Partnerships to Build Healthier Societies in the Developing World

The International Federation of Pharmaceutical Manufacturers & Associations is the global non-profit NGO representing the research-based pharmaceutical, biotech and vaccine sectors. Its members comprise 25 leading international companies and 44 national and regional industry associations covering developed and developing countries. The industry’s R&D pipeline contains hundreds of new medicines and vaccines being developed to address global disease threats, including cancer, heart disease, HIV/AIDS and malaria. The IFPMA Clinical Trials Portal (www.ifpma.org/clinicaltrials), the IFPMA’s Ethical Promotion online resource (www.ifpma.org/EthicalPromotion/) and its Health Partnerships information (www.ifpma.org/Healthpartnerships) help make the industry’s activities more transparent. The IFPMA strengthens patient safety by improving risk assessment of medicines and combating their counterfeiting. It also provides the secretariat for the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH).

The program information in this book is also available in searchable form in the IFPMA website, at www.ifpma.org/healthpartnerships/, and on the Global Health Progress website www.globalhealthprogress.org
Cover photo: 2008 marks the tenth anniversary of the Global Alliance to Eliminate Lymphatic Filariasis. More than 1 billion people in approximately 80 countries live at risk of contracting lymphatic filariasis (LF). More commonly known as elephantiasis, LF is a devastating parasitic infection spread by mosquitoes. Currently over 120 million people are infected, with more than 40 million incapacitated or disfigured by the disease. GlaxoSmithKline and Merck & Co., Inc. work with the Global Alliance to Eliminate Lymphatic Filariasis, the goal of which is to free the world of this disfiguring and disabling disease by 2020. The WHO currently recommends that LF be prevented with a combination of albendazole (donated by GSK) with either DEC, or Mectizan® (donated by Merck & Co., Inc.). Medicine administration for people living in endemic areas is recommended by WHO once a year for at least five years to break the cycle of transmission. So far, Egypt, several Pacific Island countries, Sri Lanka, Zanzibar, and Togo have completed the WHO recommended five annual mass medicine administrations. WHO estimates that over 130 million people – 30 million of whom are children – have begun to be protected from LF. The photo shows a youngster’s height being measured. This will determine how many tablets he will receive. (GlaxoSmithKline)
Partnerships to Build Healthier Societies in the Developing World
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Note: "Merck & Co., Inc." has its headquarters in Whitehouse Station, NJ, USA and operates in most countries outside the USA as Merck Sharp & Dohme. "Merck KGaA" has its headquarters in Darmstadt, Germany; "Bayer Schering Pharma AG", with its headquarters in Berlin, Germany, is a division of "Bayer HealthCare AG", which has its headquarters in Leverkusen, Germany; "Schering-Plough" has its headquarters in Kenilworth, NJ, USA. Merck & Co., Inc., Merck KGaA, Bayer HealthCare and Schering-Plough are all members of the IFPMA.
Good health depends on access to medicines and on adequate public health care systems. Health programs implemented by the research-based pharmaceutical industry and partners are helping to address both issues. (GlaxoSmithKline)
INTRODUCTION

This publication provides an overview of long-term health development programs implemented by the research-based pharmaceutical industry and partners to help achieve the health-related Millennium Development Goals (MDGs) and improve global health.

Eight Millennium Development Goals (MDGs) were adopted by 189 United Nations’ member states in 2000. Some target poverty and illiteracy, but three specifically target health: 4 – Reduce child mortality, 5 – Improve maternal health and 6 – Combat HIV/AIDS, malaria and other diseases.

Improving health in resource-poor countries presents society with a complex challenge that requires a far larger mobilization of resources, capacities and skills than either the public sector or any single industry can achieve on its own. Public-Private Partnerships have now become a distinctive feature of the healthcare landscape in low- and middle-income countries. Carrying the burden of some of the world’s worst diseases whilst also facing severe shortages of all kinds, these countries need very broad health interventions, which experience has shown can only be delivered through multi-sector partnerships.

In this publication, partnership programs are grouped by disease area. The programs listed in the sections on HIV/AIDS, Tuberculosis, Malaria, Tropical Diseases and Preventable Diseases are focused on MDG 6. A further section is devoted to Child and Maternal Health programs, aimed at MDGs 4 and 5. There is also a section for programs addressing Chronic Diseases, which are not strictly speaking the focus of the MDGs, but which pose a growing health challenge for middle- and even low-income countries, while "Other Health Initiatives" documents programs which are not focused on a specific disease area.

Some partnership programs focus on improving access to medicines, through donations or preferential pricing. Others aim to build health care capacity in recipient countries, primarily by training local health workers, or by providing material support, such as equipment and buildings. Many programs also aim to educate patients or the general population about specific health threats. Finally, there are many partnership programs which are focused on research and development for diseases of the developing world. The program information in this book is also available in searchable form in the IFPMA website, at www.ifpma.org/healthpartnerships/, and on the Global Health Progress website www.globalhealthprogress.org.

The long-term contributions by the pharmaceutical industry to help improve developing world health are substantial. The IFPMA Health Partnerships Survey showed that, in the period 2000-2006, the industry provided enough health interventions – medicines, vaccines, training and education – to help nearly 1.4 billion people in developing countries. This assistance was valued conservatively at USD 6.7 billion (the survey methodology and data have been validated by the London School of Economics and Political Science). This contribution is consistent with the pharmaceutical sector’s established position as a leader in corporate philanthropy. The Committee Encouraging Corporate Philanthropy, the corporate philanthropy forum of global company CEOs, surveyed 136 major corporations’ giving in 2006. Overall, it found companies gave an average of 0.88% of pre-tax profit, but within the Health Sector (in which 10 out of 16 companies are pharmaceuticals) the average was far higher, at 3.70%.¹

While this publication it is not necessarily exhaustive, it does cover the great majority of initiatives currently underway in resource-poor countries. The short description of each program provides a general overview of objectives and achievements but cannot do justice to the economic, organizational and even political challenges that have to be overcome.

The essence of any partnership is that it can only succeed through a collaborative effort on the part of all those willing and able to contribute. The pharmaceutical industry will continue to play its part in working to secure achievement of the Millennium Development Goals by making a sustained contribution to building healthier societies.

Dr. Harvey E. Bale
Director General
IFPMA

Estimated adult and child deaths from AIDS during 2007 (2006)

North America
21,000 (18,000)

Caribbean
11,000 (19,000)

Latin America
58,000 (65,000)

Middle and North
25,000 (30,000)

A total of 33.2 million people were living with HIV in 2007. That year, an estimated 2.5 million people became newly infected with HIV and an estimated 2.1 million lost their lives to AIDS.

Sub-Saharan Africa remains the most affected region: more than two thirds of all people living with HIV live in this region, 22.5 million people in 2007. New HIV infections are heavily concentrated among young people and more adult women than ever before are now living with HIV.

Access to antiretroviral therapy in low- and middle-income countries continued to grow, with more than two million people living with HIV/AIDS receiving treatment in December 2006, a 54% increase over the 1.3 million people on treatment one year earlier in these countries.

The increasing resistance to first-line antiretroviral therapies underlines the need for continued R&D to develop new therapies. In 2007, pharmaceutical researchers were testing 92 medicines and vaccines to treat and prevent HIV/AIDS and related conditions. A total of 30 medicines to treat HIV/AIDS have been approved since the virus was first identified more than 20 years ago, including two in 2007.

<table>
<thead>
<tr>
<th>Region</th>
<th>2007 estimate (2006 estimate)</th>
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<tr>
<td>Western and Central Europe</td>
<td>12,000 (12,000)</td>
</tr>
<tr>
<td>Eastern Europe and Central Asia</td>
<td>55,000 (84,000)</td>
</tr>
<tr>
<td>East Africa</td>
<td>36,000 (36,000)</td>
</tr>
<tr>
<td>Sub-Saharan Africa</td>
<td>1.6 million (2.1 million)</td>
</tr>
<tr>
<td>East Asia</td>
<td>32,000 (43,000)</td>
</tr>
<tr>
<td>South and South-East Asia</td>
<td>270,000 (590,000)</td>
</tr>
<tr>
<td>Oceania</td>
<td>1,400 (4,000)</td>
</tr>
</tbody>
</table>

Total AIDS deaths in 2007: 2.1 million (2.9 million)

The Accelerating Access Initiative (AAI), begun in 2000, is a partnership between UNAIDS, the World Health Organization (WHO), the UN Children’s Fund (UNICEF), the UN Population Fund (UNFPA), the World Bank and nine research-based pharmaceutical companies (Abbott, Boehringer Ingelheim, Bristol-Myers Squibb, GlaxoSmithKline, Gilead Sciences, Merck & Co. Inc., Pfizer, Roche and Tibotec). Participants in AAI are committed to working with governments, international organizations and other stakeholders to find ways to broaden access, whilst ensuring rational, safe and effective use of medicines for HIV/AIDS.

The strong commitment of the AAI companies to improve access to treatment has manifested itself in many innovative ways. All AAI companies have individual programs through which they provide their own antiretroviral medicines at more affordable prices in developing countries. Some AAI companies have also expanded manufacturing capacity to meet product demand in the developing world. Individual AAI companies are also taking other actions to increase the overall availability of ARVs, including the granting of voluntary licenses or non-assert declarations, contract manufacturing with generic manufacturers and technology transfer agreements. These efforts are delivering results. As of October 1, 2007, some 830,000 patients in developing countries were estimated to be taking one or more medicines supplied at preferential prices by an AAI company. In addition, the number of patients in developing countries treated with generic ARVs – including those through cooperative efforts with AAI companies – has increased significantly.

AAI companies also recognize that expanded access to medications requires a collaborative approach with governments, NGOs, multilateral organizations, and other public and private bodies. Many AAI companies are involved in initiatives to strengthen healthcare systems, streamline product registrations, and conduct clinical studies in developing countries. AAI companies also continue to invest significantly in research and development of new medications – including pediatric formulations – and diagnostics, to help combat the global HIV/AIDS pandemic.

In 2002, Abbott made a commitment to sell its HIV medicines at USD 500 per patient per year in Africa and least developed countries (LDCs), as defined by the United Nations. In 2006, Abbott announced that the heat-stable Aluvia™ (lopinavir/ritonavir) tablet, too, would cost USD 500 per patient per year in Africa and the LDCs. The Abbott preferential price of USD 500 for Africa and LDCs is lower than any known generic lopinavir/ritonavir price, and no generic versions of Kaletra are WHO pre-qualified.

Some of the realities of the HIV/AIDS epidemic have changed since Abbott made the commitment in 2002. It became clear that concerns with affordability and access were not limited to Africa and LDCs. Therefore, Abbott expanded its preferential pricing program to create a new tier for low- and lower-middle-income countries, as defined by the World Bank, in August 2006. In April 2007, Abbott announced a further reduction in the mid-tier price to USD 1,000 per patient per year in these countries. After these reductions in the mid-tier price, Kaletra® and Aluvia are now the most affordable protease inhibitors (PIs), compared to other boosted or unboosted PIs that are recommended in WHO, U.S. Department of Health and Human Services (DHHS), the British HIV Association (BHIVA), and the International AIDS Society (IAS)-USA guidelines.

Designed to ensure long-term sustainable access to high-quality HIV medicines, this program includes:

- Sustainable pricing for governments, non-governmental organizations (NGOs), and public funders of HIV medicines in developing countries;
- Broad registration of the new, non-refrigerated lopinavir/ritonavir tablet formulation throughout the world, including Africa, Asia, Latin America and the Caribbean;
- Investment in additional manufacturing capacity to meet demand for high-quality second-line HIV treatments; and
- Broad registration of the new, pediatric low-dose tablet formulation of lopinavir/ritonavir to meet the treatment needs of HIV-positive children worldwide.

Abbott also offers a rapid (15 minute) HIV test at no profit to testing programs in Africa and the LDCs. Rapid on-site testing can have a significant impact in the fight against HIV/AIDS. Using a small amount of whole blood, serum or plasma, any hospital or program in a remote setting can obtain results regardless of access to lab equipment or electricity. To date, Abbott has shipped more than 93 million rapid HIV tests at no profit.
Boehringer Ingelheim Access

HIV/AIDS
Boehringer Ingelheim
Governments in most recipient countries
Since 2000
Access – Donation, Pricing
59 countries
www.boehringer-ingelheim.com

As part of its policy to extend access to Viramune®, Boehringer Ingelheim offers its product Viramune® (nevirapine) for single-dose use in the prevention of mother-to-child transmission for free through the Viramune® Donation Program. So far, more than 1.3 million mother/child doses have been made available to 166 programs in 59 countries.

For chronic treatment, Boehringer Ingelheim charges a substantially reduced price for all countries classified by the World Bank as low income, all Least Developed Countries according to UN definition and for all countries in sub-Saharan Africa – a total of 78 countries. In addition, all middle income countries qualify for a lowered price (63 countries).

For more information on the company’s other HIV/AIDS activities, see the HIV/AIDS – Mother & Child Programs section, ARV Licensing in Developing Countries (non-assert declarations) and Additional Health Initiatives.

Bristol-Myers Squibb Global Access Program

HIV/AIDS
Bristol-Myers Squibb
Various partners, including Health Ministries
Since 2001
Access – Pricing
Africa & least developed countries
www.bms.com

The goal of the Bristol-Myers Squibb Global Access program is to enable broad access to the company’s HIV medicines at no-profit prices in the regions most impacted by HIV and with limited ability to pay, notably sub-Saharan Africa. The Global Access program is based on three essential pillars of activity and policy: 1) no-profit pricing policy; 2) patent policy; and 3) efforts to enable generic manufacturing. Information on the latter two activities can be found below under the heading “ARV Licensing in Developing Countries”.

In 2001, BMS announced that it would provide all of its HIV medicines at no-profit prices in sub-Saharan Africa, because of the extreme burden of disease there, combined with the region’s limited ability to pay for HIV medicines. In July 2005, the company announced a further reduction in the price of pediatric formulations from no-profit to significantly below cost in an attempt to reduce all barriers hampering accelerated, broad access to treatment for the millions of children in sub-Saharan Africa who need these medicines most. BMS has also implemented a differential pricing policy globally, to enable collaboration with and support for government activities in regions with high incidence and low ability to pay for HIV medicines.

Salvatory (Tanzania) was tested and found to be HIV+, but is healthy and coping well due to the medical care and social support he receives at Mt. Meru hospital, a facility that has been strengthened by Abbott Fund. (Abbott)
Gilead Access Program

HIV/AIDS
Gilead
Various partners
Since 2003
Access – Pricing
Least-developed countries
www.gilead.com/Gilead_Access_Program

Gilead Sciences, Inc. is committed to providing access to its HIV medicines to all patients who need them worldwide, regardless of income or geography. Gilead has developed a tiered pricing system for its HIV medicines, including Viread® (tenofovir disoproxil fumarate) and Truvada® (emtricitabine and tenofovir disoproxil fumarate), based on a country's economic status, HIV prevalence, and other specific country requirements or issues. It offers substantial price reductions through its Access Program in more than 125 countries, representing two-thirds of the countries in the world, and the regions hardest hit by the AIDS epidemic.

Gilead has established an international network of distributors, whose local knowledge helps to accelerate regulatory approval of its medicines in different countries. They also provide local outreach and on-the-ground logistics, and help to ensure secure distribution of Gilead’s HIV medicines in the developing world.

GlaxoSmithKline Access to ARVs

HIV/AIDS
GlaxoSmithKline
Various partners
Since 1997
Access – Pricing
31 developing countries
www.gsk.com

GlaxoSmithKline has offered sustainable preferential pricing for certain antiretrovirals (ARVs) since 1997. All its ARVs are now available at not-for-profit prices to public sector customers and not-for-profit organizations in all Least Developed Countries and all of sub-Saharan Africa – 64 countries in total. In addition, all private employers in sub-Saharan Africa who provide care and treatment to their uninsured staff can purchase its ARVs at not-for-profit prices. All CCM projects fully funded by the Global Fund to Fight AIDS, TB and Malaria and projects funded by the US President’s Emergency Plan for AIDS Relief (PEPFAR) are also eligible.

GSK’s prices are sustainable – it does not make a profit on them, but it does cover its costs. This means that it can sustain supply of these high-quality products for as long as they are needed. GSK’s not-for-profit prices are applicable to orders of any size and are not dependent on large order quantities. They also include insurance and freight costs. In February 2008, GSK introduced significant new price reductions averaging 21% across the range of its ARVs. This was the fifth time GSK has reduced its ARV prices as part of its pioneering preferential pricing policy. The most significant reduction, of almost 40 per cent, was on Ziagen® oral solution (abacavir), which is recommended by the World Health Organization (WHO) for use in first-line and second-line regimens within resource-limited settings, particularly for children. Combivir® was reduced by 17% to 54 cents per day.

In 2007, GSK shipped 13 million tablets of not-for-profit Combivir® and 72 million tablets of not-for-profit Epivir® to 31 developing countries* compared with 27 million and 59 million tablets respectively in 2006. This decrease was expected and is primarily due to more customers purchasing ARVs from generic manufacturers, including those licensed by GSK. In 2007, GSK licensees supplied more than 180 million tablets of their versions of Epivir® and Combivir® to Africa. In many ways, this a positive indication that GSK’s licensing policy is working (see section on ARV Licensing in Developing Countries).

Two-thirds of all people living with HIV/AIDS are in sub-Saharan Africa. (GlaxoSmithKline)
Since 2001, Merck & Co., Inc. has had a differential pricing policy whereby the Company provides its anti-retroviral medicines in the poorest countries and those hardest hit by the AIDS pandemic – as defined by the United Nations – at prices at which Merck does not profit. The offer extends to the governments of these developing countries as well as to international donor agencies, non-governmental organizations (NGOs), charitable organizations and private-sector employers.

Merck’s ARV pricing policy applies to all of the company’s ARVs (Crixivan™, Stocrin™, Atripla™ and Isentress™). For each product, Merck gives its lowest price to the world’s least economically developed countries and those countries hardest hit by the HIV/AIDS pandemic, as measured by adult HIV prevalence. Countries with a higher degree of economic development and/or lower prevalence rate receive a significantly discounted price. For the most economically-developed countries, Merck applies competitive, market-based principles in pricing its ARV products.

- Of the approximately 2 million people on ARV treatment living in low and medium income countries, more than one-third – or an estimated 720,000 patients – are being treated with regimens containing one of Merck’s ARVs;
- More than 86% of patients using Merck ARVs live in countries where Merck offers them at not-for-profit prices;
- More than 94% live in Africa, Asia/Pacific, Latin America and the Caribbean, where the HIV/AIDS pandemic has had the biggest impact;
- Merck’s not-for-profit or significantly discounted ARV prices are available to patients in more than 136 countries and territories;
- Children represent an estimated 11% of all patients being treated with a Merck ARV, using pediatric formulations.

In 2002, Roche recognized that, as efforts to scale up the number of people on first-line therapy in resource-limited countries became successful and greater numbers of people received treatment, the need for second-line treatment options would also become increasingly important. In response, Roche committed to innovative, transparent policies to remove barriers to its second-line HIV protease inhibitor medicines in countries where resources are fewest and the need for treatment is greatest.

Roche supplies its HIV protease inhibitors, Invirase® and Viracept® (including pediatric powder), at no profit prices for people living in Least Developed Countries (as defined by the United Nations) and in sub-Saharan Africa. These prices are the lowest at which these medicines can be provided in a sustained, long-term manner, and have been shown to be similar or less than that of generic versions of the medicine.

In addition, Roche established significantly reduced pricing for Invirase and Viracept for low and lower middle income countries (as defined by the World Bank), where there is need for access to HIV/AIDS treatments, and where local governments are able to play a greater role and make a more significant contribution towards the provision of public healthcare.

The no profit prices apply to more than 23 million people in 63 countries, covering 70% of all people living with HIV/AIDS in Least Developed Countries. Including low and lower middle-income countries, reduced prices are offered to 86% of all people living with HIV/AIDS.
Combinations of different ARVs are used to treat people living with HIV/AIDS to reduce the risk of them developing resistance. Fixed dose combinations make life easier for HIV/AIDS patients and increase compliance by reducing the number of pills to be taken each day. Atripla® – the first once-daily single tablet regimen for the treatment of HIV infection in adults – is a fixed dose combination of the non-nucleoside reverse transcriptase inhibitor (NNRTI) efavirenz, and the nucleoside reverse transcriptase inhibitors (NRTIs) emtricitabine and tenofovir disoproxil fumarate. Efavirenz is marketed by Bristol-Myers Squibb as Sustiva® and by Merck & Co., Inc. as Stocrin®. Emtricitabine and tenofovir disoproxil fumarate are commercialized by Gilead Sciences under the tradenames Emtriva® and Viread®.

Atripla® was developed by Bristol-Myers Squibb and Gilead and approved by the US FDA in July 2006, Health Canada in October 2007 and the European Commission in December 2007. On January 15, 2008, the WHO granted Atripla® with prequalification status.

In August 2006, Gilead and Merck announced an agreement for the distribution of Atripla® in 94 developing countries around the world. Gilead is manufacturing Atripla® using efavirenz supplied by Merck, and Merck is distributing Atripla® in these markets. In all of these countries, Atripla® is being sold at significantly discounted prices. As of 1 April 2008, 55 countries – including most in sub-Saharan Africa – had either granted regulatory approval for Atripla® or allowed the product to be imported. Tens of thousands of patients are already benefitting from this first-of-its-kind fixed dose combination ARV.
Pharmaceutical companies’ preferential pricing of antiretrovirals make effective, safe, high quality HIV/AIDS treatments available to developing countries. In some cases, companies also issue voluntary licenses (VLs) which allow local manufacturers in developing countries to produce and sell generic versions of their products. VLs are not a universal solution to HIV/AIDS but a response to specific circumstances. Local factors encouraging VL use include a severe HIV/AIDS epidemic, adequate health care infrastructure, suitable economic conditions and sufficient manufacturing expertise. Local manufacturers must ensure a long-term supply of good-quality medicines and implement safeguards to prevent diversion of medicines to wealthier markets.

Along with its policy to expand access to nevirapine in Least Developed Countries, low income countries and all countries in Africa, Boehringer Ingelheim offers a non-assert declaration to all WHO pre-qualified manufacturers, stating that it will not enforce its nevirapine patent rights in these countries, in order to ensure supply at lowest possible cost. To date, seven generic producers have accepted the non-assert declaration.

Since 2001, Bristol-Myers Squibb has had a policy of not enforcing its patents for HIV products in sub-Saharan Africa and has immunity from suit agreements for stavudine and didanosine with five African generic companies. In February 2006, it concluded technology transfer agreements with generic companies Aspen PharmaCare (South Africa) and Emcure Pharmaceuticals (India), for its newest antiretroviral, atazanavir (sold as Reyataz® in the US). Bristol-Myers Squibb has transferred intellectual property and technical know-how related to the manufacturing, testing, packaging, storage and handling of the active pharmaceutical ingredient and finished dosage form. Aspen and Emcure are now working on regulatory submissions for sub-Saharan Africa and India.

GlaxoSmithKline granted its first VL in 2001 and has now negotiated eight licensing agreements for its ARVs in Kenya and South Africa. Some of these cover just parts of Africa, while others apply to all of sub-Saharan Africa. In 2006, GSK-licensed manufacturers significantly increased their manufacturing capacity to supply larger quantities of ARVs at lower prices. This trend is welcome, as it gives customers in sub-Saharan Africa greater choice and improves security of supply. In 2007, GSK licensees supplied more than 180 million tablets of their versions of Epivir® and Combidivir® to Africa.

Merck & Co., Inc. is committed to seeking additional ways to reduce the cost of is ARVs and increase access for people living in the world’s poorest countries and those hardest hit by the pandemic, including partnering with low cost manufacturers and suppliers to achieve incremental efficiencies. For example, in 2008, Merck granted non-exclusive, royalty-free licenses to the manufacturing companies Cipla and Aurobindo for the manufacture and supply of a generic form of efavirenz for southern Africa, including South Africa. These licenses are in addition to those previously provided to Adcock Ingram and Aspen Pharmacare, two of South Africa’s largest generic manufacturers.

Roche has committed not to file any new patents or enforce existing patents for any of its medicines in the UN-defined Least Developed Countries. Nor will it file new ARV patents or enforce existing patents for its antiretrovirals in sub-Saharan Africa. As a result, generic versions of ARVs can be produced in these countries, encompassing 86% of all people living with HIV.

In 2006, Roche committed to an “AIDS Technology Transfer Initiative”, to help local firms in Least Developed Countries and sub-Saharan Africa to manufacture second-line HIV medicines. Agreements have been signed with 9 companies in Bangladesh, Ethiopia, Kenya, South Africa, Tanzania and Zimbabwe. Expressions of interest have been received from 36 more companies in 16 eligible countries and assessment visits have been conducted with 32 of these. Roche has expanded its program in 2008 to include training seminars for local manufacturers across sub-Saharan Africa, focused on the development of good manufacturing practices to improve locally produced medicines – not just ARVs.
## Abbott Fund’s Program for Supporting Children Affected by AIDS

Abbott has been a longstanding leader in improving the lives of children affected by HIV/AIDS and continues to make a significant contribution to advancing pediatric HIV treatment. Abbott Fund is partnering with several organizations to expand access to health care for mothers and children affected by HIV/AIDS in developing countries. Since 2001, more than 700,000 children and adults have received services in Burkina Faso, India, Kenya, Malawi, Romania, Tanzania and Uganda.

Abbott Fund supported the Baylor College of Medicine in establishing a pediatric HIV/AIDS treatment program in Romania that reduced the death rate for children with HIV in the program by more than 90 percent. Baylor is now replicating this model program across Africa, including opening the first pediatric treatment center in Malawi in 2006 with the support of the Government of Malawi and Abbott Fund. Baylor and Abbott Fund also partnered to establish the Baylor Children’s Clinical Centers of Excellence Network to train health professionals and share best practices in HIV care. These pediatric health workers together treat 20,000 children with HIV – the largest number of children with HIV in any treatment program worldwide.

Abbott Fund is working with Catholic Medical Mission Board (CMMB) to provide services to help prevent mother-to-child HIV transmission in 70 health facilities in six provinces in Kenya. Through the partnership, testing, care and treatment will be provided to pregnant women and exposed babies and infants.

The Abbott Fund-Elizabeth Glaser Pediatric AIDS Foundation (EGPAF) partnership in Tanzania and Uganda is working to accelerate enrollment of HIV-infected children into care and treatment programs, and to train and support health care workers.

Abbott Fund and Family Health International (FHI) are partnering in Tanzania and Malawi to reduce HIV transmission from mother to child; expand access to comprehensive care and treatment for HIV infected children; and support the government in creating an enabling environment through policy formulation and guidelines on pediatric HIV and AIDS management, in order to ensure the project’s sustainability.

## Elizabeth Glaser Pediatric AIDS Foundation

The Elizabeth Glaser Pediatric AIDS Foundation (EGPAF) was set up in 1988 to prevent pediatric HIV infection and to eradicate pediatric AIDS through research, advocacy, and prevention and treatment programs. It works in two broad program areas: HIV/AIDS Research and Training Programs, and International Family AIDS Initiatives. Abbott, Boehringer Ingelheim and Johnson & Johnson are major supporters of EGPAF and its work.

Through its International Family AIDS Initiatives, the Foundation is increasing access to services for prevention of mother-to-child transmission (PMTCT) as well as care and treatment services, including antiretroviral therapy for women, children and families.

EGPAF collaborates with host governments, international healthcare facilities, non-governmental organizations and community-based organizations to plan, implement and/or expand programs. It also provides technical assistance and support for community mobilization and training of health care workers, HIV counseling and testing, mother-to-child prevention regimes and infant feeding education.

As of June 2007, more than 3.9 million women have accessed Prevention of Mother-to-Child (PMTCT) services and almost 3.5 million have been counseled. Among these, over 3.1 million individuals have been tested, 330,000 identified as HIV-positive, and ARV prophylaxis (primarily single dose nevirapine) has been provided to over 260,000 women and over 160,000 infants.

EGPAF is working with Abbott Fund on a pilot project in Tanzania to increase identification, care and treatment of young HIV-positive or exposed children and their mothers, through Reproductive and Child Health (RCH) clinics, general clinics and inpatient wards. EGPAF is also implementing routine testing of children and/or mothers of unknown HIV status in well-child clinics and inpatient pediatric wards.

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 a direct collaboration in the PMTCT Donation Program, for instance in Swaziland and Tanzania.

J&J has partnered with the EGPAF since 2003 and now expanded to 770 sites in six countries. As of June 2007, the EGPAF–J&J PMTCT Partnership has directly contributed to reaching more than 860,000 women with counseling, providing nearly 760,000 women with HIV testing, and administering ARV prophylaxis to over 39,000 HIV-positive mothers.
Life Skills: Community Support for Children Affected by HIV/AIDS

HIV/AIDS
Johnson & Johnson
The Life Skills Development Foundation
Since 2005
Capacity Building – Training, Education
Thailand
www.lifeskills-stl.org

There are some 150,000 AIDS orphans in the Upper Northern region of Thailand. From economic struggle and emotional hardship to social stigma and isolation, they face many problems. The Life Skills Development Foundation, a NGO that provides life skills education and training for children, youth, women and families, works in many districts to reach children affected by HIV/AIDS. With the help of Johnson & Johnson, the foundation provides assistance to these children and their caregivers through HIV/AIDS education, psychological and financial support, and community education. Using a holistic approach, the foundation extends its support to the people it serves, and to the communities and schools that have a stake in the well-being of their children.

Mothers 2 Mothers Mentoring Program

HIV/AIDS
Johnson & Johnson
Mothers 2 Mothers (M2M)
Since 2005
Capacity Building – Training, Education
South Africa
www.m2m.org

Mothers 2 Mothers (M2M) provides education for South African HIV-positive pregnant women about how to prevent mother-to-child transmission of the disease and later mentor other HIV-positive pregnant women. Program participants learn about medications, nutrition, formula feeding, and how to combat stigma and societal pressures. After their infants are born, the women become mentors to new women entering the program. Mentors are paid a small salary and participate in other entrepreneurial projects, such as beading and blanket-making groups, giving them a chance to become financially independent.

Johnson & Johnson began its partnership with M2M in 2005 in East London, focusing on hospitals with high numbers of HIV-positive patients who needed better health care. Since the Company’s association with M2M, 50% more women in the area are now getting tested for HIV. Through 2006, six sites had been established with Johnson & Johnson funding in East London. M2M has established itself in five provinces in South Africa, and is looking to expand its efforts to countries such as Kenya, Rwanda and Zambia.
Each year, approximately 800,000 babies around the world become infected with HIV during their mothers’ pregnancy, during birth or through breastfeeding. Enabling pregnant women to know their HIV status before they give birth is the first step in preventing mother-to-child transmission (PMTCT) of HIV. However, for many pregnant women living in the developing world, testing is limited because of cost, time required to receive results, and lack of trained health care staff and testing facilities.

Rapid on-site testing can have a significant impact in the fight against HIV/AIDS. Using a small amount of whole blood, serum or plasma, any program in a remote setting can obtain results regardless of access to laboratory equipment or electricity. To facilitate access to rapid HIV testing, Abbott has made a commitment to donate a rapid (15 minute) HIV test to PMTCT programs in 69 countries, including all of Africa and the Least Developed Countries, as defined by the United Nations. Abbott also has extended its PMTCT donations to include testing of spouses and children of pregnant women who are found to be HIV positive through the program.

To date, Abbott has donated more than 8 million rapid HIV tests in 39 countries: Angola, Benin, Botswana, Burkina Faso, Burundi, Cambodia, Cameroon, Central African Republic, Chad, Côte d’Ivoire, Djibouti, Democratic Republic of Congo, Ethiopia, Gabon, Ghana, Guinea Bissau, Guinea, Haiti, Kenya, Laos, Lesotho, Liberia, Madagascar, Malawi, Mali, Mozambique, Namibia, Niger, Nigeria, Rwanda, Senegal, Sierra Leone, South Africa, Swaziland, Tanzania, Togo, Uganda, Zambia and Zimbabwe.

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 for Prevention of Mother-to-Child-Transmission (PMTCT) of HIV-1. There are about 120 countries eligible according to the World Bank list of developing and transient economies.

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. Next to Viramune® tablets and suspension the donation includes oral syringes for the paediatric dose and pouches for the filled oral syringe to be taken home by the mother.

The first deliveries in this program by Boehringer Ingelheim were made in late 2000 to the Republic of Congo (Brazzaville) and the Senegal, and since then more than 166 programs in 59 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. The 1 millionth mother/child dose was delivered to a program in Malawi in June 2007.

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 Ministries of Health, the Elizabeth Glaser Pediatric AIDS Foundation (EGPAF), Rotary International, church-based organizations and UNICEF.
Regional Psychosocial Support Initiative

**HIV/AIDS**
Novartis
REPSSI, Swiss & Swedish Development Agencies
Since 2002
Capacity Building – Support
13 developing countries
www.novartisfoundation.org

In Southern and Eastern Africa, the Novartis Foundation, in collaboration with the Swiss and Swedish Development Agencies, supports the Regional Psychosocial Support Initiative (REPSSI). Its aim is to widely disseminate and mainstream psycho-social support (PSS) approaches for children and adolescents affected by HIV/AIDS, conflict and poverty. REPSSI provides capacity building assistance, knowledge and information to NGOs, public services and other organizations that want to integrate psycho-social support into their programs. Elements of PSS are individual counseling to help children cope with their situation, social and economic empowerment skills development as well as access to credit and income generating activities.

