Donation Programmes for HIV/AIDS-Related Drugs : Documenting the Early Experience of the Diflucan®Partnership Programme and Viramune® Donation Programme

Sibongile Pefile PhD

Independent Consultant, London, United Kingdom

2003

A study commissioned by the

Initiative on Public-Private Partnerships for Health

Initiative on
Public-Private
Partnerships
for Health

Donation Programmes for HIV/AIDS-Related Drugs : Documenting the Early Experience of the Diflucan® Partnership Programme and Viramune® Donation Programme

by Sibongile Pefile, PhD

Published by The Initiative on Public-Private Partnerships for Health,
Global Forum for Health Research, August,2003
ISBN 2-940286-11-6

Author Sibongile Pefile
Editor Sheila Davey

Additional copies of this publication are available (at no charge) from:

The Initiative on Public-Private Partnerships for Health
ICC (Block G, 3rd Floor)
Route de Pré-Bois 20
P.O. Box 1826
1215 Geneva 15
Switzerland

E-mail: info@ippph.org
Website: www.ippph.org

The Initiative on Public-Private Partnerships for Health is supported by contributions from the Bill and Melinda Gates Foundation, The Rockefeller Foundation and the World Bank. It operates under the aegis of the Global Forum for Health Research - Website www.globalforumhealth.org

Contents

Acknowledgements

The following are acknowledged for their contributions and willingness to be interviewed:

Ms Marie-Helene Besson, Axios International

Dr Helene Clary, Boehringer Ingelheim, GmbH, Germany

Ms Heather Houlihan, Axios International

Adv. Patricia Lambert, Ministry of Health, South African Government

Mr Imraan Munshi, Pfizer, South Africa

Mr Sowedi Muyingo, Axios International

Mr Kevin McKenna, Boehringer Ingelheim, South Africa

Dr Anne Reeler, Axios International

Dr Joseph Saba, Axios International

Dr Konji Sebati, Pfizer, USA

Dr John Wecker, formerly with Boehringer Ingelheim, GmbH, Germany

Ms Tanya Welz, Africa Centre, South Africa

Staff at IPPPH.

Abbreviations

AIDS	Acquired Immune Deficiency Syndrome
HIV	Human Immunodeficiency Virus
IPPPH	Initiative on Public-Private Partnerships for Health
PPP	Public-Private Partnership
MTCT	Mother-to-child-transmission
NGO	Non-governmental Organization
SADC	Southern African Development Community
UNAIDS	Joint United Nations Programme on HIV/AIDS
US/USA	United States of America
WHO	World Health Organization

1. Introduction

1.1 Background

Lack of access to affordable medicines and other health interventions is a major problem in low-income countries. In response, new public-private partnerships (PPPs) have been established — harnessing the skills, expertise and resources of both the public and private sectors — to provide much-needed medicines and other health interventions through integrated and sustainable programmes. These new initiatives are based on the recognition that the scale of health needs is so great in developing countries that no one sector alone can have a sufficient impact on health.

The new working environment created by public-private initiatives brings with it new challenges and constraints. In responding to access problems in developing countries, donors have had to take account of a number of issues such as the poor state of local infrastructure, the sustainability funding, the need to provide incentives for new medicines research and development, and the role of PPPs in overall health systems.

In developing countries, poorly functioning health care systems affect the quality and sustainability of development programmes[1] and hinder many efforts to improve access to health care. Many health settings lack adequate financial and human resources to address the problems they face. Meanwhile, the lack of adequate transportation to health facilities further reduces access to any meaningful health care. The challenge faced by many developing country governments is to provide quality health services amidst dwindling financial resources, growing populations and an increasing burden of disease.

The recent upsurge in private pharmaceutical involvement in national and international drug donation partnerships is often attributed to increasing pressure for social responsibility. Views on the role of the pharmaceutical industry in the improvement of health care in developing countries are often polarized, due to the ongoing debate over the issue of pharmaceutical patents and the high price of medicines needed in low-income countries. An additional source of concern is the fact that less than 1% of new chemical entities registered by health authorities in the industrialized countries are for the treatment of so-called 'orphan' diseases which occur mainly in low-income countries[2].

This paper reviews how two pharmaceutical companies — Boerhinger Ingleheim and Pfizer — forged partnerships with governments and nongovernmental organizations (NGOs) to improve access to new medicines for HIV/AIDS.

With an estimated 42 million people living with HIV/AIDS worldwide and over 29 million afflicted in sub-Saharan Africa alone, HIV/AIDS is not only a health issue, but also a demographic, economic and social problem, especially in African countries[3]. One of the major barriers to efforts to address HIV/AIDS is the continuing lack of access to new medicines at affordable prices.

In July 2000, Boehringer Ingelheim announced the donation of Viramune® free of charge for five years for the prevention of mother-to-child-transmission of HIV-1. Then in December 2000, Pfizer announced its partnership with the South African government to donate Diflucan® for the treatment of oesophageal candidiasis and cryptococcal meningitis, two debilitating HIV-related opportunistic infections. The latter programme includes the provision of Diflucan® free of charge through the national health care system as well as

[1] McCoy, D., Besser, M., Visser, R. and Doherty, T. Interim Findings of the National PTMCT Pilot Sites – Lessons and Recommendations. Health Systems Trust, Republic of South Africa, 2002.

[2] Trouiller, P., Olliaro, P., Torreele, E., Orbinski, J., Laing, R. and Ford, N. Drug Development For Neglected Diseases: A Deficient Market and a Public-Health Policy Failure. The Lancet 2002; 359.

[3] http://www.who.int/hiv/facts/regionalstats_m.jpg

the training of health care professionals in the diagnosis and treatment of HIV/AIDS-related opportunistic infections. This study documents the progress of each donation programme early 2003. The report analyses the introduction of the Diflucan® partnership and Viramune® donation programmes in African countries. Both programmes are now also operating in Asia, South America and, most recently, in Eastern Europe. (The participating countries for each programme are listed in Appendix 1 and 2.)

The report provides a description of the origins of each programme, the negotiations involved and the evolution and implementation of the programme, with a particular focus on decision-making processes, governance structures, stakeholder representation and the way each programme measures its effectiveness and supports national health priorities. It focuses on progress to date and does not attempt to make a critical analysis of either programme. A more in-depth study should be undertaken to review Diflucan® and Viramune® use in each of the countries involved, presenting specific case studies, comparative experiences and detailed analyses.

