centre for social markets

# BUSINESS & ECONOMIC DEVELOPMENT RESEARCH PROJECT

## Report on The Pharmaceutical Sector in India

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# REPORT ON THE PHARMACEUTICAL SECTOR IN INDIA

*Project in Association with*

**ACCOUNTABILITY & BUSINESS FOR SOCIAL RESPONSIBILITY**

Editor & Project Manager: Malini Mehra
Researcher: Dhruba Das Gupta

**Published by**

**Centre for Social Markets**
39, Hindusthan Park
Kolkata - 700 029
Tel : +91 33 2465 5898, 2465 5711/12/13
Fax : +91 33 2465 5650
Email: info@csmworld.org
Website: www.csmworld.org

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## 1 SUMMARY

This research, conducted by the UK- and India-based **Centre for Social Markets (CSM**), forms Phase II of the research programme on *"Business and Economic Development: The Impact of Corporate Responsibility Standards and Practices: Insights from Recent Experiences"*, initiated by **AccountAbility** and **Business for Social Responsibility**. It addresses the following research question:

**How well does the pharmaceutical sector, and its key players, understand the economic impacts[1] of its activities and act to manage them to ensure desired outcomes and enhances corporate impacts on low income, excluded and disadvantaged communities?**

Unlike the previous research addressing the question on "impact of business on economic development", CSM will be using a *product/service-based* approach to understand the economic impact of the pharmaceutical service providers in question.

The **pharmaceutical industry** is seen as crucial to achieving the Millennium Development Goals (MDGs) and in fulfilling health sector priorities as a subset of broader economic development objectives. At one level, this translates directly into financial impacts on companies and connects with issues such as improving health to enhance national productivity, use of R&D for developing medicines with better therapeutic value, treating more diseases of the developing world at affordable cost, serving traditionally under-served communities, and gaining new and profitable markets in the process.

Globally, however, the pharmaceutical industry is also struggling with debates on product patent issues, protection of innovation and intellectual property rights, distrust of and opposition to generic competition, and issues of access to medicines. Despite the immense potential for growth in developing country markets with products that serve their needs, the pharma industry has chosen to focus more on developed country markets and lifestyle diseases as their main revenue earners.

With regard to this research, AccountAbility and Business for Social Responsibility (BSR) have developed a methodology that helps businesses have a more explicit understanding of their impact on society in the context of broader economic development imperatives. Following this, companies can align their decision-making processes or "domain" of business activity in the light of that understanding. Given this methodology, this research has tried to focus on the areas where health and business impacts and social responsibilities converge.

[1] Economic impacts take many forms. Direct impacts include monies paid to employees, suppliers, investors, governments, while indirect impacts relate to how those monies are used in subsequent decisions by those actors. At the broader level, CSM will assess the extent to which companies understand and/or report on their economic impacts in terms of their ***direct*** economic impacts – payments to employees, suppliers, investors, government; efforts to understand and report on their ***indirect*** impacts or supply multiplier, which are the second round impacts of that expenditure – such as employment created in supplier companies; and a step further, their ***induced*** impacts or income multiplier which measures the subsequent impacts. Having an understanding of companies direct, indirect and induced impacts may be useful to make comparisons across sectors and regions.

This study focuses on the challenges faced by the Indian pharma sector in a specific product area: **anti-retroviral (ARV) drugs**. It outlines the hurdles facing HIV medication in India and the possibilities of more expanded reach in the light of international and national attention to the issue of access to medication, and the emergence of various public-private initiatives to help national governments cope with health sector and development goals. This study found that though the price of medicines was high compared to the earnings of the target population, the most important issue was **not a lack of** access **to medicines**, it was the **lack of adequately scaled-up public health infrastructure** and an **untrained private health sector**. In this context affordable medicines would have little health impact.

The Human Immuno-deficiency Virus (HIV) was first detected in the USA among men having sex with men in 1981, but it has rapidly become a disease of the developing world. At first it was feared to be a death sentence, but since the invention of medicines in 1986 and triple combination therapy in 1996, HIV has been converted into a manageable chronic disease. However, these life-saving medicines, manufactured in developed countries, have been prohibitively priced and are largely beyond the reach of most people in the developing world.

On the upside, India also had a thriving generic manufacturing industry of which the now well-known company Cipla is a prime exemplar. From 2000 onwards, this company began supplying medicines to sub-Saharan Africa where the crisis was most acute. As a result it became prominently embroiled in a battle with global pharma giants on patent-protected prices and access to medicines.

HIV is not just a disease, it is a threat to development. It adds to the plethora of social deterrents to development such as unsafe sexual behavior due to long period of stay away from home, disadvantaged gender, low rate of literacy etc. For example, a gender analysis reveals that one in every four cases reported to be living with HIV is a woman. Surveillance data from ante-natal clinic attending women, which is taken as a proxy for the general population, stand testimony to the need for urgent policy intervention in this area as it increases the risk of peri-natal transmission.

In the larger context of health and development goals, HIV therefore requires an appropriate multi-stakeholder response with the pharma industry as an important participant. One key policy development is that from 1 January 2005 laws admitting product patents will become operational in all the member nations of the World Trade Organisation (WTO). This will protect global pharma innovation but is likely to put HIV medicines outside the reach of underserved communities in developing countries. This despite the Doha Declaration permitting government intervention for medicines used in a public health crisis.This study also found that unlike the micro-finance sector, social responsibility of the pharma sector in India is not a foregone conclusion. The generic pharma sector in India is rapidly re-orienting itself to the changing disease and demographic profile across the globe and choosing to focus on lifestyle diseases wherever opportunity affords. Given this context, corporate social responsibility is often treated as an adjunct or by-product of business, rather than being at the core of business practices.

