to "Smile China," a non-profit organization founded by Dr. Joseph K. Wong, a renowned paediatric facial plastic surgeon based in Toronto, to repair cleft palates of children in China. In addition, globally, AstraZeneca has provided $835 million in 2005 alone and $241.6 million halfway through 2006.

**Call to Action**
HIV/AIDS
Boehringer Ingelheim and Johnson & Johnson
Since 1999
Access: medicines provision, testing, training, counseling, education
Resource limited countries including Swaziland & Tanzania
www.pedaids.org
"Call to Action" is a multi-country approach to the prevention of mother-to-child transmission (PMTCT) of HIV in resource-limited settings, which has been initiated by the Elizabeth Glaser Pediatric AIDS Foundation (EGPAF) in 1999. The project funds international healthcare facilities, non-governmental organizations and community-based organizations to plan, implement and/or expand programs. It also provides funding for community mobilization and training of health care workers, HIV counseling and testing, mother-to-child prevention regimes and infant feeding education. Since program inception, more than 2.1 million women have accessed PMTCT sites; more than 1.9 million have been counseled and more 1.6 million have received voluntary HIV testing. EGPAF is expanding its operations to include prevention, diagnosis and treatment of opportunistic infections such as pneumonia, malaria and tuberculosis. Boehringer Ingelheim is assisting EGPAF and also has direct collaboration in the PMTCT Donation Program, for instance in Swaziland and Tanzania. Following a successful pilot program in India that reached almost 19,000 women in 2003, Johnson & Johnson (J&J) expanded its partnership with the EGPAF in 2004 and then again last year. The partnership has expanded to seven nations and included training of health care workers, plus delivery of HIV counseling, voluntary testing, critical drug intervention, and referrals for care and support. This combination of services significantly reduces the chances of a mother passing HIV to her newborn. Through the EGPAF partnership, J&J now supports over 200 healthcare delivery sites in China, India, Russia, Malawi, the Republic of Georgia, Zimbabwe and the Dominican Republic, reaching more than 300,000 pregnant women.

**China-MSD HIV/AIDS Partnership**
HIV/AIDS
Merck & Co.
Since 2005
Access: prevention, care, treatment & training
China
www.china-msd-aids.org
The China-MSD HIV/AIDS Partnership (C-MAP) aims to develop a comprehensive, replicable model that joins together prevention, patient care, treatment and support in areas where the HIV/AIDS epidemic is concentrated among injection drug users and other high risk populations.

On May 11, 2005, Merck & Co., Inc. and the Chinese Ministry of Health signed a memorandum of understanding that established a public-private partnership to create a comprehensive program to address HIV/AIDS. Merck & Co., Inc and The Merck Company Foundation have committed $30 million over five years to the partnership, making it the largest public-private HIV/AIDS undertaking in China to date.

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**Diflucan® Partnership Program**
HIV/AIDS
Pfizer
Since 2000
Access: product donation & training
44 countries in Africa, Asia, the Caribbean & Latin America
www.diflucanpartnership.org
Pfizer has been collaborating with governments and non-governmental organizations (NGOs) since 2000, to donate its antifungal medicine, Diflucan® (fluconazole), to HIV/AIDS patients in the developing countries hardest hit by HIV/AIDS. Although not a cure for HIV/AIDS, Diflucan® is efficacious in treating two AIDSrelated opportunistic infections: cryptococcal meningitis and oesophageal candidiasis. Through the Diflucan® Partnership Program, Pfizer is providing the medicine free of charge and without time limits to public health clinics for distribution to patients. Partners include Axios International, Interchurch Medical Assistance and the International Dispensarz Association (IDA).

As of October 2005, Pfizer had donated medicine worth more than $300 million to governments and NGOs operating in more than 44 countries, in Africa, Asia, the Caribbean and Latin America. This medicine has been used to treat more than 200,000 patients. More than 20,000 health care providers have been trained in the countries participating in the program.

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**Enhancing Care Initiative (ECI)**
HIV/AIDS
Merck & Co.
Since 1998
Access: care, counseling, testing, ARV treatment & training
Brazil, Puerto Rico, Senegal, South Africa & Thailand
www.eci.harvard.edu
Launched in 1998 with a five-year, $5 million grant from the Merck Company Foundation, the Enhancing Care Initiative is a program of the Harvard AIDS Institute and the Francois-Xavier Bagnoud Center at the Harvard School of Public Health. ECI is a multidisciplinary, multinational collaboration that seeks to improve the care of people living with HIV/AIDS in resource-limited settings. Its purpose is to identify practical, country-led approaches to providing effective HIV/AIDS care, tailored to the needs and resources of each country. Currently, teams are active in Brazil, Senegal, South Africa (KwaZulu-Natal province - KZN) and Thailand. An additional team, supported by the U.S. Health Resources and Services Administration, HIV/AIDS Bureau, operated in Puerto Rico.

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**GlaxoSmithKline's Positive Action on HIV/AIDS**
HIV/AIDS
GlaxoSmithKline
Since 1992

Access: capacity strengthening, testing, treatment, support & advocacy
30 countries including major new projects in India, Kenya & Mexico
www.gsk.com/positiveaction/
GlaxoSmithKline's Positive Action on HIV/AIDS is GSK's international program of HIV education, care, and community support. Set up in 1992, Positive Action aims to strengthen the capacity of community based organizations providing HIV/AIDS healthcare services and to increase the number of people coming forward for testing and treatment by reducing stigma and discrimination. It recognizes that involving people affected by HIV/AIDS is key to controlling the HIV pandemic. During 2005, Positive Action supported 20 international programs in 30 countries, including major new partnerships in India, Kenya and Mexico. Positive Action is supporting the Reach India project, which aims to make HIV/AIDS prevention, financial and business education available to millions of poor women in rural India. GSK is giving $500,000 to develop the capacity of community organizations and self-help groups to reach women in rural areas. In its first three years, this is expected to benefit 500,000 women and 2.5 million family members. Reach India is a Freedom from Hunger project, supported by Catholic Relief Services and Positive Action.

In Kenya, GSK is giving $1.8 million over three years to integrate HIV/AIDS treatment and support services into 60 general healthcare clinics. This will enable patients to avoid the stigma of visiting an HIV clinic. Fewer than 10% of Kenyans know their HIV status. Fear of stigmatization is a significant barrier to people seeking testing, diagnosis and treatment services. Positive Action will also focus on training for healthcare professionals and the creation of patient self-help groups to increase awareness and support patients in sticking to their treatment regimes. The program is a collaboration between GSK, AMREF (the African Medical and Research Foundation), Elizabeth Glaser Pediatric AIDS Foundation and the National Empowerment Network of People Living with HIV and AIDS in Kenya.

Medicines are accessing the developing world from Canada: GSK Mississauga, for example, has the World Product Mandate (WPM) for Malarone, to treat malaria, and for Retrovir, Eivir/3TC and Mepron, just some of GSK's treatments for the opportunistic infections associated with HIV/AIDS.