1.2 The study

1.2.1 Objectives

This study has two major objectives:

- To analyse and explore policy development to date of the Viramune® Donation and Diflucan® Partnership programmes
- To review the appropriateness, relevance, competence and accountability of each programme as an example of public-private partnerships and within the context of national and international health development.

The report is divided into the four main sections:

- An introduction that discusses the processes leading to the establishment of each donation programme
- An overview of the Viramune® Donation programme
- An overview of the Diflucan® Partnership programme
- An overview of the challenges and some of the key lessons learned.

1.2.2 Information and data collection

Interviews were conducted among key people working in the Diflucan® partnership and Viramune® donation programmes, including those from the pharmaceutical donor, policy specialists, health care researchers and senior managers. The interviews were either by telephone or in person and there was minimal use of prompting. Additional information was obtained mainly from the following sources:

- Internet searches using key words such as 'Viramune', 'Viramune donation programme', 'mother-to-child-transmission' and 'Boehringer Ingelheim' for the Viramune® programme and 'Diflucan', 'Diflucan donation programme', 'Pfizer', 'cryptococcal meningitis' and 'oesophageal candidiasis' for the Diflucan® programme
- Publications
- Document reviews
- Country visits.

1.2.3 Study limitations

Limited time and financial resources were the two main constraints to conducting a detailed investigation of every aspect of each programme. This initial study paves the way for a more extensive qualitative and quantitative study of the real impact that donation programmes have on health systems and the extent to which PPPs contribute to addressing health disparities.

Other limitations included:

- Insufficient study penetration: A more in-depth study of the donation programmes in operation at country level would be ideal. Relating this knowledge to progress achieved in developing countries would provide useful information.
- No evaluation of the degree to which donation programmes impact on public access to donated drugs. Such an evaluation would need to take into account a range of other factors that are said to impede access to essential drugs.
- Only limited assessment of the 'value added' of PPPs, especially in leveraging technical and financial resources to improve access to affordable health care.
- The short time over which the programmes have operated.

- The need to determine appropriate measures of success for each programme.

1.3 Key findings

The challenges faced by the pharmaceutical donor and recipient governments are complex and the solutions rarely simple. One of the findings of the study is that a wide range of different approaches are being explored by organizations currently addressing health problems in developing countries. Although it is still too early to evaluate the success of more recent strategies, it appears that multifaceted programmes with a comprehensive approach to problem solving achieve better results overall. Some of the key findings of the study are identified below.

- There has been considerable debate over the extent to which drug prices impede access to essential drugs. However, recent studies on the economic impact of donation programmes show that, while price plays an important role in limiting access, the supply of free drugs does not immediately lead to improved access to medicines. An assessment study of the capacity of developing country health systems to manage a donation programme revealed that the cost of the drug itself amounted to less than 2% of overall health costs[4]. The remaining 98% of estimated costs to health care systems are attributed to factors such as poor infrastructure, inefficient delivery networks and poorly functioning health facilities. Many in the pharmaceutical industry believe that seeking solutions to these related problems are beyond their mandate and sphere of expertise[5].
- The positive accomplishments of some of the newer donation programmes are partly attributed to ensuring that processes are fully consultative and that commitment from key stakeholders in both the public and private sectors is assured. The donation programmes have raised questions about the nature of PPPs: what does it mean to be a PPP and to be in one; and what is the contribution and value that each party brings to the partnership?
- A key success factor during the planning of the programmes has been the quality of the 'donor-recipient' relationship. Spending considerable time, attention and effort in relationship-building is essential to developing trust and credibility. Also critical for successful negotiations are transparency and an understanding of the motivations, institutional cultures, and personalities of the parties involved.
- The measures of success used by the donation programmes studied included:
  - Ease of drug distribution and therefore access and receipt of the drug
  - Awareness of the programme by the public and health workers and an understanding of what it is capable of achieving
  - Financial means to ensure delivery of the drug
  - The number of drug prescriptions given to patients. (This measure does not take into account the number of prescriptions repeated due to treatment failure or recurring infection.)
- Donation programmes are accused of skewing national health care agendas. Therefore such programmes need to be sensitive towards overall delivery and service expectations and such sensitivities need to be managed appropriately.
- A major concern about donation programmes is the issue of long-term sustainability. Governments channel considerable resources towards the implementation of donation programmes. As a result, other sectors of the health care system are adversely affected. Instead of alleviating health problems, badly planned and managed donation programmes can place even greater strain on health systems in resource poor countries. Hence, opportunity costs need to be carefully assessed.

(Some of these issues have subsequently been assessed by an IPPPH pilot study of access partnerships in Uganda)

[4] ftp://ftp.hst.org.za/pubs/other/labisa_pmtct_cost_report.pdf

[5] Personal communication, John Wecker, Boehringer Ingelheim, 2002.

2. Viramune® Donation Programme

2.1 Background

In sub-Saharan Africa, which has the highest prevalence of HIV/AIDS worldwide, an estimated 8.8% of the adult population are living with HIV/AIDS. In most cases, the virus is transmitted through heterosexual encounters. Of major concern is the increasing number of HIV infections among young women and the resulting epidemic among children infected through mother-to-child-transmission (MTCT)[6]. MTCT is the most common source of HIV infection in children under the age of 15 and accounts for 90% of infections within this age group[7]. The virus is normally transmitted to infants during pregnancy, labour, delivery or breastfeeding. HIV infection in children progresses rapidly to AIDS, resulting in a very high mortality rate in the under-15 age group. UNAIDS and WHO estimate that, since the HIV/AIDS epidemic began, over 2 million infants have been born HIV-positive as a result of MTCT of the virus[8].

Although there is as yet no cure for AIDS, effective and feasible interventions to reduce MTCT are now available which could save the lives of 800 000 children a year. A UNAIDS-recommended three-pronged strategy for the prevention of MTCT of HIV is now being widely adopted by programmes fighting the disease[4]. This strategy involves: efforts to prevent HIV infections in women and to prevent unwanted pregnancies among women who are HIV-positive or at high risk of infection; efforts to prevent HIV transmission during pregnancy, labour, delivery or breastfeeding through the use of antiretroviral therapy; and access to voluntary counseling and testing services.

Short-term prophylactic treatment has shown to be a highly effective and feasible method of preventing MTCT. The therapeutic regimens are based on the use of nevirapine (Viramune®) or Zidovudine. Nevirapine is administered as a single dose to the mother during delivery and one dose is given to the infant within 72 hours of birth. A USA-Uganda study assessing the efficacy of single-dose nevirapine showed that at 12 months of age, only 16% of breastfed infants who received nevirapine were HIV-positive[10].