Although one cannot generalize, there does appear to be a lack of tools needed by business to measure the impact of their products on health and economic development. This study recommends the establishment of such tools within specific parameters. These parameters include adherence to good manufacturing practices, responsible marketing and drug promotion, better education of doctors, and greater stakeholder engagement at the core of their own decision-making structure on ARV issues. The study has not, however, suggested any specific quantification method.

At present, the main issues before the Indian generic ARV industry revolve around how to optimise the product use by greater stakeholder engagement to enhance the access and impact of ARVs on the second highest sero-positive population of the world. By beginning to assess the product impact on the target population, the pharma industry can connect responsibility, impact and benefits, and be better equipped to accommodate future constructive steps that link their business with broader societal expectations.

Public policy interventions are integral to ensure success of achieving health sector goals, where pharma is such an important player. This research examines the public policy environment, which seen in the light of national and international developments, has helped set the scene for expanded access of ARV products in India. Public policy settings will continue to determine the level of success achieved by the move to enhance the reach of ARVs. This research argues that given the present national political position despite the challenges involved, it is time for pharma to use the product impact assessment approach to integrate social concerns with the core of their business.

This research is primarily based on interviews with pharma companies and their stakeholders. It has also referred to secondary literature but does not lay any claims to originality. Rather it weaves together an existing body of knowledge and presents it with a new analysis in the public domain. The study highlights the hurdles and possibilities of the ARV medication segment in India in terms of economic development impact and public policy support.

## 2 RATIONALE

To understand the impact of corporate responsibility standards and practices in the pharmaceutical sector in India, the focus of this research will be specifically on one particular pharmaceutical product - HIV/AIDS medication, and more specifically *anti-retroviral (ARV) drugs* - and issues related to their manufacture, pricing and affordability, distribution and availability, in the broader social, political and public policy context.

The rationale for the choice of pharmaceutical product rests on the fact that India has the second largest HIV positive population in the world. Despite this an adequate public policy response has yet to be mounted at a national level to address this major public health and economic challenge. Nevertheless, India's own domestic generic manufacturers have been in the forefront of the international debate on pricing, patents and availability of life-saving HIV/AIDS drugs. This study will look at how their positive economic impact can be enhanced.

At present, there are four generic manufacturers who manufacture anti-retrovirals in India but a variety of stakeholders who deal with the product. CSM therefore conducted a survey of key stakeholders as well as three case studies of leading manufacturers of HIV/AIDS medicines to examine the above issues in further detail.

The study sought to understand – using case studies as a model – best practices prevalent in this sector, and examined them against the backdrop of both national policy and international developments to see how the companies understood and managed the impact of their products on the poor and disadvantaged communities, with a view to enhancing their positive outcome.

The overall objective of the research was to normalize Economic Development as an aspect of business performance and outcomes.

### Background & Research Question

This research forms Phase II of the research programme on "***Business and Economic Development****: The Impact of Corporate Responsibility Standards and Practices: Insights from Recent Experiences*", launched by AA and BSR, and addressed the following research question:

How well do pharmaceutical companies understand the economic impacts[2] of their activities and take action to manage them to ensure desired outcomes and enhance corporate impacts on low income, excluded and disadvantaged communities?

[2] Economic impacts take many forms. Direct impacts include monies paid to employees, suppliers, investors, governments, while indirect impacts relate to how those monies are used in subsequent decisions by those actors. At the broader level, CSM will assess the extent to which companies understand and/or report on their economic impacts in terms of their ***direct*** economic impacts – payments to employees, suppliers, investors, government; efforts to understand and report on their ***indirect*** impacts or supply multiplier, which are the second round impacts of that expenditure – such as employment created in supplier companies; and a step further, their ***induced*** impacts or income multiplier which measures the subsequent impacts. Having an understanding of companies direct, indirect and induced impacts may be useful to make comparisons across sectors and regions.

Unlike previous research addressing the question of the economic development impact of business, CSM used a ***Product-based*** approach to understand the economic impact of the pharmaceutical companies in question.

**Public Policy Considerations**

As noted above, we also looked at public policy considerations across the identified areas of focus. There are potential implications for education, investment, industrial, health policies to name a few. The rationale is that while businesses are and should be accountable for their economic impacts, they share responsibility with other societal actors, including governments. Policies can be shaped to support and enable corporate responsibility with respect to their economic impacts and we sought to explore the extent to which businesses desired government support for their efforts.

## METHODOLOGY & RESEARCH PHASES

CSM conducted the research in three phases, actively outreaching to relevant stakeholders and partner organizations at each stage to ensure their valuable input.

**Phase One: Information Gathering & Consultative Meetings** (Period: Nov 2003 – Feb 2004)

Information gathering involved desk research as well as telephone and direct interviews / consultative meetings with key companies and their stakeholders. The consultative meetings comprised both one-on-one meetings as well as seeking responses to a detailed questionnaire largely focused on assessing corporate policies.

**Phase Two: Case Studies** (Period: Feb – March 2004)

CSM conducted case studies on the following pharmaceutical companies who are all playing a distinctive role on the production, pricing and distribution of HIV/AIDS medication in India: Citadel Aurobindo Biotech Ltd and Ranbaxy as well as GlaxoSmithKline India for comparison at an international level.

The case studies will provide audiences with a practical look at industry best practice and illustrate how these three companies are starting to understand, manage and measure their influence on a community's economic development. The case studies will describe and assess key aspects of the companies' policies such as product development, pricing, distribution and access and their broader public policy engagement. The case studies will be incorporated into the *Pharmaceutical Industry Benchmark Briefing on Managing Economic Impacts* published by AA and BSR in Summer 2004. The case study findings will also be reflected in the Final Report of the Business and Economic Development project.

**Phase Three: Public Dissemination & Advocacy** (Period: April 2004)

CSM's research findings were launched at a Multi-stakeholder Convening held in New Delhi on 6 April 2004. The objective was to both disseminate the research results as well as to discuss how a broader

outreach strategy to engage companies in more actively managing their economic impacts in this particular field may be advocated.