But GSK's approach is more than simply providing medicines. GSK makes a vital contribution to health care in the developing world in four ways:

- **Preferential pricing** of its antiretrovirals, anti-malarials and vaccines. Its ARVs are available at not-for-profit prices in some 100 countries and, in the last 3 years, GSK has supplied over 100 million tablets of *Combivir* to the developing world at preferential prices. Some 90% of all the vaccines we supply go to the developing world.
- **Research and development** (R&D) that targets diseases particularly affecting the developing world through a dedicated research facility in Spain. GSK has numerous active R&D programmes for both treatments and vaccines for HIV/AIDS, TB and malaria. In 2003 GSK launched *Lapdap* the first antimalarial to be developed through a Public Private Partnership. GSK Mississauga alone provides Malarone, for the treatment of Malaria, to the developing world, and was the first company to develop a treatment just 6 years after HIV was discovered. GSK is developing the world's most advanced malaria vaccine which could be submitted for regulatory approval as early as 2010.
- **Community investment** activities and partnerships that foster effective healthcare. GSK funds community-led initiatives in over 100 countries around the world. In the developing

world, GSK's activities span four major developing world diseases lymphatic filariasis (LF), HIV/AIDS, malaria and diarrhoeal disease. Since 1998 GSK has provided free of charge, through Health Partners International (HPIC), over 500 million albendazole treatments reaching over 100 million people in its endeavour to eliminate (LF). In total, GSK's global community investment activity was valued at $850 million in 2005. We work together with organizations like the Bill and Melinda Gates Foundation, AMREF and others to better health care in the developing world. GSK's Positive Action is at work in 60 facilities in Kenya thanks to a $1.8 million investment in improving health care services including clinical practices, counseling, testing and women's programmes.

- **Innovative solutions**. GSK has granted 8 voluntary licences to African generic companies to enable them to produce versions of our leading ARVs. GSK is helping to build clinical expertise in Africa by supporting 28 HIV/AIDS collaborative studies in developing countries, including 23 in Africa. These studies involve more than 18,000 patients.

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**GSK's HIV-collaborative research program for resource-poor settings**
HIV/AIDS
GlaxoSmithKline
Since 2000
R&D: donates study medicines for public health research
Mainly Africa
GSK is supporting clinical trials that are sponsored by external organizations - such as the WHO, the UK's Medical Research Council and US National Institutes of Health (NIH) - through its HIV-collaborative research program for resource-poor settings. Twenty-four trials, including 18 in Africa, are currently underway, mainly focusing on public health-related issues and involving more than 12,500 patients in the developing world. GSK donates study medicines (and/or financial support) and provides scientific input.

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**Health Systems**
HIV/AIDS
Abbott
Since 2003
Access: health infrastructure, testing & treatment
Tanzania
www.abbottglobalcare.org
Tanzania Care is a Global Care Initiative from Abbott and The Abbott Fund, which together with the Government of Tanzania have formed a unique public-private partnership to address critical areas of need in the fight against HIV/AIDS. In total, the Abbott Fund has invested $35 million to modernize the health care system and expand access to HIV testing and treatment. The partnership is implemented through Axios, an organization specializing in health management in developing countries. Strengthening Health Care Infrastructure and Systems. Adapting resource-limited health systems to meet the lifelong treatment needs of people with HIV requires a bold approach. The Abbott Fund is supporting one of the most comprehensive initiatives in Africa to strengthen a country's health care system. Centered at Muhimbili National Hospital in Dar es Salaam, Tanzania, the country's leading teaching and reference hospital, the Abbott Fund initiative also encompasses support for 82 additional hospitals and rural health facilities. Key program components include:

- A modern, three-story outpatient treatment center at Muhimbili National Hospital;
- State-of-the-art hospital laboratories at Muhimbili National Hospital;

- Training health care staff across Tanzania; and
- Strengthening hospital management and "back office" functions.

Expanding Access to HIV Testing and Treatment Across Tanzania. By strengthening facilities and training, the Abbott Fund initiative is accelerating the availability of both voluntary counseling and testing (VCT) and HIV treatment programs. More than 100,000 people have received VCT services due to improvements, including patients accessing VCT in some rural locations for the first time.

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**HIV/AIDS Awareness and Education**
HIV/AIDS
Merck & Co.
Since 2003
Access: prevention, education & counseling
Latin America
With some 600,000 people infected with the HIV/AIDS virus, Brazil has one-third of Latin America's infected population. In response to the epidemic and in support of the Brazilian government's well-recognized commitment to address AIDS comprehensively, the Merck Company Foundation, Merck's Office of Corporate Contributions and MSD Brazil have donated more than $350,000 to HIV programs developed by local NGOs, focusing primarily on prevention, education and awareness.

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**HIV South Africa**
HIV/AIDS
Johnson & Johnson
Since 2003
Access: healthcare products, training & logistical support
South Africa
http://www.hivsa.com/hivsa/index.stm
With the support of Johnson & Johnson, HIV South Africa (a program of the Baragwanath Hospital Perinatal HIV Research Unit) has provided a wide variety of J&J healthcare products to community-based organizations that provide care and support to HIV patients in their homes. The project has both an urban and a rural component, which together serve approximately 3,500 households at any given time. The product donation is complemented by distribution support, caregiver training and program monitoring. Supplemental support also is provided to selected hospice organizations.

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**Infectious Diseases Institute**
HIV/AIDS
Pfizer & Abbott
Since 2002
Access: training, care, treatment, research & product donation
Uganda
www.academicalliancefoundation.org
In recognition of African health care professionals' growing need for training in the latest treatment options for HIV/AIDS, Pfizer and the Pfizer Foundation helped to establish the Infectious Diseases Institute (IDI), located at Makerere University Medical School in Kampala, Uganda. Pfizer partnered with the Academic Alliance for AIDS Care and Prevention (an association of African and North American infectious disease experts) and several non-governmental organizations (including

the Academic Alliance Foundation, the Pangaea Global AIDS Foundation, the Infectious Diseases Society of America and the AIDS Support Organization (TASO) in Uganda) to establish the clinic, which is funded by Pfizer and operated by the Academic Alliance in partnership with Makerere University. The IDI provides high-quality HIV/AIDS care and treatment to thousands of patients each year and trains health care professionals from throughout Africa. Since its establishment in 2002, the IDI has trained approximately 650 healthcare professionals from 21 African countries in HIV/AIDS care. Institute staff members also conduct operational research. Abbott Laboratories also donates HIV diagnostic tests.

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**Integrated Approach to addressing HIV/AIDS in the Caribbean**
HIV/AIDS
Merck & Co.
Since 2003
Access: education, prevention, care & advocacy
Caribbean countries
www.merck.com
Merck & Co. and MSD Caribbean's Integrated Approach to addressing HIV/AIDS in the Caribbean comprises a diverse range of initiatives that address HIV/AIDS comprehensively and in a strategically integrated fashion – from education and prevention to treatment, care and advocacy. These initiatives are conducted in partnership with a wide array of stakeholders, including people living with HIV/AIDS (PLWHA), caregivers (physicians, nurses and pharmacists), the business community and the public sector. Many of these projects are carried out with the US Government as a partner, including co-funding from USAID, and serve as useful models for effective public-private partnerships. MSD Caribbean / Merck have provided more than $500,000 in direct project support to non-governmental organizations operating in the Caribbean to address HIV/AIDS. The activities, projects and initiatives that MSD/Merck supports in the Caribbean generally focus on three objectives:

- To support and empower PLWHA;
- To improve standards of treatment and care among health care professionals; and
- To encourage and facilitate the private and public sector response to AIDS.