Viramune® is a non-nucleoside reverse transcriptase inhibitor that binds directly to HIV-1 reverse transcriptase. This effect reduces the rate of viral DNA synthesis and therefore inhibits viral replication. Nevirapine is able to cross the placenta following the administration of a single 200mg dose administration to a pregnant woman at the onset of labour. In addition, a single oral dose of nevirapine suspension is administered to the neonate within 72 hours following delivery. Nevirapine is on WHO's Model List of Essential Medicines and is specifically indicated for the prevention of MTCT of HIV. Due to its cost-effectiveness and practicality, nevirapine is widely seen as the drug of choice for all HIV MTCT treatment situations where resources are scarce and the potential for accurate intake of drugs over a longer period is low[11].

In July 2000, Boehringer Ingelheim announced the donation of Viramune®, free of charge to developing countries for a period of 5 years for the control of MTCT of HIV-1. Over 120 developing countries worldwide, as defined by the World Bank

[6] Karim,QA. Ann NY Acad Sci. 2000; 918: 36-44

[7] http://www.unaids.org/publications/documents/mtct/MTCT_TU4.doc

[8] http://gbgm-umc.org/health/wad97/facts.stm

[9] http://www.unaids.org/publications/documents/children/children/JC656-Child&Aids-E.pdf

[10] Guay, LA., Musoke, P., Fleming, T., et al. Lancet. 1999; 354: 795-802.

[11] Guidelines and Policy Issues – Prevention of Mother-to-Child-Transmission with Antiretrovirals in Resource Poor Settings, CI/CIDSE Policy Workshop, Wuerzburg, Germany, 2001.

Classification of Economies, are eligible to participate in the Donation Programme[12].To facilitate the implementation and management of the programme, Boehringer Ingelheim contracted the services of Axios International to implement, manage and monitor the distribution of the drug donated through the programme on behalf of the company. The Viramune® donation programme was initiated in the Republic of the Congo and has since been expanded to 41 other countries involving at least 75 programmes[13]. Viramune® donations are based on expressed interest by local governments, charitable organizations, NGOs and other health care providers. The programme adheres to WHO Guidelines for Drug Donations. Viramune® must be registered in recipient countries for the prevention of MTCT before a donation can be granted. Viramune® registration in recipient countries is the responsibility of Boehringer Ingelheim and therefore potential recipients need to be aware of in-country registration requirements. Before a donation is received, local government approval to receive the drug must be sought.

2.2 Development of the programme

The expertise of private industry lies in discovering, developing, registering and marketing new, effective, high-quality medicines, diagnostics and vaccines. The industry is much less experienced in managing the delivery of health care products and services at the patient level, especially in developing country environments. In the case of Boehringer Ingelheim, the company had very limited experience in the distribution and delivery of pharmaceutical products in much of the developing world, particularly in sub-Saharan Africa. Acknowledging this inexperience, Boehringer Ingelheim's original intention was to channel the donation of Viramune® through multilateral and bilateral organizations. The company anticipated that these organizations would be able to make the donation work on their behalf in the developing world. However, after protracted discussions with governments and multilateral and bilateral organizations, the company realized that, if the programme was to achieve its objectives, the donation needed to be made available not only to national governments and international organizations, but also directly to organizations of local health care providers who would then be able to leverage the available local health care resources.

Following the decision to make the donation available down to the level of an individual MTCT prevention programme, the company recognized that the administrative and management requirements exceeded the in-house level of internal expertise and resource capacity. Therefore, Boehringer Ingelheim began to look for an organization with an interest in and experience of working at the primary health care level with developing country health providers to assist with the day-to-day management of the donation programme. Such an organization would not only deal with national governments, but also directly with health care providers. Axios International, which was involved in creating the UNAIDS Drug Access Initiative for antiretrovirals in the late 1990s, was chosen to fulfil this role.

Axios International has experience in engaging with the private pharmaceutical and public sectors as facilitator to charitable programmes initiated by the pharmaceutical industry. The company provides strategic advice and technical assistance and, through its foundation, country level implementation of essential medicines programmes. Applications to join the Viramune® donation programme are managed by Axios International. Their mission is to ensure that the application procedure is user-friendly and that applicants encounter minimal bureaucracy. This service oriented approach has helped to foster an ongoing dialogue between Axios International and applicants and has resulted in the efficient exchange of information on field experiences. Through this network, Axios International has been able to facilitate collaboration between the organizations involved. The programme is open to a wide range of organizations including national governments, NGOs, private for-profit institutions and bilateral and multilateral agencies. One of the important benefits is that Axios International helps ensure that the application procedure is unbiased, transparent and supportive. For Boehringer Ingelheim, the use of an independent, third-party reviewer was important in order to reduce the risk of bias in deciding who should receive donated drug. Guidelines for applying to receive a donation through Axios International are included in Appendix 3.

[12] List of eligible countries obtained at http://www.viramune-donation-program.org/en/program/countries.cfm

[13] Correct as of 1 April 2003.

2.2.1 Negotiation process

In investigating how to make Viramune® available for the control of MTCT transmission of HIV, Boehringer Ingelheim consulted with health experts experienced in implementing and managing donation programmes and health systems in developing countries. This consultation raised further issues that needed to be addressed, including:

- The potential dependency of recipient countries on the donation and resultant pressures on both the donor and recipient for continued drug provision.
- Intense suspicion from the recipient coupled with concerns over the 'hidden agenda' of the other party.
- A level of unease among recipient governments who believed that the donation programme was intended to influence health policy.

Following the initial announcement by Boehringer Ingelheim of the offer to donate the drug, national governments were slow to respond. This led to a decision by the company to open up the programme to include health-based NGOs and other qualified health care providers working in eligible countries. NGOs were more successful in rapidly mobilizing the support structures needed to implement the donation programme on the ground. This has resulted in pockets of health facilities with adequate resources to provide Viramune® treatment. When applying for the programme, NGOs need to ensure that they do not circumvent national health care policies and that agreement is received from the government concerned to operate a Viramune® programme.

Some of the African governments interested in taking advantage of the donation programme were quick to realise that the poor state of health infrastructure and weak health care systems would make it difficult to effectively manage a Viramune® treatment programme. In Lesotho, for example, before the donation could be accepted, the government needed to evaluate the impact of the programme on its health care system. Lesotho asked Boehringer Ingelheim to help develop local capacity in health administration and provide support to its health care system. In response, the company directed the need for support to WHO and UNAIDS who were then able to intervene at the health service delivery level. Through contributions from and working through various agencies with a range of different professional expertise, the Viramune® donation programme is now successfully operating in countries such as Lesotho, Botswana and Namibia.