This meeting included senior business (company and industry) representatives from the pharmaceutical sector; key influencers and stakeholders from the public sector, standards organizations, affected peoples organisations, medical establishment, NGOs, the investment community, the donor community and media.

## 3.0 HIV MEDICATION: GLOBAL AND INDIAN SCENARIO

Anti-retroviral medicines, invented in 1986, are still the only tool to suppress the HIV virus in infected communities world over. (See annex I for details of medicines invented and their date of approval). Globally, the World Health Organisation (WHO) estimates that 30 million people have died of the Human Immuno-deficiency Virus in two decades and more than 40 million are currently infected by it. In poorer countries 6 million people are in immediate need of anti-retroviral therapy (ART), but less than 8% receive it.

India has the unfortunate distinction of being home to the second highest population of people living with HIV in the world, second only to South Africa. This sadly growing sero-positive population presents both a medical and a developmental challenge. A positive development, in this context is that since 2000, Indian companies - in particular Cipla, which manufactures generic versions of anti-retrovirals (ARVs) - have also been at the forefront of a debate on pricing and access to medicines.

That year saw the signing of the Accelerated Access Initiative (AAI), an agreement between the United Nations and five big pharma companies – GlaxoSmithKline, Bristol Myers Squibb, Merck, Boehringer Ingleheim and Hoffman La Roche – to offer ARVs to developing countries at not-for-profit prices. This happened just before the 13th International AIDS Conference in Durban in 2000, which focussed on treatment. In actual practice, however, the price of anti-retrovirals came down only after Cipla began supplying generic copies of anti-retrovirals to Uganda in October 2000[3].

In early 2001, Cipla created a furore by offering to sell its triple AIDS cocktail to a doctor's group *Medicines Sans Frontiers* (Doctors Without Borders) working in Africa and South-East Asia, for the treatment of AIDS at $350 per patient per year. Global pharma companies were charging between $10,000 to 15,000 per patient per year, for the same regimen. The South African government had allowed the sale of these generics in its country, and Glaxo and 38 other companies had filed a patent suit against the South African government, which they subsequently withdrew. Thereafter, the prices of these medicines came down substantially in developing countries, which imported low-cost generics from Indian companies.

Ever since then, more companies entered the ARV generic manufacturing market in India – Aurobindo Pharma with its Imunus division (now spun off into a 50:50 joint venture Citadel Aurobindo Biotech Ltd), Ranbaxy and Genix Pharma (subsidiary of Hetero Drugs). International brands from companies like GlaxoSmithKline Pharmaceuticals, Bristol Myers Squibb, Hoffmann La Roche, Boehringer Ingleheim, Merck and Abbott Laboratories, some of which earlier sold in India, do not have any presence now due to the much lower comparative prices of generics manufacturers, who have the major market share.

[3] Kamal Smith, M. Generic competition, price and access to medicines: The case of antiretrovirals in Uganda. Oxfam briefing paper 26.

It is essential to remember that HIV is a complex disease with a difficult and intricate management system. In India, anti-retrovirals are typically prescribed only at the later stages of the disease to those who can afford it. The size of the market therefore is not very large. This is, however, likely to change following increased international and national political commitment. One major indication of this was the announcement by the World Health Organisation and its partners on World AIDS Day (December 1, 2003) in Geneva, to launch the "Treat 3 Million by 2005" (3 by 5) Initiative.

At the same time, the Government of India announced its decision to provide anti-retrovirals free of cost in government hospitals from April 1, 2004, in the six high prevalence states of Tamil Nadu, Andhra Pradesh, Karnataka, Maharashtra, Manipur and Nagaland, for treatment of HIV/ AIDS cases. In light of this decision, CSM's present efforts to examine product impact on disadvantaged communities are all the more relevant. The hope is that with the improvement in health delivery systems, this will enable more patients to avail of treatment in a more sustainable manner.

In India as in the rest of the developing world, the stigma attached to HIV is severe. Of the 4.58 million afflicted with HIV in India[4], a large segment is resource poor, and ARV prices are still prohibitively high when considering their monthly income ranging from Rs 1000 to 2500 a month, and in many cases, even less[5].

Once a patient is put on ART, it is a lifetime financial commitment. The cost to the patient is quite high, given the attendant monitoring and nutritional issues. India does not have a sizeable documentation of adherence to ART, but existing experience has shown that lack of adherence is high[6]. There are various reasons for this – the price factor, lack of monitoring facilities, prohibitive cost of diagnostics and of course, very poor level of counselling services. From 2005 onwards, when product patents become available, there will be no additional drugs available for copying and the country will have only 11 treatment options available. Out of the 11 available options, the National AIDS Control Organisation's (NACO) ART programme, which follows the World Health Organisation's (WHO) Stage IV criteria for initiating ART, uses only five molecules to treat patients. Added to this is the lack of good infrastructure, an ill-equipped medical force, and an inadequately trained health workforce. A lot therefore needs to be done to ensure the judicious use of medicines. Given this reality the pharma industry can certainly forge helpful partnerships to improve the situation.

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[4] National AIDS Control Organisation (NACO) estimates http://www.naco.nic.in/ for 2002. There is, however, much debate on this. In late July 2003, NACO released new figures indicating that there were between 3.82 million and 4.58 million Indians living with HIV/ AIDS during 2002, of whom 38.5% were women. NACO also estimated that there were 610,000 new HIV infections in 2002. UNAIDS estimated that between 2.6 million and 5.4 million Indians were living with HIV/ AIDS at the end of 2001, with adult prevalence at 0.8%

[5] Personal communication with affected women in Kolkata as well as other documented literature.