Roche Employee AIDS Walk

**HIV/AIDS**
Roche
United Nations Children’s Fund (UNICEF) & other partners
Since 2003
Capacity Building – Support, Education
Malawi
www.roche.com

In 2003, a pilot Roche Employee AIDS Walk was initiated across three sites in Switzerland and the USA to support children orphaned as a result of AIDS in Malawi, Africa. The event is now conducted each year, across Roche sites worldwide. In 2007, over CHF 750,000 were raised. Roche doubles the amount of money raised by employees. To date, over 40,000 Roche employees from 95 sites worldwide have raised a total of over CHF 5 million.

Funds raised via the Global Roche Employee AIDS Walk supports 7 orphan day care centers in the Mulanje district of Southern Malawi where the children are given food, clothing, vocational training and the chance of a secondary school education. The centers are supported by the European Coalition of Positive People, a UK-Malawi NGO, led by and for people living with HIV and AIDS. The centers currently look after some 3,000 children. Local community leaders and villagers are being trained to manage the centers.

A further partnership was announced in 2006 with UNICEF, to strengthen the local primary schools these children attend. Seventy five percent of children are unable to access secondary school education in Malawi. It has been shown that that HIV infection rates are at least twice as high among young people who do not finish primary school, compared to those who do.

Money raised by the Global Roche Employee AIDS Walk has paid for the construction, repair and equipment of the orphan centers and school classrooms, the drilling of bore holes for water, as well as school fees and educational equipment. All efforts are designed to make a visible, long term and sustainable difference in the lives of these children orphaned by AIDS.
Secure The Future® Children’s Clinics & PMTCT

Bristol-Myers Squibb's Secure The Future® initiative (see HIV/AIDS Capacity Building), in partnership with Baylor College of Medicine, Houston, Texas, USA, funded the first clinical center in Africa for children and families with HIV/AIDS, located in Botswana. This center now has more than 1,500 children under treatment. Additional children’s clinical centers have now been opened in Lesotho and Swaziland, and two more will open in Burkina Faso, Uganda with one location still to be sited. These centers add capacity to fight HIV/AIDS by providing modern facilities for testing, treating and monitoring children and their families, as well as training of local health care professionals.

To increase the number of trained pediatric specialists, Secure The Future® and Baylor College of Medicine created the Pediatric AIDS Corps, which will send 50 doctors a year over five years to Africa to treat some 100,000 children and train local health care professionals. The first class of 50 doctors arrived in Africa in August 2006. Additional Secure The Future® projects provide education, psychosocial care and support for orphans and vulnerable children, training, food security and income-generating projects for caregivers; and works to reduce stigma and encourage testing.

Secure the Future® has linked a prevention of mother-to-child transmission of HIV (PMTCT) program with the children’s clinic in Mbabane, Swaziland, providing PMTCT-Plus services to pregnant women, their partners and families. PMTCT-Plus services provide a continuum of care, including pre-natal testing, antiretroviral therapy, voluntary counseling, nutritional advice and security, community support and pediatric care.

Since 2004, the PMTCT-Plus program has had a mother-to-child HIV transmission rate of some 7%, while the Swazi national rate is 12%. Most significantly, the program has tracked all its babies to 12 months age, when they can be definitively tested for HIV. Such close follow-up is rare in developing world PMTCT programs. The program is now being replicated at the Piggs Peak Government Hospital, Swaziland and its associated clinics in the rural northern Hhohho area, with a goal of reaching 3,000 mothers per annum.
Abbott Fund and the Government of Tanzania have formed a unique public-private partnership to address critical needs in the fight against HIV/AIDS. In total, Abbott has invested more than USD 50 million to modernize the health care system and expand access to HIV testing and treatment.

Abbott Fund opened a new program office in Tanzania in 2007 to manage its partnerships in the country. The new office is the first outside Abbott Fund’s US headquarters and one of the only corporate foundation offices in Tanzania. Abbott Fund’s implementing partners include Elizabeth Glaser Pediatric AIDS Foundation, Touch Foundation and Family Health International.

The program is centered at Muhimbili National Hospital, the country’s leading teaching and reference hospital. Key results include a new three-story outpatient treatment center that serves hundreds of patients a day, and a renovated laboratory building that provides accurate, automated diagnostic testing crucial for lifelong monitoring of HIV and other chronic diseases. Donated laboratory equipment is maintained by field service engineers supported by Abbott Fund.

More than 13,500 health care workers have been trained or retrained to date in Tanzania. At Muhimbili Hospital, 200 physicians now serve as trainers for other health staff. More than 250 staff have been trained in lab equipment operation, while 600 senior doctors and hospital directors have received management training.

One of the most extensive hospital IT systems in East Africa has been installed at Muhimbili to track health history, referrals, test results and drug prescriptions. Volunteer Abbott employees provide technical support in construction, engineering, infection control, IT, waste management, security and laboratory management.

Facilities, systems and training have been upgraded at 90 sites throughout the country to improve VCT services and prepare for treatment programs. Due to these improvements, more than 200,000 people have received VCT services. Abbott Fund also donated 1 million HIV tests to accelerate the availability of VCT services through the Tanzanian President’s National Testing campaign that was started in July 2007.

Abbott Fund also is modernizing laboratories supporting training programs at all 23 regional hospitals across Tanzania. The modernization of the first of these laboratories, at Mt. Meru Regional Hospital in Arusha, was completed and dedicated in June 2007.

The African Comprehensive HIV/AIDS Partnerships (ACHAP) was established in 2000 by the Government of Botswana, The Merck Company Foundation, Merck & Co., Inc. and the Bill & Melinda Gates Foundation, to enhance Botswana’s response to the HIV/AIDS epidemic through a comprehensive approach to prevention, care, treatment and support. The two foundations are each contributing USD 56.5 million over several years and Merck is donating its antiretroviral (ARV) medicines Crixivan® and Stocrin® to Botswana’s national ARV treatment program, Masa (dawn), for the partnership’s duration.

Masa is one of the largest government-sponsored HIV/AIDS treatment programs in Africa. With more than 92,000 people on treatment as of January 2008 and adherence rates comparable to the developed world, Botswana has, according to the WHO, the highest percentage of ARV coverage of any low- or middle-income country in the world. The program has achieved a measurable decline in adult mortality rate, especially in the districts where ARV therapy was first made available and where ARV coverage is most extensive.

The program has built 32 regional treatment centers, increased laboratory testing capacity to screen more than 20,000 patients per year; improved information systems to track patient adherence; provided more than 4,000 health care workers with clinical training by HIV and AIDS experts; supported 17 counseling centers for people living with HIV and AIDS, trained 450 counselors; and funded more than 100 community-based projects. The program pioneered routine HIV and AIDS testing, which greatly increased the number of people knowing their HIV status, getting on treatment and reducing stigma and discrimination.

ACHAP is also supporting the development of a national plan to scale up prevention, under the leadership of the National AIDS Coordinating Agency. Its other prevention activities including condom distribution, behavioral change communication, sexually transmitted disease management and blood safety and youth prevention programs. ACHAP has also provided awareness and destigmatization education for nearly 21,000 school teachers. Prevention is starting to pay off: HIV antenatal prevalence has declined in most age groups since around 2001 and the proportion of HIV-positive infants born to HIV-positive mothers has declined from 40% to 4%.

In 2006, ACHAP expanded its support to target tuberculosis, as 65-85% of TB patients in Botswana are HIV positive, and TB is the leading cause of death among adult AIDS patients.

The partnership’s strength lies in integrating government strategy with private-sector expertise, and its success demonstrates the value of public-private partnerships in the fight against HIV/AIDS – the lessons which are being applied elsewhere. Priorities for ACHAP beyond 2007 include improving prevention programs, ARV program support, expansion of HIV testing and strengthening post-test services.
The Associação Saude da Familia (ASF) mobilizes community support in poor favelas in Sao Paulo, Brazil, to protect young people from unwanted pregnancies and sexually transmitted diseases. This includes raising awareness and spreading information about HIV/AIDS. In these teeming slums, where drugs and violent crime are a constant reminder of the fragility of civil societies, ASF works with local community leaders, and municipal and state governments, to implement its programs to encourage safer and healthier behavior.

In its newest program, ASF trains lay persons in poor communities to become outreach workers. They make door-to-door visits providing HIV prevention education and offer voluntary testing and counseling services. With a grant from Johnson & Johnson, ASF was able to expand the scope of this program, and to help local health care units to provide diagnosis, prevention, treatment and care for people living with HIV/AIDS.

AstraZeneca has recently extended its commitment to the African Medical Research Foundation (AMREF) and are supporting them in their work to strengthen healthcare systems and integrate the management of HIV/AIDS, TB and malaria programs in Uganda, where there is a high burden of all three diseases. The Ministry of Health in Uganda has a national policy for integrating HIV/AIDS and TB. However this has not been translated into practice at the community level and malaria is usually addressed in isolation of the other two major diseases. Donor and government plans for the three major diseases have been vertical and fragmented, and integration has been non-existent. Investment has tended to remain at the higher level of the health service (district level hospitals), limiting investment within the peripheral level of the health system, the first stop of the majority of Uganda’s predominantly rural population.

The program launched in October 2007 and aims to benefit the poor and rural communities in Luwere and Kiboga districts of central Uganda, prioritizing pregnant women, young people and children under 7. These districts were chosen because of high incidence rates, partly as a result of lack of funding in healthcare and conflict in preceding years, which has destroyed much of the health care infrastructure.

The program is focused on:

- Training health workers in Kiboga, only 50% of staff places are filled due to lack of funding and qualified staff. AMREF will train community health workers and health staff in rural clinics to better prevent, diagnose and treat HIV, TB and malaria;
- Improving efficiency and work practices in laboratories in Luwere, funding is available for lab technicians, but there are no qualified staff available to fill these vacancies. AMREF will train laboratory staff to diagnose results more accurately and prevent samples from being contaminated, leading to misdiagnosis;
- Improving health information management systems: Important health information is not being collected and analyzed, which leads to poor planning, particularly in terms of drug supplies. The project will train health workers to gather and analyze information and use this information for better health planning, including ordering the correct amounts of the drugs needed;
- Promoting a more integrated approach to disease: AMREF will advocate at district, national, regional and international levels for more integrated approaches to HIV, TB and malaria.

Talking to people about health issues related to HIV/AIDS, TB and malaria. (AstraZeneca)
The Cambodia Treatment Access Program (CTAP) was launched in 2003 by 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. CTAP aims to widen access to sustainable HIV healthcare, including antiretrovirals and train healthcare professionals in Cambodia, where the adult prevalence of HIV is estimated to be the highest in Asia. Roche donates ARVs for use in the program.

In 2004, a treatment centre for people living with HIV/AIDS was established in Phnom Penh, to provide counseling, clinical care, treatment for opportunistic infections and HIV therapy, and to support HIV training and research. Roche’s support had enabled the CTAP to enroll more than 1,700 men, women and children for free care and treatment since the clinic opened in 2004.

Roche additionally funded training events for 400 healthcare professionals from all over Cambodia, allowing them to expand their knowledge and share their experience in treating HIV/AIDS. CTAP’s permanent Social Health Clinic for HIV outpatient care in Phnom Penh was formally opened in 2006. In 2007, Roche committed to fully fund the operational costs of CTAP’s clinic in Phnom Penh for a further year during the transition into the local health system.

In recognition of the impact that CTAP has had on HIV/AIDS treatment, the Royal Government of Cambodia have presented the program’s founding partners with an Award of Recognition, the highest possible distinction for such a contribution. Cambodia has constantly improved its HIV care and treatment and is one of very few countries which has exceeded its WHO treatment target. Recent figures show that HIV prevalence there is now in decline.

CARE, the Cohort program to evaluate Access to antiRetroviral treatment and Education, is designed to provide antiretroviral medicines to people living with HIV/AIDS and serve as a model for providing HIV healthcare in resource-limited countries worldwide.

The program was launched in 2001 by PharmAccess Foundation and Roche in four treatment centers in Cote d’Ivoire, Kenya, Senegal and Uganda. Funding, diagnostic and monitoring tests, as well as support for training of healthcare professionals and education for patients, were provided by Roche, which also donated ARVs for use in the program.

Roche and PharmAccess Foundation have since held five CARE training and experience exchange events, which have brought together over 600 healthcare professionals from 28 African countries to discuss HIV/AIDS and share knowledge, to help improve care and treatment, and to develop strategies to overcome challenges. In 2006, a three-day HIV/AIDS education event was organized for over 170 healthcare professionals, focused on African issues. The event gathered over 1,400 insights and comments, providing a unique overview of the needs of Africans and how their perspectives differ from those in the West.

The countries represented at the 5th CARE experience exchange event in Uganda, April 2008 are: Angola, Benin, Botswana, Burkina Faso, Cameroon, Côte d’Ivoire, Democratic Republic of Congo, Ethiopia, Gabon, Ghana, Kenya, Lesotho, Madagascar, Malawi, Mali, Mauritius, Namibia, Nigeria, Rwanda, Senegal, Seychelles, Sierra Leone, South Africa, Tanzania, Togo, Uganda, Zambia and Zimbabwe.

Many programs supported by industry involve training to strengthen local health care capacity. (GlaxoSmithKline)
Set up in 1992, Positive Action is GlaxoSmithKline’s international HIV/AIDS education, care and community support program, which helps to strengthen the capacity of community-based organizations providing HIV/AIDS healthcare services. The program aims 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 pandemic. During 2007, Positive Action supported 17 international programs in 19 countries.

Positive Action is helping the Reach India project to make HIV/AIDS prevention, financial and business education available to millions of poor women in rural India. GSK is giving USD 500,000 over three years to develop the capacity of community organizations and self-help groups to reach 500,000 women and 2.5 million family members in rural areas. Reach India is a Freedom from Hunger project, supported by Catholic Relief Services (CRS) and Positive Action.

In Kenya, GSK is giving USD 1.8 million over three years to integrate HIV/AIDS treatment and support services into 38 general healthcare clinics, to enable patients to avoid the stigma of visiting an HIV clinic. Fewer than 10% of Kenyans know their HIV status and fear of stigmatization is a significant barrier to seeking testing. Positive Action also helps to train healthcare professionals and create patient self-help groups, to increase awareness and adherence to treatment. Other partners include the African Medical and Research Foundation (AMREF), Elizabeth Glaser Pediatric AIDS Foundation (EGPAF) and the National Empowerment Network of People Living with HIV and AIDS in Kenya (NEPHAK).

In Mexico, GSK is working on a three-year project with the International HIV/AIDS Alliance (IHAA) and its Mexican partner, Colectivo Sol, to improve quality of life for people with HIV/AIDS, reduce stigma and discrimination, and educate people about HIV/AIDS.

The TREAT Asia program is run by the Foundation for AIDS Research (amfAR) with support from Positive Action and seeks to teach proper, safe and effective use of HIV therapies, working with clinicians and other health care workers in 25 clinics across a number of Asian countries, including Cambodia, China, Thailand and Vietnam. Clinics and hospitals are being linked with patient support groups to educate and prepare communities for the treatment and care that is being introduced.

The GlaxoSmithKline Foundation supports a range of HIV/AIDS-related programs around the world. Since 1998, the GSK France Foundation has supported 86 programs to improve healthcare through prevention, education and training in 14 developing countries. During 2007, 9 new programs were implemented in 5 countries with grants of USD 1,091,461. The GSK Foundation Canada also supports community programs in Africa, including AIDS Orphans Uganda, working with the African Medical Research Foundation (AMREF).

GSK supports community programs in Botswana, Cote d’Ivoire, Ethiopia, Ghana, Kenya, Malawi, Mozambique, Namibia, Nigeria, Senegal, South Africa, Swaziland, Tanzania, Uganda and Zambia. These provide treatment for HIV/AIDS patients, counseling and testing, home-based care, training for health care professionals and community volunteers, life skills training for orphans, hospice care, day care centers, feeding schemes, as well as support for basic primary healthcare and HIV/AIDS clinics.

For example, GSK has supported the AIDS Care Treatment and Support (ACTS) initiative in Masoyi, South Africa, since 1999. GSK provided funds to buy land, build a dedicated HIV/AIDS primary health care clinic and training center, and to cover all running costs for the first three years. The ACTS clinic opened in May 2001 and by the end of 2007 more than 20,000 patients had entered its doors. It is now a specialist HIV primary care clinic, complemented by a home-based care team and an eight-bed community hospice. There are 1,200 patients on ARVs, 100 of which are children under 12. Nearly 2,000 patients are seen each month.

In 2004, GSK’s US Business launched a project called “Hope after HIV: Africa.” Through the Children’s AIDS Fund, GSK has helped open 6 clinics in Uganda, Malawi, Zambia, and South Africa that have treated more than 9,000 HIV/AIDS patients. The sponsored clinics offer testing, medicines, education, mother-to-child transmission care, counseling and follow-up. Patients are also supported by more than 1,500 volunteers who provide adherence counseling, disease education for family members and palliative care.

GSK has also established the Hope after HIV 501(c)(3) Fund, a charitable program that allows employees and others to donate funds to support life-enhancing, non-medical needs of patients receiving care at the clinics. The fund has been used to improve nutrition and generate income for patients and their families; provide bicycles, pumps and refrigerators; and education for promising young HIV-positive people.
HIV South Africa

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 Johnson & Johnson 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.

Humana: Total Control of the Epidemic

“Only people can liberate themselves from the AIDS epidemic.” These are the motivating words behind the Total Control of the Epidemic (TCE) program, which was created by the International Humana People to People Movement. Driven by a grassroots door to door approach, TCE has reached more than 4.5 million individuals. Created “by the people, for the people,” TCE informs communities through HIV risk assessments and prevention education.

For the past four years, Johnson & Johnson has sponsored TCE efforts in four South African communities. Through 2006, the Company’s collective support has achieved: 89,000 homes registered; 393,000 one-on-one counseling sessions; 7,800 briefings for pregnant women about preventing transmission of disease to their newborns and 2.3 million condoms distributed.
"I Want to, I Can… prevent HIV/AIDS," is the slogan behind the Instituto Mexicano de Investigación de Familia y Población (IMIFAP) HIV prevention programs, which mobilize citizens to raise neighborhood HIV/AIDS awareness in Mexico.

Johnson & Johnson supports an educational program for youth that utilizes the existing national network of middle schools to teach students about HIV prevention before they become sexually active, increasing the likelihood that these adolescents will practice safe sex in the future. IMIFAP engages all levels of the community from the Ministries of Health and Education, to the school administrators and local politicians, to the teachers and students.

The program includes teacher training, a software program, and Web site support. The 10,400 schools in Mexico with Internet access bring this program to more than 300,000 students. For those schools without Internet access, IMIFAP trains teachers and students to run the program, and has partnered with UNETE, a member of The Resource Fund, to raise educational levels using technology to distribute the program in more rural and remote areas.

The Johnson & Johnson – UCLA Management Development Institute (MDI) was created in 2006 as an intensive one-week program designed to enhance the management skills of health care leaders of East African organizations devoted to the care, treatment and support of people and their families living with HIV/AIDS.

Dr. Ernest O. Nyamato, director of services at Liverpool Voluntary Counseling & Testing (LVCT) care & treatment centers in Kenya, attended the program in 2006. “MDI changed the way I oversee operations at 15 voluntary counselling and testing sites across Kenya," he said. “My involvement in the program has helped me to more effectively get our patients treated."

“Attending the MDI training… pointed me in the right direction,” noted Dr. Nyamato. With a new mental picture of how his LVCT sites should operate, he began building better communication channels between the staff, creating new human resources and compensation policies, and focusing more on patients’ perspectives, expectations and feedback.
The Japan Pharmaceutical Manufacturers Association (JPMA) has, at its own expense, commissioned the ASEAN Institute for Health Development (AIHD) to train medical professionals in ASEAN member countries in the prevention and control of HIV/AIDS. The training is intended to contribute to the promotion of the physical and mental health care of patients and residents through the professional development of health workers in the AIDS-related divisions of public institutions.

For example, the training program in Thailand (approximately 2 weeks) included lectures focusing on HIV/AIDS prevention measures and fieldwork involving the care and counseling of AIDS patients in hospitals and patient communities.

To date, 77 health professionals have been trained, distributed as follows: Bhutan (4), Cambodia (14), China (2), Indonesia (4), Laos (17), Myanmar (10), Nepal (1), Pakistan (2), Sri Lanka (1), Thailand (8), Vietnam (18).

In 1989, Sister Gill Horsfield began training local health workers to provide home-based care to individuals suffering from HIV/AIDS and related illnesses in one of the poorest areas of Nairobi, Kenya. The program offered medical, pastoral counseling, and social services. Today, the Medical Mission Sisters group cares for more than 1,000 people affected by the disease. The program also includes a hospice facility and IV Rehydration Unit, distribution of prepared meals and dry food to families with sick parents, nutrition and social support for children, and educational programs for deaf and handicapped youth. Funding from Johnson & Johnson supports Sister Gill’s continued involvement in caring for people with HIV/AIDS.

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Merck & Co., Inc. HIV/AIDS programs – Africa

Merck & Co., Inc. has helped provide 2,200 African doctors from 24 countries with clinical HIV training since 1997. It supports the West Africa HIV/AIDS Degree Program run by Ouagadougou University, the Pierre et Marie Curie University and the Société française de lutte contre le SIDA, which trains 100 professionals each year. It also helped the Avicenne Hospital/Bobigny Medical University and the Kamenge Hospital Medical University, Bujumbura, to launch the Great Lakes Region HIV/AIDS Degree Program in 2006, which aims to train 40 professionals per year.

In 2006, Merck funded an International Rescue Committee HIV/AIDS training course for 23 health workers in Ethiopia and a Health Coordinators Conference for 45 staff in Uganda.

In 2006 and 2007 Merck funded the Health Economics and HIV/AIDS Research Division (HEARD) of the University of KwaZulu-Natal, South Africa. An HIV/AIDS Workshop was held in Durban, South Africa and was attended by 16 delegates from diverse organizations.

Merck’s partnership with the Côte d’Ivoire’s National Agency for Support to Rural Development (ANADER) began with an HIV prevention and workplace care program, including ARV treatment access for its 2,500 employees. ANADER now covers 3.8 million people in rural areas.

In Nigeria, Merck supports a community program on Bonny Island, to promote safe sex, manage STDs; prevent and treat malaria, and provide ARVs.

Since 2005 Merck has funded the HIV/AIDS Coordination, University of Cape Town, HAICU. This program seeks, with TSIBA – Xhosa University, to allow Xhosa-speaking students to talk freely and learn about sexual health.

Since 2002, Merck has supported Voluntary Services Overseas / Regional AIDS Intervention Southern Africa, which works with 80 partner organizations to combat discrimination and provide HIV and AIDS information.

Since 2005, Merck has worked with the UNHCR to improve refugees’ access to quality HIV/AIDS programs, promote their integration into host country HIV/AIDS strategies, combat discrimination and provide HIV and AIDS information. Merck supported the UNHCR Behavior Sentinel Survey of the Kawanbwa and Mporokos camps and host communities in Zambia.

Merck & Co., Inc. HIV/AIDS programs – Asia-Pacific

Merck & Co., Inc. and the Chinese Ministry of Health set up the China-MSD HIV/AIDS Partnership (C-MAP) in 2005 to develop a comprehensive program to address HIV/AIDS. Merck and the Merck Company Foundation have committed USD 30 million over five years to this, the largest public-private HIV/AIDS partnership in China. C-MAP’s initial focus is in Liangshan Prefecture in southern Sichuan Province, hard hit by the HIV epidemic.

In 2007, C-MAP supported Liangshan’s Disease Control Center (CDC) to establish an HIV testing laboratory and a service network of 49 HIV testing and counseling sites in 3 targeted counties. C-MAP worked with the National CDC to train 160 lab workers. To prevent mother-to-child transmission, C-MAP worked with local government to establish 58 Antenatal Clinics (ANCs) and provide training to 937 health care workers. As of December 2007, these had counseled 2,499 women and tested 2,459 women. C-MAP completed a set of training materials in December 2007 and plans to provide HIV/AIDS training to 5,000 health care workers in 2008.

To raise awareness among the Yi ethnic community, C-MAP sponsored the Liangshan Yi for Empowerment (LYFE) Center to conduct a Yi Drama Tour to reach 54,000 people by November 2007. C-MAP worked with Sichuan University, the Sichuan CDC & the Liangshan CDC to conduct 7 base line surveys of groups including intravenous drug users, commercial sex workers, migrant workers, and families with an HIV+ member. By the end of 2007, these surveys had reached 3,498 people out of the target total of 8,630.

Merck partners with the Malaysian Society of HIV Medicine and the Malaysian AIDS Council to support the “It Begins With You” program, which addresses the need for more HIV/AIDS medical providers through education, awareness and involvement among medical students.

Merck is also working with several Australian companies to help address Papua New Guinea’s burgeoning AIDS epidemic, by strengthening local HIV/AIDS health care teams through workshops and mentoring visits by trained personnel.
Merck & Co., Inc. helps address HIV/AIDS in the Caribbean through education, prevention, treatment, care and advocacy, in partnership with people living with HIV/AIDS, caregivers, the business community and the public sector.

In 2004-5, Merck gave the Jamaica AIDS Support counseling and care group a USD 40,000 grant. Together with USAID, it will provide technical assistance and related program support over the next five years.

Merck, USAID, the University of the West Indies, the University of Washington and others provide HIV training for health care providers through the Caribbean HIV/AIDS Regional Training Network (CHART), with centers in, Bahamas, Barbados, Haiti and Jamaica. In 2007, Merck and The Merck Company Foundation granted USD 36,500 to the Caribbean Coalition of National AIDS Programme Coordinators (CCNAPC), a peer-based organization working to improve national AIDS Programs in 35 Caribbean countries, committed to and Commissions. The grant is to support efforts to increase prevention and awareness.

Also in 2007, Merck sponsored an exchange between Caribbean and Botswana business leaders to promote understanding of the private sector role in fighting HIV/AIDS.

Merck & Co., Inc. helps organizations throughout Latin America to fight AIDS, supporting awareness and prevention programs in Argentina and Brazil, treatment and care programs in Chile, Peru, and Venezuela, empowerment and advocacy groups in Central America and Colombia, outreach to health care professionals in Argentina, Brazil, Chile and Mexico, and HIV/AIDS business coalitions in Mexico and Venezuela. Merck helped the Pan American Health Organization and the Voice of America to create an innovative health journalism CD-ROM to improve reporting of HIV/AIDS. Workshops also help to promote better health journalism.

Brazil has 600,000 people infected with HIV/AIDS; one-third of Latin America’s infected population. To help the Brazilian Government address AIDS, Merck & Co., Inc. has donated more than USD 400,000 to local NGOs’ HIV programs, focused on prevention, education and awareness. The Centro Corsini’s “Prevention Just in Time” project aims to increase testing and early treatment of HIV/AIDS and other sexually transmitted diseases among low-income people in Campinas, and has trained 12 educators who have reached over 2,000 people.
Since 2001, GlaxoSmithKline has helped Mildmay International to strengthen HIV/AIDS healthcare in sub-Saharan Africa, through provision of appropriate training. Mildmay is active in Kenya, Nigeria, Tanzania, Uganda and Zimbabwe.

GSK and Mildmay have developed a “palliative care and use of ARVs in resource limited settings” training program to increase health workers’ skills and knowledge, with a view to improving the quality and effectiveness of care offered to people infected with HIV/AIDS. These courses, which are held at Mildmay project sites, last 7 to 10 days, depending on need and availability, and attract great attention within the area. Attendance usually includes not only staff from the project site but also healthcare workers from government hospitals and clinics, NGOs, faith-based organizations and military health facilities in the surrounding district. Mildmay also provides appropriate training in HIV/AIDS care for community and home-based health care providers in various community projects.

With the support of GSK, Mildmay is planning to undertake a needs assessment survey of HIV/AIDS care service development in Malawi in 2008. The aim is to develop a strategy to help organizations in Malawi to improve of existing services and developing new innovative approaches to care for people living with HIV/AIDS where appropriate. The needs assessment will look at both health care services and related training institutions and will also be used to develop proposals for financial support. Mildmay has had similar requests for assistance from other countries in the region including Ethiopia and Zambia.

Pfizer created the Diflucan® Partnership in 2000 to provide treatment for two AIDS-related fungal infections in developing countries. Pfizer and its partners distribute millions of Diflucan® (fluconazole) treatments free of charge to governments and NGOs in developing countries. Pfizer also provides materials to support patient education and healthcare worker training.

Pfizer’s partners provide technical assistance, support program management and distribute Diflucan to participating governments and organizations. These partners include Aoxis International, Interchurch Medical Assistance and International Dispensarz Association.

The Diflucan® Partnership involves the following activities:

- Treat: donating Diflucan® to governments and organizations to treat patients;
- Teach: Distributing materials to train healthcare workers in the diagnosis and treatment of AIDS-related infections;
- Build: Providing inventory management training tools for pharmacists to improve medicine handling and distribution;
- Serve: Sharing best practices for effective medicine distribution and supporting industry collaboration on access to medicines.

Since 2000, Pfizer has provided medicine worth USD 629 million to more than 1,300 sites in 59 countries in Africa, Asia, the Caribbean and Latin America and provided training and education materials to 20,000 healthcare professionals.
Pfizer allows its employees to take paid leave of absence to help address health challenges in developing countries. Since 2003, more than 155 Pfizer Fellows have worked with and transferred skills to local partners and NGOs during three-to-six month assignments to share knowledge, learn new skills and explore solutions to improving healthcare. Their goal is to improve basic healthcare infrastructure in the developing world.

Pfizer Global Health Fellows include physicians, nurses, lab technicians, marketing managers, financial administrators and health educators from the U.S., Europe, Latin America, Australia, Canada and Asia. Assignments range from helping hospitals to improve data collection and information technology, to providing clinical training for healthcare workers and supporting the expansion of services of local clinics.


The Global Health Fellows program involves the following activities:

- **Treat**: Distributing medicines and resources to health organizations and patients;
- **Teach**: Training and supporting local partners to improve education and prevention;
- **Build**: Training front-line and back-office health workers to strengthen health systems;
- **Serve**: Transferring knowledge, expertise and best practices to organizations while helping them influence policy and patient advocacy.

Pfizer, the Academic Alliance Foundation, Makerere University, the Infectious Diseases Society of America, Pangaea Global AIDS Foundation and others partnered to establish the Infectious Diseases Institute (IDI) in Uganda in 2004. The IDI, a major medical training and research center headquartered within Uganda’s Makerere University, aims to improve health in Africa by training medical professionals in the treatment and prevention of HIV/AIDS and related infectious diseases and providing them with skills and resources to use in their communities.

The Infectious Diseases Institute involves the following activities:

- **Treat**: Providing care and treatment to more than 9,000 patients each year;
- **Teach**: Training African healthcare workers in prevention, diagnosis and treatment of HIV/AIDS and related infectious diseases;
- **Build**: Training healthcare workers to transfer skills and knowledge to local health professionals and building research capacity through mentoring and fellowships;
- **Serve**: Sharing best practices to improve healthcare and attracting additional partners and supporters.

IDI has trained more than 1,700 healthcare workers from 26 African countries since 2004, 98% of whom are providing anti-retroviral therapy and other care for patients with HIV/AIDS. IDI-trained workers indicate they have trained, on average, 20 additional healthcare workers per month.

IDI is partnering with: Exxon Mobil to expand training programs; with Becton Dickinson to establish an excellence-in-laboratory-training program; and with Gilead Sciences to support a new generation of African clinical scholars and infectious disease fellows.
Pfizer – PDA Positive Partnership

Since 2004, Pfizer Foundation, the Population and Community Development Association (PDA) and the Pfizer Thailand Foundation have collaborated to improve the quality of life of people living with HIV/AIDS. This micro-credit loan scheme provides economic security for people living with AIDS while reducing stigmatization and discrimination in their communities. Pfizer provides financial and technical support for the program. This results in improved overall quality of life and health. The project has provided new opportunities to 910 HIV+ people nationwide and has recently been recognized by UNAIDS as “Best Practice” subject for duplication on international stage.

Secure The Future®

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.

The initiative now is reaching women, children, their families and communities in 11 nations: Botswana, Burkina Faso, Côte d’Ivoire, Lesotho, Malawi, Mali, Namibia, Senegal, South Africa, Swaziland and Uganda.

Secure The Future®’s six Community-Based Treatment Support Centers are showing for the first time that comprehensive medical treatment and care, combined with broad-based community support, can be successful in fighting HIV/AIDS in resource-poor settings. Located in remote areas where healthcare and other resources are limited, the CBTS programs integrate strong community support services such as nutrition, psychosocial care, income generation and home-based care with medical treatment to achieve and sustain good clinical outcomes.

Bristol-Myers Squibb’s Secure The Future® program has created the first African NGO Institute to develop NGO’s organizational and individual skills in the delivery of support and care for people living with HIV/AIDS. The NGO Institute, which has created training modules in management, finance, good governance and leadership, runs training programs in Botswana, Lesotho, Namibia, South Africa and Swaziland. More than 2,000 NGO leaders and managers have been trained since the Institute was started in 2003.

After nearly a decade working in the hardest hit areas of Africa, Secure The Future® is sharing key lessons through technical assistance and skills transfer initiatives, by making available capacity-building resources and programs, including an implementer’s manual for the integration of community supportive services into HIV/AIDS treatment. The manual, which is available on-line at www.bms.com/foundation, is a guide for creating a continuum of care for people affected by HIV/AIDS in limited resource settings. It offers clear and methodical guidance, focusing both on results and on the means to achieve them, and its lessons come directly from Secure The Future®. By extending the role of Secure The Future® to become a technical advisory resource, the Foundation intends to work with governments and NGOs to scale up treatment and care programs tailored to their specific needs.
Johnson & Johnson, its Tibotec subsidiary and the African Medical Research Foundation help the Ugandan NGO Sikiliza Leo to provide HIV testing, counseling, treatment and care in rural Uganda. Since March 2003, HIV testing and counseling have been offered to 3,586 community members, of whom 559 have tested positive for HIV. A total of 272 persons receive Home Based Care and a first group of 20 are now receiving ARV therapy. Basic drug kits containing a variety of essential medicines, including miconazole MAT and co-trimoxazole prophylaxis, are among the tools used by home care volunteers.