2.2.2 Public sector contribution

When applying to participate in the Viramune® donation programme, applicants are expected to demonstrate a capacity to implement a MTCT programme, including the safe delivery of Viramune®. Organizations need to demonstrate the following:

- Adherence to national medicines policy
- Viramune® must be registered for the prevention of MTCT in the country of use
- Understanding and observation of guidelines for MTCT prevention programmes
- Feasibility of programme implementation
- Programmatic approach or programme design
- Efficient and effective drug distribution channels
- Programme sustainability
- The spread of organizations involved in the programme is illustrated on next page[14]:

2.3 Structure of the donation programme

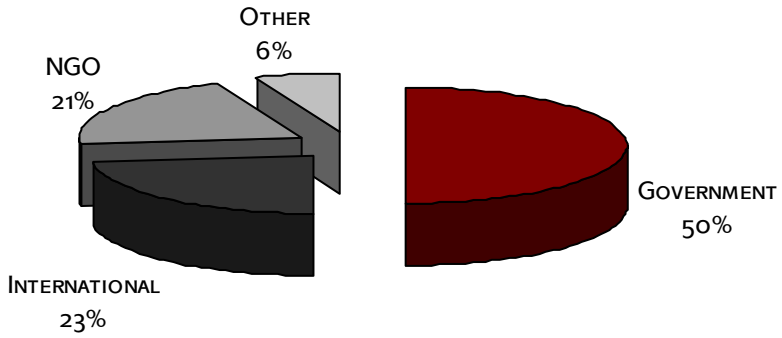
2.3.1 Management

The donation programme is managed by representatives from Axios International and Boehringer Ingelheim. On behalf of the pharmaceutical company, Axios International receives regular progress reports from participating organizations on existing programmes. Axios follows up on any problems and, where needed, offers assistance to programmes in the field. To strengthen its monitoring role, Axios uses its network of organizations to obtain reports of progress in the field. Monthly reports detailing progress and any new developments are sent to Boehringer Ingelheim. Axios's responsibilities in the programme include:

- Facilitating communication between Boehringer Ingelheim and HIV care programmes

[14] Marie-Helene Besson, Viramune Donation Programme – For Prevention of Mother-To-Child-Transmission of HIV-1, XIV International AIDS Conference, Barcelona, Spain.

Figure 1. Spread of organizations involved in the programme



- Sensitizing programmes to issues of procurement, storage and distribution of offered products
- Ensuring appropriate dispensing and use of products
- Ensuring adequate patient management
- Discussing and evaluating quantities of products needed
- Assisting some programmes to improve their programme design
- Facilitating contact between institutions that can lend support to one another where needed.

2.3.2 Anticipated achievements

During interviews with Boehringer Ingleheim and with other representatives of the private pharmaceutical sector, it was frequently mentioned that planning for the donation began as a result of a compelling need for the company to respond to a critical health need. Through a donation programme the donor hoped to achieve the following outcomes:

- An operating donation programme that has a real and significant impact on health delivery in developing countries
- Wide coverage of the donation programmes in order to provide access to as many needy people as possible
- Working through partnerships with the public sector to promote understanding between the two sectors and to apply the experience and expertise of each sector towards the fulfilment of common health goals.

(Boehringer Ingleheim did not anticipate financial gain from the programme).

2.4 The donation programme in African countries

The Republic of the Congo was the first country to receive nevirapine through the Viramune® Donation Programme. Together with the French Red Cross, the Congolese government initially distributed Viramune® at eight national hospitals. The initiative included training of health staff and patient counselling. To date, 17 health sites are in operation in the Congo, providing treatment to 3000 women.

In May 2002, the Kenyan government announced that Viramune® would be made available free of charge to pregnant women who were HIV-positive. Boehringer Ingelheim committed to provide Kenya with the supplies of Viramune® needed to successfully operate a donation programme. The drug is distributed at 52 sites (including four district sites) with the capacity to use the drug appropriately. To qualify for the donation, private and mission-based hospitals need to demonstrate

that their staff are qualified to administer the drug and are able to offer counselling services to patients under treatment.

In Zimbabwe, the Viramune® Donation Programme was launched in nine health clinics. The main challenge faced by health implementers was the lack of capacity of many of its clinics to administer the drug. As a result, progress was slowed by the amount of work required to prepare health facilities for appropriate management of the programme. An additional problem is that many women refuse Viramune® treatment due to lack of familiarity with the drug and limited knowledge of the health benefits. To address this problem, Zimbabwe is being urged to step up information dissemination at health centres about the health benefits of Viramune® and to promote its use in reducing HIV transmission from mother to child.

In Tanzania, a Nevirapine Outreach Programme has been established in two districts, where all health facilities, from hospitals to dispensaries, will be enabled to offer voluntary counselling and testing and Viramune® treatment to pregnant women. The programme is designed to suit local needs and is specifically directed at women who are difficult to reach. To improve access to treatment, the programme aims to strengthen its outreach services by using mobile clinics and village health days and by mobilizing local women's groups, traditional birth attendants and village leaders to identify and counsel pregnant women at community level.[15]

In 1997, Makerere University in Kampala, Uganda, partnered with the US-based National Institute of Allergy and Infectious Diseases (NIAID) of the National Institutes of Health (NIH) and Johns Hopkins University to examine the effectiveness of Viramune® in preventing the transmission of HIV from mother to child. Through enrolment in the study, HIV-positive mothers attending Mulago Hospital received free Viramune® treatment. The availability of Viramune has since been extended to other health facilities around the country. Uganda's success in dealing with its HIV/AIDS epidemic is largely attributed to an aggressive HIV awareness campaign. In addition, the advantage of being the site for the US NIAID HIVNET clinical studies (see USNIH website, www.nih.gov.) and the country's long-standing academic collaboration with developed country institutions has helped improve the quality of health care provided to women who are HIV-positive. However, a major drawback is that HIV/AIDS drugs are not always available where they are needed[16].

The Viramune® Donation Programme continues to expand beyond the earliest countries identified above and others to which it had extended by late 2002 (Appendix 1). For up-to-date information readers should contact Axios International or Boehringer Ingelheim.