[6] Ekstrand, Maria, Lisa Garbus and Elliot Marseille of AIDS Policy Research Center say in their study,
**HIV/ AIDS in India**, that data from India indicates that drug cost can be a significant barrier to adherence. In a study of 100 patients on triple-drug ART treatment in India, 60 per cent of patients stopped within a few months because of high cost and also because they preferred to take alternative treatment. The paper says that these data have been derived from conference proceedings, but have not been published. An operations research programme under Dr Ekstrand for effective adherence technique specific to India is also being undertaken in Bangalore.

## 4.0 THE CONTEXT OF MEDICATION

### The 3 by 5 Initiative

The latest figures provided by the World Health Organisation show that South East Asia is in urgent need of expanded ART coverage. Research has already firmly established that in these countries the major age group of people afflicted with HIV is 15-49[7], the most productive years of a person's life.

Coverage of adults in developing countries with anti-retroviral therapy (ART), by World Health Organisation Region, 2003

| REGION | NUMBER OF PEOPLE ON TREATMENT | ESTIMATED NEED | COVERAGE |
|---|---|---|---|
| **Africa** | 100 000 | 4 400 000 | 2% |
| **Americas** | 210 000 | 250 000 | 84% |
| **Europe** (Eastern Europe, Central Asia) | 15 000 | 80 000 | 19% |
| **Eastern Mediterranean** | 5 000 | 100 000 | 5% |
| **South-East Asia** | 60 000 | 900 000 | 7% |
| **Western Pacific** | 10 000 | 170 000 | 6% |
| **All WHO regions** | **400 000** | **5 900 000** | **7%** |

Source: World Health Organisation

The Call to Action at the UN General Assembly Special Session on HIV/AIDS (June 2001), pushed forward a new global consensus on the need for ART. This led to a cumulative response from diverse quarters. It put pressure on pharmaceutical manufacturers with resulting drug price revisions. Brazil's national ART distribution programme added to the public debate. The WHO also pushed the agenda by releasing guidelines for anti-retroviral use in resource constrained settings in April 2002, adding 10 ART drugs to its list of "essential medicines" for all countries, and for the first time qualifying a number of generic manufacturers. (The WHO guidelines for anti-retroviral use in resource-constrained settings have since been revised in June 2003.)

Furthermore, in September 2003, the WHO declared the lack of access to ARV treatment for HIV/AIDS a "global health emergency" and announced that it would release an emergency plan to scale up access to ARV treatment for at least three million people by the end of 2005. This joint WHO/UNAIDS announcement popularly came to be known as the **3 by 5 initiative**.

It is hoped that successful implementation of 3 by 5 will accelerate the attainment of Millennium Development Goals (MDGs) for HIV/AIDS, as well as associated health and development MDGs. The

[7] International Labour Office (ILO) estimates.

WHO is consulting intensively with national authorities and relevant international partners, including the World Bank, to ensure the coordination of efforts.

**Indian Scenario**

Where does India stand in this scenario? Prior to the World AIDS Day announcement in 2003, India's proposal to the *Global Fund to Fight AIDS, Tuberculosis and Malaria* (GFATM) approved in January the same year, offered a detailed plan for increasing access to ART. GFATM aims to provide Voluntary Counselling and Testing to seven million pregnant women and their families every year, offer antiretroviral prophylaxis to 350,000 women with HIV, and offer quality antiretroviral treatment to 4,500 women infected with HIV and to 15,000 People Living with HIV/AIDS (PLHA) in the private sector[8]. India's proposal stressed prevention of parent to child transmission but targeted an additional 15,000 PLHA to receive structured ART by 2008, with a target of 200 institutions to be enabled to provide ART[9].

The Government of India's response to the issue of access to anti-retrovirals occurred at the same time as the WHO's announcement on World AIDS Day. The Union Ministry of Health and Family Welfare announced its decision to provide anti-retrovirals treatment to 100,000 people living with HIV/AIDS, free of cost, with implementation starting on 1st April, 2004. This means that the government will provide ARVs free of cost through its hospitals in the six high prevalence states of Tamil Nadu, Andhra Pradesh, Karnataka, Maharashtra, Manipur and Nagaland. Implementing this decision will require Rs 237 crore in just the start-up phase.

This decision was followed by a January 2004 announcement by the Government of Kerala, a low prevalence state, to provide treatment free of cost to people living with HIV/ AIDS. This would require an anticipated annual commitment of Rs 1.65 crore. A sum of Rs 1500 a month would be required for a person and there are an estimated 10,000 to 15,000 HIV positive people. According to the announcement, all persons living with HIV/AIDS would be given antiretroviral drug therapy free of charge.

Kerala has thus become the first state in India to offer free medical treatment to those living with HIV/ AIDS. It is expected that in the beginning, the drugs will be distributed through medical college hospitals and subsequently through all the other government hospitals.

[8] India GFATM Country Coordinating Mechanism. Proposal to the GFATM: Expansion of Effective Public and Private Sector Interventions in HIV, TB, and Malaria Prevention and Treatment in India. New Delhi, September 24, 2002 <http://www.globalfundatm.org/fundingproposals/indiauk.pdf, accessed in March 2004

[9] India GFATM Country Coordinating Mechanism. Proposal to the GFATM: Expansion of Effective Public and Private Sector Interventions in HIV, TB, and Malaria Prevention and Treatment in India. New Delhi, September 24, 2002 <http://www.globalfundatm.org/fundingproposals/indiauk.pdf

The main obstacles for the use of anti-retroviral drugs in developing countries have been the high costs of these drugs and very poor health infrastructure. There are concerns that difficulties in adherence to complicated medical regimens and a lack of monitoring facilities would promote and spread drug resistance. At both the national and state level, therefore, the foremost task is to improve the current health delivery systems and upgrade it in order to be fit for administering and managing anti-retroviral therapy.