The program has also established two day-care facilities that support some 250 orphans and vulnerable children in Mulanda and Lwala parishes. Psychosocial development, education, nutrition and care are offered to children from 3 to 8 years of age. The program has been recognized by the American Embassy, and a grant has been provided to improve facilities and food.

Johnson & Johnson’s Tibotec subsidiary makes TibozoleTM Miconazole MAT, a muco-adhesive buccal tablet that can treat oral thrush in AIDS patients. To date, Tibotec has sold at cost or donated over two million patient treatments of Miconazole nitrate 10 mg MAT for use in sub-Saharan Africa. Of these, more than 1,300,000 treatment units have been sold to international procurement agencies for distribution in resource poor settings, through Tibotec’s Cost recovery distribution program. Tibotec collaborates with major not-for-profit suppliers to the developing world, such as IDA and MSF, to maximize access and ensure sustainable product supply. Pilot collaborations with voluntary organizations have led to an increase in donations of patient treatments in a number of sub-Saharan African countries.

One community-based program benefiting from at-cost miconazole is the Comprehensive Community Based Rehabilitation center in Dar es Salaam, Tanzania (CCBRT). Dr. Geert Vannesie, Medical Director of the holistic HIV program at CCBRT, said “the product has really provided us with a convenient, fast acting topical product, which can be used at the lowest level of care, and represents a real advance in the armamentarium for our home based care workers.” The home based care providers working in the program have also spoken out regarding the product benefits: its efficacy, minimal side effects and good compliance.

A lab worker at Nyumbani Diagnostic Laboratory, Nairobi, Kenya, which provides specialized HIV tests and other general diagnostic lab services for abandoned and orphaned children. (Willie Davis, Johnson & Johnson)
“Youth Speak-Up!” HIV Peer Education

Young people in Indonesia account for 46 percent of all HIV/AIDS infections. “Youth Speak-Up!” was initiated by the Indonesian Youth Partnership (IYP), a nationwide network of youth leaders fighting for Adolescent Reproductive Health and Rights. “Youth Speak-Up!” uses a network of peer educators to raise awareness about HIV/AIDS transmission and prevention.

Johnson & Johnson supports “Youth Speak-Up!” programs in which adolescents from 12 provinces are trained to educate others in their communities. With the support of the IYP, the program is growing into a sustainable network of peer educators with the capacity to ensure education in the provinces. The IYP collaborates with the national media to spread the importance of their message.
### Gilead Clinical Development Partnerships

- **HIV/AIDS**
- **Gilead**
- Various government and NGO partners
- **Since 2000**
- **R&D**
- Uganda, Zimbabwe
- www.gilead.com

Gilead is committed to making its products available for treatment and prevention research in the developing world. It provides its HIV medicine at no cost for use in multiple clinical studies and works with healthcare organizations, patient advocacy groups and public health institutions to raise awareness and increase diagnosis and treatment of HIV/AIDS.

Gilead partners with organizations such as the Bill and Melinda Gates Foundation, Family Health International, the UK Medical Research Council, the US Centers for Disease Control and Prevention (US CDC) and France’s *Agence Nationale de Recherches sur le SIDA* (ANRS), providing its products for more than 20 clinical studies that will together enroll more than 10,000 patients in Africa, Asia and Latin America. The largest of these studies is the “Development of Antiretroviral Therapy” (DART) study with two sites in Uganda and one site in Zimbabwe. To date, the company has committed more than 50,000 patient-years worth of medicines for developing world research.

In addition, multiple pre-exposure prophylaxis studies with once-daily Viread® and Truvada® are ongoing, sponsored by the US Centers for Disease Control, Family Health International and other third-party organizations. Gilead has other development programs in HIV, including an HIV integrase inhibitor, as well as programs in hepatitis B and hepatitis C.

### GSK’s HIV-Collaborative Research Program for Resource-Poor Settings

- **HIV/AIDS**
- **GlaxoSmithKline**
- WHO & other partners
- **Since 2000**
- **R&D**
- 14 developing countries
- www.gsk.com

Through its HIV-collaborative research program for resource-poor settings, GlaxoSmithKline is supporting clinical trials that are sponsored by external organizations – such as the World Health Organization (WHO), the UK Medical Research Council and the US National Institutes of Health (US NIH).

Twenty trials, including 16 in Africa, are currently underway, mainly focusing on public health-related issues and involving more than 19,700 patients in the developing world. GSK donates study antiretrovirals and/or financial support, and also provides scientific input. Countries in which HIV clinical trials are being conducted under the aegis of this program include: Botswana, Brazil, Cambodia, Haiti, India, Kenya, Malawi, Peru, South Africa, Tanzania, Thailand, Uganda, Zambia, Zimbabwe.
International AIDS Vaccine Initiative (IAVI)

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 and 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 GlaxoSmithKline, Merck & Co., Inc., Novartis & sanofi-aventis. 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 research vaccines against HIV strains that circulate predominantly in Africa. IAVI contributes technical expertise and funding, and GSK and IAVI researchers form a joint research team. The partnership is doing preclinical research for a vaccine using a vector derived from an adenovirus common in non-human primates carrying pieces of the HIV genome. Disabled adenoviruses are innocuous and produce a very strong immune response. Previous exposure to naturally occurring adenoviruses may limit the potency of such vaccines, which is why GSK and IAVI are concentrating on adenoviruses that do not occur in humans.

International Partnership for Microbicides (IPM)

Johnson & Johnson's Tibotec affiliate established a first-of-its-kind public-private partnership with the non-profit International Partnership for Microbicides (IPM) in 2004, providing a royalty-free license and technology transfer to develop, manufacture and distribute TMC120 as a topical vaginal microbicide to reduce sexual transmission of HIV in developing countries. IPM is conducting safety trials of TMC120 as a vaginal gel in Belgium, South Africa, Rwanda and Tanzania.

In October 2005, Bristol-Myers Squibb and Merck & Co., Inc. jointly announced that each had granted separate royalty-free licenses to IPM to develop, manufacture and distribute their new antiretroviral compounds as microbicides to protect women from HIV in resource poor countries. The compounds concerned are “entry inhibitors”, some of which bind directly to the HIV itself, others to the CCR5 receptor. They are designed to prevent HIV from entering host cells efficiently, thus preventing infection.

In December 2006, Gilead granted royalty-free rights to the IPM and Conrad to develop, manufacture, and distribute tenofovir gel as a microbicide. The gel is currently being evaluated in Phase II/III clinical studies conducted by the HIV Prevention Trials Network (HPTN), Microbicide Trials Network (MTN), and the Centre for the AIDS Programme of Research in South Africa (CAPRISA).

In January 2008, Pfizer agreed to give IPM a royalty-free license to maraviroc, its newly-approved HIV treatment, as a microbicide for the prevention of HIV infection. Maraviroc is one of a new class of antiretroviral drugs known as CCR5 blockers. Under this agreement, IPM will work to develop maraviroc as a vaginal microbicide with the right to develop, manufacture and distribute it in developing countries. Pfizer has granted these rights to IPM without a royalty.

In March 2008, Merck agreed to provide a royalty-free license to IPM to develop a novel antiretroviral compound for use as a potential vaginal microbicide. The compound is a fusion inhibitor, which prevents the virus from fusing with the surface of target cells, an early step in the HIV infection process. The project could provide a novel way to block infection.
Merck & Co., Inc. HIV Vaccine R&D

Merck & Co., Inc.’s HIV vaccine research program began in 1986 and continues today.

STEP, a Phase II “test of concept” clinical trial of Merck’s lead HIV vaccine candidate, a trivalent adenovirus based vaccine, was conducted in partnership with the HIV Vaccine Trials Network (HVTN) and the National Institutes of Health (NIH). The study began in 2004 in Australia, the Caribbean, and North and South America. Another Phase II study of this vaccine candidate – called Phambili – was initiated in South Africa by the HVTN and NIH in February 2007.

In September 2007, Merck, the HVTN and NIH announced that vaccination and enrollment were discontinued in both STEP and Phambili trials because in interim analyses of STEP the vaccine was found to be ineffective. In scientific meetings in November 2007 and February 2008, results from STEP were presented which showed that the vaccine neither prevented infection in uninfected volunteers nor reduced viral loads in those who became infected with HIV during the course of the study. In STEP, in certain subgroups, there were more infections in those volunteers who received the vaccine than in those who received placebo. Merck, HVTN and NIH are conducting extensive analyses to better understand the STEP data and the reason for this result.

While the STEP study results were disappointing to the entire HIV community, additional analyses are ongoing and the partners are committed to gaining scientific insights from STEP to inform the ongoing search for an HIV vaccine. The partnership between Merck, HVTN and NIH in this endeavor has been hailed by many as a model for collaboration between industry, government and academia in the advancement of science.

The HVTN is an international collaboration of scientists and institutions whose goal is to accelerate the search for an HIV vaccine by sharing trial results and facilitating parallel, concurrent testing. The HVTN is funded and supported by the National Institute of Allergy and Infectious Disease (NIAID) at the National Institutes of Health (NIH), an agency of the US Department of Health and Human Services.
Pediatric Formulations for ARVs

HIV/AIDS

Abbott, Bristol-Myers Squibb, Gilead, GlaxoSmithKline

Various partners

Since ?

R&D

(clinical programs include developing countries)


Of the 2.5 million HIV-positive children in the world in 2007, nearly 90% were in sub-Saharan Africa, according to UNAIDS. Antiretrovirals (ARVs) are developed for adults, most clinical trials are in adults, with doses and dosage forms designed for adults. But children cannot be dosed like small adults, as their metabolic capacity to absorb ARVs is not simply proportional to their weight. Safety, efficacy and dosage need to be determined via specific pediatric trials. Most ARVs were developed in tablet form, yet these are impractical for children under five, who require special liquid formulations. While older children can take tablets, those intended for adults often contain too large a dose.

The treatment of children has always been integral to Abbott’s HIV research. Abbott conducted clinical studies of its protease inhibitor (PI) HIV medicines in children at the same time as it studied them for adult use, and both of Abbott’s PIs are available around the world in liquid formulations. Abbott’s new, lower-strength tablet formulation, Aluvia® (lopinavir/ritonavir), is the only co-formulated protease inhibitor tablet that can be used in children. The tablets do not require refrigeration and can be taken with or without a meal. The WHO recommends lopinavir/ritonavir as the preferred treatment for children who no longer respond to first-line HIV medicine.

Bristol-Myers Squibb currently produces pediatric formulations of Videx® (didanosine), Zerit® (stavudine) and Sustiva® (efavirenz), and is working with the Pediatric AIDS Clinical Trials Group to develop Reyataz® (atazanavir) for infants from 3 months old to 18 years. It is also developing Sustiva® oral solution for children from 3 months to 16 years. Sustiva capsules are currently approved for use in children 3 years and older.

Gilead Sciences is working to advance development of a pediatric formulation of tenofovir. To address issues with the initial formulation, Gilead has developed a new heat-stable encapsulated sprinkle formulation for future studies. Two Phase III studies in pediatrics are currently enrolling patients.

GlaxoSmithKline has developed a number of ARV liquid formulations for children, all available at not-for-profit prices in the world’s poorest countries. GSK has also committed to support four pediatric clinical trials in resource-poor countries to determine the best ways to expand access to HIV/AIDS treatment. The development of oral solutions for its combination therapies, Combivir® and Trizivir®, is complicated because two key components (zidovudine and lamivudine) require different pH ranges to maintain stability, and daily dosing issues associated with abacavir have hampered a Kivexa® pediatric formulation.

In 2007, GSK gained European Commission approval for new scored tablets for Epivir, Combivir and Ziagen. This will enable children above 14kg of weight to benefit from a solid dosage form. Scored tablets enable ARVs to be broken into two smaller doses which simplifies treatment for children. Tablets are often easier to store and distribute, and also less complicated to administer than the liquid formulations currently available – particularly when two or three medicines are combined in one pill. For example, a child weighing 20kg can now take half a tablet of Combivir in the morning and the second half in the evening in combination with another ARV, instead of requiring 8ml of Epivir solution twice a day plus 12ml of Retrovir solution three times daily.
The US President’s Emergency Plan for AIDS Relief (PEPFAR) Partnership for Pediatric AIDS Treatment was launched in 2006. This public-private partnership includes innovator and generic pharmaceutical companies and multilateral organizations such as UNAIDS, WHO and UNICEF. The initiative will identify scientific obstacles to treatment for children, take practical steps to address key barriers, share best practices and develop systems for clinical and technical support.

In addition to making medicines available at preferential prices to PEPFAR, Abbott is also working with PEPFAR to advance treatment for children with HIV in developing countries by actively participating in the PEPFAR Partnership for Pediatric AIDS Treatment.

Bristol-Myers Squibb is an active partner in the PEPFAR Partnership for Pediatric AIDS Treatment, working to find solutions to issues concerning pediatric HIV treatment, formulations and access. In 2004, Bristol-Myers Squibb agreed to allow the FDA to make right of reference to its confidential dossiers and product registration files to facilitate approval of generic combination products under the PEPFAR program.

Gilead is an active member of the Accelerated Access Initiative and several United Nations’ agency working groups, as well as the PEPFAR Partnership for Pediatric AIDS Treatment. GlaxoSmithKline is a major supplier of ARVs to PEPFAR at not-for-profit prices and has also participated in the State Department’s program to expand the number of pediatric formulations for HIV medicines that are appropriate for PEPFAR and other child access programs in the developing world.

Merck & Co., Inc. is an active member of the PEPFAR Partnership for Pediatric AIDS Treatment, working to identify scientific and technical solutions to improving access to antiretroviral treatment for children living with HIV/AIDS in resource-limited settings.

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 also will receive the diaphragm and gel so researchers can assess the HIV and STI infection rates of women who use them versus their counterparts. Study results are expected late 2007.

Children orphaned by HIV/AIDS throw an additional burden on developing countries. (Abbott)
Approximately one third of the world’s population is infected with Mycobacterium tuberculosis. While only 1 in 10 infected people with healthy immune systems will develop tuberculosis (TB) symptoms, those with weakened immune systems, such as those with HIV, are much more likely to contract TB. More than 90% of TB cases and deaths occur in the developing world, primarily among young adults. TB is a major cause of death among people living with HIV/AIDS.

Globally, 9.2 million new TB cases and 1.7 million deaths from TB occurred in 2006, of which 0.7 million cases and 0.2 million deaths were HIV-positive people. TB prevalence and death rates have probably been falling globally for several years. In 2005, the total number of new TB cases was still rising slowly, because the case-load continued to grow in African, the eastern Mediterranean and South-East Asia.

Directly Observed Treatment Short-Course (DOTS) is the WHO-recommended therapy for TB control, and uses a combination of different antibiotics over a 6-8 month period. Patients are observed taking their medication, to ensure the continued compliance needed for complete eradication of the bacteria. More than 21 million TB patients have been treated under DOTS since 1995. Although a vaccine exists to prevent childhood tuberculous meningitis, a 100% effective, affordable and practical vaccine has yet to be developed against adult pulmonary TB.

Multidrug-resistant TB (MDR-TB) is linked to poor compliance and does not respond to standard first line treatments. It is a widespread and growing problem, especially in the former Soviet Union and China. WHO estimates there are nearly half a million new cases of MDR-TB a year, which is about 5% of new TB cases of all types. Extensively drug-resistant TB (XDR-TB) occurs when resistance to second-line drugs develops and is extremely difficult to treat.

The pharmaceutical industry has been active in the bringing new TB drugs and vaccine candidates into the development pipeline and in programs to increase access to TB medicines and care.

Estimated TB incidence rates, 2000
Range of rates per 100,000

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Since 2002, AstraZeneca has helped the British Red Cross to combat TB in Kyrgyzstan and Turkmenistan, where many live below the poverty line and the incidence of TB remains seriously high. With funding from AstraZeneca, the Red Cross/Red Crescent’s community-based work has focused on improving patient compliance, encouraging early diagnosis, raising awareness of TB, fighting the stigma associated with the disease and building local capabilities in prevention and control. Progress to date includes over 6,000 patients in Central Asia successfully completing their TB treatment and a significant increase in community awareness of TB following media campaigns and health education sessions in schools and public places that have reached over 750,000 people.

Since 2006, AstraZeneca has also supported the British Red Cross and national Red Crescent program in Kazakhstan, to mitigate the consequences of TB/HIV co-infection, which is a significant public health threat. TB and HIV each speed the other’s progression and TB is the biggest killer of people living with HIV. The Red Crescent is establishing effective, sustainable and replicable models of community-based social support for patients with TB and HIV, and their families. The program brings together social workers, psychologists and employment lawyers, along with volunteers – many of them former patients – to support those on treatment and those who have recently completed it. This project has helped to reduce the proportion of patients giving up on treatment from 33% in 2006 to 13% in 2007.

In 2007, AstraZeneca further expanded its partnership with the British Red Cross to help local communities to combat HIV-TB co-infection in hard-hit areas of South Africa and Lesotho. In South Africa, where over 50% of the population lives below the poverty line, HIV is the single most important factor determining the increasing incidence of TB across the country and over 72,000 adults living with HIV have TB. In Lesotho, HIV and TB have helped reduce life expectancy to around 39 years and the increasing number of TB cases is fuelled by the prevalence of HIV. In South Africa, the Red Cross is currently working in 10 areas within the four provinces of Western and Northern Province, Free State and Limpopo. By the end of 2007, over 2,000 people living with TB or TB/HIV had received improved TB care and treatment and a mobile team of volunteers had run awareness campaigns with 7,000 school children. In Lesotho, work is focused on providing vital support to isolated rural communities. A five-day training workshop was held for 45 carers and 11 project officers, while 132 patients are already receiving TB treatment in 3 districts. The Red Cross is also working with the Ministry of Health on a national Stop TB campaign.

In 2003, Lilly launched a USD 70 million initiative to fight the growing threat of multidrug-resistant tuberculosis. Because of the complexity of MDR-TB prevention and control, Lilly and its partners developed a comprehensive, multi-pronged strategy to strengthen health care systems at country level. Today, Lilly works with leading health care organizations and TB stakeholders to transfer Lilly manufacturing know-how to pharmaceutical companies in affected countries, to supply medicines at preferential prices; implement MDR-TB health care training programs; to involve communities and business in MDR-TB prevention and treatment, and to strengthen surveillance of drug resistance. In 2007, Lilly renewed its support to the MDR-TB Partnership with an additional USD 50 million commitment over a four year period.

Lilly and Purdue University assisted four countries hardest hit by MDR-TB (China, India, Russia and South Africa) to produce two much-needed second-line medicines, capreomycin and cycloserine. WHO provides technical assistance to MDR-TB countries and the WHO Green Light Committee has enrolled to date around 30,000 patients in over 40 countries. Several thousand health care professionals and community health workers have been trained in MDR-TB diagnosis, treatment and prevention. Harvard Medical School and Partners in Health have created an MDR-TB training Center of Excellence and are working with five Russian TB Research Institutes to provide standardized MDR-TB treatment training nationwide. Also in Russia, the US Centers for Disease Control and Prevention are launching a cutting edge electronic surveillance system for monitoring of MDR-TB.

The International Council of Nurses has developed TB and MDR-TB guidelines for nurses and carries out training in high MDR-TB burden countries. The World Medical Association’s physician training tools provides access to the latest international standards of care. The International Hospital Federation developed a comprehensive TB and MDR-TB-control training manual for hospital managers which was field tested in South Africa. The manual is now being disseminated to 40,000 public and private hospital and clinic members throughout the world. The International Federation of the Red Cross and Red Crescent Societies is working to improve community support, home care and compliance via educational programs.

In December 2003, the Novartis Foundation for Sustainable Development signed a Memorandum of Understanding with the World Health Organization committing itself to donate the WHO-recommended tuberculosis treatment for 500,000 patients over five years. The WHO's DOTS (Directly Observed Therapy Short-Course) TB control strategy combines political commitment to sustained TB control activities, case detection by sputum smear microscopy, a standard treatment regimen lasting 6 to 8 months, standardized recording and reporting system, and regular, uninterrupted supply of all essential anti-TB medicines.

Novartis donates rifampicin-based fixed-dose combination (FDC) tablets for the intensive and continuation phases of treatment. The medicines are given to the Global Drug Facility of the Stop TB Partnership for use in programs supported by the Global Fund against AIDS, Tuberculosis and Malaria. Tanzania is the recipient country of the Novartis’ TB DOTS Donation.

Novartis also funds logistics and independent quality control, in addition to the quality control of the Novartis group. The FDC medicines are provided in blister packs which permit the simultaneous intake of several different TB medicines, thereby reducing the risk of resistance. They also reduce the number of tablets patients need to take, simplify logistics and minimize prescription errors. The use of rifampicin reduces the duration of treatment from 8 to 6 months.

The Novartis Foundation works with health ministries to help develop innovative solutions to improve patient compliance and de-stigmatize the disease — both major challenges in TB. Often patients cannot comply with treatment, due to the cost of going to a health facility every day to take their treatment and the related loss of wages. A patient-centered approach that gives patients a choice of where their treatment is supervised and by whom is currently being piloted in three districts in Tanzania. A Tuberculosis social marketing campaign is being carried out in the same districts, to raise awareness about the disease, reduce stigma and to increase demand for TB services.

Established in 1998 and hosted by the World Health Organization (WHO), the Stop TB Partnership aims to provide global leadership, strategy, and coordinating mechanisms. The Stop TB priorities are to expand, adapt, and improve strategies to control and eliminate TB in support of the World Health Assembly Targets set by 2005 (70% case-detection and 85% cure-rates) and the Millennium Development Goals. The mission is to ensure that every TB patient has access to TB treatment and cure, to protect vulnerable populations from TB and to reduce the social and economic toll that TB exerts on families, communities and nations.

The partnership develops advocacy and resource mobilization strategies in support of these priorities, and coordinates and “brokers” resource flows. Other partners in this program include GlaxoSmithKline, Lilly and Novartis, as well as Médecins sans Frontières and the IFPMA.

The Global Drug Facility, run by the Stop TB Partnership, is expanding access to medicines for DOTS scale up; in just 5 years it has committed over 7 million TB treatments. Projects managing MDR-TB can apply through the Green Light Committee for access to quality MDR-TB medicines at reduced price – in some cases by as much as 99%. The Committee is operated by WHO and the Stop TB Partnership.

In 2005, 46 African Health Ministers declared TB an emergency in Africa; the Regional Director for WHO's European region also warned of a TB emergency in Europe. From 1995 to March 2006, more than 21 million TB patients have been treated under DOTS since. 183 countries have adopted DOTS (although a quarter of the world's population still has no access to DOTS services). Through its partners, Lilly distributes two critical anti-TB medicines for treatment of MDR-TB to countries including Peru, Russia and the Philippines. Novartis is donating 500,000 FDCs to the Global Drug Facility over five years (2005-2009).

AstraZeneca and Lilly represent the private sector at the Stop TB Partnership for Europe, which was launched in 2006 at a meeting of 25 leading European organizations hosted by the International Federation of Red Cross and Crescent Societies in Geneva. It is a regional-level entity established under the umbrella of the Global Partnership to Stop TB, and aims to accelerate progress against the TB epidemic by promoting full funding and implementation of the Global Plan to Stop TB 2006-2015 in the European region. AstraZeneca and GlaxoSmithKline participate in the Stop TB working group looking at new medicines for tuberculosis.
In March 2002, sanofi-aventis and the Nelson Mandela Foundation established the TB Free program, a five-year, EUR 15 million effort to increase detection and treatment rates for tuberculosis in South Africa. The partnership aims to train volunteers to support patient compliance during the 6-month treatment. The WHO-recommended DOTS (Directly Observed Therapy Short-Course) strategy is being used, to help ensure patient compliance.

The agreement mandated TB Free to (1) provide infrastructure for training and conduct training and (2) develop and implement education and awareness programs. The actions would help to increase the TB cure rate by as much as 80 percent through improved compliance to TB treatment. In each of the country’s nine provinces, a TB Free Center has been established, which works closely with the Ministry of Health. During 2004-2007, nine training centers were opened, in which 16,500 “DOTS supporters” were trained.

TB Free provides a fully accredited training program which equips the DOT supporters with skills to provide care and support to TB patients and their family. The training program is also aligned to the South Africa Community Workers Program designed to capacitate Community Workers in the fields of health, social welfare and other disciplines.

A comprehensive TB advocacy, communication and social mobilization program is being implemented, to increase testing, compliance and cure rates. The program comprises of television and radio adverts and information programs, billboards campaigns, print media and other channels such as taxis advertisements and door to door visits by DOTS supporters to provide TB information. Such activities are helping to change community attitudes to TB and put TB high on decision makers’ agendas.

In Kenya, sanofi-aventis works with the Kenya Association for the Prevention of Tuberculosis and Lung Diseases to train health-care workers in 200 targeted treatment centers. sanofi-aventis also supports the Kenya’s World TB day awareness activities.

In India, sanofi-aventis formed a partnership with the Association Père Ceyrac in 2007 to fight tuberculosis and to provide support to TB-affected families living in the slums of Mumbai, Navi-Mumbai and Pune.
The Aeras Global TB Vaccine Foundation was founded in 1997 to develop new concepts and tools to control the global TB epidemic. It is the goal of Aeras to develop, test, characterize, license, manufacture and distribute at least one new TB vaccine within 10 years.

In partnership with the Aeras Global TB Vaccine Foundation, Crucell is developing a recombinant vaccine against tuberculosis. The Crucell-Aeras TB vaccine program focuses on improvement of the only currently available TB vaccine, the Bacillus Calmette-Guérin (BCG) vaccine. Aeras and Crucell began jointly developing this vaccine candidate, called AERAS-402, in 2004.

A Phase I clinical trial completed in the USA in BCG naïve healthy adults indicates that the vaccine candidate is well tolerated and stimulates an immune response. A second South African Phase I study in progress in healthy adults vaccinated at birth with BCG appears to show safety, tolerability and immunogenicity of the AERAS-402 vaccine. A new Phase I trial was initiated in the USA in 2007. After demonstration of safety, studies will also be conducted in infants and children.

In 2005, GSK Biologicals and Aeras formed a partnership to collaborate in preclinical and clinical work to establish proof-of-concept, in infants in developing countries, of a potential tuberculosis vaccine candidate originating from GSK Biologicals (formerly Corixa). The candidate vaccine, Mtb72F/AS, had already started clinical trials in the USA and Europe in 2004, to investigate safety, tolerability and immunogenicity in healthy adult volunteers.

Aeras’ aim is to conduct the next stage of clinical trials of the candidate vaccine in regions where TB remains a major public health issue, despite BCG vaccination and improved treatment strategies. To this end, two clinical studies were initiated in early 2008 in adult healthy volunteers in South Africa and in the Philippines. These studies will evaluate different formulations and doses of the vaccine, as well as an improved form of the vaccine antigen, M72.

AstraZeneca’s Bangalore Research Institute in India combines TB research and manufacturing capabilities. The Bangalore facility, opened in June 2003, is dedicated to finding a new therapy for TB that will act in drug-resistant disease and reduce the complexity and/or the duration of treatment. Today, AstraZeneca is the only pharmaceutical company with a research program in India totally dedicated to TB.

In addition to the USD 20 million initial investment in buildings and state-of-the-art equipment, AstraZeneca has committed a minimum of USD 5 million a year to supporting the research program. More than 80 scientists recruited from leading research institutions and universities now work at the facility and there are plans to recruit more international experts over the coming years. The Bangalore-based scientists work closely with AstraZeneca’s infection research center in Boston, USA and with external academic leaders in the field.

The research team at Bangalore has focused its efforts on four specific goals:

- Shortening the duration of therapy to improve patient compliance;
- Eradicating disease, even latent disease, to reduce the chances of relapse;
- Developing new agents that will act on drug-resistant strains; and
- Developing agents that are compatible with HIV therapies.

AstraZeneca is also part of a new European Union Framework Program VI collaboration (NM4TB – New Medicines for Tuberculosis) that will enable them to work with academic opinion leaders involved in TB research. AstraZeneca is the only major pharmaceutical company involved in this project, which began in 2006. Funded by a grant from the EU Framework VI program and consisting of around fifteen groups of Europe’s most prominent scientists and researchers in the field, this consortium seeks to combine academic and pharmaceutical skills to further the discovery of new therapies for TB.
### Global Alliance for TB Drug Development (TB Alliance)

**Tuberculosis**  
Bayer HealthCare, Cumbre, GlaxoSmithKline, KRICT, Novartis  
Various partners  
Since 2000  
R&D  
China, India, Kenya, South Africa, Tanzania and Zambia  
www.tballiance.org

The Global Alliance for TB Drug Development (TB Alliance), established in 2000, brings together industry, NGOs, governments and foundations to work together with more than 30 partners around the world to accelerate the discovery and development of cost-effective new medicines. The TB Alliance draws on the best practices and resources of the public and private sectors. Its mission is to accelerate the discovery and development of cost-effective new anti-TB medicines, which should shorten or simplify treatment, provide a more effective treatment of multidrug-resistant TB and improve treatment of latent TB infection.

Company partners include: Bayer HealthCare, Cumbre, GlaxoSmithKline, the Korea Research Institute of Chemical Technology (KRICT) and Novartis. Other partners include the Beijing Institute of Materia Medica, the Beijing Tuberculosis and Thoracic Tumor Research Institute, the National Institute of Allergy and Infectious Disease (NIAID), University of Auckland, University of Illinois, Yonsei University. Funders include the Bill and Melinda Gates Foundation (BMGF), the Rockefeller Foundation, the US Agency for International Development (USAID), Irish Aid, the Netherlands’ Ministry of Foreign Affairs and the UK Department of International Development (DFID).

The partnership functions as a virtual R&D organization. By outsourcing medicine research and development projects, medicine compounds are moved along the development line to achieve regulatory approval and bring them to market at affordable prices for those countries experiencing the highest burden from TB.

The TB Alliance activities in developing countries include clinical trials in Kenya, South Africa, Tanzania and Zambia and non-clinical or preclinical work in China and India.

### GSK – TB Alliance Drug Discovery Program

**Tuberculosis**  
GlaxoSmithKline  
Global Alliance for TB Drug Development (TB Alliance)  
Since 2005  
R&D  
South Africa  
www.gsk.com

In March 2005, GlaxoSmithKline and the Global Alliance for TB Drug Development (TB Alliance) announced a joint discovery partnership to improve the treatment of tuberculosis (TB). All compounds will be screened to ensure they can be taken with HIV treatments, since people living with AIDS are often susceptible to TB infection. The TB Alliance supports 25 full-time scientists working exclusively on the TB drug program at the GSK R&D facility in Tres Cantos, Spain. GSK will contribute a matching number of staff and all remaining overhead costs. Around 1.5 million compounds have been tested for anti-TB activity and any medicines discovered will be made as affordable and accessible as possible to those most in need.

The program broadens the worldwide TB medicine pipeline by adding several novel classes of compounds that use new mechanisms of action. The joint research program consists of four projects intended to yield new compounds that attack *Mycobacterium tuberculosis* (*M.tb*) on multiple levels. Drug candidates arising from these projects could shorten the standard duration of treatment and treat patients who are resistant to conventional therapies.

The program includes the pleuromutilins, a novel class of antibiotics, and two target-based projects, isocitrate lyase (Icl) and InhA. The fourth project will screen GSK’s antimicrobial libraries for novel compounds that can kill *M.tb*. Compounds will also be screened for ability to be used with antiretroviral HIV/AIDS treatments. A shorter TB regimen is expected to improve patient compliance, increase cure rates and lower toxic side effects, thereby limiting the rise of new resistant strains. A novel TB regimen that is compatible with HIV treatments would improve TB control and help in the fight against AIDS.

In January 2008, GSK announced a 3-year extension of its program with the TB Alliance. Dr. Mel Spigelman, Director of R&D, TB Alliance, said “We are encouraged by the success of our pioneering work with GSK, which has nearly doubled the number of TB drug discovery projects in our pipeline. This collaboration is advancing the TB Alliance’s mission to develop revolutionary, faster and better TB treatment regimens by exploring new ways to attack the disease.”

GSK’s lead TB project on Mycobacterium Gyrase Inhibitors expects to select a candidate for development in the first half of 2009.

In partnership with Stellenbosch University in South Africa, GSK is supporting a program to identify “biomarkers” in people who may respond to specific treatments. Such biomarkers can be used to predict whether or not individuals will respond quickly to treatment or if TB is likely to recur.
Lilly – Partnership for TB Early Phase Drug Discovery

In June 2007, Lilly announced a USD 15 million investment over 5 years to create the Lilly Not-For-Profit Partnership for TB Early Phase Drug Discovery in Seattle, to conduct early-phase discovery research of new medicines to treat tuberculosis, including emerging resistant strains. The partnership aims to employ up to 25 full-time researchers.

The National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH), and the Foundation for the NIH will partner with the Lilly Not-For-Profit Partnership for TB Early Phase Drug Discovery to facilitate the identification and further development of the most promising drug leads for TB. Other partners contributing to the effort include Afya World Medicines, Inc., the Infectious Disease Research Institute, Jubilant Biosys (India), Merck & Co, Inc. the Seattle Biomedical Research Institute, and the University of Washington’s Department of Global Health. The TB Alliance will have representation on the governing committees of the partnership to ensure coordination of efforts.