2.5 Monitoring impact

Precise information on the extent of the coverage of outreach initiatives and the effectiveness of existing donation programmes is not readily available as they are in the process of expanding. Many donation programmes have been slow to get off the ground, due partly to extensive planning requirements and protracted negotiations with national health authorities. This has resulted in a time lag between receiving expressions of interest to launch a donation programme and its implementation. Meanwhile, many programmes are still in the process of establishing suitable record-keeping systems from which useful data can be obtained. As a result, information gathered to date is not sufficient to draw conclusions on the effectiveness of community outreach, the impact of medical interventions on health, the quality of care after introducing a donation programme or the cost-effectiveness of the donation programme within overall health systems.

[15] http:/www.axios-group.com/documents/projectlist%20en%2023-07-02.pdf

[16] http:/www.aidsinfonyc.org/tag/taglines/2000/0012.html

3. Diflucan® Partnership Programme

3.1 Development of the programme

As early as 1995, Pfizer (South Africa) began to explore the best way of making a contribution to help counter the looming socioeconomic problems presented by the HIV/AIDS pandemic. Following extensive consultation with clinicians and HIV/AIDS specialists, Pfizer decided that of all the products it produces, the donation of its drug Diflucan® (fluconozole) would have the biggest impact on the health of people with HIV/AIDS.

Diflucan® is used for the treatment of two AIDS-related opportunistic infections — cryptococcal meningitis and oesophageal candidiasis. Cryptococcal meningitis occurs in approximately 10% of AIDS patients and is associated with a mortality rate of over 20%[17]. The prognosis for untreated cryptococcal meningitis is very poor and relapse rates are in the region of 50%-60%. Oesophageal candidiasis, which occurs in 20%-40% of all HIV/AIDS patients, leads to painful swallowing and chest pains that cause severe discomfort, weight loss and fatigue.

The Pfizer (South Africa) proposal was submitted to its international operation and in early 2000 the company offered to supply Diflucan® free of charge in South Africa for all those suffering from AIDS-related cryptococcal meningitis. After Pfizer's announcement, the South African Minister of Health began a process of consultation with other health ministers in the region, government representatives, various NGOs and representatives of AIDS councils to discuss ways of optimizing the benefits from the donation. The South African government then put forward the following conditions for acceptance of the offer:

- Diflucan® should be made available for the treatment of oesophageal candidiasis as well as cryptococcal meningitis.
- To avoid theft of the drug, the South African Ministry of Health would be responsible for managing security issues and supply of the drug at health facilities. In turn, Pfizer would be responsible for managing, storing and distributing the drug. To relieve pressure on government facilities, Diflucan® is provided to health clinics on an as-needed basis.
- The programme would be extended to include all countries who are members of the Southern African Development Community (SADC).
- Pfizer would assist in capacity building to ensure appropriate management of the programme at health facilities.
- The programme would not become part of a clinical study.

Following extensive negotiations between Pfizer and the South African government, in 2000 Pfizer announced the donation of Diflucan® for the treatment of both cryptococcal meningitis and oesophageal candidiasis for as long as patients enrolled in the programme required treatment. In the agreement, Pfizer also agreed to support the training of health care professionals in the diagnosis and treatment of AIDS-related opportunistic infections. In 2001, Pfizer announced *that the programme would be extended to the 50 least developed countries, with no limits on time or costs.*

3.1.1 Negotiation process

At the time that Pfizer started to negotiate the introduction of the Diflucan® donation programme with the South African government, 39 leading pharmaceutical companies were challenging the South African government in court over a proposed law that would allow the government to import cheaper generic versions of patented drugs including AIDS drugs. The fact that Pfizer was not involved in this case had a positive

[17] Diflucan® partnership Fact Sheet. Pfizer, 11/13/2002.

impact on its negotiations between Pfizer and the South African government. Other key factors that contributed towards successful negotiation between the two parties included:

- Trust and transparency on both sides
- A commitment to programme sustainability
- Full participation of all stakeholders in jointly designing the programme
- The commitment of both parties to the success of the partnership.

3.1.2 Public sector contribution

To support the Diflucan® donation, the South African health ministry needed to develop internal expertise for proper management, distribution and delivery of Diflucan® at health facilities. The major cost incurred by the health department during implementation of the programme has been allowing health workers time off work for to attend training programmes. The process required considerable planning and supervision, especially at centres where staff capacity is limited and human resources are always in demand. The health department also needed to ensure that systems are in place for the secure transportation and storage of the drug.

3.2 Structure of the programme in South Africa

3.2.1 Programme management

The Diflucan® partnership programme in South Africa is managed through a structured committee consisting of three teams:

- A pharmaceutical services team, which addresses technical, logistical and distribution issues
- A legal team, which is responsible for agreements and contracts
- A clinical team, which manages guidelines and management protocols.

These teams are represented in the ministerial task team led by the minister of health or by a representative of the minister. The ministerial team consists of representatives from

- The HIV/AIDS unit of the health ministry
- Provincial health departments
- An auditing company
- Pfizer
- The International Association of Physicians in AIDS Care (IAPAC).

The minister has overall responsibility for ensuring that the programme operates efficiently and effectively.

3.2.2 Achievements

Pfizer has received no financial gain through the programme. For the company, the achievements include:

- Establishing goodwill between public and private sector organizations
- Relationship building between the different stakeholders
- Developing a trusting relationship with the public sector
- A more positive public image.

3.2.3 Training

The African Regional Office of IAPAC is responsible for developing and delivering physician and allied health professional training programmes within the Diflucan® partnership initiative[18]. The training programmes are designed to strengthen the capacity of health professionals in the correct handling of Diflucan® and in the management of treatment for cryptococcal meningitis and oesophageal candidiasis. To date, IAPAC has trained over 10 000 health workers in Southern Africa. The training programme is now being expanded to include countries in East and West Africa (see below).

3.2.4 Monitoring and reporting mechanisms

Pfizer has allocated the equivalent of three full-time and one half-time staff member to manage the donation programme. At the time of publication, the partnership programme was operating at 321 sites in South Africa. Drugs are prescribed by a doctor and dispensing pharmacists record and monitor the number of treatments provided. At field level, it has been difficult to monitor every patient, including the number of times that patients return to the health facility as a result of recurring or persistent infection. As a result, health workers are only able to record the number of prescriptions given to patients.