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**International AIDS Vaccine Initiative (IAVI)**
HIV/AIDS
Bristol-Myers Squibb, GlaxoSmithKline, Merck & Co., Novartis Vaccines & Diagnostics (formerly Chiron)
Since 1996
R&D and Access: medicine development, advocacy, education & policy
Global operations, country teams
www.iavi.org
The International AIDS Vaccine Initiative (IAVI) was created in 1996 out of the recognition that the best long-term solution to the growing AIDS epidemic is a vaccine. As a global organization operating across borders to meet the challenges posed by the epidemic, IAVI is working to ensure the development of safe, effective, accessible and preventive HIV vaccines for use throughout the world. IAVI's work focuses on four areas:

- Mobilizing support through advocacy and education (by identifying and filling other scientific gaps);

- Accelerating scientific progress (by supporting promising vaccine development partnerships);
- Encouraging industrial participation in AIDS vaccine development (by expanding public-private collaboration and creating incentives for private sector investment and participation in HIV vaccine development); and
- Assuring global access (by creating the policies necessary for getting the vaccines to all those who need it). IAVI collaborates with developing countries, governments.

International agencies that are dedicated to accelerating the development of a vaccine to halt the AIDS epidemic. Partners in the private sector include pharmaceutical companies such as Bristol-Myers Squibb, GlaxoSmithKline, Merck & Co. Novartis Vaccines & Diagnostics (formerly Chiron). Funding is provided by the Rockefeller Foundation, World Bank, USAID, the Bill & Melinda Gates Foundation and other donors. In 2005, GSK launched the first formal public-private partnership with IAVI to develop an AIDS vaccine using non-human primate adenovirus vector technology. The collaboration – the first-ever in AIDS vaccine research between IAVI and a major vaccine company – will facilitate research into vaccines against types of HIV that circulate predominantly in Africa. Under the agreement, IAVI will contribute technical expertise and funding, and GSK and IAVI researchers will form a joint research team.

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**International Partnership for Microbicides (IPM)**
HIV/AIDS
GlaxoSmithKline and Johnson & Johnson
Since 2004
R&D: screening compounds
Focus on use by developing countries
www.gsk.com
GSK has entered into a material transfer agreement with the International Partnership on Microbicides (IPM), under which GSK will select and provide proprietary anti-HIV compounds to be tested for possible use as microbicides to prevent transmission of HIV. Johnson & Johnson's Tibotec affiliate established a first-of-its kind public-private partnership with IPM in 2004, when it provided a royalty-free licence to develop, manufacture and distribute TMC120 as a topical vaginal microbicide to reduce sexual transmission of HIV in resource-poor countries. IPM's safety trials of TMC120 (dapivirine) as a vaginal gel are underway in Belgium, South Africa, Rwanda, Tanzania and soon in Uganda. The partnership received public accolades from global health leaders, including the Gates Foundation, and is indicative of the collaborative approach Johnson & Johnson has taken to address the pandemic.

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**Mission for Essential Drugs & Supplies (MEDS)**
HIV/AIDS
Johnson & Johnson
Since 2003
Access: at cost & donated medicines, capacity building
Kenya
www.tibotec.com
Since 2003, Johnson & Johnson and its Tibotec affiliate have partnered with the Mission for Essential Drugs & Supplies (MEDS) in the Miconazole MAT Award Program, which awards grants to NGOs and public health facilities throughout Kenya that support sustained community

initiatives. J&J is helping to advance the core mission of MEDS by offering TibozoleTM at no profit. The income MEDS accumulates from selling these tablets to clients at a reduced price is then used to issue grants to local organizations dedicated to improving community health. Johnson & Johnson matches these amounts to result in twice the available funding. This program is a model for "rainmaker" sustainability and local community engagement. Through a variety of different programs, more than one million patient treatments of miconazole have been either donated or sold at cost by Tibotec since 2000. TibozoleTM Miconazole MAT is a muco-adhesive buccal tablet to treat oral thrush in AIDS patients in sub-Saharan African countries.

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**PMTCT Donations Program**
HIV/AIDS
Abbott & Boehringer Ingelheim
Since 2003
Access: donation of HIV tests & ARV treatment
For developing world
www.pmtctdonations.org
In 2003, Abbott and Boehringer Ingelheim established a cooperative arrangement that helps prevent the transmission of HIV from mother to child in the developing world through their respective donation programs. Through this arrangement, organizations can receive Determine® HIV rapid tests and Viramune® (nevirapine), an antiretroviral medicine developed by Boehringer Ingelheim (see Viramune® Donation Program). In addition to providing tests and treatment, the two companies are committed to provide greater access to these donated products while making it easier for organizations to receive the donated products and encouraging the creation of new PMTCT programs in developing countries. Any organization that provides testing and treatment for PMTCT through a sound and sustainable program of care may request a donation of Determine® HIV through Axios International, which administers the application process for both programs. A common web site has also been established to simplify the process by which PMTCT programs obtain free HIV tests and Viramune® (nevirapine). Abbott, Boehringer Ingelheim and WHO recognize the potential for PMTCT sites to serve as a natural entry point for providing access to chronic treatment. Functioning PMTCT sites catalyze the improvement of infrastructure and access to healthcare in resource-poor settings. This is primarily due to the multi-disciplinary approach required for a successful program.

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**Secure the Future®**
HIV/AIDS
Bristol-Myers Squibb
Since 1999
Access: medicine donations, care, treatment, research & training
10 nations: Botswana, Burkina Faso, Côte d'Ivoire, Lesotho, Mali, Namibia, Senegal, South Africa, Swaziland & Uganda
www.securethefuture.com
Secure The Future® is a comprehensive initiative to fight HIV/AIDS in sub-Saharan Africa, sponsored by Bristol-Myers Squibb and the Bristol-Myers Squibb Foundation. It combines medical treatment and care, access to antiretroviral medicines, with research, social support with community education, and training for health care professionals with new facilities and infrastructure investments in remote areas of sub-Saharan Africa where resources are extremely limited. Three key program areas are: community-based treatment support, children's health and capacity-building of implementing agencies. Secure The Future's six pilot Community-Based Treatment Support Centers

are showing for the first time that comprehensive medical treatment and care, including broad-based community support, can be successful in fighting HIV/AIDS. In collaboration with Baylor College of Medicine, Houston, Texas, USA, it funded the first clinical center in Africa for children with HIV/AIDS, located in Botswana. Additional children's clinical centers have opened in Lesotho and Swaziland, and two more are under construction in Burkina Faso and Uganda. To increase the number of trained pediatric specialists, Secure The Future and Baylor created the Pediatric AIDS Corps to send up to 250 doctors to Africa to treat approximately 80,000 children and train local health care professionals over the next five years. The first class of 50 doctors will be working in Africa by September 2006. Capacity building of implementing agencies is part of the integrated approach of Secure The Future. It has created the first African NGO Institute to develop model training modules to build leadership, management and good governance skills among organizations working to fight HIV/AIDS and is training participants in Botswana, Lesotho, Namibia, South Africa and Swaziland. The program emphasizes collaboration with government leaders, ministries of health, medical institutions in the U.S. and Africa, physicians and other health care professionals, non-governmental, community-based and faith-based organizations, and people living with HIV/AIDS. Since its inception in 1999, Secure The Future has grown in size and scope to support some 200 individual programs through a commitment now totaling $150 million. The initiative is now reaching women, children, their families and communities in 10 nations: South Africa, Swaziland, Lesotho, Botswana, Namibia, Senegal, Burkina Faso, Mali, Côte d'Ivoire and Uganda.