As part of its commitment, Lilly will fund the leasing of laboratory space to host the partnership’s drug researchers. Lilly also will equip the facility with high-tech machinery and biological tools used for drug screening and testing. Further, the company will open its library of more than 500,000 Lilly medicinal compounds to researchers, who will test and screen them for possible TB treatments.

Moxifloxacin TB Clinical Trials (Bayer HealthCare)

In October 2005, Bayer HealthCare announced a partnership with the Global Alliance for TB Drug Development (TB Alliance) to coordinate a global clinical trial program to study the potential of an existing antibiotic, moxifloxacin, to shorten the standard 6-month treatment of pulmonary tuberculosis. If the trials are successful, the partnership aims to register moxifloxacin for a pulmonary tuberculosis indication and is committed to making it affordable and accessible in developing countries where patients need it most.

Moxifloxacin is currently being studied in different clinical trials for the extension of the present indication to include pulmonary tuberculosis treatment. The clinical development program includes four Phase II and III trials that together will enroll more than 3,000 TB patients. Sites are in Africa, Europe, and the Americas, including 10 US States. Two drug regimens are being evaluated, each substituting moxifloxacin for one of the drugs in the standard four drug treatment. The first substitutes moxifloxacin for ethambutol, and the second substitutes moxifloxacin for isoniazid. Bayer donates moxifloxacin for each trial site and will cover the costs of regulatory filings.

Current TB therapy is based on four medicines discovered forty or more years ago that must be administered for six to eight months, often under the direct observation of a healthcare provider. Preclinical studies in vivo showed moxifloxacin reduced treatment time by two months when substituted for isoniazid, a cornerstone medicine of TB treatment. Moxifloxacin is approved in 104 countries.
The USD 122 million Novartis Institute for Tropical Diseases (NITD) research center in Singapore is a public-private partnership between Novartis and the Singapore Economic Development Board (SEDB) and focuses exclusively on the discovery of innovative medicines for the treatment of diseases that are endemic to developing countries. With 100 scientists employed, and activities that range from target discovery, screen development and compound optimization to preparation for clinical testing, NITD also offers teaching and training in the field of tropical diseases.

The goal of NITD’s Tuberculosis Unit is to apply new genomic and bioinformatic technologies to develop novel treatments for multidrug-resistant TB. NITD researchers are using the tuberculosis mycobacterium genome sequence to identify vulnerable parts that could be targeted by small molecules. Those molecules can then be further refined to produce resulting medicines that will be made available at no profit in developing countries where the disease is endemic.

In 2006, together with Imperial College, NITD and 10 other collaborators also received a grant from the Grand Challenges for Global Health Initiative to discover new targets for latent and persistent TB infection.

A recent Collaboration and License Option Agreement between NITD and the Global Alliance for TB Drug Development aims at accelerating development of potential cost-effective new drugs towards clinical use.

To secure direct access to hospitals and patients in a real-life context, in 2007 NITD also teamed up with the Hasanuddin University and Eijkman Institute in Indonesia to form NEHCRi – a clinical research initiative that aims to strengthen translational research in tuberculosis, and also malaria and dengue fever, all of which NITD is working on.

At a preclinical level, Otsuka Pharmaceutical’s OPC-67683 has shown particularly strong bactericidal activity on Mycobacterium tuberculosis. The compound has also been confirmed to have no cross-resistance with any of the currently used anti-tuberculosis agents and its strong bactericidal effect is seen even on clinically isolated strains of multidrug-resistant tuberculosis (MDR-TB) and extensively drug-resistant tuberculosis (XDR-TB). The pharmacological effects of OPC-67683, however, still need to be evaluated in late clinical phases.

In March of 2004, a Phase I clinical trial started in the UK, and a Phase II-a study has started in the Republic of South Africa. A Phase I study in Japan has been completed and a clinical pharmacological study is underway. Phase II-b studies for MDR-TB are scheduled in 7 countries including Japan in 2008.

A program to facilitate access to OPC-67683 in developing countries is under discussion.
sanofi-aventis helps various international organizations such as the US Centers for Disease Control and Prevention (US CDC) and US National Institutes of Health (US NIH), the US CDC Foundation, the Global Alliance for TB Drug Development (TB Alliance), the Consortium to Respond Effectively to the TB/AIDS epidemic (CREATE) and the International Consortium for trials of chemotherapeutic agents in tuberculosis (INTER-TB) at St. George’s Medical School, in their clinical research into new therapeutic regimens for both latent and active tuberculosis, using Rifapentine and other TB drugs. The aim is to reduce treatment duration and the number of tablets, without compromising efficacy.

sanofi-aventis is also researching new treatment mechanisms, using two parallel approaches:

- A systematic screening of sanofi-aventis’ product portfolio to identify new drugs which are active against M. tuberculosis, especially drug-resistant strains.
- An evaluation of new compounds proposed by external partners.

The objectives of this new sanofi-aventis research and development program coincide with those of the global Stop TB program backed by the WHO and the United Nations “Millennium Summit”, namely to arrest the spread of tuberculosis and begin reducing its incidence by 2015.

In addition, sanofi pasteur, the vaccine branch of sanofi-aventis, has entered into a collaborative research and license agreement with the Statens Serum Institute of Denmark for the development and marketing of a new vaccine against tuberculosis. SSI TB vaccine candidates are recombinant protein sub-units, including one currently in a Phase I clinical trial.

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**GSK is working on various new candidate therapies for TB.**  
(GlaxoSmithKline)
MALARIA
Malaria is now recognized as a major disease of poverty, alongside HIV/AIDS and tuberculosis, but it has become harder to combat, as drug-resistant forms have developed and health infrastructures in malaria-endemic areas have deteriorated. Malaria is caused by a unicellular parasite transmitted to humans through the bites of infected female *Anopheles* mosquitoes. In the absence of immunity or medicines, the most virulent species of the parasite, *Plasmodium falciparum*, can cause death within 24 hours of the appearance of noticeable symptoms. Malaria symptoms include anemia, chills, coma, exhaustion, fevers, partial paralysis, seizures and speech disorders. Up to 500 million cases occur annually worldwide, resulting in more than 1 million deaths each year, of which 90% occur in sub-Saharan Africa. Most of the victims are children under 5 years old; malaria kills an African child every 30 seconds. Pregnant women are also particularly vulnerable, being three times more likely to develop serious malaria than other adults during a malaria epidemic.

Because of resistance, WHO recommends a combination of effective, low-cost interventions for malaria control and prevention, but these remain very much underutilized, primarily due to inadequate funding and poor health infrastructure in endemic countries. The WHO recommends sleeping under insecticide-treated mosquito nets, spraying the interior of dwellings with approved insecticides, preventive antimalarial treatment for pregnant women, and rapid diagnosis and treatment with effective, appropriate antimalarials for anyone suspected of having malaria. The pharmaceutical industry is at the forefront of the growing number of R&D projects, looking for new medicines, vaccines, diagnostics and other health products to fight malaria. They are important actors in access programs to make current malaria treatments more widely available to those worst affected by the disease.

(Sources: Roll Back Malaria, What Exactly Is Malaria?; WHO, World Malaria Report 2005)
Since 2003 the Novartis Foundation for Sustainable Development, together with the Ifakara Health Research and Development Centre and the Swiss Tropical Institute, has been supporting the ACCESS Project in two rural districts in Tanzania. It aims to identify and analyze the main obstacles to effective malaria treatment and to address them by designing appropriate interventions.

On the demand side, the project includes social marketing campaigns to motivate people to seek timely and correct malaria treatment. On the supply side, quality of care including malaria case management at public health facilities has been strengthened. A second supply channel of accredited drug dispensing outlets (ADDOs) has been set up with the Tanzanian Food and Drug Authority and the Management Science for Health organization. These are especially important for people living in areas without health facilities. Finally, ACCESS made Coartem® – the first line treatment in Tanzania – available in ADDOs at a reduced price. Novartis agreed with the financing party, the Presidential Malaria Initiative of the USA, on a preferential price.

By end of 2007, all 150 villages – 500,000 inhabitants – had been covered by the social marketing campaigns. Equally, all health facilities in the two districts have been reached with quality assurance tools to improve quality of care. Impact data on malaria-related mortality will be available by mid 2008.

From April 2008, the Foundation and its partners will start a new project phase – ACCESS II (2008-2010). While activities to further strengthen quality of care and malaria case management in public health facilities as well as sensitization campaigns on timely and correct treatment will continue, additional measures to enhance patients’ resources will be implemented in order to allow people to pay for the treatment needed.

GlaxoSmithKline offers its anti-malarials at not-for-profit prices to public sector customers and not-for-profit organizations in 64 countries – all the Least Developed Countries and all of sub-Saharan Africa. All CCM projects fully funded by the Global Fund to Fight AIDS TB and Malaria are also eligible. GSK does not make a profit at these prices, but it does cover its costs, so it can sustain supply of these high-quality products for as long as they are needed. These prices apply to orders of any size and include insurance and freight costs.

GSK’s African Malaria Partnership was set up in 2003 to support education programs in eight African countries, through partnerships with Freedom from Hunger, AMREF and Plan International. These focused on prevention and prompt treatment, particularly among children and pregnant women. GSK funding for these initiatives has now ended, but the investment will have a long-term positive impact.

The scale of the malaria problem requires a significantly bigger response, so in 2005, GSK gave a USD 1.5 million three-year grant to a new partner, the Malaria Consortium, to launch the Mobilising for Malaria program. Through media coverage, it aims to generate political commitment and sustained funding to combat the disease. It will increase the number of NGOs engaged in tackling malaria, and give more African communities the knowledge and tools they need to prevent transmission of malaria. In 2006, national Coalitions Against Malaria were launched in Belgium, Cameroon, Ethiopia, France and the UK, bringing together advocates from the public sector, NGOs, the media, the private sector and the political, academic and scientific communities. During 2007 Innovation Grants for Malaria Advocacy were awarded to four organizations working in Nigeria, Democratic Republic of Congo, Senegal and Uganda.
Impact Malaria (sanofi-aventis)

The Impact Malaria program embodies sanofi-aventis’ longstanding commitment to fight malaria.

In R&D, sanofi-aventis is investigating new treatment mechanisms that are affordable and adapted to patients’ needs, especially children, and can help circumvent growing resistance to existing medicines. The most advanced project is ferroquine, a new 4-aminoquinoline derivative, developed with Lille University, which is in Phase II clinical trials. Upstream projects include development of “bicational compounds” with Montpellier University and “tioxaquins” with Palumed in Toulouse. Antigens from Plasmodium falciparum identified by Institut Pasteur in Paris will be used by sanofi pasteur to develop a safe and efficacious candidate vaccine.

sanofi-aventis seeks to improve access to antimalarials, by making its branded products available at a “no profit, no loss” prices to needy populations. In 2006-2007, more than 7 million Artemisinin-based combination treatments were provided at preferential prices to 21 malaria-endemic countries.

sanofi-aventis and DNDi launched a new artemisinine-amodiaquine fixed-dose combination treatment in early 2007. The Group has relinquished its patents and will supply it at prices scaled to income. In the poorest countries, this is less than USD 1 for an adult treatment and a less than USD 0.5 for a pediatric one. Tablets are soluble, facilitating their use with children.

sanofi-aventis, WHO, DNDi, Médecins Sans Frontières and Epicentre are preparing clinical trials to generate good efficacy and safety data on the new artemisinin-amodiaquine FDC in “real life” conditions, and help build clinical trial and pharmacovigilance expertise in Africa.

sanofi-aventis provides malaria training and education for health workers and the public. In 2007, over 30 African health professionals received high-level malaria training in France, Madagascar and Tanzania. Material has been developed with national malaria control programs and NGOs, while the www.impact-malaria.com website provides information about the disease, prevention and treatment, plus educational tools and an online library.

In 2007, sanofi-aventis started a malaria prevention and treatment program with Actions de Solidarité Internationales and the Agence pour la Médecine Préventive in Makoua, Republic of Congo. In Benin, the Group works with PlanetFinance to help local NGOs to train health workers to educate communities about malaria. sanofi-aventis, Total and the CFAO have created a “Practical Guide for the Corporate Fight Against Malaria”, to help companies to provide malaria care for employees, families and host communities. A revised version is being prepared for NGO use.

Novartis Coartem®

Coartem® is the first WHO-prequalified fixed-dose, oral artemisinin-based combination therapy antimalarial, approved by stringent regulatory authorities and on the World Health Organization (WHO) Model List of Essential Medicines. Coartem® is fast-acting and cures over 95% of patients after a 3-day treatment course. It was developed by Novartis and the Institute for Microbiology and Epidemiology in Beijing. Coartem® combines artether, a derivative of artemisinin (from the Chinese medicinal plant Artemisia annua), with a synthetic substance, lumefantrine, which has not been used as a monotherapy.

Novartis agreed with the WHO in May 2001 to make Coartem® available on a “not-for-profit” basis to public sector agencies. The Coartem® supply chain is unusually complex due to the agricultural cycle involved with Artemisia annua; Novartis has worked with Chinese and African partners to help expand production to meet rising demand. In 2007, Novartis shipped 66 million Coartem® treatments – helping to save an estimated 200,000 lives. Novartis has supplied over 155 million Coartem treatments since the beginning of the project in 2001.

In KwaZulu-Natal, South Africa, case management, Coartem® and indoor spraying led to a 95% decrease in malaria deaths and a similar drop in hospital admissions and outpatient visits. Zambia was the first country in sub-Saharan Africa to adopt Coartem® as first-line treatment in 2003. Malaria deaths dropped from 50,000 in 2003 to 33,000 in 2004.

A study published in Malaria Journal in 2007 showed that Coartem® is more cost-effective than sulfadoxine pyrimethamine, because it eradicates malaria infection in most patients within a 28-day period. The study suggests that Coartem® is justifiable on both economic and public health grounds.

Novartis provides a “Coartem® and Malaria” education program, to improve patient compliance and increase response and cure rates in developing countries. For years, Novartis has provided a platform for National Malaria Control Program Managers to exchange Best Practices in the areas of policy implementation, training, communication, supply chain management and health impact measurement.
Mobilize Against Malaria is Pfizer’s latest initiative to help close critical gaps in malaria treatment and education in Ghana, Kenya and Senegal. At the 2006 Clinton Global Initiative, Pfizer announced a five-year (2007-2012) program to prevent infection and spread of malaria by improving malaria symptom recognition, treatment and referral through local grassroots training, education and awareness. The program goal is to help close gaps in malaria treatment and education.

The Mobilize Against Malaria program involves the following activities:

- **Treat**: Helping local organizations reach patients with prompt and appropriate malaria treatment;
- **Teach**: Training healthcare workers to improve diagnosis, treatment and referral, and supporting community education campaigns;
- **Build**: Strengthening local organizations to enhance malaria treatment through technical assistance, evaluation support and networking resources;
- **Serve**: Partnering with international and local experts to evaluate program interventions and sharing learning and best practices with other organizations addressing the malaria epidemic.

Pfizer is working with the London School of Hygiene and Tropical Medicine to evaluate the program impacts.

To provide a coordinated global approach to fighting malaria, the Roll Back Malaria (RBM) Partnership was launched in 1998 by the World Health Organization (WHO), the United Nations Children’s Fund (UNICEF), the United Nations Development Program (UNDP) and the World Bank to provide a coordinated global approach to fighting malaria.

The RBM Partnership has expanded exponentially since its launch and is now made up of a wide range of partners, including malaria endemic countries, their bilateral and multilateral development partners, the private sector, nongovernmental and community-based organizations, foundations, and research and academic institutions. These bring a formidable array of expertise, infrastructure and funds to the fight against the disease. The partners are working together to scale up malaria-control efforts at country level, coordinating their activities to avoid duplication and fragmentation and to ensure optimal use of resources.

A key role of the RBM Partnership is to lead continuing advocacy campaigns to raise awareness of malaria at the global, regional, national and community levels, thus keeping malaria high on the development agenda, mobilizing resources for malaria control and for research into new and more effective tools, including a vaccine, and ensuring that vulnerable individuals are key participants in rolling back malaria.

GlaxoSmithKline, Novartis and sanofi-aventis are part of the Private Sector delegation to the Partnership Board. IFPMA member companies also take part in the various working groups.
### Artekin® International Development Program

| Malaria | Chong Qing Holley, Sigma-Tau | Medicines for Malaria Venture (MMV), Oxford University | Since 2004 | R&D | India, Laos, Thailand | www.mmv.org |

In March 2004, Chong Qing Holley Holding of China, Sigma-Tau of Italy, Medicines for Malaria Venture (MMV) and Oxford University signed an agreement for the international development of dihydroartemisinin-piperaquine (Artekin®), a fixed dose combination of dihydroartemisinin (a derivative of artemisinin) and piperaquine.

Artemisinin is extracted from the *Artemisia* plant, a traditional medicine with a 2,000-year history, which acts very quickly without the side effects of many other antimalarials. A combination medicine further reduces the chances of resistance developing and improves its efficacy. The fixed-dose combination antimalarial medicine is registered as Artekin® in China and has been used effectively there against drug-resistant malaria.

Two batches of tablets, one for children and one for adults, were manufactured and released by Sigma-Tau to supply clinical trials. The long-term goal is to transfer responsibility for the manufacture of the active ingredients and the tablets to Chong Qing Holley, which is working to bring its production facilities up to international GMP standards.

The clinical development plan includes three pharmacokinetic studies and two confirmatory Phase III trials. One Phase III trial is currently ongoing in India, Laos and Thailand, with a goal of 1,050 patients. The comparator is artesunate-mefloquine. The second Phase III trial was completed with 1,500 patients in five centers in Africa, with artemether-lumefantrine as comparator. The pharmacokinetics program completed in 2006 included one trial in healthy volunteers, one in the pediatric patient population, and one in adults with malaria. All trials were conducted at the highest international Good Clinical Practice (GCP) level.

### Crucell’s Malaria Vaccine R&D

| Malaria | Crucell, GlaxoSmithKline | Various partners | Since 2003 | R&D | (Phase I in USA) | www.cruccell.com |

Many of the vaccines Crucell develops combat diseases severely affecting developing countries, including vaccines against tuberculosis and malaria. Crucell is currently developing a malaria vaccine in collaboration with the US National Institute of Allergy and Infectious Diseases (NIAID), part of the US National Institutes of Health (NIH).

The vaccine is specifically targeted at the *Plasmodium falciparum* malaria parasite, the most deadly of the malaria parasites. Under a cooperative research and development agreement with the Walter Reed Army Institute of Research (WRAIR) and GlaxoSmithKline Biologicals (GSK), Crucell’s malaria vaccine candidate was tested in preclinical studies as a stand-alone vaccine and in combination with GSK’s RTS,S malaria vaccine candidate. These studies demonstrated that a combination of GSK’s candidate vaccine with Crucell’s candidate vaccine can lead to improved immunogenicity of the former.

A Phase I study of a stand-alone vaccine is currently underway in the USA. Initial findings of the Phase I trial are expected to be available in 2008.
GlaxoSmithKline has created a dedicated R&D group to focus on diseases of the developing world (DDW), specifically malaria and TB, with a DDW 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 by their social and public health benefits rather than commercial return. GSK works closely with the Medicines for Malaria Venture (MMV), which subsidizes 30 scientists at Tres Cantos. GSK provides the clinical, regulatory and manufacturing expertise to advance compounds in clinical development.

GSK’s malaria treatment projects include:

- Tafenoquine, a potential new treatment for the radical cure of P. vivax malaria being developed in partnership with MMV and the US Walter Reed Army Institute of Research (WRAIR);
- Pyridones, a new class of compounds with the potential to be highly effective against drug-sensitive and drug-resistant strains of both P. falciparum and P. vivax malaria. Pyridone GSK932121 is being developed in partnership with MMV. It is expected to enter ‘First Time in Human’ clinical trials in October 2008. A back-up program included in the GSK/MMV miniportfolio is now well advanced and a candidate for development is expected by late 2008;
- Novel Antimalarial Macrolides, are effective against P. falciparum and multi-drug resistant (MDR) strains. This project is being developed by a joint team at GSK Zagreb and Tres Cantos. An agreement with MMV was announced in January 2008 to include this project in the GSK/MMV miniportfolio;
- Ongoing work on Falcipain inhibitors, compounds which prevent the malaria parasite from developing.

The Medicines for Malaria Venture (MMV), founded in 1999 as a public-private partnership, seeks to discover, develop and deliver new antimalarial medicines suitable for use in developing countries. MMV now manages the largest portfolio of malaria medicine research in history, with 19 projects in different developmental stages entering into 2006.

Its objective is to develop one new antimalarial every 5 years with the first one registered before 2010. With a number of medicines in Phase II and III clinical trials, it is likely that its goal will be reached well before the end of the decade. Its 39 R&D partners include academic research institutes, biotech firms and pharmaceutical companies. Major pharmaceutical partners include GlaxoSmithKline, Novartis, Roche, Sigma-Tau, and Ranbaxy. Under its mini-portfolio agreement with GSK, MMV subsidizes 30 scientists at GSK’s Tres Cantos facility drug discovery facility. As compounds move into clinical development, GSK provides the clinical, regulatory and manufacturing expertise and resources through its global R&D and supply network. The Novartis Institute for Tropical Diseases (NITD) in Singapore is working with MMV, the Singapore Economic Development Board and the Wellcome Trust to discover new malaria medicines and is developing a one-dose cure for P. falciparum, the most dangerous form of malaria, and a curative modality for P. vivax, the most frequent-occurring and widely distributed type of malaria.

MMV’s funding comes from various foundations, donor governments and corporations with the largest contribution from the Bill and Melinda Gates Foundation (BMGF), The World Health Organization (WHO) and the Roll Back Malaria (RBM) partnership also consider MMV an important partner in its fight to control and defeat malaria. The projects that are in clinical trials include, Artekin® with Chong Qing Holley and Sigma-Tau, and Pediatric Coartem® with Novartis. Roche developed Synthetic Peroxide (OS277) and then handed it on to Ranbaxy to take through clinical trials. In January 2008, GSK announced a new collaboration with MMV to identify novel drugs for the treatment of malaria. Research will focus on macrolide antibiotics, based on azithromycin, which may have promise as an antimalarial treatment. Under the new agreement, MMV will provide funding for research to be performed at GSK. Macrolide antibiotics are a well-established class of antimicrobial agents that have a significant role in the treatment of infectious diseases. The macrolide azithromycin is known to have antibacterial activity, but it has also shown some activity against malaria. The research collaboration between GSK and MMV will investigate the potential of azithromycin-based drugs to treat drug resistant malaria.
Novartis R&D for Malaria

- **Malaria**
- **Novartis**
- **Various partners, including TDR**
- **Since 2006**
- **R&D**
- Benin, Colombia, Kenya, Mali, Mozambique, Tanzania, Zambia
- [www.novartis.com](http://www.novartis.com)

Novartis is working with the WHO’s Tropical Disease Research Programme (TDR) and the Government of Zambia to study the use of Artemisinin Combination Therapy to treat uncomplicated *P. falciparum* malaria in pregnant women, for which there is currently little reliable data available.

Novartis is also working with the Medicines for Malaria Venture (MMV) to develop a pediatric formulation for Coartem®; an important need, given the disproportionate vulnerability of children under 5 year to malaria. Clinical development took place in several African countries.

Since 2007, the Novartis Institute for Tropical Diseases (NITD) in Singapore has been working with MMV, the Singapore Economic Development Board and the Wellcome Trust to discover new malaria medicines.

The partnership is focusing on the development of a one-dose cure for *P. falciparum*, the most dangerous form of malaria, and a curative modality for *P. vivax*, the most frequent-occurring and widely distributed type of malaria. NITD will manage the program and conduct research jointly with several institutes including the Genomics Institute of the Novartis Research Foundation, the Swiss Tropical Institute and the Biomedical Primate Research Center.

PATH Malaria Vaccine Initiative (MVI)

- **Malaria**
- **GlaxoSmithKline**
- **PATH Malaria Vaccine Initiative (MVI)**
- **Since 1999**
- **R&D**
- Burkina Faso, Gabon, Ghana, Kenya, Malawi, Mozambique, Tanzania
- [www.malariavaccine.org](http://www.malariavaccine.org)

The PATH Malaria Vaccine Initiative (MVI) was launched in 1999 to accelerate development of malaria vaccines and ensure their availability and accessibility in the developing world. MVI was funded by a USD 50 million grant from the Bill & Melinda Gates Foundation and the Initiative is administered by the US not-for-profit Program for Appropriate Technology in Health (PATH). MVI is guided by Technical Advisory Groups, a Strategic Advisory Council and PATH’s board. Partners include malaria experts around the world, government agencies, academia, public and private research institutions, and vaccine producers.

GSK’s candidate RTS,S/AS, in development for more than 15 years, is the only malaria vaccine so far to demonstrate significant efficacy in young children and infants. A trial in 2,000 children in Mozambique in 2004 showed it to be effective for up to 18 months, reducing clinical malaria by 35% and severe malaria by 49%. The candidate vaccine has a promising tolerability and safety profile, and is intended specifically for use in Africa. GlaxoSmithKline’s GSK Biologicals has so far spent some USD 300 million on malaria vaccine development.

Several more years of clinical investigation will be needed. A Phase II trial is evaluating the optimal adjuvanted formulation and suitability of the vaccine when administered with national immunization schedules (WHO Expanded Program on Immunization EPI).

RTS,S/AS is indeed expected to enter Phase III trials in Africa in late 2008, with 16,000 infants and young children between the ages of 6 weeks and 17 months of age in 10 sites in Burkina Faso, Gabon, Ghana, Kenya, Malawi, Mozambique and Tanzania. This could become the largest vaccine clinical trial ever conducted in Africa. All children in the phase III trials will be followed for safety and efficacy for at least two years.

The Bill & Melinda Gates Foundation has announced a new grant to MVI, primarily to support the phase III clinical trial. GSK will at least match from its own funds the USD 21.4 million it receives from MVI, to help defray some of the clinical development costs.
Pfizer – Zithromax®/chloroquine for Malaria

Malaria
Pfizer
Various partners
Since 2006
R&D
Burkina Faso, Colombia, Ghana, India, Kenya, Mali, Zambia
www.pfizer.com/responsibility

Through the company’s Zithromax®/chloroquine clinical trial program, Pfizer scientists are developing a potential malaria treatment based on our widely used antibiotic, Zithromax®. Dosed in combination with chloroquine, Zithromax® demonstrated positive results in the treatment of adults with malaria in Africa. Currently, clinical studies are ongoing at centers in Africa, India and South America.

sanofi-aventis – DNDi Malaria Medicine

Malaria
sanofi-aventis
Drugs for Neglected Diseases initiative (DNDi) & other partners
Since 2005
Access – Pricing, Capacity Building – Training & Support, R&D
Cameroon, Gabon, Madagascar, Mali, Senegal

In April 2005, sanofi-aventis signed an agreement with the Drugs for Neglected Diseases initiative (DNDi) foundation to develop a new medicine against malaria, in response to a call from the World Health Organization (WHO) for malaria to be treated by drug combinations to combat resistance.

DNDi and sanofi-aventis have developed a fixed-dose combination of two antimalarial compounds, artesunate and amodiaquine (AS/AQ) that is easier to use and more affordable than any other combination currently available. DNDi developed the formulation combining the two active ingredients in a single tablet and carried out the initial pharmaceutical and clinical development, before choosing sanofi-aventis as its industrial partner for further development.

Building on DNDi’s studies, sanofi-aventis helped develop the product at industrial level, carried out additional clinical studies, prepare the dossier for regulatory authorities and applied for WHO prequalification. sanofi aventis is now launching this new FDC in malaria endemic countries and embarking on a large follow-up clinical trial program with DNDi, Médecins Sans Frontières and Epicentre, to collect good efficacy and safety data on this new medicine in “real life” conditions, in Cameroon, Gabon, Madagascar and Senegal.

The medicine, which is manufactured in Morocco, received its first market approval in February, 2007 and is now registered in most sub-Saharan African countries. It is under review by the WHO for prequalification. The new formulation simplifies adult treatment to 2 tablets once a day for three days, instead of 8 tablets per day. The pediatric dose is also simplified: one tablet a day for three days. Tablets are soluble in water or in semi-liquid food, making them suited to the needs of children, the population most at risk of complications from malaria.

sanofi-aventis committed to sell the product “at no profit-no loss” to health ministries in affected countries, intergovernmental institutions, NGOs and programs promoting access to drugs in pharmacies. A full treatment costs less than USD 0.50 for children less than 5 years old, and less than USD 1 for older children and adults. sanofi-aventis has elected to waive all patents on this new FDC, which offers practical advantages over co-blister packs or loose combinations.
Most of malaria victims are children under 5 years old; malaria kills an African child every 30 seconds. Pregnant women are also particularly vulnerable, being three times more likely to develop serious malaria than other adults during a malaria epidemic. (GlaxoSmithKline)
Weight of specific tropical diseases by death and by annual DALY\(^1\) losses, 2001

<table>
<thead>
<tr>
<th>Disease</th>
<th>Death (1,000's)</th>
<th>%</th>
<th>DALYs (millions)</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Leishmaniasis</td>
<td>59</td>
<td>43.5</td>
<td>2.4</td>
<td>18.1</td>
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<tr>
<td>Trypanosomiasis</td>
<td>50</td>
<td>36.2</td>
<td>1.6</td>
<td>12.3</td>
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<tr>
<td>Schistosomiasis</td>
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<td>10.9</td>
<td>1.8</td>
<td>13.5</td>
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<tr>
<td>Chagas disease</td>
<td>13</td>
<td>9.4</td>
<td>0.6</td>
<td>5.0</td>
</tr>
<tr>
<td>Lymphatic filariasis</td>
<td>0</td>
<td>0</td>
<td>5.6</td>
<td>43.4</td>
</tr>
<tr>
<td>Onchocerciasis</td>
<td>0</td>
<td>0</td>
<td>1.0</td>
<td>7.7</td>
</tr>
<tr>
<td>TOTAL</td>
<td>138</td>
<td>100.0</td>
<td>13.0</td>
<td>100.0</td>
</tr>
</tbody>
</table>

\(^1\)Disability Adjusted Life Years (DALY) combines in one measure the time lived with disability and the time lost due to premature mortality. One DALY can be thought of as one lost year of ‘healthy’ life and the burden of disease as a measurement of the gap between current health status and an ideal situation where everyone lives into old age free of disease and disability. (http://www.who.int/healthinfo/boddaly/en/)

At least 1 billion people – 1 person in 6 – suffer from tropical diseases such as Buruli ulcer, cholera, dengue, dracunculiasis (guinea-worm disease), leishmaniasis, lymphatic filariasis, onchocerciasis, schistosomiasis, soil-transmitted helminthiasis, trachoma, and trypanosomiasis. These diseases, many of which are vector-borne, primarily affect poor people in tropical and subtropical areas. Some affect individuals for life, causing disability and disfigurement, often lead to stigmatization. Others are acute infections, with transient, severe and sometimes fatal outcomes.

With the end of the colonial era, developed countries lost interest in these diseases, research waned and they came to be known as “neglected diseases”. Thanks in part at least to committed public-private partnerships, these diseases are now receiving greater attention, both with regard to improved access to treatment and increased R&D activity.

More than 14 million people have been cured of leprosy: the number of people infected with guinea-worm has dropped from 3 million to just 25,000 cases; blinding diseases such as onchocerciasis and trachoma are being brought under control; millions of people are now protected from disfiguring lymphatic filariasis. Schistosomiasis has been effectively controlled in Brazil, China and Egypt, and eliminated from Iran, Mauritius and Morocco. Intestinal helminths have been eliminated in South Korea and are under control in many endemic countries. These successes demonstrate that interventions against neglected tropical diseases are technically feasible, immediate, visibly powerful and highly cost effective.

What are the tropical diseases?

Tropical-cluster diseases:
- Trypanosomiasis (known as sleeping sickness)
- Chagas disease (the Americas version of trypanosomiasis)
- Schistosomiasis (sometimes called bilharziasis)
- Leishmaniasis (kala azar or black fever)
- Lymphatic filariasis (elephantiasis)
- Onchocerciasis (river blindness)

Also referred to or included as tropical diseases:
- Dracunculiasis (guinea worm)
- Leprosy
- Dengue
- Japanese encephalitis
- Trachoma
- Intestinal nematode infections (hookworm, among others)

(Source: World Health Report 2004, Annex Table 2)
In 2002, Bayer HealthCare agreed to supply – at no cost and for an initial five-year period – as much of the sleeping sickness medicine Germanin® (suramin) as the WHO determines is needed to eliminate the disease. The initial donation contained 50,000 ampoules. Bayer also is in favor of supporting an “Integrated Sleeping Sickness Initiative” fostered by a broad base of institutions and covering all aspects of the disease from infection, diagnosis and therapy to prevention.

In April 2007, Bayer signed a new agreement to provide the WHO with 2.5 million Lampit® tablets and additional funding for the distribution of the drug. The latest agreement assures the supply of Lampit® until 2012.

To widen access of patients to affordable medicines, Bayer Healthcare signed agreements with the World Health Organization (WHO) in 2004 and 2005 for donations of its medicine Lampit® (nifurtimox) to combat Chagas disease, the form of sleeping sickness found in Latin America. A total of 500,000 tablets was given to the WHO, which informs the governments of disease endemic countries of the availability of the free supplies, including the procedure to be followed for obtaining such supplies, and decides about its distribution.