[18] http:/www.iapac.org/dpp.asp?catid=900

3.2.5 Delivery and distribution

Many lessons were learnt during the early stages of implementing the programme. The first Diflucan® shipment to South Africa from Pfizer contained 2.5 million doses. During the first year of the programme, the task team overestimated the amount of drug required and only half of the doses were used. Part of the reason was that many health facilities were not ready for the donation and it took time to prepare clinics and dispensaries for the programme. In addition, few health facilities had the capacity to treat cryptococcal meningitis. Since then, some 180 facilities in South Africa have been upgraded to manage cryptococcal meningitis treatment. Over the past two years, a reliable delivery and distribution system has been established that provides adequate access to Diflucan® through a large number of rural and urban health facilities.

3.3 Structure of the programme in other countries

After launching the partnership programme in South Africa, Pfizer began to donate Diflucan® in nine other African countries through partnership agreements with governments. However, many governments initially found it difficult to implement the programme on a wide scale. To overcome this problem, Pfizer invited NGOs to participate in the programme in order to help increase patient access to Diflucan®.

3.3.1 Management structure

As the programmes grew and expanded, Pfizer partnered with Axios International, which now manages application procedures and the reporting process.

On behalf of Pfizer, Axios International receives applications from countries or institutions wishing to participate in the partnership programme. Applications are reviewed and, if satisfactory, are recommended for inclusion in the programme. Axios also receives and reviews progress reports from participating organizations on the development of the programmes in operation. Clinic and hospital data are sent to Axios International for review and analysis. Axios follows up on any problems and, where needed, visits programme sites. Monthly progress reports detailing progress and new developments are sent to Pfizer.

3.3.2 Training

As in South Africa, IAPAC-AFRO is responsible for developing and delivering physician and allied health professional training programmes within the Diflucan® partnership initiative. The training programme has now been expanded to include countries in East and West Africa. Overall, IAPAC has trained more than 11 000 health providers in 11 countries (Botswana, Lesotho, Malawi, Mozambique, Namibia, Rwanda, Swaziland, South Africa, Uganda, the United Republic of Tanzania, and Zimbabwe).

3.3.3 Donation, delivery and distribution

Pfizer has recently partnered with Interchurch Medical Assistance, which is an official recipient of the Diflucan® donation, and with the International Dispensary Association, which will handle the distribution of Diflucan® to all participating countries except South Africa.

Most African governments receiving Diflucan® donationsfollow WHO guidelines for drug donations[19]. The common criteria laid down in government policies are that donated drugs should:

- Match the health needs of the country and therefore appear on the Essential Medicines List
- Be compatible with overall government policy
- Be of appropriate quality, efficacy and safety
- Be accompanied by appropriate legal and administrative documents
- Be reviewed through a national medicines regulatory body
- Be registered for use by a medicines regulatory authority in the donating country
- Be appropriately presented, labelled and packaged
- Be of suitable quality and have adequate shelf-life.

[19] National Drug Policy for South Africa; National Pharmaceutical Policy, Swaziland; Guidelines on Donation of Drugs, The National Drug Policy and Authority Regulations, Uganda.

4. Challenges and lessons learned

This section outlines, firstly, the challenges faced by the different partners involved in the Diflucan® and Viramune donation programmes and, secondly, some of the lessons learned from the development and operating experience of both partnerships.

4.1 The challenges faced by individual partners

4.1.1 The pharmaceutical donor

The primary role of the pharmaceutical donor (as articulated by interviewees) is to:

- Contribute to ensuring equitable and affordable access to health technologies and products
- Ensure efficient and effective provision of health care through products they manufacture.
- Continue the development of new health technologies and products, especially in the area of neglected diseases.
- Ensure the appropriateness of donation programmes and that duplication of services is avoided.

Some of the immediate challenges that the pharmaceutical donors faced include:

- Pressure from other pharmaceutical companies who believed that donations would "open a can of worms" and lead to unrealistic expectations by the public sector of the philanthropic role of industry.
- The lack of health infrastructure in developing countries.
- Ensuring that the donation programme was aligned with current government initiatives to ensure integrated health programmes.
- A lack of public awareness of the programme and what it can be expected to deliver. For example, there was a need to educate the public that Diflucan® does not cure HIV/AIDS.
- Providing the correct dosages to simplify use in the field.
- Developing guidelines to ensure correct use of drugs.
- Educating patients to ensure compliance.
- Language barriers experienced during training.
- Forecasting the number of patients who would seek treatment for some sort of HIV/AIDS related conditions if donation programme was initiated.
- Determining the number of people with access to public health facilities with the qualifying conditions and therefore, the number of people who would participate in programmes.
- Site management.
- Inventory control.

4.1.2 Governments

The primary role of government (as articulated by interviewees) is to:

- Secure financing for health service delivery
- Strengthen the management of the public health system
- Regulate health care programmes
- Develop health policy and legislation
- Provide health care.

Despite significant advances in improving access to much needed treatment for HIV/AIDS, the burden of disease remains high. The cost of ancillary resources that are essential for effective HIV/AIDS treatment is straining many health systems and these mostly have to be absorbed by national governments. With the cost of medication partly eliminated, voluntary counselling and testing is the major expense in total programme costs. Decisive intervention supported by strong political, financial

and technical commitment from national governments is essential in efforts to limit the spread of HIV/AIDS. Without a concerted effort by the public in concert with private sector, the opportunity to make a significant impact on the HIV epidemic will be lost[20].

4.1.3 Public sector health workers

Health workers in most developing countries with a high prevalence of HIV/AIDS invariably work in resource-poor environments. Typical problems include financial pressure, poor infrastructure and a shortage of staff. Logistical problems hinder the efficient distribution of donated drugs and, even when drugs are available, health personnel require training on proper drug use, monitoring and storage. In addition, extra personnel are often needed in order to provide appropriate counselling for patients on treatment. Unless these additional investments are made, the impact of a donation will be severely reduced . The application procedure helps to minimize this risk and ensure that all the components are in place to maximize the benefits of the donation.

4.1.4 NGOs and others

NGOs play a pivotal role in addressing specific gaps in health service provision and are often able to respond more rapidly to emerging health problems. In addition, NGOs have made a major contribution to tackling the problem of social stigma and discrimination surrounding HIV/AIDS. The knowledge, experience and expertise that exists among NGOs are valuable resources for alleviating the burden of disease, and should be recognized by donors of drugs.

NGOs also play a key role as educators and service providers in many communities but it needs to be recognized they may do this outside formal health care settings. In the case of Viramune®, for example, treatment up to the present time has often been accessible only to women who deliver at clinics and hospitals that are equipped to provide education on nevirapine therapy[21]. As a result, the large proportion of women who deliver outside the formal health system have no access to treatment. In response, some NGO-run programmes have started providing Viramune® to pregnant women during antenatal visits for use during home delivery.