Research has shown that India is set to surpass South Africa as the HIV capital of the world. Since the generic anti-retrovirals are the most important medical tools in the country's battle against HIV, it is important to use these tools judiciously. As with the medical community and the public health system, manufacturers of these medicines will need to be vigilant to ensure careful use of these tools and not fritter away the advantages as treatment options are already so limited. For the benefits to accrue to business, they will certainly need to understand the impact of their product on the economic development process, and manage the impact with responsibility.

## 5. HEALTH AND ECONOMY

In mid-2003, India's population reached 1.07 billion, with poverty continuing to be a persistent feature. After liberalisation and structural adjustment measures launched in the 1990s, there were benefits to the economy, including increases in foreign investment. However, both the central and state governments are currently facing a deteriorating fiscal situation. There are also stark income disparities between India's different states. In 2001, India's Gross National Income (GNI) per capita of US$480 ranked 162 out of 208 countries[10].

During the 1990s, the structural adjustment programmes adopted by successive governments largely resulted in the shift of healthcare delivery to the private sector. Public spending on health, as a percentage of Gross Domestic Product (GDP), scarcely rose during the 1990s (0.9%). In 2000, private expenditure on health was at 4.0% of GDP, or 81.6% of all health spending[11]. The gap in health spending by rich and poor states with regard to public health is increasing, as is the outcome of such policies. There is considerable variance in health financing among states. Studies have found that states with a better quality of public spending are better placed in terms of health status[12].

The National Family Health Survey 2 (NFHS-2) found that 65 per cent of Indian households go to private hospitals/ clinics or doctors for treatment when a family member falls ill. Only 29 per cent normally use the public health sector. Even among the poor households, only 34 per cent normally go to public hospitals in case of ailment[13]. According to a June 2001 World Bank report, for 80% of Indians, the private sector is the main, sometimes the only, provider of health services. The report also found that both private and public sector health services were generally poor quality[14].

As the role of the government in healthcare delivery is reduced, with private healthcare filling up the gap, the poor will be worst hit, especially as the state governments' ability, given their current fiscal problems and debt burden, to provide basic healthcare is imperiled.

The World Bank argues that the private health sector in India is unlikely to substantially improve the health and nutritional status of the poor. The quality of care in the private sector, which remains virtually unregulated, is highly variable[15]. However, the government's response to HIV/ AIDS, at least with regard to ART, is predicated on strong partnerships with the private sector. This finding, and the fact that only 10% of Indians have some form of insurance, has important implications for the ability of the public healthcare system to target needy patients with anti-retroviral therapy.

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[10] Ekstrand, Maria, Lisa Garbus, Elliot Marseille. *HIV/ AIDS in India*. California. AIDS Policy Research Centre, University of California. 2003.
[11] UNDP Human Development Report 2003. New York http://www.undp.org/
[12] Ekstrand, Maria, Lisa Garbus, Elliot Marseille. *HIV/ AIDS in India*. California. AIDS Policy Research Centre, University of California. 2003.
[13] Ekstrand, Maria, Lisa Garbus, Elliot Marseille. *HIV/ AIDS in India*. California. AIDS Policy Research Centre, University of California. 2003.
[14] World Bank. *India: Country Assistance Strategy: Progress Report*. Report No.25057-IN. Washington, DC: January 15, 2003 <http://lnweb18.worldbank.org/SAR/sa.nsf/Attachments/tes/$File/prrpt.pdf>
[15] World Bank. India: Policies to Reduce Poverty and Accelerate Sustainable Development. Washington, DC: January 31, 2000

## 6 POLICY ENVIRONMENT

The latest programme implementation guidelines by NACO[16] for a phased scale-up of access to anti-retroviral therapy for people living with HIV/ AIDS have in Phase I targeted three sub-groups as priorities: (i) sero-positive mothers who have participated in the prevention of parent to child transmission (PPTCT) programme; (ii) sero-positive children below the age of 15 years; and (iii) people with AIDS who seek treatment in government hospitals.

Some practitioners feel that the order of targeting these three different afflicted groups should have been just the reverse. However, this is a very politicized decision which NACO is not empowered to alter, with the result that NACO's present programme could remain off target[17].

The Government of India is in dialogue with the pharmaceutical industry and is reviewing fiscal incentives to further bring down the cost of ART drugs. Since the avowed aim is "a 100-fold increase in public sector provision of ARV treatment, and a 50-fold increase in overall numbers accessing ART in government hospitals", the Government of India will soon emerge the biggest buyer for the pharma companies. It is, therefore in a very good position to insist on better corporate responsibility practices from the pharma industry.

With the stage set for expansion of the ARV market there are possibilities of more competition emerging in this field. While the number of entrants may not be high due to the specialised nature of the product, some companies like Dr Reddy's have already conducted demand and market assessment surveys. It is therefore a very opportune time for exploratory research on product impact on disadvantaged communities.

**Box 1: Facts about HIV and AIDS**

The Human Immunodeficiency Virus (HIV) which causes AIDS is transmitted through body fluids – in particular blood, semen, vaginal secretions and breast milk. It has been established that transmission takes place in four ways: unprotected sexual intercourse with an infected partner (the most common); blood and blood products through, for example, infected transfusions and organ or tissue transplants, or the use of contaminated injection or other skin-piercing equipment; transmission from infected mother to child in the womb or at birth; and breastfeeding. HIV is not transmitted by casual physical contact, coughing, sneezing and kissing, by sharing toilet and washing facilities, by using eating utensils or consuming food and beverages handled by someone who has HIV; it is not spread by mosquitoes or other insect bites.

[16] These guidelines http://naco.nic.in/nacp/arvimp.htm have to be seen in conjunction with the guidelines on anti-retroviral therapy.
[17] Report on CSM consultation on *Corporate Responsibility and Economic Development in India – Pharmaceutical Sector: focus on HIV medication*, April 6, 2004. Delhi.