The goal of the WHO is to distribute Lampit® in all 21 endemic countries in Latin America. Currently, the medicine is approved in Argentina, El Salvador, Honduras, Nicaragua, Chile, Guatemala and Uruguay. Lampit® will also be provided in small quantities, as needed, in some non-endemic countries, like Canada, France, Japan, Spain, UK and the USA.
Gilead – AmBisome® for Leishmaniasis

Gilead's therapeutic AmBisome® (amphotericin B) liposome for injection has shown potent anti-parasitic and fungicidal activity against multiple pathogens, including mucosal and visceral leishmaniasis in clinical studies.

Gilead's goal is to expand access to AmBisome® for the treatment of leishmaniasis in settings where the disease has the largest impact. Gilead works closely with the World Health Organization and NGOs to provide AmBisome® at a preferential price for the treatment of leishmaniasis in resource-limited settings. Gilead also actively supports multiple clinical research studies aimed at elucidating the best treatment course for visceral leishmaniasis.

Global Alliance to Eliminate Lymphatic Filariasis (GAELF)

The Global Alliance to Eliminate Lymphatic Filariasis (GAELF) was created to eliminate one of the world's leading causes of disability and disfigurement as a public health problem by the year 2020. An estimated 120 million people in at least 80 countries of the world are infected with lymphatic filarial parasites and one billion (20% of the world's population) are at risk of infection.

Initiated by the World Health Organization and GlaxoSmithKline in 1998, the Global Alliance has evolved into a global partnership between international organizations in the public and private sectors, academia and non-governmental organizations working in partnership with ministries of health in tropical countries where lymphatic filariasis (LF) is endemic. Merck & Co., Inc. joined the Alliance in 1998, when it widened the scope of its Mectizan® Donation Program to include LF in African countries where river blindness and LF co-exist.

The WHO currently recommends that lymphatic filariasis be prevented with a combination of albendazole (donated by GSK) with either DEC, or Mectizan® (donated by Merck). Drug administration for people living in endemic areas is recommended by WHO once a year for at least five years to break the cycle of transmission. In 2007, GSK donated 150 million treatments of albendazole to prevent transmission in Africa, America, the eastern Mediterranean, Mekong basin, the Indian Sub-continent and the Pacific region. To date, GSK has donated 750 million treatments to 46 countries.

Over the 20 year life of the program, GSK expects to donate up to 6 billion preventative albendazole treatments across the 80 endemic countries that are accepted into the program by the WHO. Merck donated 48 million treatments of Mectizan® to LF elimination programs in 12 African countries and Yemen in 2007, bringing the cumulative total to 215 million. Merck and GSK have also provided financial grants to support partners in research programs, coalition building, workshops and communications. WHO estimates that over 100 million people – 30 million of whom are children – have begun to be protected from LF.
Guinea Worm Eradication Program (GWEP)

Dracunculiasis (Guinea worm)
Johnson & Johnson
WHO & other partners
Since 1986
Access – Donation, Capacity Building – Support, Education
9 African countries
www.cartercenter.org/healthprograms/program1.htm

Established in 1986 and operating under the auspices of the Carter Center’s Global 2000 Program, the Guinea Worm Eradication Program aimed to rid future generations of guinea worm by the year 2005. This multilateral partnership brings together organizations like the WHO, UNICEF, the CDC and the World Bank, as well as national governments and the pharmaceutical industry in a program combining eradication efforts, training and research. To accelerate the eradication of Guinea worm disease, the partners:

• maintain a community-based surveillance system with monthly reporting of cases, supervision, and integration of surveillance for other major preventable diseases (where appropriate and feasible);
• target specific interventions (provision of safe water, health education, community mobilization, filter distribution, and treatment of selected water sources);
• maintain global and national dracunculiasis databases;
• monitoring of the epidemiological situation and map all endemic villages;
• sustain advocacy for eradication of the disease;
• certify dracunculiasis eradication country by country worldwide.

Johnson & Johnson has donated enough medical supplies, such as Tylenol®, forceps and gauze, to treat more than 3,000 villages in the endemic countries.

Today, through the joint efforts of this initiative’s many partners, the numbers of this disease have been reduced worldwide by 99 percent, from an estimated 3.5 million cases in 1986 to less than 35,000 reported cases in 2003. Today, it is the last 1 percent of the disease that is being fought.

International Trachoma Initiative (ITI)

Trachoma
Pfizer
Edna McConnell Clark Foundation & other partners
Since 1998
Access – Donation, Capacity Building – Training & Support, Education
15 developing countries
www.trachoma.org

The International Trachoma Initiative (ITI) was founded in 1998 by Pfizer and the Edna McConnell Clark Foundation to treat and prevent blinding trachoma, the world’s leading cause of preventable blindness. ITI supports the implementation of the World Health Organization-recommended SAFE strategy, a comprehensive public health approach that combines treatment with prevention, involving sight-saving surgery, mass treatment with the Pfizer-donated Antibiotic Zithromax®, Facial cleanliness, and Environmental improvement to increase access to clean water and improved sanitation. ITI’s goal is to eliminate blinding trachoma, resulting in improved health and livelihood in some of the world’s poorest countries. ITI supports the WHO’s Alliance for Global Elimination of Trachoma by 2020 (GET 2020) as well as Vision 2020: The Right to Sight. Other ITI partners include AmeriCares, the Carter Center, Helen Keller International, Lions Club, the United Nations Children’s Fund (UNICEF), WaterAid, and World Vision.

The International Trachoma Initiative involves the following activities:

• Treat: provide patients in developing countries with antibiotics and providing surgery to treat advanced cases of trachoma;
• Teach: Educating communities about trachoma prevention and training healthcare workers to conduct surgeries for advanced trachoma cases;
• Build: Providing training and technical assistance to support national trachoma control campaigns;
• Serve: Advocating for increased funding for trachoma control and catalyzing partnerships to work towards trachoma elimination.

Since 1998, ITI has administered 74 million treatments of Zithromax® in 15 countries and trained thousands of healthcare workers who have performed more than 328,000 surgeries to treat advanced cases of trachoma. With the support of the ITI, Morocco became the first country to complete the campaign for trachoma control in 2006, and is now working toward WHO certification to signify that blinding trachoma has been eliminated as a public health problem.
The advent of multidrug therapy (MDT) in the early eighties changed the face of leprosy dramatically. Recommended by the World-Health Organization, MDT cures patients, interrupts the transmission of leprosy and prevents disabilities. Novartis developed two of the three medicines in MDT and has provided MDT, free of charge, for all patients in the world through the WHO since 2000. This is a core element in the WHO Elimination Strategy of creating awareness of the early signs of leprosy, improving patients’ access to free diagnosis and treatment, and close monitoring.

Strong support from countries, the WHO and partners has led to the cure of over 14 million people, more than 4.3 million through the Novartis-WHO collaboration. The prevalence rate has dropped by over 90% since 1985, from 21 per 10,000 inhabitants to less than 1 per 10,000 inhabitants worldwide. All but 4 countries in the world have successfully eliminated leprosy at a national level. Detection of new leprosy cases has decreased by 20% per year over the past three years.

Novartis and the Novartis Foundation for Sustainable Development also provide funds to cover the costs of freight and insurance, as well as independent quality control in addition to that carried out by the Novartis group. The value of the first phase of the donation, 2000-2005, was USD 40 million. In 2005, Novartis and WHO signed a new MoU to ensure the continued uninterrupted supply of high quality MDT, free of charge for all patients in the world, until the end of 2010. The Novartis Foundation has also been active in supporting national health ministries, the WHO and NGOs in field programs since the mid 1980s. It pioneered the use of social marketing in combating this disease. The underlying concepts of generating and meeting demand for leprosy treatment are now an integral part of the WHO leprosy elimination strategy.

The Foundation has also made a significant contribution to simplifying the provision of disability prevention services in communities. Many of the approaches devised in the Novartis Comprehensive Leprosy Care Association in India have now been incorporated in the disability care package of the government and of NGOs.

Merck Mectizan® Donation Program

Onchocerciasis, or river blindness, is a leading cause of infectious blindness in the developing world. The Merck Mectizan® Donation Program (MDP) was launched in 1987, when Merck & Co., Inc. announced that it would donate Mectizan® (ivermectin), for the treatment of onchocerciasis to all who needed it for as long as necessary. A multi-sectoral partnership was established with governments in countries where onchocerciasis is endemic, their ministries of health and other national and international stakeholders, including the World Health Organization, to ensure appropriate infrastructure, distribution and support. 2007 marked the 20th anniversary of the MDP. By the end of 2007, Merck had donated over 2.1 billion Mectizan® tablets worldwide (with an estimated value of USD 3.2 billion) with more than 600 million cumulative treatments approved since 1987. The program now reaches more than 70 million people a year in 33 countries in Africa, Latin America and Yemen. More than 125,000 affected communities manage the planning and distribution of Mectizan® through Community-Directed Treatment programs.

The MDP has made a substantial impact in the fight against onchocerciasis:

- In 2007, Merck and the World Bank announced an initiative to raise USD 50 million in support of the African Program for Onchocerciasis Control (APOC). Merck will donate up to USD 25 million to enable all affected African countries to have self-sustaining river blindness programs by 2015;
- In Africa, onchocerciasis control programs using Mectizan® are reported to have an economic rate of return of 17%;
- The program prevents 40,000 cases of blindness annually in Africa;
- In 9 of the 13 original endemic onchocerciasis foci in Latin America, ocular morbidity (eye disease) attributable to onchocerciasis has been eliminated;
- In 2007, treatment with Mectizan® was stopped in Colombia – the first country to eliminate river blindness transmission. Treatment has also been stopped in areas of Guatemala and Ecuador; in total, more than 74,000 people in 190 communities are no longer at-risk of contracting onchocerciasis – 13% of the former at-risk population in the Americas.

Community distributors, initially trained to distribute Mectizan®, are helping in the treatment of other maladies, such as lymphatic filariasis and Vitamin A deficiency. Polio immunization, Guinea worm disease eradication, and the diagnosis of cataracts and trachoma are also being linked to Community-Directed Treatment, a mechanism pioneered through Mectizan® distribution. In 1998, the MDP was expanded to include the elimination of lymphatic filariasis in African countries and Yemen, where it co-exists with onchocerciasis.
According to estimates by the World Health Organization (WHO), up to 300 million people suffer from schistosomiasis, a worm disease caused by schistosomes, parasitic worms that multiply as swimming eggs in certain water snails. Infection occurs when human skin comes into contact with freshwater contaminated by snails carrying the schistosome parasites, which migrate through the body and spread the infectious disease. Schistosomiasis causes anemia, stunted growth and learning disabilities. It is the second-most common tropical disease in Africa after malaria and is also prevalent in Asia, Africa, the Caribbean, the Middle East and South America. Some 600 million people at risk and around 200,000 people die of this disease every year.

In April 2007, Merck signed a partnership agreement with the World Health Organization to supply 200 million tablets of Cesol® 600 (praziquantel) for the treatment and prevention of schistosomiasis over a 10 year period. Some 27 million African school children will benefit from the Merck donation, with an estimated value of approximately USD 80 million, which is focused on 33 African countries. Angola, Benin, Cameroon, Central African Republic, Madagascar and Senegal have been designated by WHO/AFRO for priority control of neglected tropical diseases (NTDs).

Praziquantel is the most effective therapy to date for schistosomiasis infections – often even after just one dose – and it is well tolerated. It is therefore on the WHO list of essential drugs. The donation will address the issue of the affordability of praziquantel, which has been a barrier to access in poor communities and the main obstacle to implementing preventive anthelminthic chemotherapy in many African countries. Anthelminthic chemotherapy refers to drug treatment for worm infections, such as schistosomiasis, that disrupt the metabolism of the worms responsible, also known as helminths.

As part of its 5-year agreement with the World Health Organization (WHO) in October 2006 to extend its partnership in sleeping sickness (see separate entry below), sanofi-aventis also undertook to support a collaborative program with WHO to improve treatment for some “most neglected diseases”, namely leishmaniasis, Chagas disease and Buruli ulcer.

sanofi-aventis is providing USD 6.4 million to WHO for development of training, diagnostics and optimization of treatment for leishmaniasis. It will transfer the worldwide production of its leishmaniasis medicine Glucantime to its Brazilian subsidiary, to optimize product price. sanofi-aventis will also provide Glucantime at a tiered-price in all developing countries.

sanofi-aventis’ Brazilian subsidiary is developing a joint leishmaniasis control program with the Aggeu Magalhaes Research Center and the Oswaldo Cruz Foundation to set up a screening, care and follow-up program for 4,000 poor families in Pernambuco, to fight leishmaniasis and other endemic diseases in the region, such as tuberculosis or dengue. Similar programs are also being developed with the governments of Panama and Peru.

sanofi-aventis is also giving WHO USD 2 million for new programs to intensify disease management of Buruli ulcer and Chagas disease and USD 4 million to support field activities of its Innovative and Intensified Disease Management program.

In addition to the above-mentioned agreement with WHO, sanofi-aventis has partnered in 2007 with Handicap International to set up a five-year national campaign in Togo to reduce the death rate and the serious post-disease effects caused by Buruli ulcer.
<table>
<thead>
<tr>
<th>sanofi-aventis Sleeping Sickness Program</th>
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<tr>
<td>Sleeping sickness</td>
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<tr>
<td>sanofi-aventis</td>
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<td>WHO &amp; other partners</td>
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<td>Since 2001</td>
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<td>Access – Donation, Capacity Building – Support, R&amp;D</td>
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<tr>
<td>Sub-Saharan African countries</td>
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<td><a href="http://www.sanofi-aventis.com">www.sanofi-aventis.com</a></td>
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Considered all but conquered in the 1960s, sleeping sickness has reemerged in Africa with a vengeance as hunger, war, absence of surveillance and ignorance have contributed to the spread of the disease. In May 2001, sanofi-aventis committed USD 25 million over five years (2001-2006) to work in close collaboration with the World Health Organization (WHO) on a three-point strategy of adequate medicine supplies, disease surveillance and management, plus R&D for new treatments.

From July 2001 to March 2006, sanofi-aventis donated more than one million vials of eflornithine, pentamidine and melarsoprol to the WHO and delivered them to Médecins sans Frontières (MSF), which is providing storage, distribution, and administration of the medicines on behalf of the WHO, for national control programs and NGOs. In agreement with sanofi-aventis, Bristol-Myers Squibb funded the supply of the active ingredient for the eflornithine during the first year of the donation.

sanofi-aventis funds disease management and control programs, including screening of populations in endemic areas, medical staff training, surveillance of resistance to treatments. Thanks to this program, screening and treatment teams were back in the field in more than 25 sub-Saharan countries, mainly Angola, Cameroon, Chad, Central African Republic, the Democratic Republic of Congo and the Republic of Congo. In 2002, Bristol-Myers Squibb provided a complementary USD 400,000 cash donation to the WHO.

sanofi-aventis also provided financial support for development of new therapies through the UNDP-World Bank-WHO Special Program for Research and Training in Tropical Diseases (TDR). The R&D projects supported in this program included an oral form of eflornithine and a combination of eflornithine and nifurtimox. Based on promising results from the first range of clinical trials, the development of this combination has been continued. Bayer HealthCare provides nifurtimox for free in the quantities required for the clinical trials.

After five years, WHO and sanofi-aventis' efforts are estimated to have saved 110,000 lives. In October 2006, the company renewed its contract with the WHO and expanded it in order to address several additional “most neglected diseases” (see separate entry above). It has committed to provide a further USD 25 million over 5 years (2006-2011), with continued medicine donation for sleeping sickness, and a budget for training, control & diagnostic programs. In addition, a joint effort has been made to develop a kit to facilitate the use of eflornithine as a more “ready to use” solution.

<table>
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<tr>
<th>Soil-Transmitted Helminthiasis</th>
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<td>Soil-transmitted helminthias</td>
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<tr>
<td>Johnson &amp; Johnson</td>
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<tr>
<td>Task Force for Child Survival and Development</td>
</tr>
<tr>
<td>Since 2007</td>
</tr>
<tr>
<td>Access – Donation</td>
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<tr>
<td>Endemic countries</td>
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<tr>
<td><a href="http://www.jnj.com">www.jnj.com</a></td>
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Globally, up to 400 million children suffer from Soil-Transmitted Helminthiasis (STH), an infection of intestinal worms, but fewer than 20 percent of at-risk children were reached with de-worming treatment in 2005, falling far short of the World Health Assembly’s target to treat 75 percent of at-risk children by 2010. STH is especially dire for children because it causes malnutrition, increases susceptibility to other serious infections, and stunts growth during a critical development period.

STH has been identified by the WHO and the US Centers for Disease Control and Prevention as a “target of opportunity,” meaning that with existing diagnostic tools and treatments and greater support, it can be prevented, treated and controlled.

In 2007, Johnson & Johnson partnered with the Task Force for Child Survival and Development to develop and launch a program to donate 50 million doses of mebendazole in 2007 to treat children with or at high risk for STH. Mebendazole is one of a class of medicines known as antihelmintics that are used to treat numerous kinds of worm infections. This is the largest pharmaceutical donation, to date, to treat intestinal worms.
In March 2008, GlaxoSmithKline (GSK) and the Drugs for Neglected Diseases initiative (DNDi) announced a collaborative research effort targeting visceral leishmaniasis (kala azar), human African trypanosomiasis (sleeping sickness), and Chagas disease.

The collaboration, which has been established for an initial period of two years, will focus on identifying and developing compounds from existing GSK programs and will leverage the expertise of researchers at GSK’s Tres Cantos facility and leading academic centers like the London School of Hygiene & Tropical Medicine (LSHTM).

The collaboration has been formed to address unmet patient needs, as current treatments for these diseases have significant drawbacks, such as difficulty of administration, severe side effects, length of treatment, cost and emerging parasitic resistance.

Sitamaquine is GlaxoSmithKline’s potential new once-a-day oral treatment for visceral leishmaniasis. This disease affects half a million people a year in the developing world and is usually fatal if untreated.

Data from two Phase II proof-of-concept studies in Kenya and India are encouraging overall. After a 28-day course, 85 percent of patients remained cured at six months. Sitamaquine was generally well tolerated by patients in these studies. However, there were some concerns regarding renal adverse events seen in a few subjects, some of which appear to be treatment-related.

Interpretation of these data is complicated, in particular because VL itself is associated with renal impairment. Before proceeding to Phase III trials, GSK set up a Phase IIb study to compare the safety and tolerability of a 21 day course of sitamaquine with that of intravenous amphotericin B. Early results showed comparable efficacy to previous studies, despite the shorter course, and sitamaquine was very much better tolerated than amphotericin. A small number of patients had mild, reversible renal side effects.

GSK is currently providing all the funding for this project. A new treatment for visceral leishmaniasis is urgently needed, since current medicines are either impractical or becoming ineffective due to drug resistance, or are simply unaffordable.
Next-Generation Onchocerciasis Treatment R&D

Onchocerciasis
Wyeth
TDR
Since 1998
R&D
Democratic Republic of Congo, Ghana, Liberia
www.wyeth.com

Wyeth is collaborating with the UNICEF-UNDP-World Bank-WHO Special Programme for Research and Training in Tropical Diseases (TDR) to evaluate moxidectin as a new-generation macrofilaricidal agent for the control and potential eradication of onchocerciasis (river blindness) in the endemic countries.

Phase II proof-of-concept clinical trials with moxidectin were initiated in Ghana in September 2006. Pending positive outcomes from Phase II, Wyeth plans to initiate Phase III studies in Liberia and the Democratic Republic of Congo (DRC) in the third quarter of 2008. Wyeth will be providing substantial funding support to TDR to ensure successful implementation – and completion – of the Phase III studies. To this end, a comprehensive legal agreement between Wyeth and the TDR is expected to be signed by the two parties in the first quarter of 2008.

Nifurtimox-Eflornithine for Sleeping Sickness

Sleeping sickness
Bayer HealthCare, sanofi-aventis
Various partners
Since 2003
R&D
Democratic Republic of Congo, Uganda

Bayer HealthCare and sanofi-aventis provide financial support for development of new therapies through the UNDP-World Bank-WHO Special Program for Research and Training in Tropical Diseases (TDR). R&D projects supported include an oral form of eflornithine, manufactured by sanofi-aventis, and a combination of eflornithine and nifurtimox – the active ingredient of Lampit®, originally used to treat Chagas disease. Bayer HealthCare provides nifurtimox free in the quantities required for the clinical trials. Other partners involved include the Drugs for Neglected Diseases initiative (DNDi), Epicentre, Médecins sans Frontières (MSF) and the Swiss Tropical Institute. The Nifurtimox-Eflornithine Combination Trial (NECT) is currently in Phase III. The TDR program originally expected the approval of the combination therapy by 2008.

Onchocerciasis, or river blindness, is a leading cause of infectious blindness in the developing world. (Wyeth)
In October 2006, Pfizer announced a program with the UNICEF-UNDP-World Bank-WHO Special Programme for Research and Training in Tropical Diseases (TDR) to speed the search for new medicines to combat some of the world’s most deadly parasitic diseases, including malaria, leishmaniasis, African trypanosomiasis (sleeping sickness), onchocerciasis, schistosomiasis and Chagas disease.

Under the arrangement, scientists in institutes affiliated with the TDR-sponsored Compound Evaluation Network are screening thousands of compounds from the Pfizer library for “hits”: signs of activity against a range of tropical parasites. Developing country researchers, supported by another TDR-sponsored group, the Medicinal Chemistry Network, are working with scientists at Pfizer’s laboratories in Sandwich, UK, to evaluate the “hits” and from those select “lead” compounds with the greatest potential to be developed into new medicines for parasitic disease treatment and prevention. They are also being trained by Pfizer in the latest drug discovery research methods, before returning home to use their new knowledge and skills.

“This agreement with Pfizer is a step forward in expanding worldwide capacity in tropical disease research, because it enhances access to research tools for developing country researchers and expands access to large numbers of compounds for screening to identify new leads,” said Dr. Robert Ridley, director of TDR. “This collaboration also supports the sharing of knowledge between developed and developing country scientists, necessary to build research capacity in developing countries.”

Pfizer has initially provided 12,000 compounds, many of which are known to have activity against protozoan or helminth parasites. As TDR increases screening capacity across its network, Pfizer will provide more compounds. The company’s scientists will identify the compounds most likely to address biochemical targets associated with anti-parasitic activity.

The Singapore Dengue Consortium was founded in 2003 and has grown in the mean time to include 11 organizations together with NITD. The aim of the consortium is to explore ways to understand and better manage dengue infection, and ultimately minimize the incidence of dengue. In recent years, there has been an increased reporting of dengue incidence from various parts of the world; 50-100 million people get infected per year, of which 250-500,000 with the potentially fatal hemorrhagic form of the disease. At present, there is no cure or vaccine for this disease.

The Dengue Consortium will provide a platform for different parties to participate and share current work on dengue. The other consortium members include the DSO National Laboratories, Duke-NUS Graduate Medical School Singapore, Experimental Therapeutics Centre, Genome Institute of Singapore, Institute of Molecular and Cell Biology, Nanyang Technological University, National Environment Agency, National Healthcare Group, National University of Singapore and Singapore Health Services.

The NITD is contributing its drug discovery know-how to find new therapies for dengue, while being fully complementary to the other members of the consortium. The first project on the drawing board is the dengue virus-sequencing project, which will provide information on the entire virus genome together with annotation of clinical data and patient history. This information will be valuable for surveillance as well as understanding the genetic variations of different serotypes.

Long-term goals of those studies are to characterize virus- and host-specific factors responsible for the onset of the disease, as well as to correlate viral genetic markers with the clinical severity of the disease.
Patients in a leper colony in Mumbai, India. (Prashant Sawant, Novartis)
Milestones in saving and improving lives through immunization

Smallpox
Smallpox was eradicated in 1977 after a 10-year WHO campaign. When the program began, smallpox threatened 60% of the world’s population and killed every fourth person infected.

Polio
Launched in 1988 by the WHO and partners, the Global Polio Eradication Initiative has reduced infections by more than 99% and some 5 million people have escaped paralysis.

Measles
Measles is virtually eliminated in the Americas. Measles deaths worldwide dropped by more than almost 40% 1999-2003, thanks to the WHO and partner organizations.

Neonatal tetanus
Neonatal tetanus mortality has been reduced by about three quarters. The estimated number of deaths has decreased from 800,000 in the 1980s to under 200,000 in recent years.

Hepatitis B
An estimated future 600,000 hepatitis B-related deaths (from liver cirrhosis and cancer) are now being prevented on an annual basis through infant vaccination.

(Source: WHO immunization work: 2005 highlights, WHO/IVB/06.02)

Distribution of the estimated deaths from diseases that are preventable by vaccination in 2002 (WHO)

<table>
<thead>
<tr>
<th>Diseases</th>
<th>death &lt;5 years of age (000)</th>
<th>deaths total (000)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Measles</td>
<td>540</td>
<td>610</td>
</tr>
<tr>
<td>Hib</td>
<td>386</td>
<td>386</td>
</tr>
<tr>
<td>Pertussis</td>
<td>294</td>
<td>294</td>
</tr>
<tr>
<td>Tetanus</td>
<td>198</td>
<td>213</td>
</tr>
<tr>
<td>Yellow fever</td>
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<td>30</td>
</tr>
<tr>
<td>Diphtheria</td>
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<td>5</td>
</tr>
<tr>
<td>Polio</td>
<td>&lt;1</td>
<td>&lt;1</td>
</tr>
<tr>
<td>Hepatitis B</td>
<td>&lt;1</td>
<td>600</td>
</tr>
</tbody>
</table>

Diseases for which vaccination is part of most national immunization schedules

- Japanese encephalitis 5 14
- Meningococcal 10 26
- Rotavirus 402 449
- Pneumococcal 716 1,612

TOTAL DEATHS FROM ALL CAUSES 10,468 57,029
National immunization programs cover more than 70% of the world’s targeted population. It is estimated that the vaccinations done in 2003 alone will prevent more than 2 million deaths from vaccine-preventable diseases and an additional 600,000 deaths related to hepatitis B that would otherwise have occurred in adulthood among the children immunized in that year. However, an estimated 27 million infants and 40 million pregnant women worldwide remained in need of immunization in 2003. The cost of not immunizing is higher because people who are not vaccinated as infants remain vulnerable for the rest of their lives.

New vaccines are being developed against major infectious diseases and several have just been licensed recently. Among the illnesses targeted are rotavirus diarrhea, pneumococcal disease, and cervical cancer (caused by human papillomavirus), which together kill more than a million people each year, most of them in developing countries.

Moreover, continuing efforts are under way to develop vaccines for AIDS, malaria, tuberculosis, dengue, leishmaniasis, and intestinal diseases, among others and to adapt new technologies to improve formulation and delivery. In September 2005, the United Kingdom, France, Italy, Spain, and Sweden committed nearly USD 4 billion to immunization in developing countries over the next decade, using an innovative new mechanism called the International Finance Facility for Immunization (IFFIm). IFFIm and innovative finance mechanisms such as Advance Market Commitments (AMCs) reflect a growing willingness on the part of developed countries to make significant financial resources available to meet important health needs in resource-poor countries.


<table>
<thead>
<tr>
<th>Presently Available Vaccines</th>
<th>R&amp;D Pipeline Vaccines</th>
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<tbody>
<tr>
<td><strong>Bacterial</strong></td>
<td><strong>Viral</strong></td>
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<tr>
<td>Anthrax</td>
<td>Clostridium difficile</td>
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<td>Cholera</td>
<td>Q Fever</td>
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<td>Diphtheria</td>
<td>Tetanus</td>
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<td>Hib</td>
<td>Tuberculosis (BCG)</td>
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<td>Typhoid</td>
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<td><strong>Viral</strong></td>
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<td>Cytomegalovirus</td>
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<td>Hepatitis B</td>
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<td>Epstein-Barr Virus</td>
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<td>and Other Vaccines</td>
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<td><strong>Cervical Cancer</strong></td>
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<td><strong>Cocaine Addiction</strong></td>
<td>Pediatric Tumors</td>
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<td><strong>Colorectal Cancer</strong></td>
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Source: IFPMA Inquiry – Oct. 2007  
1 Haemophilus influenzae Type b  
2 (A, C, Y, W135 and combinations)  
3 Human Papillomavirus  
4 Hay Fever
EPIVAC (from EPIdemiology & VACcinology) is a comprehensive, one-year, on-the-job professional training program in epidemiology, applied computing, vaccinology and management of health programs for doctors in West Africa, culminating in an inter-university diploma in “Organization and Management of Public Immunization Programs in Developing Countries” awarded by the universities of Cocody-Abidjan (Ivory Coast) and Paris-Dauphine (France).

The program is a sanofi pasteur (the vaccine branch of sanofi-aventis) contribution to the GAVI Alliance. Implemented by the Agence de Médecine Préventive, the program was developed in partnership with national governments of eligible countries and the participating universities, in collaboration with the WHO, UNICEF, the Vaccine Fund and other partners working in Africa. EPIVAC is coordinated with the GAVI subregional working group and complements other GAVI support to African countries.

EPIVAC seeks to strengthen the GAVI process within each country in coordination with the Interagency Coordinating Committee (ICC). The ICC assists in the selection of EPIVAC enrollees. EPIVAC not only utilizes classroom, on-the-job training, and distance learning, but also combines two subject matters that are usually taught separately: applied vaccinology and management sciences. Participants are trained while continuing to provide vital public health services to their communities. Studying on-the-job also enables learning to be put into practice immediately.

The EPIVAC program monitors and evaluates the impact of training on immunization delivery and management in the district. Between 2002 and 2007, approximately 250 doctors have been enrolled in EPIVAC training. Another 50 have been enrolled in EPIVAC’s 6th consecutive year of operation in November 2007. Doctors have been trained from Benin, Burkina Faso, Cameroon, Côte d’Ivoire, Mali, Mauritania, Niger, Senegal and Togo.

GAVI Alliance

The GAVI Alliance was created to reduce childhood morbidity and mortality from vaccine preventable diseases by increasing immunization rates and improving vaccine access for children in developing countries, in response to stagnating global immunization rates and a widening gap in vaccine access in developing countries. The GAVI Fund provides financial support to low-income countries, based upon applications to and recommendations by the GAVI Alliance Board.

The Alliance’s partners include industrialized countries vaccine manufacturers (Crucell, GlaxoSmithKline, Merck & Co., Inc., Novartis, sanofi-aventis, Wyeth – all IFPMA members), developing countries vaccine industry, industrialized and developing country governments, UNICEF, the WHO, the World Bank, charitable foundations and NGOs. Industry partners invest in the development of new vaccines and in enhanced global vaccine manufacturing capacity, including facilities in developing countries. They also help to educate healthcare providers and develop technologies to facilitate vaccine distribution.

Crucell support for GAVI includes supplying the world’s first monodose fully liquid pentavalent (5-in-1) vaccine Quinvaxem™, which protects children against 5 diseases (DTP-HepB-Hib) in one single shot. Country applications for Hib antigen have doubled in 2007 and over 110 million doses of pentavalent vaccine have been requested for 2008-2012.

As part of its support for the GAVI Alliance, the Merck Company Foundation funds the Merck Vaccine Network – Africa. Merck also provided 1 million doses of MMR II vaccine for mumps, measles and rubella to Honduras over a three-year period and also committed to donate 5 million doses of hepatitis B vaccine in support of GAVI. Merck is also providing rotavirus vaccination for all infants in Nicaragua for a three-year period.

sanofi pasteur supports GAVI’s polio eradication efforts and has donated 120 million doses of oral polio vaccine (OPV) since 1997. It also supports the GAVI Yellow fever vaccine initiative for Africa. In December 2007, sanofi pasteur sponsored the 1st EPIVAC technical conference on yellow fever, which drew 150 participants from Benin, Burkina Faso, Cameroon, Côte d’Ivoire, Guinea, Mali, Senegal and Togo.

In November 2006, the GAVI Board approved investment in pneumococcal and rotavirus vaccines, including Wyeth’s Prevenar® vaccine from 2008-2010. In February 2007, donor countries approved an Advance Market Commitment (AMC) pilot program to encourage development of new pneumococcal vaccines.
Global Polio Eradication Initiative

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<tr>
<th>Polio</th>
<th>HPV Vaccine &amp; Cervical Cancer</th>
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<tr>
<td>Novartis, sanofi-aventis</td>
<td>Cervical cancer</td>
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<td>WHO &amp; other partners</td>
<td>GlaxoSmithKline, Merck &amp; Co. Inc.</td>
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<td>Since 1988</td>
<td>Program for Appropriate Technology in Health</td>
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<td>Afghanistan, Egypt, India, Indonesia, Nigeria, Pakistan</td>
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<td><a href="http://www.polioeradication.org">www.polioeradication.org</a></td>
<td>Access – Pricing</td>
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<td>India, Peru, Uganda, Vietnam</td>
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In January 2004, a new plan was unveiled to immunize 250 million children in the remaining polio-endemic countries to eradicate finally a disease that once paralyzed hundreds of thousands of children each year. Working in cooperation, the World Health Organization (WHO), Rotary International, the US Centers for Disease Control and Prevention (US CDC) and the United Nations Children’s Fund (UNICEF) agreed to accelerate efforts targeted at eradicating polio.

In 2002, sanofi pasteur, sanofi-aventis’ vaccine division, announced that it would donate 30 million doses of the Oral Polio Vaccine (OPV) to the Global Polio Eradication Initiative through 2005. sanofi pasteur, the longest-standing corporate partner in the Initiative, has donated 120 million OPV doses since 1997. At the WHO’s request, sanofi pasteur developed and licensed a new vaccine in record time in 2005 – Monovalent Oral Polio Vaccine 1 or MOPV1 – for use first in Egypt as a critical part of a new WHO strategy to end polio transmission. sanofi pasteur also provides bulk mOPV1 to a manufacturer in India, to fill and package for local use. In 2007, sanofi pasteur donated 270,000 doses of inactivated polio vaccine (IPV) to Indonesia for a WHO sponsored study on IPV introduction in Lombok.