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**Step Forward – Abbott Program for Helping Children and Families Affected by AIDS**
HIV/AIDS
Abbott
Since 2000
Access: education, health infrastructure, counseling & testing
Burkina Faso, India, Malawi, Romania & Tanzania
www.abbottglobalcare.org
Step Forward for the World's Children is a Global Care Initiative from Abbott and the Abbott Fund, which is working to improve the lives of orphans and vulnerable children affected by HIV/AIDS through model programs in Burkina Faso, India, Malawi, Romania and Tanzania. Working with international partners – Axios, Baylor College of Medicine and the International HIV/AIDS Alliance – and governments and non-governmental organizations, the Abbott Fund initiative addresses specific community needs through four critical activities: education, health services and infrastructure, voluntary counseling and testing, as well as the provision of basic needs. To date more than 500,000 children and families have received services through the Abbott Fund.

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**Viramune® Donation Program (now part of PMTCT Donation program)**
HIV/AIDS
Boehringer Ingelheim
Since 2000
Access: medicine donations & training
58 countries in Sub-Saharan Africa, Eastern Europe, Central & Southeast Asia & Latin America
www.pmtctdonations.org
Boehringer Ingelheim's Viramune® Donation Program was announced in July 2000 as a program that offers the antiretroviral medicine Viramune® free-of-charge to developing countries and has been designed to prevent Mother-To-Child-Transmission of HIV-1 (MTCT). There are about 120 countries eligible according to the World Bank list of developing and transient economies. Since 2003, it has been a part of the PMTCT Donations Program. Boehringer Ingelheim donates

Viramune® in accordance with the WHO Guidelines for Medicine donations, free of charge, based on the expressed interest of governments, NGOs, charitable organizations or other healthcare providers with comprehensive Mother-to-Child-Transmission prevention programs. The first deliveries in this program by Boehringer Ingelheim were made in late 2000 to the Republic of Congo (Brazzaville) and to Senegal, and since then more than 144 programs in 58 countries have been approved to receive Viramune®. Most of them are countries in Sub-Saharan Africa, but also in Eastern Europe, Central and Southeast Asia, and Latin America. Boehringer Ingelheim also works with both governmental and private organizations to develop training programs, locally and internationally. On the local level, cooperation has been strengthened with many key PMTCT implementers, such as the International Council of Nurses (ICN), Elizabeth Glaser Pediatric AIDS Foundation (EGPAF), Rotary International, church-based organizations and UNICEF.

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**Women's Global Health Imperative**
HIV/AIDS
Johnson & Johnson
Since 2003
R&D: female-controlled prevention means,
South Africa & Zimbabwe
www.wghi.org
Established products are playing a role in HIV/AIDS prevention research headed by the Women's Global Health Imperative of the University of California, San Francisco. Johnson & Johnson's Ortho All-Flex, latex diaphragm is being used in a multi-site randomized controlled trial of 5,000 women in South Africa and Zimbabwe to measure the effectiveness of a diaphragm used with lubricant gel in preventing heterosexual acquisition of HIV infection among women. Johnson & Johnson also donated 48 pelvic models to the trial for demonstrations of proper methods for inserting and removing a diaphragm. All women receive safer-sex counseling, free male condoms as well as diagnosis and treatment of sexually transmitted infections. Half will also receive the diaphragm and gel so researchers can assess the HIV and STI infection rates of women who use them versus their counterparts.

**Abbott**

www.abbott.com

- Afghanistan is one of the deadliest places on earth for women and children. – more than 20,000 Afghan women die from pregnancy-related causes each year and an estimated 25 percent of children die before their fifth birthday, mostly from preventable illnesses and malnutrition.
- In partnership with Direct Relief International and the Afghan Institute of Learning, the Abbott Fund donated $100,000 in 2005 to train midwives affiliated with three clinics in Kabul and Herat. In addition, in 2006, Abbott will ship products, including adult and pediatric antibiotics, nutritional supplements, rehydration solution and multivitamins, valued at $1.4 million to Afghanistan to expand the level of care for women and children at these clinics.
    - Abbott has donated more than 4.7 million rapid HIV tests to approx 69 countries, including all of Africa
    - The Abbott Fund and Abbott are investing more than $100 million to advance HIV testing and treatment in developing countries.

**AstraZeneca**

www.astrazeneca.com

- AstraZeneca's product donation and patient assistance programs make its medicines available free-of-charge or at reduced prices to those who cannot afford them.
- AstraZeneca began a pilot project in Ethiopia designed to build local capability in managing breast cancer – the second most common cancer among young women in that country. In its first year, the program focused on strengthening diagnosis and treatment capabilities at Tikur Anbessa University Hospital in Addis Ababa (where the country's oncologist is based). This included the provision of a mammography machine, the introduction of receptor tests, and the development of guidelines for diagnosis, treatment and palliative care. AstraZeneca's breast cancer medicines are also being made available.
- In South Africa, teachers' perceptions of asthma are changing rapidly due to the National Schools Programme, sponsored by AstraZeneca. The program runs with the sponsorship of AstraZeneca under the auspices of the National Asthma Education Programme (NAEP), a non-profit organization dedicated to educating the general public about asthma. In less than a year, the Schools Programme has covered 20 schools in Durban, 20 in Cape Town and 9 in Johannesburg.

**Bayer HealthCare**

www.bayer.com

- To widen access of patients to affordable medicines, in 2004 Bayer HealthCare signed an agreement with the WHO for a donation of the Bayer medicine Lampit® to combat Chagas disease (the form of sleeping sickness found in Latin America). The donation consists of 250,000 tablets with the active ingredient nifurtimox. The medicine was donated to the WHO, which informed the governments of disease endemic countries of the availability of the free supplies, including the procedure to be followed for obtaining such supplies. In 2005, Bayer HealthCare agreed to support the WHO in the fight against Chagas disease with a donation of an additional 250,000 tablets.