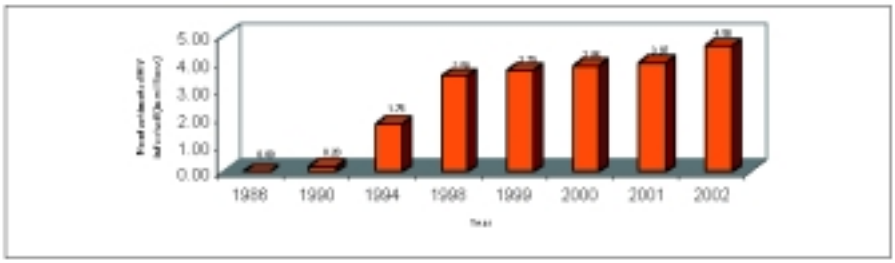
HIV weakens the human body's immune system, making it difficult to fight infection. A person may live for ten years or more after the infection, much of this time without symptoms or sickness, although they can still transmit the infection to others. Early symptoms of AIDS include: chronic fatigue, diarrhoea, fever, current skin rashes, herpes and mouth infections, and swelling of the lymph nodes. Opportunistic diseases such as cancers, meningitis, pneumonia and tuberculosis may also take advantage of the body's weakened immune system.

Although periods of illness may be interspersed with periods of remission, AIDS is almost always fatal. Research is currently under way into vaccines, but none is available as yet. Anti-retroviral drugs are available that slow the progression of the disease and prolong life; at present these are quite expensive, and consequently unavailable to most sufferers, but the situation is changing rapidly. HIV is a fragile virus, which can only survive in a limited range of conditions. It can only enter the body through naturally moist places and cannot penetrate unbroken skin. Prevention therefore involves ensuring that there is a barrier to the virus, for example condoms and protective equipment such as gloves and masks (where appropriate), and that skin-piercing equipment is not contaminated; the virus is killed by bleach, strong detergents and very hot water[18].

[18] An *ILO code of practice on HIV/ AIDS and the world of work*. This code of practice is voluntary and not legally enforceable. It deals with all workplace issues connected to HIV positive people and International Labour Office also has a publication on workplace interventions by different companies. This is confined strictly to the formal sector but efforts are underway for clearer guidelines for the informal sector.

## 7. HIV ESTIMATES IN INDIA

The estimation of HIV takes place through sentinel surveillance conducted every year from August to October. The National AIDS Control Organisation, functioning under the Ministry of Health and Family Welfare, is the nodal agency responsible for releasing the estimates annually, which are published in the NACO website.




In comparison to 3.97 million HIV infections in year 2001, in year 2002 there has been an increase of about 6 lakhs infections (4.58 million).

### AIDS Surveillance in India

| AIDS cases in India | Cumulative | This month |
|---|---|---|
| Males | 49396 | 3314 |
| Females | 18020 | 1317 |
| Total | 67416 | 4631 |

*(as reported to NACO as on 29th February 2004)*

### 7.1 Problem with estimates

India's HIV prevalence estimates are based solely on sentinel surveillance conducted at public sites. The country has no national information system to collect HIV testing information from clinical laboratories in the private sector, which provides a large percentage of health care. Moreover, those dying of opportunistic infections associated with HIV are not tested for HIV infection[19]. Although the method of basing estimates on sentinel surveillance at public sites only is comparable to that of the Center for Disease Control (CDC), the CDC also collects additional information about other sub-groups like Men who Have Sex with Men (MSM), Injecting Drug Users (IDUs) etc, which is lacking in India. The overall HIV estimates are used to note trends at the national level only, and not the state level. This makes the task of obtaining an accurate state-level picture of the state of the disease much more difficult [20].

At the state level, therefore, under-reporting of HIV cases remains a key concern. The data produced on the occasion of the 4th West Bengal Sexual Health Conference (22 – 24 Sept, 2003), provide an instructive example:

[19] Solomon, S and A K Ganesh, *HIV in India*. Vol 10 Issue 3. 2002. Topics in HIV Medicine, International AIDS Society, USA
[20] Report on CSM consultation on *Corporate Responsibility and Economic Development in India – Pharmaceutical Sector: focus on HIV medication*, April 6, 2004. Delhi