In 1996, Chiron Vaccines, now Novartis Vaccines, and two other OPV manufacturers pledged to donate a total of 100 million doses of polio vaccine for international vaccination campaigns to support the Global Polio Eradication Initiative. Through 2006, Novartis has donated 33.3 million doses, one-third of the industry pledge. Novartis has also invested in the specific development of monovalent polio vaccine (mOPV) instead of classical trivalent (tOPV) to eradicate the disease.

Cervical cancer is the second most common cancer in women worldwide, with about 500,000 new cases and 250,000 deaths occurring each year. Almost 80% of cases occur in low-income countries, where cervical cancer is the number one cause of cancer in women. Virtually all cervical cancer cases (99%) are linked to genital infection with human papillomavirus (HPV), a family of virus types which also causes genital warts and other forms of cancer.

PATH, the Program for Appropriate Technology in Health, is an international, nonprofit organization that creates sustainable, culturally relevant health solutions, and works to advance acceptable and affordable new technologies for low-resource settings. PATH is partnering with GlaxoSmithKline and Merck & Co., Inc., both of which have developed HPV vaccines, to conduct pilot HPV vaccination programs in adolescent females, looking at acceptance and accessibility. The countries selected are India, Peru, Uganda and Vietnam. The PATH project also looks at issues such as adapting vaccination schedules to fit with the school year, to maximize potential uptake. PATH has received a grant for this project from the Bill & Melinda Gates Foundation.

As part of Merck’s comprehensive approach to bringing newer vaccines to the developing world, Merck launched The Gardasil® Access Program at the Clinton Global Initiative in 2007. This initiative aims to donate at least 3 million doses of Merck’s cervical cancer vaccine to support vaccination programs in lowest income nations. To implement this program, Merck expects to establish a partnership with a non-governmental organization to establish formal criteria for the program and to review proposals from developing world nations working independently and/or with non-governmental organizations, governments, or international organizations. Merck will provide free doses of Gardasil® for use in these programs.

Vaccination is a cost-effective health measure. (WHO, PAHO)
One of the major reasons for low vaccination rates in developing countries, according to the World Health Organization, is the lack of skilled health care professionals. As part of Merck & Co., Inc.’s commitment to the GAVI Alliance, the Merck Vaccine Network – Africa (MVN-A) was developed to help increase the capacity of immunization programs in Africa. MVN-A is one of Merck’s major programs in Africa and reflects the Company’s commitment to improving access to medicines in the developing world through disease education, training, and service initiatives.

Funded by The Merck Company Foundation, MVN-A launched in 2003 through a competitive grants process. Since that time, MVN-A training Centers in Kenya, Mali, Uganda, and Zambia have been established to train health professionals in vaccine management and immunization services. Training materials are based on curricula and educational training source materials developed by WHO and other GAVI partners. In November 2007, The Merck Company Foundation provided renewed funding to expand training for health workers in Kenya and Mali and committed to fund the establishment of two new MVN-A training Centers, in Uganda and Zambia.

MVN-A training center partners include: Indiana University School of Medicine and Moi University Faculty of Health Sciences (Kenya); Center for Vaccine Development, University of Maryland School of Medicine and the Center for Vaccine Development, Centre national d’appui à la lutte contre la maladie (Mali); Task Force for Child Survival and Development, Emory University and Makerere University School of Public Health (Uganda); and Brighton and Sussex University Hospitals NHS Trust and the University of Zambia School of Medicine (Zambia).

MVN-A course graduates, mid- to high-level level immunization program managers, return to their home medical facilities and share their expertise and knowledge with front-line colleagues. More than 270 health professionals have completed MVN-A training to date.

Social factors make poor countries particularly vulnerable to an influenza pandemic and they are less able to afford vaccines and antiviral medicines.

GlaxoSmithKline has invested some USD 2 billion in developing vaccines to combat H5N1 influenza, and to increase production capacity for its influenza vaccines and antiviral flu treatment Relenza® (zanamivir). It has set a preferential price for Relenza® for Least-Developed Countries (LDCs) and has granted Simcere, China, a voluntary licence to make zanamivir and sell it in China, Indonesia, Thailand, Vietnam, and all LDCs.

GSK’s pre-pandemic H5N1 vaccine received a positive opinion from the EU Committee for Medicinal Products for Human Use in February 2008. It obtains strong immune responses from a small dose, allowing more people to be protected with a given amount. In 2007, GSK announced it would donate 50 million doses of H5N1 vaccine to a WHO stockpile. This vaccine will also be sold at preferential prices to the WHO stockpile and poorer countries.

Roche has increased its capacity to make Tamiflu® (oseltamivir) antiviral medicine by 50% since 2002. By 2007, it could produce 400 million courses per year if required. It sells Tamiflu® at a reduced price for pandemic stockpiling and offers further price reductions to low-income countries. Production can be increased if key inventories drop below target levels or the WHO declares a phase 4 pandemic (human-to-human transmission).

Roche and Gilead (which developed Tamiflu®) hold no patents on it in LDCs, whose governments are free to make generic versions. Roche has granted sublicenses to Shanghai Pharmaceuticals and HEC Group, China and Hetero Pharmaceuticals, India, to make oseltamivir, and has transferred technology to Aspen Pharmaceuticals, South Africa, for pandemic stockpiling by African governments. Roche has also donated over 5 million treatment courses of Tamiflu® for WHO central and regional pandemic stockpiles.
Rotavirus Vaccine Program

Rotavirus-induced gastroenteritis
GlaxoSmithKline, Merck & Co. Inc.
GAVI Alliance & other partners
Since 2003
Access – Pricing
Australia, Brazil, El Salvador, Mexico, Nicaragua, Panama, Venezuela
www.rotavirusvaccine.org

Rotavirus infection is the leading cause of severe diarrhea and vomiting (gastroenteritis) in children under two and kills around 600,000 children each year, mostly in developing countries. With funding from the GAVI Alliance and the Vaccine Fund, the Program for Appropriate Technology in Health (PATH) established the Rotavirus Vaccine Program (RVP) in 2003. With its strategic partners, the World Health Organization (WHO) and the US Centers for Disease Control and Prevention, RVP is working to accelerate introduction of the two available vaccines.

GlaxoSmithKline’s vaccine, Rotarix™, is a two-dose oral vaccine targeting one rotavirus strain. GSK has completed trials in a number of developing countries, with more underway in conjunction with PATH in the course of 2006. GSK received approval from the Mexican regulatory authorities in July 2004 and launched the vaccine officially in Mexico in January 2005. Rotarix™ has now been approved in various countries in Europe, Latin America and Asia. By early 2006, four countries – Brazil, Panama, Venezuela and El Salvador – had decided to vaccinate all newborn babies. To date, GSK has distributed 1.4 million doses in Latin America, enough for 700,000 babies.

Merck & Co., Inc.’s vaccine, RotaTeq®, is a three-dose, ready-to-use oral vaccine that protects against five common rotavirus strains. It has been tested in clinical trials in over 70,000 infants in 11 countries and Merck is working with RVP/PATH to conduct further trials in Africa and Asia. To date, Merck has filed for marketing authorization of RotaTeq® in more than 130 countries, and it is approved in over 80, including the USA, most European countries, Australia, Canada, Mexico and others.

In September 2006, Merck and the Nicaraguan Ministry of Health announced the RotaTeq® Partnership, to provide rotavirus vaccine to all Nicaraguan infants and to demonstrate the facility and public health impact of universal immunization with RotaTeq®. Through this partnership, all infants born in Nicaragua in a three-year period will receive free RotaTeq® vaccine.

The RotaTeq® launch in Nicaragua in October 2006 made it the first GAVI-eligible country to introduce rotavirus vaccine and was the first time that a vaccine was introduced in the public sector of a developing country in the same year as in the industrialized world. Historically, it has taken up to 15 years for new vaccines to reach the world’s poorest countries. At the end of the project, Merck will sell RotaTeq® to the Nicaraguan government at prices significantly lower than those for the developed world. Merck is committed to working with its partners to make RotaTeq® available to infants and children worldwide as quickly as possible, and at no-profit prices for those in developing countries.
### IFPMA Influenza Vaccine Supply International Task Force

**Influenza**

**IFPMA IVS**

World Health Organization (WHO) & other partners

Since 2002

R&D

Worldwide


The IFPMA Influenza Vaccine Supply International Task Force (IFPMA IVS), established in 2002 under the IFPMA Biologicals and Vaccines committee, brings together research-based influenza vaccine manufacturers from around the world, representing more than 95% of the world seasonal influenza vaccine production. IFPMA IVS members* conduct the R&D needed to develop safe, effective, high-quality human vaccines against seasonal, avian and pandemic influenza threats.

The IFPMA IVS works within antitrust law to address the advocacy, communication, policymaking, regulatory, scientific and technical issues related to influenza vaccines. IVS members are committed to make their unique expertise in R&D, logistics, manufacturing, safety and regulatory issues available to help regional/national governmental and intergovernmental bodies as well as non-governmental stakeholders in pandemic planning and decision-making.

The IFPMA IVS Scientific, Production and Regulatory working group looks at technical issues related to developing, licensing and producing influenza vaccines. It works closely with national and international agencies, including the World Health Organization (WHO), the WHO Collaborating Centers and Reference Laboratories in Australia, Japan, the UK and the USA.

The IFPMA IVS Policy, Practices and Communication working group articulates key industry messages, promotes the societal value of influenza vaccination and organizes technical briefings on avian/pandemic influenza issues. It helped collect data on influenza vaccine distribution worldwide and conducted a large health economics study on the expansion of influenza vaccination for adults 50 years and older instead of the recommended 65 years of age, which confirmed the cost-effectiveness and economic value of influenza vaccination for public health.

The IFPMA IVS also develops position papers providing the industry perspective on pandemic preparedness and helps fund the development of high-growth reassortants and influenza virus egg isolates, as well as a computerized analytical system to monitor change in influenza viruses. This work is currently conducted by the WHO Collaborating Centers and Reference Laboratories, New York Medical College and the University of Cambridge in the UK.

* IFPMA IVS members: Baxter, Biken, CSL Limited, Crucell, Denka Seiken, GlaxoSmithKline Biologicals, Kaketsuken, Kitasato Institute, MedImmune (AstraZeneca), Nobilon International (Schering-Plough), Novartis, PowderMed (Pfizer), sanofi pasteur, Sanofi Pasteur MSD, Sinovac and Solvay Pharmaceuticals.

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### Infectious Disease Research Institute (IDRI)

**Leishmaniasis, tuberculosis**

GlaxoSmithKline, Lilly

Infectious Disease Research Institute (IDRI) & other partners

Since 1994

R&D

India

www.idri.org

The Infectious Disease Research Institute (IDRI) was established in 1994 as a tax-exempt, not-for-profit US scientific organization to optimize the development of vaccines, therapeutics and diagnostics for leishmaniasis and other diseases of the poor. It was supported by public funds and the former Corixa Corporation, an R&D-based biotechnology and vaccine company that was merged with GlaxoSmithKline in mid-2005. IDRI is also funded by the Lilly Foundation.

In March 2000, IDRI received a USD 15 million grant from the Bill and Melinda Gates Foundation (BMGF) to fund its efforts to develop a vaccine to prevent leishmaniasis. IDRI has conducted clinical trials for leishmaniasis candidate vaccines in Brazil, Colombia and Peru, and has a trial ongoing in India.

IDRI helped develop a tuberculosis vaccine being tested by the Aeras Global TB Vaccine Foundation. It also developed a blood test for Chagas disease in collaboration with Corixa and is working on a possible vaccine.
Novartis Vaccines Institute for Global Health (NVGH)

Novartis Vaccines Institute for Global Health (NVGH) is a research institute with a nonprofit mission dedicated to the translational research and development of vaccines for diseases of the developing world.

Inaugurated in February 2008, NVGH is located on the Novartis Campus in Siena, Italy where it shares the world-class facilities and technologies of the company's vaccines research headquarters. The Institute will work with universities, research institutes and other public and private organizations to develop the scientific basis for vaccine development and bridge an existing gap between the discovery of promising vaccine candidates in academic research institutes and their manufacturing and distribution, by providing the facilities and expertise for scale vaccine production and human proof of concept studies. NVGH will also collaborate with organizations such as the GAVI Alliance, the WHO and UNICEF.

At present, most NVGH research is focused on conjugate vaccines for enteric diseases. Initial disease areas will be Salmonella enterica serovar typhi (S. typhi), Salmonella paratyphi A and nontyphoidal salmonellae (NTS), which are important causes of infection and disease in children. In Africa, multidrug-resistant non-typhoidal salmonella (NTS) is one of the leading causes of morbidity and high mortality in children under 5 years of age, second in importance only to pneumococcal disease. With more than 4.5 billion cases per year, diarrheal diseases are ubiquitous around the globe.

Pediatric Dengue Vaccine Initiative (PDVI)

Dengue fever is the second most widespread tropical disease after malaria. The Pediatric Dengue Vaccine Initiative (PDVI) was established in 2001 to accelerate the development of a dengue vaccine that is appropriate, safe and accessible to poor children in endemic countries. The PDVI headquarters are at the International Vaccine Institute, in Seoul, Korea. Some of the Initiative’s goals include: Country surveys to define better the burden of dengue illness; Support R&D and enhance developing country science capacity; A scientific blueprint for a safe, effective and affordable pediatric dengue vaccine.

No specific treatment is currently available and vector-control strategies have been insufficient. Dengue vaccines offer an impending solution to control this major global health problem and there are several robust dengue vaccine candidates, but many challenges remain. A focused effort should achieve a safe, broadly protective dengue vaccine for children in a matter of years.

The Initiative is supported by governments of endemic countries, academic research centers in the USA and South-East Asia and the pharmaceutical industry, including sanofi pasteur and GlaxoSmithKline. Every two years the Novartis Institute for Tropical Diseases co-organizes the Asian Regional Dengue Research Network Meeting with PDVI.

In September 2006, sanofi pasteur and the PDVI announced a partnership to develop a Dengue vaccine and make it widely available for global prevention. At the forefront of dengue vaccine development with an active research and development program which started in the 1990s, sanofi pasteur is currently evaluating its lead vaccine candidate in expanded Phase II clinical trials in Mexico and the Philippines. In 2007, sanofi pasteur announced that immunization with sanofi pasteur’s tetravalent dengue vaccine candidate generated a sero-neutralizing antibody response against all four serotypes of the virus responsible for dengue fever in 100% of adults who participated in the a clinical trial in the United States.
Wyeth Pneumococcal Vaccine Studies in Africa

In 2002, a joint study by the World Health Organization (WHO) and South African Medical Research Council 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 then, 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.

Wyeth also helped fund the provision of the newly developed pneumococcal conjugate vaccine for a five-year clinical trial in the Gambia. The UK Medical Research Council conducted this study in cooperation with the Bill and Melinda Gates Foundation (BMGF), the US National Institutes of Health (NIH), the US Agency for International Development (USAID), the WHO and others.

Results 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 serotypes; 3) there were 37 fewer cases of pneumonia in the children who received the vaccine compared with children who received a controlled vaccine.
The timeframe for developing a new vaccine is usually longer than that for developing a new medicine. (GlaxoSmithKline)
Neonatal and maternal mortality are related to the absence of a skilled birth attendant.

Each year 3.3 million babies – or maybe even more – are still-born, more than 4 million die within 28 days of coming into the world, and a further 6.6 million young children die before their fifth birthday. Moreover, children suffer from the same illnesses as adults but they are more seriously affected by certain conditions such as respiratory tract infections, malaria and diarrhoeal diseases. Financial resources are needed to increase priority interventions for these preventable, manageable and treatable conditions.

Maternal deaths also continue unabated and the annual total now stands at 529,000. These are often sudden, unpredictable deaths which occur during pregnancy itself, during childbirth, or after the baby has been born – leaving behind devastated families, often pushed into poverty because of the cost of health care that came too late or was ineffective.

In developing countries, interventions that are known to be effective in lowering maternal and perinatal mortality and morbidity are not universally provided. Scaling-up the coverage of maternal and newborn health care provided by skilled personnel is expected to have a considerable impact in helping to achieve Millennium Development Goal 5, which aims to improve the health of mothers, and also 4, which focuses on reducing child mortality.

The main constraint is the shortage of skilled professionals: it is necessary to train nurses, midwives and health educators to provide skilled assistance during labor and delivery, as well as care for infants and children. Moreover, countries, donors and multilateral agencies must mobilize resources to strengthen health infrastructure: to create new hospitals, to upgrade equipment and facilities, and provide them with essential medicines.


Global distribution of cause-specific mortality among children under five

Malnutrition is a significant contributor of early morbidity and mortality among young children in Cambodia. According to UNICEF, the mortality rate for children under five increased from 115 per 1,000 live births in 1990 to 143 in 2005; nearly 45 percent of all children under five are underweight. Since 2006, Abbott and Abbott Fund have partnered with Direct Relief International (DRI) and Angkor Hospital for Children in Siem Reap in an effort to reverse these troubling trends.

Abbott and Abbott Fund have provided grants and products to support the work of Angkor Hospital for Children, a pediatric teaching hospital providing free comprehensive care for more than 180,000 children in Siem Reap and neighboring provinces. DRI, a global humanitarian assistance organization, manages the distribution of Abbott's grants and product donations.

In 2005, Angkor Hospital for Children became the country's first teaching hospital and is one of two sites selected to host the World Health Organization’s Integrated Management of Children’s Illnesses training programs. Abbott Fund is focused on improving health professional and caregiver awareness, knowledge and ability to treat pediatric nutrition through formal training, local and regional educational workshops, cooking demonstrations, and donations of essential products.

Abbott has donated products to improve maternal and child health, including Pedialyte® rehydration solution, the antibiotic Biaxin®, multivitamins and the nutritional supplement Ensure® and Pedialyte®.

Since the partnership began, more than 135,000 children have received nutritional assessments, more than 3,000 families have attended nutrition information workshops, and more than 270 health professionals have received nutrition training. The program’s success has helped Angkor Hospital for Children serve as a role model for hospital nutrition programs in Cambodia.

According to the World Health Organization, Afghanistan has the second highest maternal mortality rate in the world, with 1,900 deaths per 100,000 live births. In addition, one in four Afghan children will not live to see their fifth birthday. To improve the lives of women and children in Afghanistan, Abbott and Abbott Fund are partnering with the Afghan Institute for Learning (AIL) and Direct Relief International (DRI) to help reverse the country's high maternal mortality rate, and increase the survival and overall health of infants and children.

Abbott and Abbott Fund have provided USD 3 million in grant funding and product donations to support the work of AIL, founded by Nobel Prize nominee Sakena Yacoobi, a long-time advocate for women’s rights in Afghanistan. DRI, a global humanitarian assistance organization, manages the distribution of Abbott’s grants and product donations to AIL.

With three clinics serving mostly rural areas in Afghanistan (two in Herat province, one in Kabul province), AIL is staffed and operated by Afghan women. Abbott Fund support is focused on empowering Afghan women through the training of female nurses, midwives and health educators to provide skilled assistance during labor and delivery, as well as care for infants and children. Abbott Fund also is supporting AIL women’s health workshops that provide health education directly to Afghan women.

Abbott has donated products to improve maternal and child health, including Pedialyte® rehydration solution, the antibiotic Biaxin®, multivitamins and the nutritional supplements Ensure® and Ensure Healthy Mom®.

Since the partnership began in November 2005, more than 100,000 women and children have received its services. Nineteen nurses/midwives have been trained, with most now employed in clinics and hospitals. Abbott Fund supported the training of 25 additional women in 2007.
AstraZeneca – Promoting Safe Motherhood in India

Maternal health

AstraZeneca

Federation of Obstetric & Gynaecological Societies of India

Since 2005

Capacity Building – Training, Education

India

www.astrazeneca.com

Each year, more than 500,000 women die of pregnancy-related causes in the developing world. During 2005, AstraZeneca India initiated a “Safe Motherhood” program, in partnership with the Federation of Obstetric & Gynaecological Societies of India. Focused on making labour and delivery safer for mothers, the program included over 60 conferences for healthcare professionals in 2005, as well as media campaigns to build public awareness.

With AstraZeneca’s support, the Federation of Obstetric and Gynaecological Societies of India started a campaign to educate rural women in India about “Safe Motherhood” and other issues related to women and adolescence. In its most recent campaign, SuPraBha Ganga Yatra, the partners organized a unique “walkathon” along the river Ganges. The aim was to spread Safe Motherhood messages and practices among the rural population in areas with high maternal mortality by educating them, using local languages. A team of 27 doctors accompanied by children from local villages covered 5 states in 108 days, met 200,000 people, conducted health camps for 25,000 women and visited 80 schools.

Main achievements include:

- Rubella vaccination for over 1,000 teenage girls;
- Distribution of medicines;
- Educational films on anemia, HIV/AIDS and female feticide shown to 500 people / day;
- Visits to over 100 schools covered around 80,000 children in rural areas;
- 1-1 talks on education, marital age, gender bias, female feticide, HIV/AIDS, sanitation, environment and nutrition.

Bayer Schering Pharma & Family Planning

Family planning

Bayer HealthCare

Governments, multilateral organizations, private organizations

Since 1961

Access – Pricing, Capacity Building – Training, Education

Worldwide

www.bayerscheringpharma.de

For more than 46 years, Bayer Schering Pharma AG (part of Bayer HealthCare) has been supporting family planning programs in over 130 countries with its high quality products in close co-operation with government organizations (BMZ – German Federal Ministry for Economic Cooperation and Development, KFW – German Development Bank, GTZ – German Association for Technical Cooperation, the UK’s DFID and DANIDA), multilateral organizations (UNFPA, the World Bank, the WHO, and USAID), and private organizations (International Planned Parenthood Federation, Population Services International, Marie Stopes, IMRES and Missionpharma).

In that time, more than 2.5 billion cycle packs of oral contraceptives have been provided to family planning organizations and users in the developing world. The product range include a wide choice of contraceptive methods, (mono- and triphasic combined oral contraceptives and progestogen-only products), injectables (one- and three-monthly), implants and intrauterine devices/systems. These products are of the same quality as those available on the private market but they are sold at no profit to organizations running family planning projects in developing countries. In 2007, Bayer contributed about 40 million cycles of oral contraceptives and more than 3 million injectables worldwide.

With its family planning programs, Bayer wants to help people to make informed and independent decisions concerning their family size, taking into account the best possible conditions for the future of their children. Family Planning reduces women’s exposure to health risks of unwanted childbirth and unsafe abortions.

Bayer is committed to making universal access to fertility control means a reality by 2015, as recommended by the International Conference on Population and Development. Through its long-term commitment to family planning, Bayer is making a substantial contribution to the UN Millennium Development Goals, including empowering women, reducing child mortality and improving maternal health by 2015.

Training programs for family planning providers are also part of Bayer’s commitment. Since sexual education is vital to contraception, Bayer supports programs like the CELSAM project (Centro Latinoamericano Salud y Mujer), providing detailed information on sexual education in all Latin American countries by radio, educational programs for schools and universities, telephone hotlines and information booths on the streets.

A family planning consultation in Lusaka, Zambia. (Bayer Schering Pharma)
In Indonesia, 20,000 women die each year as a result of pregnancy or delivery, and 165,000 infants die before, during or directly after birth. Midwives are crucial to improving reproductive health services. Working with the Johns Hopkins University’s JHPIEGO unit, the Indonesian Midwives Association is trying to increase the standard of care among private practice midwives in the country. The Bidan Delima Program, a component of the Sustaining Technical Achievements in Reproductive Health/Family Planning project operated by IMA, was implemented in 2003.

Johnson & Johnson has supported this midwife training program since its inception in 2003. This past year, the Company provided funds to train 600 midwives in the national clinical standards of midwifery. These standards cover family planning services, infection prevention, contraceptive technology and safe delivery care. The Association also was able to produce an updated version of its national safe delivery training video, which is used to train 76,000 practicing midwives in Indonesia.

For more than 25 years, Organon, a part of Schering-Plough, has supplied a range of high-quality contraceptives at discounted prices to family planning programs of Ministries of Health of developing countries, both directly, and in cooperation with organizations that finance and support these programs such as the United Nations Population Fund (UNFPA), the World Bank, the US Agency for International Development (USAID), the German Development Bank (KFW), and UK Department for International Development (DFID).

These products have also been supplied to NGOs that have programs in developing countries that improve access and service delivery in maternal health such as Population Services International, Marie Stopes International, DKT International, Menschen für Menschen and companies that supply institutional programs such as IMRES, International Development Association (IDA) and Missionpharma.
Each year in China, as many as 125,000 babies may succumb to neonatal asphyxia, the inability to breathe at or immediately after birth. Johnson & Johnson Pediatric Institute, L.L.C., has joined with the Chinese Ministry of Health, the American Academy of Pediatrics, the Chinese Society of Perinatal Medicine and the Chinese Nursing Society to form the “Freedom of Breath, Fountain of Life” national neonatal resuscitation program.

The program aims to reduce infant mortality through education, with a goal of ensuring that there is at least one trained person is present at every hospital birth by 2010. The program has trained more than 18,000 medical professionals across China since 2004 in the techniques of neonatal resuscitation.

Founded in December 2003, the Fuyang AIDS Orphan Salvation Association (AOS) addresses the social stigma and discrimination associated with HIV/AIDS. With support from Johnson & Johnson, this NGO serves the needs of more than 400 children affected by HIV/AIDS in An Hui Province in eastern China. AOS assists more than 200 families in 20 different villages, providing stipends for basic health and education needs, clothing, food, vocational education and emotional support. AOS strives to reduce social stigma by encouraging meaningful dialogue within Chinese communities to raise public awareness about HIV/AIDS.
Pfizer Spain is supporting the Sabera Foundation, which runs a small Children’s Hospital in Ghazipur, in the outskirts of Calcutta in India. The hospital provides specialized residential health care and rehabilitation services for the children of poor families. Pfizer helps fund maintenance of the building and the hospital’s operating expenses infrastructures and makes available the company’s expertise in health care. Therapeutic areas covered include physiotherapy, tuberculosis and ophthalmology. The hospital also provides out-patient support to the surrounding community.

As a part of its corporate social responsibility strategy, Pfizer allows its employees to work at the Ghazipur Hospital, performing support, management and medicine distribution activities for two to four weeks, as well as helping with rehabilitation tasks. To date, 56 Pfizer volunteers have participated in this program.

Fistula is a serious and painful disorder that develops when blood supply between organs or vessels is cut off during prolonged obstructed labor. Johnson & Johnson works with organizations in Africa to prevent and treat fistula. In Eritrea, it helps the Global Campaign to End Fistula, led by UNFPA (United Nations Population Fund), which seeks to make this problem as rare in the developing world as it is in industrialized countries today. This project focuses on addressing obstetric fistula by increasing the caesarean section rate and the number of fistula repairs, thereby contributing to the ultimate goal of reducing maternal mortality and morbidity.

Addis Ababa Fistula Hospital is a key partner in the Global Campaign to End Fistula. Serving as the only health facility in Ethiopia dedicated exclusively to victims of obstetric fistula, the hospital has been treating fistula patients for more than three decades.

Johnson & Johnson provides support to the hospital for education outreach programs throughout the region, including training for traditional birth attendants. Furthermore, health care professionals also are educating communities on the risks of unattended childbirth. Through the hospital’s efforts, over a thousand women each year are treated.
### Global Fund for Women

**Maternal & women’s health**  
Johnson & Johnson  
Global Fund for Women  
Since 2005  
Education  
Developing countries  
[www.globalfundforwomen.org](http://www.globalfundforwomen.org)

The Global Fund for Women (GFW) advocates for and defends women’s human rights by making grants to support women’s grass-roots organizations around the world. The GFW works to promote economic security, awareness of the endemic problems of violence against women, education, health, and leadership.

Maternal prenatal care and reproductive health are of especially great concern. Estimates are that 500,000 women worldwide die each year in childbirth and another 18 million are left disabled or chronically ill. Johnson & Johnson provides support, through the GFW, to 17 community-based groups in several countries that address maternal health issues.

### GSK and Integrated Management of Childhood Illness

**Child health**  
GlaxoSmithKline  
WHO, UNICEF & other partners  
Since 1996  
Capacity Building – Training & Support, Education  
Ethiopia, Ghana, Namibia, Nigeria & South Africa  
[www.gsk.com](http://www.gsk.com)

The World Health Organization (WHO) and UNICEF developed Integrated Management of Childhood Illness (IMCI) as an improved delivery strategy for child survival interventions, to help reduce morbidity and mortality in children. GlaxoSmithKline has been involved with the program since 1996, when it initiated a unique partnership with the South African Ministry of Health. Since then GSK has entered into public-private partnership agreements with WHO, UNICEF and national Ministries of Health for IMCI programs in Ethiopia, Namibia, Nigeria and Ghana.

IMCI aims to reduce morbidity and mortality due to the major killer diseases for children under five: malaria, diarrhea, malnutrition, measles, acute respiratory infection and HIV/AIDS. The IMCI strategy looks at the child holistically, as children often have more than one condition. It promotes the accurate identification of childhood illnesses, ensures the appropriate combined treatment of the major diseases, and speeds up the referral of severely ill children. The first component of IMCI focuses on improving the case management skills of health workers. To support IMCI implementation, the second component focuses on strengthening the health system through improved essential drug supply and management, through support supervision and by facilitating appropriate and timely referral of severe cases. Although GSK supports all three components of IMCI, its main focus is on the third component: Community IMCI, which aims to improve family and community practices, including seeking care for sick children, appropriate feeding practices and adherence to recommended treatments.
GSK’s Midwife Training in Vietnam

Since 2004, GlaxoSmithKline has been supporting a unique training program based in Tu Du Hospital, Ho Chi Minh City, Vietnam. The project is training 500 birth attendants to provide maternal healthcare services in rural villages and aims to reduce childbirth complications and decrease newborn fatalities from the current unacceptably high level of 6%.

Supported by Tu Du medical and nursing staff, and housed within a residential training centre built by GSK, the trainees spend four months gaining practical knowledge of maternal and child health care.

Over 350 midwives have now graduated with a government-recognized qualification. Each midwife has been equipped with a medical pack and some are provided with a motor scooter to facilitate access to remote areas.

GSK’s Personal Hygiene & Sanitation Education (PHASE) Program

GlaxoSmithKline’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 so far invested over USD 3.1 million in the program. PHASE is run in partnership with AMREF, Save the Children and Plan International, as well as national Ministries of Health and Education in countries where the program is active.

The program has had impressive results so far. 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 Mexico and Tajikistan during 2006 and now operates in a total of eight countries. The total number of children reached by PHASE is now estimated to be 375,000.

GlaxoSmithKline has a PHASE steering committee with representatives from its partner organizations to help expand the program into more countries. Bolivia and Indonesia are planned for 2006, along with its launch into in Kibera, Kenya: Africa’s largest slum. This will be the first time PHASE has operated in an informal settlement, creating a model for improving children’s health in one of the world’s harshest urban environments.
### International Rescue Committee

**Child health**  
**Johnson & Johnson**  
**The International Rescue Committee (IRC)**  
**Since 2004**  
**Capacity Building – Support, Education**  
**Uganda**  
www.theirc.org

During the two-decade conflict between the Ugandan army and the Lord’s Resistance Army (LRA), more than 30,000 children were abducted by the LRA. Pressed into service as frontline LRA soldiers, the children experienced, and were forced to commit, unthinkable abuses. Of the children who have been released or managed to escape, many are now without family and must enter camps for Internally Displaced Persons (IDP).

The International Rescue Committee (IRC) has taken on the challenge of reintegrating these children into everyday life. Girls are at a particular disadvantage. Not only have they missed years of education, but many also return pregnant with the children of their captors. Without family and with a child to support, their future is bleak. The IRC, with funding from Johnson & Johnson, has created a network of educational and psychosocial resources to help them within the IDP camps.

“Girls’ Clubs” have been formed for various age groups as a safe place for girls and young women to share their experiences and provide support to each other. Through these clubs, the girls get guidance on child development, health and HIV/AIDS. To address academic needs, the girls attend literacy classes, available at three levels of study. While the girls are in class, “Nursery Corners” provide care for their children. To complement their studies, libraries were created, with partial sponsorship from Johnson & Johnson, and stocked with practical information about health and other life issues.

### Laos Sexual & Reproductive Health Program (Schering-Plough)

**Child & maternal health**  
**Schering-Plough**  
**Laos Department of Public Hygiene and Prevention**  
**Since 2005**  
**Education**  
**Laos**  
www.schering-plough.com

In 2005 Organon, a part of Schering-Plough, established a program to strengthen sexual and reproductive health services at selected factories and health facilities in the Laos People’s Democratic Republic. This initiative focuses on factory workers and urban youth in Vientiane City and Pakse. This program is in partnership with the Department of Public Hygiene and Prevention, and supervised by the Ministry of Public Health.

Mobile Maternal and Child Health (MCH) teams have provided reproductive health education and services to some 1,000 factory workers, mostly young women. A key part of the project has been the establishment of a peer education structure within participating factories. In addition, “youth friendly” reproductive health service facilities have been established at local clinics to improve the accessibility of reproductive health information. Counseling and other specific reproductive health services are offered at the clinics.