4.2 Lessons learned

Over the past two years, a global public-private partnership network has emerged, committed to engaging the public and private sectors in efforts to combat diseases that disproportionately afflict the poor. It is too early to measure the outcomes and impact of this partnership network. However, it is possible to summarize some of the lessons learned so far:

- While the aim of the pharmaceutical donor is to ensure that the benefits of their humanitarian contribution reach the maximum number of people in need, it is difficult, as yet, to determine the extent to which donation programmes contribute to equitable access to much-needed drugs.
- The key factor involved in a successful partnership is having a common goal to which all stakeholders are committed.
- One of the key functions of PPPs is to address so called 'market failures' by developing health programmes designed to improve access not only to much needed drugs but also to quality health care overall. The challenge now is to move public-private collaboration away from narrowly focused activities involving a single product or disease to broader efforts across many drugs and diseases. It is difficult to know how to shift to broader efforts in which governments take the lead. An additional hurdle is to find ways to motivate the private sector to assume broader responsibilities in collaboration with governments.
- The donation programmes provide an opportunity for stakeholders who have had little previous interaction with one another to pool their respective strengths and expertise in pursuit of a shared humanitarian goal.
- The donation programmes have helped to identify and bring attention to areas in health care systems that require greater attention and support. These areas include the development and financing of ancillary resource needs that are essential to efficient programme operations.

[20] Dabis,F. and Ekpin,RE. HIV-1/AIDS and Maternal and Child Health in Africa. The Lancet 2002; 359: 2097 – 2104.

[21] Marseille, E., Khan, JG., Mmiro, F., Guay, L., Musoke, P., Fowler, MG. and Jackson, JB. Cost Effectiveness of Single-dose nevirapine Regimen for Mothers and Babies to Decrease Vertical HIV-1 Transmission in Sub-Saharan Africa. The Lancet 1999; 354 : 803 – 809.

5. Conclusions

There is a need for a detailed assessment of the long-term impact of donation programmes. Some argue that the current system of incentives encourages governments to readily accept drug donations over other, perhaps better policy options which, in the long term, would be more sustainable and cost-effective for the public sector[22]. However, donation programmes have not only ensured a reasonable standard of care and treatment for people with HIV/AIDS in developing countries but also contributed to overall improvements in health care. Better trained health professionals have helped to improve generally patient management overall — not only for HIV/AIDS. In addition, improved drug logistics management expertise probably helped improve access to drugs for the treatment of other diseases. Yet despite the efforts of PPPs to combine capacities and resources for much-needed humanitarian work, the impact of PPPs is insufficient to meet the vast and complex health needs of populations in developing countries. PPPs can contribute significantly, but do so best where government and bilateral aid resources underpin parallel strengthening of health infrastructure.

[22] http:/www.essentialdrugs.org/edrug/hma/e-drug.200011/msg00056.php

Appendix 1:

List of countries: Viramune® Donation Programme

The Viramune® Donation Programme for the Prevention of Mother-to-Child Transmission of HIV-1 includes about 52 programmes in 35 countries*. Boehringer Ingelheim has committed to donate to these programmes the amount of drugs needed to treat approximately 100,000 pregnant women and their newborn babies.

The following is a list of the participating countries:

COUNTRIES	NUMBER OF PROGRAMMES APPROVED	NUMBER OF WOMEN INCLUDED IN APPROVED PROGRAMMES	NUMBER OF PROGRAMMES UNDER REVIEW FOR APPROVAL
BENIN	1	350	1
BOTSWANA			1
BURUNDI	1	500	
BURKINA	2	350	
CAMEROON	3	2,350	
CENTRAL AFRICAN REPUBLIC	1	500	
CÔTE D'IVOIRE	2	2,950	
CONGO (Republique of the)	1	3,000	
CONGO (Democratic Repubic of the)	2	1,170	1
DOMINICAN REP.			1
ECUADOR	1	60	
GABON			1
GHANA	1	500	
GUYANA	1	632	
HAITI			1
KENYA	5	19,117	1
MALAWI	5	4,369	
MALI	1	250	
MOZAMBIQUE	1	3,000	

*Status as of 16 September 2002

OUNTRIES	NUMBER OF PROGRAMMES APPROVED	NUMBER OF WOMEN INCLUDED IN APPROVED PROGRAMMES	NUMBER OF PROGRAMMES UNDER REVIEW FOR APPROVAL
NAMIBIA	1	5,000	
NIGERIA	3	3,232	1
PAPUA NEW GUINEA			1
PERU			1
RUSSIA			1
RWANDA	3	1,350	
ST VINCENT	1	25	
SENEGAL	1	3,000	
SIERRA LEONE	1	1108	
SOUTH AFRICA	3	5,452	
TANZANIA	1	200	
UKRAINE	1	1,200	
UGANDA	2	9,270	
VIETNAM	1	1,800	
ZAMBIA	2	5,400	1
ZIMBABWE	4	10,934	

Appendix 2:

List of Countries: Diflucan® Partnership Programme

- BOTSWANA
- HAITI
- GAMBIA
- GHANA
- KENYA
- LESOTHO
- MALAWI
- MOZAMBIQUE
- NAMIBIA
- RWANDA
- SOUTH AFRICA
- SWAZILAND
- TANZANIA
- UGANDA
- ZAMBIA
- ZIMBABWE

Appendix 3:

AXIOS guidelines for completion of the application form to receive VIRAMUNE® free of charge

VIRAMUNE® DONATION PROGRAMME FOR

THE PREVENTION OF MOTHER-TO-CHILD TRANSMISSION OF HIV-1

Guidelines for completion of the application form

Introduction

VIRAMUNE® (nevirapine) is included on the World Health Organization (WHO) List of Essential Drugs for use in the reduction or prevention of Mother-to-Child Transmission (MTCT) of HIV-1. In July 2000 Boehringer Ingelheim announced that VIRAMUNE® will be offered free-of-charge for a period of five years for the prevention of MTCT in developing countries. In September 2000, the WHO held an international expert meeting that recommended that the use of VIRAMUNE® for prevention of mother-to-child transmission could be scaled up beyond pilot projects. Subsequently a number of governments and institutions have expressed an interest in obtaining donations of VIRAMUNE®.

Administration of the VIRAMUNE® Donation Programme

Axios International will ensure the administration of the requests for VIRAMUNE® Donation in this programme on behalf of Boehringer Ingelheim. The present guidelines are intended to help applicants provide the necessary information to Boehringer Ingelheim in order for the donation to be approved. The application form is available in a separate folder.