## 4th West Bengal Sexual Health Conference, 22 – 24 September, 2003

| Status of HIV/AIDS in West Bengal | | | |
|---|---|---|---|
| Population | 8,022 crores | Population served per doctor (Urban) | 830 |
| Area | 88,752 sq. km. | Population served per doctor (Rural) | 4727 |
| No. of inhabited villages | 37, 910 | Median prevalence in STD* Sites (2002) | 2.23% |
| No. of towns | 382 | Median prevalence in ANC* Sites (2002) | 0.31% |
| Sex ratio | 934 | Median prevalence in IDU *Sites (2002) | 1.46% |
| Decennial population growth | 17.84% | Highest STD* median prevalence | 8.0% (Haldia) |
| Population density | 904 persons per sq. km. | Highest ANC median prevalence | 1.25% (Bijoygarh, South Kolkata) |
| Crude birth rate (SRS) | 20.6 | No. of HIV +ve cases reported | **5084** |
| Crude death rate (SRS) | 7.0 | No. of HIV +ve cases estimated | **1,47,820** |
| Infant mortality rate | 51 | No. of AIDS cases reported | 2397 |
| Life expectancy (2001-06) male | 66.1 | No. of CSW* covered | 35,900 |
| Life expectancy (2001-06) female | 69.3 | No. of CSW* targeted interventions | 17 (43 sites) |
| % of urban population to total population | 28.03 | No. of MLs* covered | 1,11,000 |
| Literacy rate | 69.22 | No. of ML* targeted interventions | 10 (10) |
| % of schedule caste population | 23.62 | No. of IDUs* covered | 2,500 |
| % of schedule tribe population | 5.59 | No. of IDU* targeted interventions | 1 (multiple sites) |
| Per capita income in Rs. | Rs. 15,569 | No. of truckers covered | 96,000 |
| No. of districts | 19 | No. of trucker targeted interventions | 7 (8 sites) |
| No. of sub-divisions | 63 | No. of street children covered | 15, 000 |
| No. of municipal corporations | 6 | No. of street children targeted interventions | 1 (1 sites) |
| No. of municipalities | 117 | No. of prisoners covered | 3,500 |
| No. of Gram Panchayat | 3360 | No. of prison targeted interventions | 1 (7 central jails) |
| No. of Panchayat Samithies | 340 | No. of community care centre | 1 |
| No. of Zila Parishads | 19 | Total financial involvement | Rs. 6.51 crores |
| No. of sub-centres | 8126 | No. of STD* clinics supported by NACO* | 0 |
| Total no. of health centres at primary level | 1269 | No. of condoms procured in 2002 | 30 lakhs |
| No. of rural hospitals at primary level | 94 | No. of STD* cases treated in last year | 65,067 |
| No. of BPHC at primary level | 252 | No. of 1097 centres | 15 |
| No. of PHC at primary level | 923 | No. of schools under school AIDS | 395 |
| No. of sub-divisional hospitals | 36 | No. of Govt. blood banks | 58 |
| No. of state general hospitals | 36 | Blood collected in 2002 | 4.21 lakhs |
| No. of district hospitals | 15 | % voluntary collection | 83.14% |
| No. of P.G. teaching hospitals (SSKM & STM) | 2 | No. of VCTCs* | 18 |
| No. of medical college hospitals | 7 | No. of PPTCT* centres | 7 |

| | | | |
|---|---|---|---|
| Population served per bed (all inclusive) | 1136 | No. of CD4 centres | 1 (Medical College, Kolkata |
| No. of allopathic doctors registered | 12,213 | No. of CD4 tests done | 345 |
| No. of nurses registered | 23,702 | Annual action plan sanctioned current year | Rs. 16.31 crores |
| No. of dentists registered | 1265 | | |
| No. of ayurvedic doctors registered | 3014 | | |
| No. of homeopathic practitioners registered | 37401 | | |

*Source: Brochure by the West Bengal State AIDS Prevention and Control Society Published during 4th West Bengal Sexual Health Conference, 22 – 24 September, 2003*

***Note :**
*CSW – Commercial Sex Worker, ANC – Antenatal Clinic, STD – Sexually Transmitted Diseases, IDUs – Injecting Drug Users, ML – Migrant Labour, VCTC – Voluntary Counselling and Testing Centre, PPTCT – Prevention of Parent to Child Transmission*

Sub-optimal reporting such as this affects disease management and care and support efforts and does not provide a true picture of unmet medical need. Importantly, it also shows that there is further scope of expansion of the market for anti-retrovirals. This is where the impact assessment of the product on the economic development process becomes very important. Businesses will need to understand this in order to deal with the responsibility issues involved in ensuring greater ART coverage.

It is now well established that the larger percentage of HIV positive patients targeted by the government programme are poor[21], while one section also belongs to the middle income group. With better information collection systems in place in future, the businesses will have a larger consumer base, and greater imperatives to connect between their decision-making processes and economic development.

[21] Doctors interviewed by CSM who spoke on the economic condition of patients were practicising in a wide range of places, starting from those practising in government hospitals, to those working in medical NGOs, or attached to clinics run by NGOs. They were located in different geographical regions, starting from the high prevalence states of Maharashtra and Tamil Nadu, to states with lower prevalence states like West Bengal. In government hospitals like J J Hospital in Maharashtra, more than 90 per cent of the patients are very poor, while in an established medical NGO like YR Gaitonde Centre for AIDS Research and Education, by and large, 50 per cent of patients are below the poverty line.

## 8. EPIDEMIOLOGY AND IMPLICATIONS

India accounts for 10% of the global HIV burden and 65% of that in South and South East Asia. In India, according to NACO estimates, about 84.20 per cent of the reported HIV positive cases in the country occurs in the sexually active and economically productive age group of 18 to 49 years. A gender analysis reveals that one in every four cases reported to be living with HIV is a woman. Surveillance data from ante-natal clinic attending women, which is taken as a proxy for the general population, stand testimony to the need for urgent policy intervention in this area as it increases the risk of peri-natal transmission. Moreover, the strongest risk of rapid progression of this disease in the general population is at least in part because many of these women living with HIV do not know of their status.

According to NACO, the increase of about 6 lakh (600,000) infections in the year 2003 has been primarily noticed in the states of Karnataka, Rajasthan, West Bengal, Tamil Nadu, Gujarat, Bihar and Madhya Pradesh[22]. The epidemic continues to shift towards women and young people, with about 25 per cent of all HIV infections occurring in women. This percentage is on the rise, and pediatric HIV is very aggressive.

In terms of demographic spread, the last four years have seen a broadening of the epidemic across the southern and western states of India as well as the continued concentration of HIV among the IDUs in the North Eastern States. There have been sharp increases in Andhra Pradesh and Karnataka, with these two states overtaking Tamil Nadu as states with higher prevalence rates. The highest, however, is Maharashtra, where 60 per cent of sex workers have been affected, and two per cent of women attending ante-natal clinics are showing HIV positive status[23].

The burden of AIDS cases is beginning to be felt in states affected early. Mumbai in Maharashtra and Manipur in the North East have recorded 20 to 40 per cent bed occupancy by HIV positive persons in certain referral hospitals[24].

Low overall prevalence masks crucial differences among regions, states, and sub-populations. While the heaviest impact of the epidemic is being felt currently in the six states of Tamil Nadu, Karnataka, Andhra Pradesh, Maharashtra, Manipur and Nagaland (classified as high prevalence), moderate prevalence states like Gujarat and Goa also contain hard-hit districts. There are growing localised epidemics in India[25].