A pilot reproductive health education program has been run with Ministry of Education in secondary schools in Vientiane City and Pakse, providing education modules for students and training for teachers. The education program in Laos also includes counseling for teachers in the area of general and sexual health problems. Organon spent USD 125,000 in 2007 on this program and a total of USD 270,000 since 2005.
Pfizer and Associação Saúde Sem Limites (Unlimited Health Association) have been working together on The Pankararu Health and Culture Project since 2005. The project provides 5,000 Pankararu Indians in townships located in the Borborema Mountain Range, in the arid interior of Pernambuco State, with basic health care information. Pfizer provides both financial and technical support to the program.

The Pankararu population also suffers from long droughts, intense social discrimination, clan conflicts and territorial disputes. To address these issues, the project has launched initiatives including diagnosis of the primary illnesses afflicting the population and training Indigenous Health Agents.

One of the initiatives is a program to assist traditional midwives and pregnant women. The project has thus far trained 40 Pankararu Indians to act as Indigenous Health Agents, provided more than 1,600 prenatal medical appointments and, on average, assisted 95 women every month. Since the beginning of the project, not a single death has been registered during pregnancy, upon delivery, or following a birth.

More than 200,000 women worldwide bleed to death each year as a result of postpartum hemorrhage, mostly in the developing world. To help address this problem, leading experts collaborated to produce the comprehensive “Textbook of Postpartum Hemorrhage”, providing practical, up-to-date and authoritative guidance for effective postpartum management in difficult conditions. The WHO Regional Office for Africa, the International Federation of Gynecology & Obstetrics (FIGO) and Princess Anne of the UK contributed to the book.

The book is complemented by a wall chart and 21-page brochure providing simple, practical and easily understood guidance to birth assistants on the immediate steps to take when faced with a mother suffering from postpartum hemorrhage, and a surgical procedures poster with a detailed description of one of the most important surgical techniques available for managing postpartum hemorrhage – a procedure now rapidly being adopted as a valuable option in appropriate cases.

Organon, a part of Schering-Plough, started an initiative in 2007 to have its employees and offices distribute the book, wall chart/brochure and surgical poster to health workers in developing countries. The wall chart, brochure and surgical poster have been translated from English into locally understood languages, including French and Spanish. In 2007, Schering-Plough invested approximately USD 11,000 to establish the project and distribute books in Burkina Faso.
Project Pampalusog Bata

Child health
Johnson & Johnson
Save the Children Federation
Since 2004
Education
Philippines
www.savethechildren.org

The Save the Children Federation and Johnson & Johnson are committed to improving the health and nutrition of school-aged children in communities surrounding Paranaque City, Philippines. Project Pampalusog Bata, part of the School Health and Nutrition program, focuses on mobilizing children, their families and the community to address the problem of soil-transmitted intestinal worm infections, and seeks to promote and sustain key positive behaviors leading to the control of the infection and prevention of other health problems.

Working in two schools, with 5,300 students, 600 parents/caregivers and 70 community volunteers, Project Pampalusog Bata works to sustain community health activities, in partnership with local government.

Renascer: Helping Poor Mothers in Brazil

Maternal health
Johnson & Johnson
Renascer
Since 2005
Education
Brazil
www.criancarenascer.org.br

Renascer is a Brazilian NGO which provides medical and educational aid to mothers with chronically ill children living below the poverty line. The program addresses the specific needs of health, education, income, housing and citizenship. During 15 years of operation, Renascer has helped 2,000 families with more than 7,000 children break the cycle of poverty and illness. The Renascer model has been so successful that it has inspired the development of 17 similar independent programs throughout Brazil.

Johnson & Johnson funds a key component of the Renascer model – education. Mothers are taught how to create healthy environments and given the skills to do so. Monthly sessions address issues of health education, disease prevention, child development, and domestic abuse. When family goals are met, the women graduate from the program prepared to provide for their families on their own.
Maternal mortality is a significant issue throughout Asia. Johnson & Johnson helps to address this through its partnership with UNICEF’s Safe Motherhood Initiative in India, the Philippines and Tibet.

In the Philippines, more than 170 of every 100,000 live births result in the death of the mother, and this figure is significantly higher in regions with the least access to Basic Emergency Obstetric Care. Most maternal deaths occur during labor or in the first 24 hours after delivery and only rarely will the child survive. Four of the worst affected provinces, Masbate, Aurora, Isabela and Camarines Norte, were identified for capacity building efforts, with doctors, nurses and midwives from each receiving training via the Basic Emergency Obstetric Care program at Fabella Memorial Hospital in Manila. Improved knowledge allows earlier detection and better management of pregnancy complications, while medical supply kits facilitate emergency obstetric interventions.

Support in Tibet, where the maternal mortality rate (MMR) is nearly 10 times China’s national average, addresses issues of transportation, lack of capacity, and cultural taboos that prevent women from seeking obstetric treatment. In India, efforts are focused on several of the least-developed states. Madhya Pradesh, a rural state with impassable terrain, has an MMR of nearly 498 deaths out of every 100,000 live births and has the second highest infant mortality rate in the country.

Despite the success of the Safe Motherhood Initiative, high rates of maternal mortality remain an international concern.

Organon, a part of Schering-Plough, started the “Development of Sexual and Reproductive Health Services for Thai Adolescents” program in 2004, to promote improved sexual and reproductive health among adolescents in Thailand. This initiative is a public-private collaboration between the company, the Thai Department of Health, the Institute of Health Research of the Chulalongkorn University and the Rajabhat Bansomdej Chaopraya University in Bangkok and is designed to promote a healthy attitude towards reproductive health amongst adolescents.

A sexual and reproductive health education curriculum was developed and implemented for adolescents and teachers in more than 40 secondary schools and six major universities. The curriculum includes education modules for students and training for teachers. Additionally, the program includes a short counseling course for teachers in the area of general and sexual health problems. In response to evidence that peer models are effective in reaching young people, the program also features a training course for peer helpers. The company invested USD 18,000 in 2007 and has contributed a total of USD 400,000 since the program was started.
Johnson & Johnson partners with Unamos al Mundo por la Vida, an organization dedicated to recruiting and educating children who beg in the streets of Caracas, Venezuela. Many of these children are homeless or live in extreme poverty, lacking opportunities to fulfill their basic needs. Program funding goes to a health clinic and shelter where these children receive basic medical, dental and psychosocial care, as well as meals, education and entertainment. Unamos al Mundo por la Vida estimates that approximately 3,500 children benefit from this program every year.
Global deaths by causes, all ages, 2005

HIV/AIDS: 2,830,000
Tuberculosis: 1,607,000
Malaria: 883,000
Cardiovascular diseases: 17,528,000
Cancer: 7,586,000
Chronic respiratory diseases: 4,057,000
Diabetes: 1,125,000

(Source: WHO Preventing Chronic Diseases: A Vital Investment, 2005)
Some 35 million deaths are attributable to chronic diseases each year; this is 60% of all deaths worldwide. Principal chronic diseases include cardiovascular disease (17 million deaths), cancer (7 million deaths), chronic respiratory disease (4 million deaths) and diabetes (1 million deaths). About 80% of chronic disease deaths occur in low and middle income countries and the number of people, families and communities affected is increasing. The impact of chronic diseases in these countries will increase as they progressively control infectious diseases.

A significant proportion of chronic disease morbidity and mortality can be prevented if medications are made accessible and affordable, which is a challenge in countries with large populations of very poor people.

The chronic disease threat can be largely managed using existing knowledge and medicines. Many solutions are effective and highly cost-effective. Public-private partnerships have a crucial role to play in accelerating progress with regard to specific diseases.

Nevertheless, access to medicines is not the only key to achieving success: inadequate access to good-quality health services, including diagnostic and clinical prevention services, is a significant cause of the social and economic inequalities in the burden of chronic diseases. Investment in chronic disease prevention programs and the development of services and infrastructure are essential for many low and middle income countries.

### Abbott Program to Advance Diabetes Care in Bolivia

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<th>Diabetes</th>
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<td>Direct Relief International (DRI), Centro Vivir Con Diabetes</td>
<td>Since 2006</td>
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<td>Access – Donation, Capacity Building – Training</td>
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Since 2006, Abbott and Abbott Fund have partnered with Direct Relief International (DRI) to support the education and outreach activities of Centro Vivir Con Diabetes, a non-governmental organization dedicated to low-income adults and children living with both type I and type II diabetes in Cochabamba, Bolivia.

Abbott Fund has provided over USD 80,000 in grants to support diabetes education, expand public outreach campaigns, train healthcare personnel in diabetes management, and create a core group of diabetes educators. Abbott has also donated over USD 30,000 in glucose screening and monitoring equipment.

In 2007, the partnership successfully trained over 600 diabetes patients, biochemists and pharmacists to become diabetes educators, and contributed to a 25% increase in people screened in the first 6 months versus the 6 months prior. In total, our donations will help screen more than 12,000 people. By the end of 2008 through an additional 6,000 people are expected to be screened and nutritional support provided to hundreds more.

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### AstraZeneca Breast Cancer Program in Ethiopia

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<th>Breast cancer</th>
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<td>Various partners</td>
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<td>Access – Donation, Capacity Building – Training &amp; Support</td>
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In 2005, AstraZeneca began a pilot project in Ethiopia, designed to build local capability to manage breast cancer – the second most common cancer among young women in that country. It works with Axios International, an organization experienced in working with the private sector to advance healthcare in developing countries, with a focus on integrating local resources and priorities in chronic disease management and drug delivery.

At the outset of our Ethiopia Breast Cancer Project, the country had only one cancer specialist for the entire population; there was no mammography; no easy access to chemotherapy or hormonal agents; no cancer screening and no national treatment protocols.

Our program focused on strengthening diagnosis and treatment capabilities at Tikur Anbessa University Hospital in Addis Ababa, where the cancer specialist was based. In the last three years, the hospital has become a centre of reference for breast cancer treatment across Ethiopia. Activities have included developing treatment guidelines, strengthening the referral system, setting up an institutional-based cancer registry, raising awareness of the facilities amongst healthcare professionals and providing training for other physicians in Ethiopia. AstraZeneca’s breast cancer medicines, Nolvadex® and Arimidex®, are also being donated.

Originally intended as a small, targeted pilot, the program has been has had a broader impact than anticipated. By collaborating with the Ministry of Health and other health institutions on the guideline development and national distribution, and by working with the Ethiopian Cancer Association to help strengthen awareness – and fund-raising capabilities, the benefits have been far wider reaching than just the Tikur Anbessa Hospital.
AstraZeneca: South African National Schools Program

Asthma
AstraZeneca
South Africa National Asthma Education Program
Since 2006
Education
South Africa
www.astrazeneca.com

In South Africa, teachers’ perceptions of asthma are being changed due to the National Schools Program, sponsored by AstraZeneca. The program runs with the sponsorship of AstraZeneca under the auspices of the National Asthma Education Program (NAEP), a non-profit organization dedicated to educating the general public about asthma. In less than a year, the Schools Program has covered 20 schools in Durban, 20 in Cape Town and 9 in Johannesburg. In 2007, the program marked World Asthma Day and AstraZeneca employees volunteered to reach out to local communities with educational materials on asthma. The objective was to create awareness around the disease and educate community members at large on some of the symptoms associated with this disease.

Bayer HealthCare Nexavar® Access Program

Diabetes
Bayer HealthCare
Various partners
Since 2007
Access – Donation
Asia-Pacific region
www.bayerscheringpharma.de

In 2007, Bayer HealthCare, in partnership with local authorities and charitable organizations, started a first patient access program for Nexavar® (sorafenib) in Asia for the treatment of renal cell carcinoma and is planning further implementation in this region. Bayer HealthCare donates its medicine Nexavar® to facilitate access for patients who cannot afford the cost of a full course of therapy.

After a patient is diagnosed with renal cell carcinoma, he or she is referred to a specialist center which evaluates the patient’s eligibility for participation in the facilitated access program. If their financial situation warrants it, the patient will receive the medicine free-of-charge, either immediately or after an initial period of treatment. Presently, the program is limited to renal cell carcinoma, but as soon as Nexavar® is approved for hepatocellular carcinoma (expected by mid-2008), a patient access program for this indication will also be initiated.

A US doctor treating a child in Peru’s Amazon Jungle. Many of their diseases are easily treated with the proper medication. Schering-Plough works with the NGO Medical Assistance Programs (MAP) International to provide “travel packs” of medicines for such clinics. (Schering-Plough)
### China Diabetes Education Program

**Diabetes**  
Lilly, Roche  
Becton Dickinson (BD), Project HOPE  
Since 1998  
Capacity Building – Training, Education  
China  
www.projecthope.org

The China Diabetes Education Program (CDEP) is a Project HOPE initiative that was launched in 1998. In May 2007, corporate partners Becton Dickinson (BD), Lilly and Roche Diagnostics announced a two-year extension in their support for this program.

The CDEP provides comprehensive diabetes training to local medical and healthcare providers – known as “Trained Trainers”. To date, Trained Trainers working in 800 local hospitals and community care centers have successfully trained nearly 37,000 medical professionals and educated about 170,000 diabetes patients. The program has established diabetes training centers, using modern training methods, and developed diabetes education and training materials that are supported by the Chinese Ministry of Health.

The two-year extension of the program will allow CDEP to further increase public awareness of diabetes and the importance of better diabetes care. It will also provide an opportunity for CDEP to help the Chinese government in its efforts to provide better community care, with a special focus on diabetes.

### Diabetes Prevention

**Diabetes**  
sanofi-aventis  
Handicap International  
Since 2006  
Capacity Building – Support  
Burundi, India, Kenya, Madagascar, Nicaragua, Philippines, Thailand  
www.sanofi-aventis.com

In 2006, sanofi-aventis has launched a pilot program in association with Handicap International and local NGOs in several countries of Africa, Asia and Latin America to help improve diabetes disease management. Several projects have been set up in 2007 in Burundi, India, Kenya, Madagascar, Nicaragua, Philippines and Thailand. The program aims to help local health care systems to manage the disease better, prevent the onset of complications and so avoid the subsequent need for surgical interventions such as amputation.

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*Treating diabetes in the Philippines. (Handicap International, sanofi-aventis)*
**Glivec® International Patient Assistance Program (GIPAP™)**

Leukemia

Novartis

Max Foundation, Axios International

Since 2002

Access – Donation

80 countries worldwide


Novartis partners with physicians and international health organizations to facilitate access to its breakthrough cancer therapy Glivec® via the Glivec International Patient Assistance Program™ (GIPAP™). This global cancer treatment access program provides Glivec® at no cost to patients with certain forms of chronic myeloid leukemia (CML) and gastrointestinal stromal tumors (GIST) who otherwise would not have access to treatment.

GIPAP™ was initiated in 2002, and operates in developing countries with no comprehensive reimbursement system or available generics. Patients must be properly diagnosed, not covered by local reimbursement or insurance, and have no other financial resources. In 2007 Novartis provided USD 535 million worth of Glivec® to more than 19,000 patients who otherwise would not have been able to afford treatment. Since the program’s launch, Novartis has provided Glivec® at no cost through GIPAP to more than 29,000 patients in 80 countries.

Unlike many donation programs, GIPAP™ is based on a “patient-direct” model, providing delivery of Glivec® to patients by their treating physicians. GIPAP™ also provides patients with access to support groups, treatment and disease information, education and emotional support. GIPAP™ operates through a global network of almost 1,000 registered physicians and more than 300 qualified treatment centers, including the leading oncology treatment centers and medical opinion leaders in each country.

Novartis’ main partners in GIPAP™ are The Max Foundation and Axios International. Novartis, as the donor company, is responsible for program development, drug donation and provision of the medicine to treatment centers. The Max Foundation (TMF) is a US-based non-profit (501c-3) leukemia advocacy and patient support group whose mission is to improve the lives and survival of patients with blood-related cancers worldwide. TMF is responsible for verifying and screening patients for qualifications, case management, and providing emotional support and education. In countries where Novartis has no local oncology representation, Axios coordinates and supervises the GIPAP™ process by working with institutions and handling logistics.

**Hypertension Program in China**

Hypertension

Pfizer

Shanghai Center for Disease Prevention and Control

Since 2007

Capacity Building – Training, Education

China

www.pfizer.com

In early 2007, Pfizer began working with the Shanghai Center for Disease Prevention and Control to help manage and reverse hypertension and related cardiovascular risk factors. Cardiovascular disease is the leading cause of death and disease burden in urban centers in China. The goal is to utilize better the resources and infrastructure of local hospitals to improve diagnosis and disease management, as well as provide education and training to improve skills at selected hospitals. Pfizer is providing financial and technical support.

The Disease Management Program in Shanghai has enrolled 876 hypertension patients. After 6 months, patients are showing better understanding of their condition, lower blood pressure, and reduced exposure to risk factors (tobacco, alcohol and salt). Patients also have access to appropriate medicines.

The program has been extended to Hangzhou, capital city of Zhejiang Province, where it has enrolled 1,442 patients.
Lilly has agreed to support the International Diabetes Federation’s program “Bringing Research In Diabetes to Global Environments and Systems” (BRIDGES) with USD 10 million funding over seven years. The BRIDGES grant research program will provide the opportunity to ‘translate’ lessons learned from clinical research to those who can benefit most: people with diabetes. Lessons learned through the supported research projects provide the opportunity to, for example, the development of treatment routines and effective behavioral interventions, leading to relevant, evidence-based health care and improved outcomes for people with diabetes.

Diabetes continues to be a growing pandemic and is the world’s fourth leading cause of death by disease. Diabetes affects more than 240 million people worldwide and is expected to affect 380 million by 2025. Over the last several decades, a revolution in science has contributed to a greater understanding of the disease and the development of new cutting-edge therapies. Still, diabetes prevalence, morbidity and mortality have continued to grow rapidly. A steering committee appointed by IDF will determine the amounts and types of grant awards. Projects designed to test pharmaceuticals or disease mechanisms are not eligible for funding through this program.

In November 2007, Bayer HealthCare, Becton Dickinson (BD) and Lilly and agreed to support Project HOPE’s “India Diabetes Educator Project”. This four-year, multi-million dollar collaborative program aims to help health care workers in India reduce morbidity and mortality related to diabetes and to combat the rapidly growing threat of diabetes there. With an estimated 40.9 million people currently living with the condition, India leads the world in the prevalence of diabetes.

The India Diabetes Educator Project offers a comprehensive and sustainable approach that will provide diabetes training to more than 5,000 health care professionals, including nurses, dieticians and nutritionists in India. The project includes mentoring support for newly trained Diabetes Educators and also addresses the role of the educator in empowering the patient to take responsibility for daily self-care and to help prevent the onset of diabetes among those at risk.

The training will be based on the International Curriculum for Diabetes Health Professional Education developed by the International Federation Consultative Section on Diabetes Education (IDF-DECS), adapted for use in India. Implementation of this curriculum will help establish a consistent and standardized protocol for diabetes treatment throughout the country, with the goal of improving patient quality of life and increasing positive self-care behaviors and control of diabetes.
In 2004, sanofi-aventis and the International Union Against Cancer (UICC) launched a mobilization and awareness program called “My Child Matters”, to fight against childhood cancers in emerging countries. The objective is to encourage institutions (hospitals, NGOs, etc.) to develop pragmatic approaches to improve awareness, early diagnosis, access to care and treatment, pain control and better management of the social and cultural aspects of the disease for both children and families.

This program has already been launched in 16 developing countries – Bangladesh, Bolivia, Egypt, Honduras, Indonesia, Kenya, Mali, Morocco, Peru, Philippines, Rumania, Senegal, Tanzania, Ukraine, Venezuela and Vietnam – via 26 pediatric oncology project.

In 2007, 7,100 children benefited from this program and 1,700 health professional were trained.

Novo Nordisk offers human insulin to the public health systems in Least Developed Countries (LDCs) at prices which do not to exceed 20% of the average price in Europe, Japan and North America. In 2007, Novo Nordisk offered this pricing scheme to all 50 LDCs, of which 36 used it to buy insulin at or below this price, compared to 34 in 2006. For reasons that are unclear, two LDCs purchase insulin outside this pricing scheme. Overall, 99% of the units of insulin sold to LDCs by Novo Nordisk are sold under the Best Possible Pricing scheme. The amount of insulin supplied to these 38 countries (36+2) was enough to treat between 150,000 and 390,000 patients, depending on the daily dose.

For various reasons, there are 12 countries in which Novo Nordisk is not selling insulin at all. In several cases, the government has not responded to the offer, either because there are no private wholesalers or other partners with which to work, or because wars or political unrest have made it impossible to do business.

Unfortunately, there is no way to guarantee that the price at which Novo Nordisk sells the insulin will be reflected in the final price on the pharmacist’s shelf. Novo Nordisk works with governments to encourage tenders so that there is a greater chance that the preferential price will benefit the people for whom it is intended.

Novo Nordisk has identified a number of barriers to accessing insulin at the preferential price and will take appropriate measures to tackle these challenges. This reflects a change in Novo Nordisk’s overall strategy for access to health, which in 2007 has been given a stronger focus on monitoring the outcome of the various initiatives, and implementation through pilot projects. Five pilot projects on barriers to access in spite of preferential prices will be launched in 2008 in Cameroon, the Democratic Republic of Congo, Guinea-Conakry, Mozambique and Tanzania. Each has different situations, thereby requiring a variety of approaches. Novo Nordisk will work with Ministries of Health and relevant business partners in the countries to influence the distribution process so that its preferential prices benefit people with diabetes. Based on the outcome of the pilots, these measures will be applied in the other LDC countries.
The Novo Nordisk Haemophilia Foundation (NNHF) was created in 2005 to address the significant need for improving hemophilia care in the developing world where hemophilia is currently not a healthcare priority and still today many hemophilia patients go undiagnosed or are inadequately treated.

NNHF is an independent trust, located in Zurich, Switzerland, and funds programs to improve hemophilia care, treatment and awareness in the developing world. NNHF programs include awards, fellowships and projects for patient education, doctor, nurse and laboratory staff training, as well as setting up diagnostic facilities and patient registries.

The geographical scope of NNHF is towards countries in the OECD Development Assistance Committee (OECD DAC) list, defined as developing but excluding the least developed countries. Furthermore, NNHF is also active in the so-called transition countries, i.e. those countries recently joining the European Union or intending to do so in the near future. In these countries, there is typically some level of hemophilia treatment, which forms the basis for support by NNHF.

NNHF cooperates with partners in these countries, such as health ministries and authorities, non-governmental and patient organizations, health care professionals, other foundations and trusts.

The diabetes pandemic will undoubtedly affect developing countries’ ability to grow and develop. The World Partner Project (WPP) was launched in 2001 to establish a foundation on which developing countries can build their own diabetes healthcare strategies and ultimately improve access to proper care. The WPP always works with local partners, usually health ministries and/or patient organizations, and is funded by a grant from Novo Nordisk.

WPP and its partners have driven 31 projects in eight focus countries (Bangladesh, Malaysia, Tanzania, Zambia, El Salvador, Costa Rica, China and India), organizing clinics, providing distance learning for healthcare professionals, educating people with diabetes and raising diabetes awareness. The countries were selected by WPP after analysis of the diabetes care situation in each country, diabetes awareness and knowledge, and diabetes care infrastructure. The focus for all projects is sustainability: they must be affordable and practical enough for long-term operation. As of 2007, it is estimated that WPP projects have trained 104,000 healthcare professionals, while 122,000 people with diabetes have been educated or treated.

During 2007, Novo Nordisk assisted the partners various projects in the focus countries to consolidate efforts in order to continue the projects. For example, Novo Nordisk funded a clinic in Dar-es-Salaam, Tanzania, where a diabetes nurse was hired to care for children with type 1 diabetes, follow up their treatment, provide diabetes education and liaise with the families. The results speak for themselves: Before, there was an average of 20 children at the clinic, with very high turnover, frequent emergency admissions and one child dying every month. Now the clinic has more than 100 children on average, very few are admitted in emergency and only one child has died in the past year.

WPP will continue to support established projects in the focus countries until it is satisfied that these projects can be self-sustaining. Funding has been reserved for projects to be launched in 2008 in three new countries: Nigeria, Mexico and Indonesia.
Pfizer – Fighting Diabetes in Mexico

Since 2005, Pfizer has been working with the Mexican Diabetes Association in Mexico City and Jalisco to educate young patients and their parents on the importance of making the necessary changes in their daily routines. This partnership, with the help of nutritionists, treatment experts, psychologists and support groups, has developed a plan that gives the members of low-income families all the tools and information they need to cope with diabetes, including a personalized nutrition plan and follow-up monitoring. In addition to support groups for children and parents, a special camp on diabetes education has also been organized for children and teenagers. In all, 140 families have learned to deal with diabetes, control glucose levels, become more independent, and have a positive attitude.

Footcare is essential in diabetes and is a focal point of Novo Nordisk’s World Partner Program activities in Malaysia. (Novo Nordisk)

Pfizer Global Health Partnerships

The Pfizer Foundation, together with the Pfizer country offices will commit USD 33 million over the next period 2007-2009 to support regional and global partnerships in oncology and tobacco control. The grants will be managed by three intermediaries: the King Baudouin Foundation, Give 2 Asia, TCC Group, and The Resource Foundation with oversight from Pfizer Foundation. The Johns Hopkins University-Bloomberg School of Public Health will provide technical assistance and evaluation support.

Other partner organizations include: Action on Smoking and Health (ASH) International, Akebono-Kai, American Cancer Society, China Tobacco Control Association, European Organization for Research and Treatment of Cancer (EORTC), International Union Against Cancer (UICC), Japan Dental-Medical Association for Tobacco Council, Korean National Council of Women, Mexican Council on Tobacco, Philippine Business for Social Progress, QUIT UK & European Network of Quitlines, Shanghai Center for Disease Control and Prevention, the New Hope in Health Foundation, the Ralph Lauren Center for Cancer Care and Prevention, the Resource Foundation, TCC Group and the Veronesi Foundation.

The Global Health Partnerships involve:

- Treat: Supporting cancer and tobacco control programs that offer cancer screening, quit-lines and counseling services;
- Teach: Working with local partners to raise awareness of the need for cancer screening and consequences of tobacco use;
- Build: Providing technical assistance and evaluation support to cancer and tobacco control organizations;
- Serve: Sharing effective public health models and supporting patient advocacy.
**Pfizer PEER Health Program**

- **Childhood obesity, diabetes, tuberculosis**
- Pfizer
- Various partners
- Since 2007
- R&D
- Philippines

**PEER (Providing an Enabling Environment for Research in Health)** is a research & development program funded by the Pfizer Philippines Foundation, in partnership with Philippine Council for Health Research and Development and the University of the Philippines National Institutes of Health. The goal of the partnership is to further enhance R&D activities, provide opportunities for collaboration between the government and private sector in health research, and to provide venues for sharing research results. The PEER program sponsors research projects conducted by Filipino research scientists that might significantly improve overall health.

Examples of PEER research projects include:

- **Childhood Obesity**: Identification of factors that contribute to childhood obesity and the effects of dietary interventions and physical fitness programs on obesity.
- **Magnet Therapy in Diabetic Neuropathy**: Determination of the effectiveness of magnet therapy as an adjuvant treatment in alleviating pain, improvement of electro-diagnostic parameters, and description of adverse effects in patients with diabetic neuropathy.
- **Diagnosis of tuberculosis and mycobacterial infections**: Development of a polymerase chain reaction method for rapid and accurate diagnosis and differentiation of cutaneous tuberculosis and atypical mycobacterial infections.

**sanofi-aventis against Epilepsy**

- **Epilepsy**
- sanofi-aventis
- Santé Sud & other partners
- Since 2004
- Access – Pricing, Capacity Building – Training
- Cambodia, Kenya, Madagascar, Mali

Sanofi-aventis, one of the major actors in the fight against epilepsy in the developed world, is also committed to the treatment of epilepsy worldwide using its two major treatments, Gardenal® and, more importantly, Depakine®.

In Mali, sanofi-aventis is working with Santé Sud and Association des Médecins de Campagne which have created Réseau Action Recherche contre l’Epilepsie (RARE). More than 1,500 patients have been diagnosed and treated, thanks to these NGOs highly motivated doctors whose close relation directly with patients in his field is a key success factor, helping to destigmatise this disease. This program started at the end of 2007 in Madagascar with the training of 10 motivated GP’s and the creation of a specific network, the REM (Réseau Epilepsie Madagascar).

Two further programs are underway:

- in Kenya (with Kenya Association for the Welfare of People with Epilepsy): thanks to the support provided over a period of nine months in 2007, 71 doctors and/or nurses have been trained as well as about 100 students.
- in Cambodia, where support has been provided to create the first association in the country to combat epilepsy. In all these programs, medicines such as Depakine® / VPA are provided on a “no-profit, no-loss” basis.
Staying Away from Tobacco for a Healthy Life

China, with approximately 350 million smokers, produces and consumes more cigarettes than any other country in the world. Pfizer China anticipated its parent company’s global tobacco control initiative (see Global Health Partnerships) by supporting the Chinese government’s efforts to promote smoking cessation through a series of community awareness and education programs, notably a three-year smoking cessation initiative by the Beijing University Medical School called “Staying Away from Tobacco for a Healthy Life.”

In 2006, Pfizer organized an anti-smoking poster design competition with the Medical School of Beijing University, with an evaluation panel of officials from the Ministry of Health and China's Center for Disease Control, as well as faculty members. Winning designs were distributed to 4,000 health care professionals in the University's affiliated hospitals. Pfizer also distributed 10,000 copies of the Tobacco Control Manual to university faculties and health professionals within the University.

In 2007, Pfizer and Beijing University hosted a four day Tobacco Control Summer Camp for students from 16 leading medical schools nationwide in China. In 2008, a smoke free hospital initiative was launched in 20 hospitals in Beijing and Shanghai.

The World Diabetes Foundation

The World Diabetes Foundation (WDF), established by Novo Nordisk in 2001 through a 10-year grant of USD 85 million, is dedicated to supporting the prevention and treatment of diabetes in the developing world through the funding of sustainable projects. Its goal is equal access to diabetes care.

To date, WDF has funded 138 projects, covering 77 countries, focusing on diabetes awareness, education and capacity-building at local, regional and global levels. A projection of the impact of the WDF’s work shows that the projects funded will positively impact 63 million people in the developing countries. WDF funding has a multiplier effect – since always working with partners it is possible to secure other sources of funding. This allows the project portfolio to be an estimated USD 125.7 million of which WDF has donated USD 42.6 million.

A further donation of USD 115 million was approved by the Annual General Meeting of Novo Nordisk in 2008, ensuring support for future projects under the auspices of the WDF, which is an acknowledged leader in addressing chronic diseases in the developing world.
ADDITIONAL HEALTH INITIATIVES

1. Brazil
Schering-Plough began the Instituto Criança é Vida (Child is Life Institute) in Brazil in the 1980s. Today, it is an independent institute, in part supported by Schering-Plough, whose objective is to provide health education to families in disadvantaged communities.

2. Cambodia
The prevalence of counterfeit drugs is increasing, posing a growing threat to the safety of people worldwide. In 2006, JPMA and the Cambodian Ministry of Health have established joint project to combat counterfeit medicines, in collaboration with the Drug Management and Policy Department, Faculty of Pharmaceutical Science, Kanazawa University, Japan.

3. Egypt
Pfizer works with the Egyptian Ministry of Health and Project HOPE to equip Egypt’s National Training Institute (NTI) to provide state-of-the-art training in Infection Control, Family Medicine, Ophthalmology, Urology, General Surgery, Research Methodology, and Healthcare Management.

4. Kososvo
Abbott Fund has provided AmeriCares with a grant of USD 86,800 to help equip four patient units in the Neonatal Intensive Care Unit at the UCCK in Pristina.

5. Pakistan
In June 2003, Otsuka Pharmaceutical set up the “Otsuka Welfare Clinic” to help serve the health needs of refugees in Peshawar, in Pakistan’s Northwest Frontier District state. Medical doctors, pharmacists, nurses and other medical professionals provide free treatment each day to some 300 patients requiring medical assistance.

6. Russia
sanofi-aventis is helping to provide social and medical support to homeless children in Moscow, Russia, in partnership with Samusocial International.

7. South Africa
Since 1992, the Johnson & Johnson Burn Treatment Centre at the Chris Hani Baragwanath Hospital in Soweto, South Africa, has treated more than 1,500 patients annually for serious and complicated burns, and has succeeded in reducing the mortality rate among critically ill patients.

8. Tanzania
The Novartis Foundation for Sustainable Development and its partners have upgraded the Ifakara Health Training Center in Tanzania. Substantial renovation, new constructions and equipment were combined with a strengthened management and maintenance system as well as with the establishment of a board as the governing body.

9. Venezuela
In Venezuela, Boehringer Ingelheim supports a training program to help physicians to treat respiratory diseases.

10. Zambia
In February 2006, the Nursing Libraries for Refugee Health partnership was launched, a collaboration of ICN, the UNHCR and Merck & Co., to provide current health care information and training to nurses and health workers serving refugee populations in Africa.
Additional Health Initiatives
(This section offers a selection of individual company programs around the world, dedicated to improving health in developing countries, outside the therapeutic areas listed above. It is not intended to constitute a definitive list of all such programs.)

Abbott
www.abbott.com

- According to UNICEF, the infant mortality rate in Kosovo is estimated at 49 per 1,000 live births and 69 per 1,000 live births for children under the age of five; both rates are at least twice as high as those in neighboring countries. Through a partnership with AmeriCares, Dartmouth University, and the University Clinical Center of Kosovo (UCCK), Abbott is supporting efforts to improve neonatal survival. Abbott Fund has provided AmeriCares with a grant of USD 86,800 to help equip four patient units in the Neonatal Intensive Care Unit at the UCCK in Pristina, the only hospital equipped to treat very sick or premature newborns, and where a third of all infants in Kosovo are born. The grant has also supported an education exchange on neonatal resuscitation and stabilization, and how to administer Survanta®, Abbott’s surfactant replacement therapy. Since 2006, Abbott has donated over USD 260,000 worth of Survanta® and Human Milk Fortifier to UCCK. Hospital results from 2007 showed a 17% reduction in mortality rate among the target range of infants weighing 1,000-1,499 grams and an overall 15% decline in the hospital’s neonatal mortality rate.