Mailing the application form

The completed application form should be sent in two signed hard copies to the address listed below. It should also be sent electronically to the administrator of VIRAMUNE® Donation Programme at the e-mail address: **adminvdp@axiosint.com**

The mailing address is:

The Administrator of VDP

AXIOS International

7, bd de la Madeleine
75001 Paris, France
Tel: +33 144 860 760
Fax: +33 144 860 122
Email: adminvdp@axiosint.com
http://www.viramune-donation-program.org

Completing the application form

1. Name and address of responsible institution/organization

This section should indicate the name of the responsible institution/organization and its full mailing address. It should be clearly indicated whether the institution is a government institution, a NGO (NGO), an academic institution, or a private agency. In other cases, please specify the nature of the institution.

2. Name and function of responsible person within the applying organization

The name and function of the responsible officer in the applying institution should be clearly indicated with appropriate contact details such as phone, fax and e-mail. Please attach updated curriculum vitae of the responsible person.

3. Registration of VIRAMUNE® and Letter of Approval

Approval from the national authorities:

A letter of support or approval by the National Authorities for the request of a donation of VIRAMUNE® must be attached to the application. In some countries, other governing structures could be considered equivalent to the national authorities. In this case, a justification should be provided with the letter of approval.

4. Expertise and brief experience of institution

Please describe the relevant expertise of your institution as well as a brief track record of your institutional experiences with MCTC, Voluntary Counselling and Testing (VCT), reproductive health services and mother and childcare. Also indicate your institutional capabilities to implement programmes at district, regional and national levels.

5. Name, address and role of other institutions involved in the programme

Please indicate whether other agencies, organizations or institutions are directly involved in the programme. Specify the nature of their involvement, their role and the level (percentage) of their contribution to the project.

6. Requested quantity of VIRAMUNE®

This section specifies the required quantities of VIRAMUNE® in total and per year. It also explains how these quantities were calculated, for instance:

- Number of women likely to receive antenatal care in the project
- Number of women likely to deliver in the health facility or would be reachable around delivery
- Number of women offered HIV counselling and testing
- Number of women accepting HIV counselling and testing
- Estimated number of women coming for their results and testing positive for HIV
- Number of HIV-positive women likely to accept the intervention

This number may be adjusted in accordance with special efforts to bring women to the facility for delivery, number of women who would drop out before delivery or other initiatives that may increase the number of women requesting VIRAMUNE® for prevention of MTCT.

7. Procedures for customs clearance

This section describes the procedures in terms of customs clearance, VAT requirements and tax exemptions for the donation. It is important to mention whether any obstacles can be expected.

8. Distribution channels

Please list the channels and mechanisms that will be used to distribute VIRAMUNE® from the port of arrival in the country to your institution or facility.

9. Proposed MTCT programme

This section gives an overview of your existing and/or planned MTCT programme. The section should explain clearly how the MTCT programme will be carried out and how that fits into your existing structure and activities. Where there are identified needs before full use of a VIRAMUNE® donation can be made, - for instance lack of training or privacy for VCT -, it should be explained how your institution intends to address these needs.

Name of the programme

Please state the name of the proposed programme.

Objectives

The objectives of your proposed MTCT programme should be stated as well as how the donation of VIRAMUNE® will enable the achievement of the objectives. The objectives should be precise such as a percentage decrease in infant mortality, an increase in women who test for HIV before delivery or the effectiveness of a new model for MTCT.

Scope/scale and HIV context

Please describe the geographical area and the number of health facilities that will be covered by your proposed programme. List the available data on trends in HIV prevalence in women coming for antenatal care and the current infant mortality in your target area. If possible, recent figures on VCT attendance should also be given, preferably by sex.

Outcomes

The expected outcomes should be stated clearly and realistically in terms of how many women you expect to reach at the time of delivery and the impact of the programme on infant mortality, VCT attendance and health facility capacity.

Structure

Explain how the programme will be structured in terms of functions and responsibilities and indicate how it will fit into existing structures and related programmes, for instance, on reproductive health and child health programmes or VCT initiatives.

Activities

List all the activities that will be carried out under the programme with specific attention to the following components:

- Training and capacity building of staff
- Development of standards of care and clinical guidelines
- Voluntary counselling and testing policies and procedures
- Integration of MTCT information into prenatal care policies and procedures
- Post-natal care for mother and infant including cotrimoxazole prophylaxis or antiretroviral treatment for the mother
- Replacement feeding issues

Drug dispensation

The mechanisms and procedures related to dispensation of VIRAMUNE® from the health facilities to women and babies should be described. A clear description should be provided with respect to stock management systems put in place to ensure that appropriate recipients are receiving the drugs and provide accurate reporting.

Sustainability

It is important to clarify how the proposed programme will be sustained in the future, particularly after

the donation period, and how will the related activities and the purchase of VIRAMUNE® be financed and the programme be integrated into or linked to the general health services in the area or country.

Budget (please provide breakdown per year and source of funds)

Boehringer Ingelheim will only provide VIRAMUNE®. The costs of programme implementation should be funded by other sources. The budget should clearly specify the cost of the various components of the MCTC per year and where the funds will come from. If a MTCT programme is already in existence, it should be explained how extra costs arising from the availability of VIRAMUNE® will be financed. If some kind of user fee is planned then this should also be explained.

Timeframe

The time-frame should indicate the total project period as well as the main activities and outputs per year.

10. Monitoring and reporting

The indicators for measuring success should be clearly outlined. These indicators should be simple and feasible in the context of a developing country. It should be indicated how often these indicators will be measured and how the results will be reported to Boehringer Ingelheim. At a minimum, a yearly report must be provided.

11. Other involved collaborators and funding agencies

Please list all collaborators and funding agencies that will be contributing to the project with a specification of their contribution and the timeframe for it.

12. Other comments

Any other relevant comment should be listed here.

13. Name, title and signature of responsible staff member

One of the two copies of the application form should contain the original signature of the responsible staff member.

14. Name, title and signature of head of institution/organization

The same copy should also have the original signature of the head of the institution.

Application forms may be obtained from:

The VIRAMUNE® Donation Programme (VDP)

Axios International

7, bd de la Madeleine
75001 Paris, France
Tel: +33 144 860 760
Fax: +33 144 860 122
Email: adminvdp@axiosint.com
http://www.viramune-donation-program.org

Web site: www.viramune-donation-program.org