**Bristol-Myers Squibb**
www.bms.com
In 2005, Bristol-Myers Squibb donations of approximately $70 million wholesale value were given to programs throughout the world, including Africa, Asia, Caribbean, Latin America, Mexico and the Middle East. NGO program partners include Americares, Direct Relief International, Catholic Medical Mission Board, Direct Relief International, Heart to Heart International, Interchurch Medical Assistance, MAP International, Northwest Medical Teams and Project HOPE. Some specific examples are as follows:

- In 2005, Bristol-Myers Squibb donated over $32 million worth of medicines to Direct Relief International to support long-term health care programs, medical mission trips and disaster relief efforts in 36 countries around the world.
- Bristol-Myers Squibb product donations to the Catholic Medical Mission Board (CMMB) medicines and medical supply program in 2005 were valued at $12.3 million and distributed to 21 countries.
- Working with Interchurch Medical Assistance (I.M.A), Bristol-Myers Squibb products valued at $1.8 million were used to treat poor and disadvantaged people in 47 countries throughout the world through long-term health development and emergency assistance programs.
- In 2005, donations to assist Project HOPE's worldwide efforts totaled approximately $3.3 million. Bristol-Myers Squibb continues to partner with Project HOPE to provide products for use in their Maternal Child Health and Humanitarian Assistance Programs throughout Central Asia and Latin America. Bristol-Myers Squibb has been one of AmeriCares' most valued partners in their emergency and ongoing humanitarian operations. Since 1982, Bristol-Myers Squibb donations to AmeriCares have enabled their partners to receive and distribute close to $250 million (wholesale value) of Bristol-Myers Squibb products worldwide, with over $15 million dollars worth of product donations distributed in 2005.
- Bristol-Myers Squibb granted two generic drug makers royalty-free licences to make and sell its latest AIDS medicine in sub-Saharan Africa and India in early 2006. The company granted South African company Aspen PharmaCare the rights to manufacture and sell atazanavir (called Reyataz in the United States) in sub-Saharan Africa. Emcure Pharmaceuticals, which is based in India, was given the rights in that country. Under the agreement, Bristol-Myers will also provide technical training to the companies, so they learn how to manufacture, test, package, store and handle the medicine's active ingredient. Giving local companies the rights and knowledge to make medicines locally is expected to expand supply and access to these medicines.

**Pricing Policy**
In 2001, Bristol-Myers Squibb announced that it would provide all of its HIV medicines at no-profit pricing in sub-Saharan Africa.

**Patent Policy**
Since 2001, Bristol-Myers Squibb has maintained a policy of not enforcing its patents for HIV products in sub-Saharan Africa. The company is committed to ensuring that its patents do not prevent inexpensive HIV/AIDS therapy in sub-Saharan Africa. In keeping with our policy, Bristol-Myers Squibb has finalized immunity from suit agreements in sub-Saharan Africa for stavudine and didanosine with Aspen PharmaCare, Afrika BioPharma Investments, Adcock-Ingram, Aurobindo Pharma and Thembalani. There are additional immunity from suit agreements in process. More

recently, Bristol-Myers Squibb has granted a number of licences for atazanavir in sub-Saharan Africa.

**Enabling Generic Companies**

In 2004 Bristol-Myers Squibb agreed to allow the FDA to make right of reference to our confidential dossiers and product registration files in order to facilitate the approval of generic combination products under the PEPFAR program. In February 2006, Bristol-Myers Squibb announced a highly innovative agreement for full technology transfer of its newest antiretroviral, atazanavir, to two generic companies, Aspen and Emcure.

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**Eli Lilly & Co.**

www.lilly.com

Eli Lilly and Company donates medicines and cash to help people around the world. Over the past several years, Lilly and the Lilly Foundation have provided over $100 million in product donations and cash grants to numerous causes in developing nations.

- In China, Lilly contributed $800,000 to fund a partnership with Project HOPE (in the China Diabetes Project) that creates sustainable diabetes prevention and control programs throughout the country.
- In South Africa, Lilly funded the Center for Diabetes and Endocrinology to increase diabetes public education programs and to build a primary care clinic in 2002.
- Lilly partnered with the International Diabetes Federation, the largest diabetes advocacy organization in the world, in a program to help children and young adults in Asia and Africa survive diabetes. Lilly employees donated money directly to sponsor children and the company contributed $180,000 to the program over three years.
- In Brazil, Lilly founded the "Lilly in Action" program that encouraged Lilly employees and partners to volunteer their time for important community activities. Today, there are more than 150 active volunteers working on important programs, such as the Socio-Cultural Inclusion Program, which helps people learn to read and write.

**Multi-Drug Resistant Tuberculosis Partnership**

In 2003, Lilly launched a $70 million global initiative to address the rising incidence of MDR-TB, a strain of TB infecting an estimated 400,000 people each year, notably in China, India, Africa, and the former Soviet Union. Known as the "Lilly MDR-TB Partnership," this multipronged, cross-sector initiative involves 14 partners and is focused in three ways: transferring Lilly's proprietary manufacturing technology; enhancing disease surveillance and training programs; and increasing the supply of capreomycin and cycloserine, medications effective in the treatment of MDR-TB.

**Technology Transfer**

The ongoing transfer of Lilly drug-manufacturing expertise for both of our MDR-TB medicines, capreomycin and cycloserine, to companies in India, China, Russia, and South Africa will increase global supply of these products at a lower cost. With funding from Lilly, experts from Purdue University are training scientists and plant managers from these companies in manufacturing skills and good business practices.

Shasun Chemicals and Drugs (India) has validated its manufacturing for cycloserine and dispatched its first order in February 2006.

Hisun Pharmaceutical (China) has validated its manufacturing for capreomycin. Hisun will provide the active pharmaceutical ingredient (API) to Aspen Pharmacare, which will produce the final form of the drug. Hisun is also working on an expansion of its facility so it can locally produce the final form of capreomycin. To ensure the long-term success of the manufacturing partnership, Lilly committed to provide technical assistance and necessary training.

Aspen Pharmacare (South Africa) sold its first batch of cycloserine to Botswana in late 2005 and plans to start making cycloserine in its new facility, as many as 4 billion capsules per year. Aspen began construction on another facility that will produce capreomycin vials.

SIA International (Russia) is Lilly's newest manufacturing partner as of May 2006 and expects to be making cycloserine by late 2006.

**Increasing the Supply of Medicines**
Through the transfer of technology, Lilly is increasing the supply of critically needed antibiotics. We also support the World Health Organization's DOT-Plus program (Directly Observed Treatment-short course for MDR-TB patients) by providing our MDR-TB drugs at highly discounted prices. Since the launch of the initiative, we have doubled the quantity of drugs that we provide to the WHO.

We believe that the Lilly MDR-TB Partnership will improve health care worldwide while establishing a lasting model for bringing public and private organizations together to fight pandemics and epidemics.

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**GlaxoSmithKline**
www.gsk.com

- GlaxoSmithKline is committed to playing a full part in addressing the healthcare challenges of the developing world by taking an innovative, responsible and - above all - sustainable approach. GSK is making a vital contribution to through action in four areas: preferential pricing of its antiretrovirals (ARVs), anti-malarials and vaccines; investing in research and development that targets diseases particularly affecting the developing world; community investment activities and partnerships that foster effective healthcare; as well as innovative partnerships and solutions. GSK has offered sustainable preferential pricing for ARVs since 1997 and for vaccines for over 20 years.
- GSK's AIDS medicines and anti-malarials are available at not-for-profit prices to public sector customers and not-for-profit organisations in 64 countries - all the Least Developed Countries (LDCs) and all of sub-Saharan Africa (SSA). During 2005, GSK shipped 45 million tablets of preferentially priced Combivir, its leading ARV, to the developing world, with the majority of these going to Africa. This is a 40% increase on last year and more than in the two previous years combined. Similarly, shipments of Epivir grew by 135% to 81 million tablets shipped in 2005.
- GSK has created a dedicated group in its pharmaceutical R&D organization, to focus on diseases of the developing world (DDW). This includes a dedicated drug discovery centre at its Tres Cantos R&D site in Spain and clinical development experts in the UK and US. DDW projects are prioritized according to their social and public health benefits rather than their commercial returns. A similar group exists in GSK Biological's vaccines organization based in

Belgium. In total, GSK has 13 clinical programs for medicines and vaccines against 8 diseases particularly relevant to the developing world. Seven of these projects are for diseases that disproportionately affect developing countries.