AstraZeneca
www.astrazeneca.com

- AstraZeneca’s product donation and patient assistance programs make its medicines available to those who cannot afford them, either free-of-charge or at reduced prices. In 2007, the company spent a total of USD 588 million on community sponsorships and charitable donations worldwide, including USD 518 million on product donations, valued at average wholesale prices.

Boehringer Ingelheim
www.boehringer-ingelheim.com

- For years, Boehringer Ingelheim has been involved in health educational activities and training of health personnel in the field of HIV/AIDS and other diseases in various parts of the world. For example, in Southern Africa, continued medical education has been offered to health professionals in the Boehringer Ingelheim Training and Facilitation Centre in Gaborone, Botswana, since June 2005. The training includes improvement of logistics management for medical stores. Boehringer Ingelheim also supports treatment roll-out and health education programs executed by different national and international NGOs in Eastern and Southern Africa and in Papua New Guinea. Here, Boehringer Ingelheim helps the “Collaboration for Health” in various activities, including its Strengthening Capacity of Healthcare Teams program. In Venezuela, Boehringer Ingelheim supports a training program to help physicians to treat respiratory diseases.

Crucell
www.crucell.com

- Crucell is committed to research and development of innovative vaccines and biologicals to support the developing countries in improving their population health status and reaching the UN Millennium Development Goals. The company is actively involved in private-public partnership R&D initiatives aimed at making available vaccines against malaria, tuberculosis, ebola and HIV to the most needy populations in the world. Crucell also believes in the benefit of collaboration with other vaccine manufacturers, and has recently engaged in co-developing with sanofi-aventis of anti-rabies monoclonal antibodies, thus making an important contribution to address this unmet public health need in endemic countries.
The Japan Pharmaceutical Manufacturers Association (JPMA) helps developing countries in Asia to establish efficient pharmaceutical distribution and quality control systems, via the following activities:

• Training in Japan: Since 1989, the JPMA has worked with the World Health Organization to provide annual Quality Control training courses in Japan for Asian government quality control personnel. JPMA provides practical training in medicines quality control at research laboratories and manufacturing plants, with the help of its member companies. This training strengthens the professional competence of Asian regulatory personnel and helps improve the quality of medicines in developing countries in Asia. To date, JPMA has provided training for 69 regulators.

• Contracted training in third countries: JPMA also provides training for government personnel from countries such as Bhutan, Cambodia and Laos in a third country, such as Thailand. This approach is used when there may be big differences between the standard of technical equipment in Japan and in the countries concerned. JPMA started in-country training in 2001 and has trained 22 regulators so far via this type of course.

• Donation of Analytical Instruments: A request from the Cambodian National Laboratory for Drug Quality Control for High-Performance Liquid Chromatographs equipment to improve controls for counterfeit and sub-standard medicines led to donations of analytical instruments by Eisai, Kyowa Hakko, Tanabe and JPMA. Takeda Pharmaceutical staff helped set up the devices and train Cambodian staff to use them.

• Supply of Reference Substances to ASEAN Countries: Reference substances are extremely pure active ingredients of drugs that are indispensable for assaying the content of pharmaceutical substances in medicine. Since 1992, JPMA has provided free reference substances to support a UN / WHO program which helps ASEAN countries to assay commercially available medicines. This project is now managed by the Bureau of Drugs and Narcotics (BDN), Thai Ministry of Public Health. JPMA now funds acquisition of substances from within the ASEAN region. To date, JPMA has provided a total of 169 substances.

• Anti-Counterfeiting Project in Cambodia: The prevalence of counterfeit drugs is increasing, posing a growing threat to the safety of people worldwide. In 2006, JPMA and the Cambodian Ministry of Health have established joint project to combat counterfeit medicines, in collaboration with the Drug Management and Policy Department, Faculty of Pharmaceutical Science, Kanazawa University. The project aims to allow development of effective countermeasures by investigating the prevalence of counterfeit medicines in Cambodia and helping to identify their origins. A first sample gathering campaign in 2006 was followed by another in 2007. Samples were gathered in Kampong Speu province, Kandal province and Phnom Penh, and passed to Kanazawa University and the Cambodian National Laboratory for Drug Quality Control for analysis.
Johnson & Johnson supports the Advanced Nursing Studies (ANS) and the Enrolled Nurses to Registered Nurses (ER-RN) programs at the Aga Khan University of East Africa. The program provides quality education and greater standards of evidence-based care to nurses and midwives from Kenya, Tanzania, and Uganda, to further develop their professional skills. The training, which includes some distance-learning approaches, prepares nurses to become registered nurses.

In 1992, the company built the Johnson & Johnson Burn Treatment Centre at the Chris Hani Baragwanath Hospital in Soweto, South Africa. This state-of-the-art unit treats more than 1,500 patients annually for serious and complicated burns, and has succeeded in reducing the mortality rate among critically ill patients. Johnson & Johnson continues to support the facility with management support, essential equipment, quality products, and education for nursing and medical personnel. Less visible, but of equal importance, are the investments and expertise provided at the community level with the establishment of clinics and training of caregivers. For more information, see www.jnjsouthafrica.co.za/co_social.asp.

Since its inception three years ago, Circle of Care has helped more than 1,000 families in Malaysia cope with mental illness. Individuals released from mental health institutions are often unable to reintegrate into society because of stigma. Circle of Care provides job placement support programs in nine cities, while families educated about mental illness and are connected to local support groups through the Family Link program. Johnson & Johnson supports Circle of Care’s efforts to educate and support families through Family Link, assist patients in finding jobs and re-entering their communities.

Trauma is a major health care problem and one of the leading causes of death in West Africa. In 2005, International Aid, Johnson & Johnson and the West African College of Surgeons opened the Ghana Surgical Skills Training Center at Korle bu Hospital in Accra, and conducted the first Advanced Trauma Operative Management (ATOM) course in West Africa. Since then, the center has trained nearly two dozen top trauma surgeons in the region.

The Johnson & Johnson Regional Hospital Management Program helps hospitals in the Asia-Pacific region to improve their management and operations so they can deliver better health care services. Based in Singapore and now in its ninth year, the Regional Hospital Management Program is run jointly with Singapore Management University. Each year, professors from leading Singaporean and US institutions review modern hospital management principles and techniques with 50 senior hospital administrators from different Asian countries during a five-day seminar. Since its inception in 1997, 368 hospital administrators from 305 different health care institutions have participated in the program.

SOS Children’s Villages runs 450 villages in some 130 countries, each of which provides a home, education and health care for approximately 120 neglected, abandoned and orphaned children. The organization provides vocational and professional education to prepare children for adult life. Johnson & Johnson is funding one such program for 20 student nurses in Mogadishu, Somalia, where the health care system has deteriorated due to the displacement and emigration of doctors and nurses during the country’s civil war. For more details, visit: www.sos-childrensvillages.org.

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. Over the past year in the Congo, the WWF has conducted sex education and HIV/AIDS training in eight villages, established five wildlife management committees as well as two primary schools reaching 400 students. A Congo community health center also was renovated and restocked. In Nepal, improved mcooking stoves have been installed to reduce pressure on forests and improve community health. J&J funding also has assisted in protecting freshwater streams from degradation in Khata, Nepal.

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.
• In 2007, Lilly’s philanthropic contributions totaled about USD 300 million, including about USD 225 million in products for patient assistance programs and international humanitarian causes.

• 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.

• Merck & Co., Inc. donates its pharmaceuticals and vaccines through the Merck Medical Outreach Program (MMOP), now in its 50th year, to a selected group of qualified, US-based, private voluntary organizations for use in the developing world and in support of disaster relief and emergency situations worldwide. Primary recipients include AmeriCares, Catholic Medical Mission Board, Direct Relief International, IMA World Health, MAP International and Project HOPE. In 2007, Merck’s MMOP donated USD 125 million worth of medicines and vaccines to help patients throughout the developing world. These donations supported disaster and emergency relief efforts in Peru, the Dominican Republic and Nicaragua; sustained chronic care programs in Central Asia; and reached many more worldwide through MMOP partner programs.

• In 2001, the International Council of Nurses (ICN), Merck & Co., Inc. and Elsevier Science, the world’s largest publisher of nursing books, initiated the ICN/MSD Mobile Library program for nurses working in remote areas of developing countries. Each mobile library contains some 90 selected publications, designed to provide up-to-date information for nurses who have limited access to reference books or expert advice. The libraries are packed in specially-designed transportable trunks, resistant to moisture, insects and damage. More than 175 libraries have been provided so far, to 17 countries, including Botswana, Ethiopia, Ghana, Kenya, Lesotho, Liberia, Malawi, Mauritius, Seychelles, Swaziland, Tanzania, Uganda, Zambia and Zimbabwe. Additionally, Merck has donated more than 100,000 copies of The Merck Manual Home Edition to nurses throughout Africa. A Portuguese version of the ICN/MSD Mobile Library was developed in partnership with the Ordem dos Enfermeiros, the ICN member national nurses association in Portugal, and was launched in 2007 in Angola, Mozambique and Sao Tomé & Principe.

• In February 2006, the Nursing Libraries for Refugee Health partnership was launched, a collaboration of ICN, the United Nations High Commission for Refugees (UNHCR) and Merck, to provide current health care information and training to nurses and health workers serving refugee populations in Africa. This program builds upon the work of the ICN-MSD Mobile Library project. To date, 62 libraries have been established in Tanzania and Zambia. More than 2,000 nurses and health workers have participated in related training activities.

• The Global Pharma Health Fund e.V. (GPHF) is a charitable organization initiated and funded exclusively by donations from Merck KGaA, Darmstadt Germany. The organization aims to improve health care in the context of development assistance, in particular the use of the GPHF-Minilab® in the fight against counterfeit drugs. The GPHF-Minilab® is a compact, portable toolbox that allows quick, reliable testing of more than 40 standard medicines, showing whether or not the right quantity of active ingredient is present. They have been selected on the basis of prevailing prescription practices, public health interest and existing counterfeit case reports, the current short list consisting of common antimicrobials, antihelmintics, antiretrovirals, antimalarials, antituberculosis and some other medicines. The GPHF-Minilab® is specifically designed for use in developing countries which are heavily affected by counterfeit medicines and lack facilities for effective medicine testing. To date, 274 GPHF-Minilabs have been deployed in 65 countries, mostly in Africa and Asia. For more details, go to: www.gphf.org
**Novartis**
www.novartis.com

- In Mali, the Novartis Foundation, together with the Ministries of Health and Social Development, has started a new initiative aiming at improving access to primary health care services in rural areas. This three-year program (2007-2009), called Initiative Accès, includes measures to improve availability and quality of health services, including infrastructure, equipment and qualified personnel, their geographical accessibility through mobile health services in villages and patient-provider medical communication as well as measures to strengthen management and organization of the services. The affordability of services is being tackled through the creation and strengthening of new and existing community-based health insurance schemes. This initiative builds on the five-year pilot experience of the PISAM project (2001-2006) in the Municipality of Cinzana that has been extended to 11 health zones in four districts of the Region of Ségou reaching potentially 150,000 people. For more details, see: www.novartisfoundation.org

- To strengthen human resource development in the health sector in Tanzania and beyond, the Novartis Foundation for Sustainable Development and its partners have upgraded the Ifakara Health Training Center in Tanzania that has been in existence since 1961. Substantial renovation, new constructions and equipment were combined with a strengthened management and maintenance system as well as with the establishment of a board as the governing body. The now called Tanzanian Training Center for International Health trains assistant medical officers, a priority cadre for the Ministry of Health, as they enhance the quality of essential health care services, especially at district level. Moreover, the TTCIH has developed additional own courses in various health fields and also offers course facilitation services to external course providers that hold their courses in Ifakara. These new activities allow the center increase its financial self-reliance. The improved teaching and learning environment will contribute to better medical and public health expertise, which is needed to improve the overall health situation of the population, especially in rural areas. For more details, see: www.healthtrainingifakara.org

- Every year almost 10 million children die before they reach their fifth birthday. More than half of these deaths are caused by just five preventable and treatable conditions: pneumonia, diarrhoea, malaria, measles and malnutrition, and often by a combination of these. In the early 1990s, the World Health Organization (WHO) and UNICEF developed a strategy called the Integrated Management of Childhood Illness (IMCI) with the primary objective to reduce childhood (including newborn) mortality worldwide. To make the implementation of this strategy easier, WHO and the Novartis Foundation for Sustainable Development have developed the IMCI Computerized Adaptation and Training Tool (ICATT). ICATT is an innovative computerized software application that makes it possible to adapt the IMCI guidelines at national and sub-national levels, and to develop ICATT-based training courses in a very flexible way. For more details, see: www.icatt-training.org

- In 2007 the Novartis Foundation started financing one of the Millennium Villages in Tanzania, the Ilolangulu Village. For a five-year-period the Novartis Foundation will invest in the village's transition from subsistence farming to self-sustaining commercial activity. As three out of eight MDGs are health-related, the Novartis Foundation agreed in 2007 to also support the Millennium Villages Project in health-related research. The Millennium Villages Project (MVP) was founded with the goal of helping impoverished communities in rural Africa achieve the Millennium Development Goals (MDG) formulated and agreed on by all member countries of the United Nations. The MVP is active at 12 sites in 10 African countries. For more details see: www.novartisfoundation.org

- Novartis donates intraocular lenses to NGOs for cataract surgery for patients with inadequate means in developing countries.

**Otsuka Pharmaceutical**
www.otsuka-global.com

- In June 2003, Otsuka Pharmaceutical set up the “Otsuka Welfare Clinic” to help serve the health needs of refugees in Peshawar, in Pakistan’s Northwest Frontier District state. Medical doctors, pharmacists, nurses and other medical professionals provide free treatment each day to some 300 patients requiring medical assistance.
• Pfizer works with the Egyptian Ministry of Health and Project HOPE to equip Egypt’s National Training Institute (NTI) to provide state-of-the-art training for physicians, nurses and health professionals in Egypt and the Middle East in Infection Control, Family Medicine, Ophthalmology, Urology, General Surgery, Research Methodology, and Healthcare Management. Pfizer also helped upgrade laboratories and training equipment. Over 9,000 physicians have been trained through 220 training courses and 21 symposia. Project HOPE has asked Pfizer to help extend the project for an extra year, to expand the current Emergency Medical Services modules (Basic Life Support and Advanced Cardiac Life Support), to cover Emergency Medical training, including Mass Casualty management and Pediatric Emergency Services. As Project HOPE supported the NTI’s accreditation by the American Heart Association, Pfizer will support additional accreditations related to these new courses. Pfizer will also support the development of distance learning options for new and existing courses. Pfizer will also help introduce leadership and management training in the NTI training curriculum. In 2007, NTI established some revenue generating capacity but these efforts need to be expanded and so Pfizer will help to develop a sustainability strategy and plan for the NTI.

• The Phelophepa healthcare train provides basic healthcare services to poor patients in remote rural areas of South Africa. The train is now 16 cars long and provides a pharmacy, cancer screening and education, psychology and dental and eye clinics, as well as diabetes and smear tests. It serves more than 45,000 people a year and has reached nearly 13 million in total since its inception in 1994. The train is run by the government-owned Transnet group. The Transnet Foundation funds about two-thirds of the train’s running costs and provides staff, rail access and rolling stock. Roche is the lead outside sponsor which includes other corporations such as Colgate. Phelophepa also improves rural health education through its Edu-Clinic. Sixteen people are nominated at each stop to complete five-day courses in basic health and hygiene. Many are traditional healers, people who could have felt threatened by the train’s work. Examinations and screenings are free, but nominal fees are charged for services such as prescriptions and glasses. A fund of pooled donations means, however, that no one unable to pay is refused treatment.

• In 2006, Roche launched a Secondment Policy to enable its employees to contribute their skills and expertise to help developing Countries. The policy has allows Roche employees to experience a unique personal development opportunity while contributing their skills and expertise to help make a real difference in health related projects in the world’s poorest countries. The Roche secondment policy is open to full-time employees who have had a minimum of five years service with Roche. Each secondment lasts 3-18 months, with secondees continuing to receive their salary from Roche during this period.

sanofi-aventis supports a number of other projects in developing countries not already described in the previous pages, such as:

• Setting up a pilot program with The Chain of Hope to improve prevention of childhood rheumatic fever in Cambodia’s rural Pursat province.

• In Vietnam, sanofi-aventis is helping the Sister Elisabeth Association to build a dispensary in an orphanage for sight-impaired children, to build a school for street children (to help fight against prostitution) and to create sculpture and sewing workshops to prove sources of income for the very poor.

• sanofi-aventis is helping to provide social and medical support to the homeless, in particular children in Ho-Chi-Min City, Vietnam and in Moscow, Russia, in partnership with Samusocial International.

• In Haiti, sanofi-aventis has helped set up of a medical and psychosocial program for street children in Port au Prince in partnership with Aide Médicale Internationale. At the same time, sanofi pasteur donated 1.5 million doses of diptheria-tetanus vaccine to support an immunization campaign, spearheaded by the Pan-American Health Organization (PAHO) in this country.

• In Senegal, sanofi-aventis has partnered the Kinkeliba association for its training program of bush doctors: fund of courses for final year medical students and for post-doctoral students working on such subjects as parasitology, pharmaceutics and biology.

• In total, in the course of 2007, sanofi-aventis and sanofi pasteur have donated 1.2 million boxes of medicines and 5.3 million doses of vaccines, sufficient to treat more than 5 million people, in 69 countries.
Schering-Plough
www.schering-plough.com

- Schering-Plough donated more than USD 30 million worth of pharmaceutical and over-the-counter products to several US-based NGOs in 2007. NGO partners include AmeriCares, Catholic Medical Missions Board, Direct Relief International, International Aid, MAP International and Project HOPE. These products, which included antifungal creams, oncology medicines, anti-infectives, topical creams, allergy medicines, vitamin-enriched ointments and other medicines were used for disaster relief, short-term medical missions and long-term health development programs in nearly 100 developing countries.

- Schering-Plough helps provide essential medicines in countries affected by natural disaster, disease, war and poverty through its partnership with the global relief and development NGO Medical Assistance Programs (MAP) International. In 2007, Schering-Plough provided USD 367,000 in financial support and more than USD 14 million worth of antifungal creams, topical creams, allergy medicines, vitamin-enriched ointments and other medicines for use in MAP's Travel Pack Program. In 2007, 2,700 Travel Packs, each with enough medicines to treat about 700 patients, were used by medical teams in 250 villages in 92 developing countries, notably Bangladesh, Cambodia, Cameroon, Dominican Republic, Ecuador, El Salvador, Ethiopia, Gambia, Ghana, Guatemala, Haiti, Honduras, Ivory Coast, Kenya, Malawi, Mongolia, Mozambique, Nicaragua, Paraguay, Philippines, Romania, Rwanda, Sierra Leone, Tanzania, Uganda, Venezuela and Zimbabwe.

- Schering-Plough began the Instituto Criança é Vida (Child is Life Institute) in Brazil in the 1980s. Today, it is an independent institute, in part supported by Schering-Plough, whose objective is to provide health education to families in disadvantaged communities. The program now uses more than 700 volunteer “health agents” to reach 150 institutions and more than 19,000 families. Education modules include prevention of domestic accidents, nutrition basics, and personal/household hygiene. The program has been recognized for its work by many organizations, including the American Chamber of Commerce ECO Prize, Instituto Ethos, and the Instituto Scudo di San Martino, Italy.

- Since 2005, Schering-Plough has been involved in several programs to improve the quality of life in underprivileged and indigent communities within Venezuela. These programs have focused on many community health issues, including controlling the spread of hepatitis-B and preventing drug use. The company created this community education and welfare project to provide training and awareness to children and adults on topics such as home hygiene, drug abuse prevention, sex education, hepatitis, home accidents and child mistreatment. Schering-Plough’s partners on this project include two local NGOs: Luz y Vida and Fe y Alegría. Since 2005 more than 380 volunteers from more than 100 communities have been recruited and trained to conduct community workshops. These volunteers led nearly 500 community workshops benefiting nearly 15,000 individuals in 105 communities since the start of the program.

- Schering-Plough has also partnered with various institutions in Venezuela to establish a PegIntron® donation program for Hepatitis-C. In 2006, Schering-Plough joined with the Indigenous Control Coordination Program to provide patients from the Yucpa tribe with free treatment, and in 2007 donated nearly 200 PCR (Protein Chain Reaction) confirmatory tests to measure the presence of the Hepatitis virus and its concentration (viral load) for patients in the most impoverished communities in the country. This program was established in collaboration with the Ministry of Health and Social Security Institutions.

- Rabies, a fatal neurological disease, is widespread throughout Africa with more than 25,000 people dying from the disease each year. Schering-Plough’s animal health business, Intervet, supports the Afya Serengeti (health of Serengeti) project in Tanzania, run by The Alliance for Rabies Control. In 2007, Intervet donated 200,000 doses of rabies vaccine to the Afya Serengeti project. The rabies vaccine protects dogs from becoming infected and spreading the disease to humans. Afya Serengeti’s vaccination program has produced a significant reduction of households reporting animal rabies cases, with the percentage dropping from 27% in 2003 to 2% in 2006. Injuries from rabid dogs have also declined, from 10% of households reporting bite injuries in 2003 to less than 1%.
More and better testing is essential for improving health outcomes in developing countries. This in turn requires more and better-trained health workers. (GlaxoSmithKline)
EMERGENCY RELIEF EFFORTS

1. Bangladesh
sanofi-aventis sent aid after the Cyclone Sidr in November 2007. Donations of medicines (mainly antibiotics) were made available immediately.

2. Cameroon
In February 2008, at the request of the French Humanitarian Action Commission, sanofi-aventis worked with TULIPE to ship 6 emergency packs (5,000 treatments) for Chadian refugees in Cameroon.

3. Lebanon
Johnson & Johnson responded with products and money following several major disasters in 2006, including civil unrest in Lebanon.

4. Malaysia
AstraZeneca worked with the Red Cross to set up a new Disaster Response Centre in Kuala Lumpur, Malaysia, in 2006. Designed to provide a rapid response to sudden large scale disasters, the centre is stocked with emergency aid items. In 2007, British Red Cross released emergency relief stock for the Bangladesh Cyclone disaster from the Kuala Lumpur centre.

5. Mexico
GlaxoSmithKline supplied GBP 16 million worth of humanitarian product donations for international relief efforts in 2007, including the floods in Mexico.

6. Peru
In response to the devastating earthquake in Peru in August 2007, Schering-Plough Peru employees initiated relief efforts to help the thousands of people who lost their homes and need food, shelter and medical care. Employees donated money to purchase food and other items.

7. Philippines
Johnson & Johnson responded with products and money following several major disasters in 2006, including mudslides in the Philippines.
Emergency Relief Efforts
(This list illustrates a selected range of individual company programs around the world. It is not intended to include all such programs.)

Abbott
www.abbott.com

- In response to disasters in 2007, Abbott worked closely with its relief partners to provide USD 5 million worth of products to those affected by 10 disasters; earthquake in Peru, Hurricanes Dean, Felix and Noel, floods in North Korea, Pakistan and Mexico, and Cyclone Sidr in Bangladesh. As part of Abbott’s disaster strategy, on-going donations of critical products were pre-positioned throughout the year within partners’ warehouses, in addition, targeted donations in preparation for hurricane season were pre-positioned within food banks and safety net clinics in high risk cities through partnerships with Direct Relief International and America’s Second Harvest. This strategy significantly improved the ability of the company and relief partners to respond to disasters both in terms of efficiency and effectiveness.

AstraZeneca
www.astrazeneca.com

- Following the Asian tsunami, AstraZeneca worked with the Red Cross to set up a new Disaster Response Centre in Kuala Lumpur, Malaysia, in 2006. Designed to provide a rapid response to sudden large scale disasters, the centre is stocked with emergency aid items such as blankets, tents, medical supplies and water containers for up to 12,000 people and can support a further 100,000 people by providing specialized items, such as warehouse tents and vehicles, to support the wider emergency relief efforts. In 2007, British Red Cross released emergency relief stock for the Bangladesh Cyclone disaster from the Kuala Lumpur centre. This included 7,500 blankets, 3,000 tarpaulins and 3,000 water containers. The aid was sent by sea to the port of Chittagong.

Bristol-Myers Squibb
www.bms.com

- In 2007, Bristol-Myers Squibb donations worth approximately USD 45 million at wholesale prices were given to programs throughout the world, including Africa, Asia, Caribbean, Latin America, Mexico and the Middle East through designated non-governmental organizations (NGOs). NGO partners include Americares, Direct Relief International, Catholic Medical Mission Board, Heart to Heart International, International Aid, IMA World Health, MAP International, Medical Teams International and Project HOPE. These donations supported proactive health care programs, disaster relief and medical missions.

GlaxoSmithKline
www.gsk.com

- GlaxoSmithKline supplied GBP 16 million worth of humanitarian product donations for international relief efforts in 2007, including the cyclone in Bangladesh and the floods in Mexico. In each case, GSK provided large quantities of essential medicines through a proven crisis response process that was activated immediately to support the relief efforts.

Johnson & Johnson
www.jnj.com

- Johnson & Johnson responded with products and money following several major disasters in 2006, including mudslides in the Philippines, an earthquake in Indonesia and civil unrest in Lebanon. Several Johnson & Johnson affiliates provided local assistance in the aftermath of these disasters.
• In 2007, Merck & Co., Inc. donated nearly USD 6 million in medicines, vaccines and direct financial contributions in support of relief activities following the earthquake that struck the southern coast of Peru, Tropical Storm Noel, and the severe flooding in Mexico.

Merck & Co., Inc.
www.merck.com

• In 2007, Novartis donated USD 14 million in emergency relief to major humanitarian organizations.

Novartis
www.novartis.com

• Following the natural catastrophies such as earthquakes, floods and hurricanes in Japan, Pakistan, Bangladesh and Peru in July and August 2007, the local sanofi-aventis affiliates and the Humanitarian Sponsorship Corporate Department have donated medicines and money to NGOs to help the victims.

sanofi-aventis
www.sanofi-aventis.com

• sanofi-aventis sent aid after the Cyclone Sidr in November 2007. Donations of medicines (mainly antibiotics) were made available immediately. To deliver more sustainable aid, the Humanitarian Sponsorship Division asked its partner Handicap International, which has been in Bangladesh since 1997, to evaluate emerging needs. In addition, a program for access to drinking water (treatment stations and filters distribution) has been set up with the NGO Solidarities’, in the inaccessible district of Pirojbur.

• In January 2008, after the earthquake which hit the Democratic Republic of Congo and Rwanda, sanofi-aventis and TULIPE sent 3 emergency packs (2,000 treatments) to treat those injured in Rwanda.

• In February 2008, at the request of the French Humanitarian Action Commission, sanofi-aventis worked with TULIPE to ship 6 emergency packs (5,000 treatments) for Chadian refugees in Cameroon.

• In response to the devastating earthquake in Peru in August 2007, Schering-Plough Peru employees initiated relief efforts to help the thousands of people who lost their homes and need food, shelter and medical care. Employees donated money to purchase food and other items. These donations were shipped by the local city hall to affected areas in San Borja, where the company is located. Additionally, the company donated 1,000 units of the following products to victims: Diprospan (an injectable corticosteroid), Desenfriol and Desenfriolito (regional brands of cold medicines for adults and children). These medicines were distributed through local health authorities and a local HMO.

Schering-Plough
www.schering-plough.com

• TULIPE, a non-profit organization created in 1982 by the French pharmaceutical association, Les Entreprises du Médicament (LEEM), brings together NGOs, government and industry to provide appropriate medicine donations in emergency situations. It has developed special medical kits for NGOs and the French Ministry of Foreign Affairs, adapted to their first-aid teams’ needs. In 2007, TULIPE provided medicines worth EUR 617,000 at wholesale prices, 37% of which were for emergency medical kits to meet a variety of needs, including an earthquake in Peru, cyclones in Pakistan and the Dominican Republic and conflicts in the Democratic Republic of Congo, Afghanistan, Myanmar, Burundi, Lebanon, Ivory Coast, and West Bank and Gaza. Throughout the year, Tulipe and its partner organizations were able to respond quickly to these emergency situations, as soon as countries requested relief assistance.

TULIPE (LEEM)
www.tulipe.org
• AstraZeneca’s partnership with the African Medical Research Foundation (AMREF) initially focused on TB control and management in the Eastern Cape of South Africa, heavily affected by TB, HIV and malnutrition. AstraZeneca and AMREF worked with local communities in the Chris Hani district, helping them to take action to promote good health and wellbeing. The program has seen increased knowledge, detection and defaulter tracing. The program came to an end in 2007.

• In July 2003, AstraZeneca made a GBP 60,000 grant to BookPower, a non-profit organization which provides medical and nursing text books at a subsidized price to students in English-speaking Africa, the Indian sub-continent and the Caribbean. The AstraZeneca grant funded medical texts on Cardiology, Endocrinology, Gastroenterology, Immunology and Infection. The program ended in 2005.

• AfriKids is an NGO working in Ghana which helps to protect vulnerable children’s rights, delivers basic care, improves local facilities and offers education and micro-finance programs. GlaxoSmithKline supported AfriKids for 4 years from 2003, especially Operation Sirigu, which helped reduce the child abuse, abandonment and infanticide that have been related to the “spirit child” phenomenon.

• In February 2008, Phase III clinical trials showed that Dacart™ (chlorproguanil/dapsone/arthesunate), a candidate anti-malarial combination developed by GSK and Medicines for Malaria Venture, could significantly reduce hemoglobin in patients with glucose-6-phosphate dehydrogenase deficiency (which affects 10-25% of people in sub-Saharan Africa). Consequently, GSK and MMV terminated development of Dacart™. GSK also withdrew its Lapdap™ chlorproguanil/dapsone combination. This disappointment highlights the complexity and risk of pharmaceutical R&D, but GSK remains committed to fighting malaria.

• JPMA member companies Astellas, Chugai, Daiichi, Daiichi-Asubio, Dainippon Sumitomo, Eisai, Meiji Seika, Mitsubishi Pharma, Otsuka, Sankyo, Shionogi and Takeda), worked with the Japanese Ministry of Health, Labor and Welfare (MHLW), and the Special Program for Research and Training in Tropical Diseases (TDR) of the WHO in the JPMW Alliance, formed in October 1999, to help malaria R&D. Nearly 30,000 compounds, mostly from the companies’ libraries, were screened, of which 372 showed activity against malaria. Of these, 14 showed enough promise to merit further research.

• Enhancing Care Initiative (ECI) was launched in 1998 with a five-year, USD 5 million grant from the Merck Company Foundation, as a multidisciplinary collaboration to improve the care of people living with HIV/AIDS in resource-limited settings, run by the Harvard AIDS Institute and the Francois-Xavier Bagnoud Center at the Harvard School of Public Health. It worked in Brazil, Puerto Rico, Senegal, South Africa and Thailand. See www.eci.harvard.edu.

• In 2002, Wyeth contributed USD 1 million to the Global Polio Laboratory Network, a key component of the Global Polio Eradication Initiative, comprising three regional and 13 national laboratories covering 44 African and three Eastern Mediterranean countries. Wyeth has also donated 10 million doses of vaccine for Haemophilus influenzae type b to immunize 3.3 million children.
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Photos

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2008 marks the tenth anniversary of the Global Alliance to Eliminate Lymphatic Filariasis. More than 1 billion people in approximately 80 countries live at risk of contracting lymphatic filariasis (LF). More commonly known as elephantiasis, LF is a devastating parasitic infection spread by mosquitoes. Currently over 120 million people are infected, with more than 40 million incapacitated or disfigured by the disease. GlaxoSmithKline and Merck & Co., Inc. work with the Global Alliance to Eliminate Lymphatic Filariasis, the goal of which is to free the world of this disfiguring and disabling disease by 2020. The WHO currently recommends that LF be prevented with a combination of albendazole (donated by GSK) with either DEC, or Mectizan® (donated by Merck & Co., Inc.). Medicine administration for people living in endemic areas is recommended by WHO once a year for at least five years to break the cycle of transmission. So far, Egypt, several Pacific Island countries, Sri Lanka, Zanzibar, and Togo have completed the WHO recommended five annual mass medicine administrations. WHO estimates that over 130 million people – 30 million of whom are children – have begun to be protected from LF. The photo shows a youngster’s height being measured. This will determine how many tablets he will receive. (GlaxoSmithKline)
Partnerships to Build Healthier Societies in the Developing World

The International Federation of Pharmaceutical Manufacturers & Associations is the global non-profit NGO representing the research-based pharmaceutical, biotech and vaccine sectors. Its members comprise 25 leading international companies and 44 national and regional industry associations covering developed and developing countries. The industry’s R&D pipeline contains hundreds of new medicines and vaccines being developed to address global disease threats, including cancer, heart disease, HIV/AIDS and malaria. The IFPMA Clinical Trials Portal (www.ifpma.org/clinicaltrials), the IFPMA’s Ethical Promotion online resource (www.ifpma.org/EthicalPromotion/) and its Health Partnerships information (www.ifpma.org/Healthpartnerships) help make the industry’s activities more transparent. The IFPMA strengthens patient safety by improving risk assessment of medicines and combating their counterfeiting. It also provides the secretariat for the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH).

The program information in this book is also available in searchable form in the IFPMA website, at www.ifpma.org/healthpartnerships/, and on the Global Health Progress website www.globalhealthprogress.org