- Through its Global Community Partnerships program, GSK funds community-led initiatives in over 100 countries around the world. GSK has a wide range of partnerships, with a focus on health and education programs for under served communities. During 2005 GSK donated lifesaving medicines valued at $59 million to support relief efforts in over 100 countries. In the developing world, GSK's activities span four major developing world diseases (lymphatic filariasis, HIV/AIDS, malaria and diarrhoeal disease), a number of regional health initiatives, health education, product donations and employee involvement.
- GSK granted its first licence in October 2001 to Aspen Pharmacare, sub-Saharan Africa's largest generics company, for the manufacture and sale of versions of Combivir, Epivir and Retrovir. The licence now covers both the public and private sectors across all of sub-Saharan Africa. In November 2005, GSK granted a new voluntary licence to the Universal Corporation of Kenya. In total GSK has now signed seven licensing agreements for its antiretrovirals in Africa where HIV/AIDS is having a devastating impact (five in South Africa and two in Kenya). Some cover just parts of Africa and others all of sub-Saharan Africa.
- GSK's Personal Hygiene & Sanitation Education (PHASE) project is helping to reduce diarrhea related disease by encouraging school children to wash their hands. GSK established PHASE in 1998 and has invested $2.7 million in the program. PHASE is run in partnership with AMREF, Save the Children and Plan International - as well as Ministries of Health and Education. The program has had impressive results. For example, a study by AMREF in Kenya showed that after four years, 88% of children from participating schools washed their hands after using the toilet compared with 46% from non-participating schools. PHASE was extended to Bangladesh during 2005 and now operates in six countries. Bangladesh is the first Asian country to take part in PHASE. In its first year, the program will be implemented in 64 schools, reaching 20,000 children. GSK has convened a PHASE steering committee with representatives from our partner organizations to help expand the program into more countries - Tajikistan and Mexico are planned for 2006.
- www.gsk.com/responsibility/cr_report_2005/access-to-medicines/developing-countries.htm

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**Hoffmann-La Roche**

www.roche.com

**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, Cambodia**

CARE, the Cohort to evaluate Access to anti-Retroviral treatment and Education, was established by Roche and PharmaAccess Initiative in 2001. The program was set-up in four major urban treatment centers across Africa.

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.

**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.

**No profit pricing and no patent policy initiative**

Roche's no profit and patent policies apply to more than 26 million people living with HIV/AIDS worldwide.

Reduced prices for HIV protease inhibitor medicines apply to 87 per cent of all people living with HIV/AIDS in the world

**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:**

**Patent policies for all Roche medicines:**

To file no 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.

**Roche HIV/AIDS medicines and patents:**

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

Roche will not take any action against generic manufactures of its antiretrovirals in these countries.

**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.

**Additional Roche Canada Initiatives**
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 Invirase (saquinavir), Roche's 2nd 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.

A further 22 companies across 14 countries are interested in Roche AIDS Technology Transfer Initiative.

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.

**Challenges to come/goals for future**
Access to treatment remains a challenge faced by many in least developed countries and sub-Saharan Africa, where resources are fewest and the need for treatment is greatest.
The pharmaceutical industry's challenge is to take proactive steps to reduce the barriers and improve access to treatment in the world's most needy areas.

- South Africa's mobile health clinic on rail, the Phelophepa Health Care Train, provides rural areas with primary care services. Hoffmann-La Roche has been supporting the train, which is operated by the state rail corporation, Transnet, for the last 10 years, and is the leading external sponsor. The train is fully equipped to provide general medical services and dental, eye and psychiatric care. The train has 16 coaches and 14 staff plus 40 student interns. The Health Care Train has now launched two new services - cancer screening and diabetes prevention - as a result of funding from Hoffmann-La Roche. To date the train has reached 7 million people and provided free health, dental, eye and mental care, training and education since 1994.
- Hoffmann-La Roche has undertaken actions to meet the pandemic preparedness plans of WHO and of various national governments. In order to increase the availability of Tamiflu®, a Hoffmann-La Roche medicine likely to play a key role in the management of any pandemic influenza, Hoffmann-La Roche has implemented steps to increase manufacturing capacity, doubling production capacity in 2004 and 2005, and will have the capacity to produce over 400 million treatments of Tamiflu® annually by 2007. Hoffmann-La Roche and Gilead (who

developed the medicine) hold no patents on Tamiflu® in the UN-defined list of Least Developed Countries, allowing the governments of these countries to produce their own generic versions of the medicine. Hoffmann-La Roche has offered technical information to such governments to assist with this process. Furthermore, Hoffmann-La Roche has granted sublicences to manufacture oseltamivir (the generic name of the product) to two Chinese and one Indian pharmaceutical manufacturer, allowing them to supply generics forms of the medicine for pandemic stockpiling by governments primarily in developing nations. In order to further support governments in their pandemic preparedness efforts, Hoffmann-La Roche is providing Tamiflu® to governments at a reduced price for pandemic stockpiling. In addition, in August 2005, Hoffmann-La Roche announced that it would hold a reserve of 3 million courses of Tamiflu® treatment as a rapid response stockpile to be donated for use exclusively at the site of outbreak of a pandemic in an attempt to contain or slow its spread. Hoffmann-La Roche has also announced the donation of a further 2 million courses of Tamiflu® to the WHO, which will be stored at regional locations and used to establish regional stockpiles to assist developing countries further. The regional stockpiles of Tamiflu® will be used to reduce morbidity and mortality in the event of an outbreak of avian influenza in humans and to prevent the further spread of such an outbreak.

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**Johnson & Johnson**

www.jnj.com

- Johnson & Johnson (J&J) has sought to incorporate within its focused worldwide HIV/AIDS strategy the diverse, grass-root aspirations of national and community-based programs that impact the lives of women, children and families. Since most community caregivers are women, J&J's more than 100 philanthropic investments in HIV programs in 30 countries attempt to capture the breadth of the epidemic reflected from their perspectives. J&J focuses on preventing infections in women and children, and supporting communities by empowering caregivers. Since 2003, J&J has supported the innovative "Healthy Communities, Healthy Ecosystems" projects run by the World Wildlife Fund (WWF) in East Africa, the Congo Basin and the Eastern Himalayas. The Eastern African Marine Ecoregion (EAME) program promotes environmental protection, facilitates access to health care for poor, isolated communities and builds awareness of the link between a healthy environment and local people's health. In 2005, WWF constructed a new dispensary for communities in the Kiunga Marine National Reserve in Kenya, helping to improve community health, encouraging local participation in natural resource management and providing safe drinking water supplies in the reserve's main villages. In Quirimbas National Park, Mozambique, WWF created two new marine sanctuaries to increase catches in surrounding waters. Stocks are rising, creating a more sustainable source of nutrition for local people. Similar efforts are underway in the Congo Basin and Eastern Himalayas.
- J&J and its affiliate Janssen-Cilag Brazil support "Healthy Children, Healthy Futures" - a treatment and education program established by the non-profit International Medical Services for Health (INMED), through grants and donations of Pantelmin® (mebendazol), an antiparasitic medication produced by Janssen-Cilag. The program has eliminated the threat of intestinal parasites in children and prevented re-infections by educating children, their families and communities regarding hygiene, sanitation and nutrition.
- Since 1998 J&J has partnered with Save the Children in efforts to educate children and their families in the Philippines, Vietnam and Thailand about child development, health and nutrition. The partnership's first project involved integrating personal, community and environmental hygiene instruction into school curricula in Thailand.

**Merck Frosst**

www.merck.com

In 2001, Merck & Co. announced a differential pricing policy for its two current HIV/AIDS medicines. For countries classified by the United Nations Development Program's Human Development Index (HDI) as low and medium HDI countries with an adult HIV prevalence of 1% or greater, Merck makes its medicines available at prices at which the Company does not make a profit. For medium HID countries with an adult HIV prevalence of less than 1%, Merck also provides significant discounts on its ARV medicines. These prices are available to all stakeholders who are responsible for providing HIV/AIDS care and treatment, and who can provide reasonable assurance of their capacity to ensure increased patient access. This includes international organizations, NGOs and private sector organizations such as employers, insurers and hospitals. As of the end of 2005, nearly 500,000 patients in 76 developing countries were being treated with antiretroviral regimens containing Merck's two current HIV/AIDS medicines. In March 2006, Merck implemented further price reductions.

- www.merck.com/cr/enabling_acccess/developing_world/hiv/hiv_access.html
- In 2002, the International Council of Nurses (ICN), Merck, and Elsevier Science, the world's largest publisher of nursing books, formed a partnership to create the ICN/MSD Mobile Library program that provides much-needed quality health care information to nurses in many African and Indian Ocean countries, including Botswana, Ethiopia, Ghana, Kenya, Malawi, Mauritius, Seychelles, Swaziland, Tanzania, Uganda, Zambia and Zimbabwe. More than 100 mobile libraries, each comprising 91 specially selected books, bring up-to-date information on family and community health, disease prevention, health promotion and health services training to nurses who have limited access to reference books or expert advice. The libraries, which are packed into specially designed transportable trunks resistant to moisture, insects and damage, are aimed at reaching remote locations. Altogether, the libraries have reached 83 rural communities and helped to improve the quality of care for tens of thousands of people.

Additionally, Merck has donated more than 100,000 copies of The Merck Manual Home Edition to nurses throughout Africa.

- Since 1997 the Romanian government and Merck have worked together to increase access to treatment for thousands of children and adults living with HIV/AIDS in Romania. Merck has supported the implementation of the government's national AIDS strategy at every stage, including: support for the printing/distribution of the country's first national treatment guidelines, financial support to help create a national AIDS database and a $1 million donation in 1999 to the Romanian National AIDS Committee to establish a network of seven regional AIDS treatment centers.
- In Latin America, Merck and its subsidiaries have partnered with organizations in nearly every country in Latin America in the fight against AIDS, for example, by supporting awareness and prevention programs with groups in Argentina and Brazil, treatment and care programs in Chile, Peru, and Venezuela, empowerment and advocacy with groups in Central America and Colombia, outreach to healthcare professionals in Argentina, Brazil, the Caribbean, Chile and Mexico and leading the business community's response to HIV/AIDS through creating or

supporting the creation of business coalitions to address HIV/AIDS in Jamaica, Mexico and Venezuela.

- Merck has also partnered with the Pan American Health Organization and the Voice of America to create an innovative health journalism CD-ROM that will enhance the skills and knowledge of journalists reporting on the HIV/AIDS pandemic. Through hands-on workshops, including a seminar in Argentina attended by over 25 journalists from 13 countries, the project promotes greater expertise in health journalism across the region.
- Since 2002 Merck has supported Voluntary Services Overseas /Regional AIDS Intervention Southern Africa (VSO/RAISA), which forms partnerships with a range of organizations at all levels, from government to grassroots, and works with them to overcome HIV/AIDS challenges. A series of workshops, involving approximately 80 partners (grassroots organizations, government institutions and AIDS focused and PLWHA organizations) have been conducted to build capacity within these grassroots communities.
- Merck supports the Health Economics and HIV/AIDS Research Division (HEARD) at the University of KwaZulu-Nata, in South Africa. Merck identified HEARD for the excellent training workshops and the broad area of HIV/AIDS as one of its strategic research initiatives. HEARD reaches the broader community in South Africa, through presentations, policy briefs and linking with the people at the Provincial level. HEARD 2005 introduced the HIV/AIDS Mainstreaming Workshop which took place in Durban and targeted government ministries from all over Africa. A total of 6 ministries and 30 delegates attended the workshop. Donor representatives from UNAIDS and DANIDA were also present. In addition, over 350 senior managers, many of them from the world's poorer countries and regions, have attended the courses on Planning for HIV/AIDS in Sub-Saharan Africa organized annually by the University of KwaZulu-Natal, Durban.

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**Novartis**

www.novartis.com/

For its breakthrough cancer therapy Glivec®, Novartis designed the Glivec® International Patient Assistance Program (GIPAP), available in countries where regulatory approval or at least an import licence has been obtained and where there is no comprehensive government reimbursement for Glivec®. Since its implementation in early 2002, Novartis has provided Glivec® at no cost, through GIPAP, to more than 15,000 patients in more than 75 countries who would not otherwise have access to the medicine to treat their life-threatening disease. GIPAP meets the unique challenges of providing an innovative medicine serving a select patient population on a global scale through a 'patient direct' assistance program. The patient direct approach ensures that medicines are delivered to patients through a network of more than 780 registered physicians and over 280 qualified treatment centers worldwide.

- For its employees and their families in the developing world, Novartis has established a comprehensive program of medical services that includes free or heavily subsidized facilities for diagnosis, treatment and psychosocial care of workers with HIV/AIDS or other poverty-related diseases such as TB or malaria.
- In Southern and East Africa, the Novartis Foundation, in collaboration with the Swiss and Swedish Development Agencies, supports different initiatives to improve AIDS-orphans' livelihood and future prospects through individual counseling to help them cope with their situation, capacity-building of teachers, social workers and other care-givers as well as social and economic empowerment skills development, access to credit and income generating activities.

- In Mali, the Novartis Foundation, together with the Ministries of Health and Social Development, has initiated a program aiming at improving access to primary health care services in rural areas. This program includes measures to improve geographical accessibility of health services, affordability through the strengthening community-based health insurance schemes, quality of care at local health centers, cultural acceptability of the health services as well as to improve the infrastructure of health care facilities.
- In order to strengthen human resource development in the health sector in Tanzania and beyond, the Novartis Foundation for Sustainable Development and its partners set up a new health training centre. The Tanzanian Training Centre for International Health underwent substantial renovation and received new infrastructure, new management and is now steered by a board. The Centre trains assistant medical officers, a priority cadre for the Ministry of Health, as they enhance the quality of essential primary health care services, especially at district level. It also offers course facilitation services to external course providers in health. This allows the centre to increase its own financial self-reliance. Such an improved teaching and learning environment will contribute to better medical and public health expertise, which in turn is needed to improve the overall health situation of the population, especially in rural areas.
- In Sri Lanka, the Novartis Foundation supports the efforts of the Sarvodaya Shramadana Movement that is active in over 12,000 villages, applying a holistic and integrated approach to health development in villages. In order to empower these communities on the basis of Buddhist principles, Sarvodaya has identified ten basic needs, including a clean environment (e.g. sewage and drainage system), adequate provision of clean drinking water, balanced nutrition and simple housing. Means to fulfill these basic needs are community activities to build the necessary infrastructure as well as training and education in nutrition and reproductive health for the younger generations.
- Novartis donates intraocular lenses to NGOs for cataract surgery for patients with inadequate means in developing countries.

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**Pfizer**

www.pfizer.com

- Through its Global Health Fellows program, Pfizer makes its employees available for assignments of up to six months with non-governmental organizations (NGOs) and multilateral organizations (MLOs) dedicated to addressing the health needs of people around the world. During their assignments, colleagues train and support their local counterparts, transferring skills so that the impact of their assignment is sustainable.
- Over 90 Fellows have been deployed since 2003 and include Pfizer physicians, nurses, epidemiologists, laboratory technicians, marketing managers, financial administrators and health educators from Africa, Asia, Australia, Europe, Latin America and the United States. Pfizer's partners in the program include USAID, FHI, Project Hope, WaterAid, AMREF and Population Services International. Fellowship assignments are designed and implemented by Pfizer's partners according to their needs, and Pfizer has committed to fund transportation, lodging and other expenses for the Fellows while maintaining their positions within the company.
- Pfizer committed $15 Million through President Clinton's Global Initiative to Address Critical Treatment Gaps in Malaria.

**International Trachoma Initiative** -- A public-private partnership dedicated to eliminating trachoma, the world's leading cause of preventable blindness, through health worker training, patient education and donations of the antibiotic, Zithromax(R) (azithromycin). The ITI has given 37

million treatments of Zithromax(R) (azithromycin) to trachoma patients in 12 countries as part of the WHO SAFE strategy that combines prevention and treatment. Since 1998 the program has supported the training of thousands of health workers around the world who, in turn, have completed more than 220,000 surgeries to treat advanced cases of trachoma.

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**sanofi-aventis**

www.sanofi-aventis.com

Besides combating sleeping sickness in African endemic countries with the WHO and TB in South Africa with the Nelson Mandela Foundation, and contributing to the WHO polio eradication campaign with vaccines donations, sanofi-aventis supports a number of other projects in developing countries such as:

- The creation of a healthcare center to treat leishmaniasis in Brazil;
- The development of a program to address epilepsy in Mali, which includes making treatments available and affordable to patients, fighting against social stigma and educating communities;
- The creation of a network of schools for street children and dispensaries for ethnical minorities in Vietnam;
- The provision of clean water in villages of Burkina-Faso, Benin, Togo and Senegal coupled together with hygiene education programs for school children in these villages;
- In Kyrgyzstan, satisfactory medical care is often lacking and healthcare delivery is extremely difficult in this mountainous country, where more than 60 percent of the inhabitants of rural regions are living below the poverty line. Some 18,000 people are affected by diabetes in Kyrgyzstan and as humanitarian aid, Sanofi-aventis has provided $70,000 worth of insulin; and
- Medical experts expect that the number of diabetes cases in Togo (West Africa) will triple from 60,000 today to more than 180,000 in the next 25 years. In anticipation of this development, the German Pharma Health Fund (of which Sanofi-aventis, is a member) is supporting a further training project on diabetes in Togo, aimed at familiarizing doctors, nursing staff and patients with modern methods of diagnosis and therapy. This initiative is to be expanded to other developing countries.

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**Shire BioChem Inc.**

Since 2000 Shire BioChem has donated over $2,388,979 in product, including the Fluviral vaccine to Colombia and over $32,000 in cash donations to HPIC.

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**Schering AG**

www.schering.de

For more than 45 years, Schering AG has supported family planning programs in over 125 countries with its high quality products in close co-operation with state-run organizations (BMZ - Federal Ministry for Economic Cooperation and Development, KFW - The German Development Bank, GTZ - German Association for Technical Co-operation, the UK's DFID, DANIDA, etc), multilateral organizations (UNFPA, the World Bank, the WHO, etc), and private organizations (International Planned Parenthood Federation, Population Services International, Futures Group, Marie Stopes, Missionpharma, etc).

- During 45 years, more than 2 billion cycle packs of oral contraceptives have been provided to family planning organizations and users in the Developing World. The product range offered to Family Planning Programs include a wide choice of contraceptive methods, (mono-, triphasic combined oral contraceptives and progestogen-only products), injectables (one and three monthly), implants and intrauterine devices/systems. These are of the same quality as the

products available on the private market but are sold at no profit or are given free in a number of emergency cases (e.g. oral contraceptives for refugee camps in Rwanda, Ethiopia, the former state of Zaire, and for a social marketing project in Cambodia).

- Training programs like the Materra project in Vietnam, Laos, Myanmar and Cambodia (education of young gynecologists) are also part of Schering's engagement. Since sexual education is vital to contraception, Schering AG supports programs like the CELSAM (Centro Latinoamericano Salud y Mujer) campaign in 1999, providing detailed information in all Latin American countries by radio ads, educational programs for schools and universities, telephone hotlines and information booths on the streets. With a $2 million contribution, Schering AG helped to start the project.
- Through the German Pharma Health Fund, the company also supports the development and use of portable, tropicalized Minilabs, that provide easy-to-use detection of counterfeit and substandard medicines.

Note: Schering AG is a multinational company with its headquarters in Germany. It is not affiliated with Schering-Plough (USA).

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**Wyeth**

www.wyeth.com

- In 2002 a WHO study involving 40,000 South African children showed that a new pneumococcal vaccine developed by Wyeth could save the lives of 500,000 children a year in poor countries. Until now, no vaccine was available to protect against pneumonia, the leading cause of death of children worldwide, killing about 4 million per year. The vaccine reduced the incidence of pneumonia by more than 20 percent overall. It also reduced the incidence of invasive pneumococcal disease by more than 80 percent in children not infected with HIV and more than 50 percent in those with HIV. Also participating in the study was the South African Medical Research Council.
- Wyeth also helped fund the provision of the newly developed pneumococcal conjugate vaccine for a five-year clinical trial in Gambia, as part of one of the largest clinical trials of its kind in a developing country. The Medical Research Council (U.K.) conducted this study in cooperation with the Gates Foundation, the National Institutes of Health (U.S.), the U.S. Agency for International Development (USAID), the WHO and others.
- Results from the Gambia study, which were published in The Lancet in March 2005 showed that: 1) children receiving the pneumococcal vaccine had 15 percent fewer hospital admissions than those who did not; 2) the vaccine was 77 percent effective in preventing pneumococcal infections caused by the vaccine sterotypes; 3) there were 37 fewer cases of pneumonia in the children who received the vaccine compared with children who received a controlled vaccine.
- Wyeth has also been in collaboration with the WHO to investigate the potential of moxidectin, a product of Wyeth's Fort Dodge Animal Health division, as a new generation treatment option for river blindness in sub-Saharan Africa. Phase II proof-of-concept studies with moxidectin are scheduled to start in Ghana in June 2006.