The above demonstrates that we urgently need to know more about the socio-behavioural context of the disease to understand how the medical response should be scaled up. With the epidemic slowly

[22] http://www.youandaids.org/
[23] http://www.youandaids.org/
[24] http://www.youandaids.org/
[25] Ekstrand, Maria, Lisa Garbus, Elliot Marseille. *HIV/ AIDS in India*. California. AIDS Policy Research Centre, University of California. 2003.

moving beyond its initial focus, and sub-epidemics with strong socio-economic implications evolving among groups like IDUs and men who have sex with men (MSM), one of the worst economic outcomes is lost workforce productivity. Very often, those living with HIV cannot work for more than 3 to 4 days a month, sometimes even that is not possible[26]. In many places, this has led to the encouragement of child labour, as has been documented by ILO in Churachandpur in Manipur[27].

There are several factors for such a rapid spread of this epidemic across the country. Foremost among them is the large-scale migration of labour and long periods of stay-away from homes (from economically backward areas i.e the homes of the workers, to more developed regions ) which has led to the emergence of new patterns of sexual behaviour. This has also increased the spread of the disease from urban to rural areas, although we do not have the means to monitor this. Other factors include low literacy levels leading to low awareness among the potential high risk groups, gender disparity, sexually transmitted infections and reproductive tract infections among both men and women.

One of the key characteristics is that labour migration has expanded the demand and supply sides of the commercial sex industry. Many men away from either their normal sex partners or from the social control of their home communities resort to alcohol, drugs and commercial sex workers while on the move.

Nearly half of India's goods are transported by millions of trucks. Sexual activity along their routes is common and pervasive. According to an article in the **Harvard AIDS Review**, India's long-distance truckers average 200 sexual encounters each year; at any given time, 70 per cent of them have STDs [sexually transmitted diseases] (Harvard University, 1995). They also transport HIV between commercial sex work groups and back to their home areas[28].

The large migratory population makes it difficult to target them for treatment. NACO's ART programme clarifies that only the local populace can have access to treatment, and the migratory population will normally have no domicile proof and treatment. There is need to assess the real numbers of this mobile population. Being breadwinners for their families, arguably it is they who need treatment most[29].

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[26] Interactions with positive people's networks

[27] *Enterprises & HIV/ AIDS in India: Prevention of HIV/ AIDS in the World of Work*, Produced by the International Labour Organisation (ILO), New Delhi, with support from the US Department of Labour.

[28] Collins, Joseph and Bill Rau. *AIDS in the Context of Development*. UNRISD Programme on Social Policy and Development. Paper Number 4. December 2000

[29] Report on CSM consultation on *Corporate Responsibility in India – Pharma sector: Focus on HIV medication*, April 6, 2004. Delhi.

## 9. COSTS AND RESOURCES

During the late 1990s, researchers estimated that the total annual cost of HIV/ AIDS in India was roughly equal to 1% of GDP. However, this figure did not include numerous factors such as the cost of ART, strengthening the healthcare system and retraining of workers[30]. India has about 385 million people under age 15[31], and those under 30 represent 39.7% of reported AIDS cases[32]. But by 2050, the UN projects that India's population will be 5% smaller than it would have been without AIDS. There were 2.8 million AIDS deaths in India between 1980 and 2000. During 2000-15, according to the UN projections, there will be 12.3 million AIDS deaths[33].

There is not enough current micro-level research on the cost of treatment in India. A study by YRG Care found that AIDS treatment imposes a heavy financial burden on families, leading to depletion of savings and increasing indebtedness of households. Using data from 356 HIV/AIDS clients, YRG CARE found that average monthly expenditure per HIV-infected person was Rs 1,872 (US$39), or about 80% of household income. As the illness progressed, treatment costs increased. The average loss of income because of illness was estimated at Rs 377 (about US$8) per month, or 16% of a patient's monthly wage earnings. The burden of treatment (measured as the ratio of treatment costs to household income) was much higher for low-income families than for high-income families. Treatment costs were paid for through borrowing (41%), sale of assets (24%), past savings (24%), and mortgage of assets (9%)[34].

The World Bank study shows that Indian households currently spend 5 to 7% of their income on health, and in case of those rural households below the poverty line, they spend even more of their income on health (12 to 19%[35]). As HIV prevalence goes up, this spending is also likely to go up for all households. Consequently it can be expected that consumption of other basic necessities like food and housing will go down. This effect will be more pronounced among the very poor people.

These statistics have to be tallied with a record of the resources at our disposal for financing of ART. State financing of anti-retroviral therapy (ART) programmes has an important precedent in Brazil, where the healthcare system is fully government funded. But in India, with the exception of UNICEF support for preventing parent to child transmission, official donor organisations have generally avoided financing of ART, choosing to focus on strengthening treatment of opportunistic infections instead. The ART programme announced on World AIDS Day will therefore have to be fully borne out of the government's internal resources – including expenses on improving infrastructure.

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[30] Ekstrand, Maria, Lisa Garbus, Elliot Marseille. *HIV/ AIDS in India*. California. AIDS Policy Research Centre, University of California. 2003

[31] Population Reference Bureau. *World Population Data Sheet 2003*. Washington, DC http://www.prb.org/

[32] NACO. *National Baseline General Population Behavioural Surveillance Survey: 2001*. New Delhi. http://www.naco.nic.in/nacp/publctn.htm

[33] Ekstrand, Maria, Lisa Garbus, Elliot Marseille. *HIV/ AIDS in India*. California. AIDS Policy Research Centre, University of California. 2003

[34] Duraisamy P, Daly C, Solomon S, et al. "How people living with HIV/ AIDS in South India cope with the costs of treatment." Abstract no TuPeE5117. XIV International Conference on AIDS, Barcelona, July 7-12, 2002. Quoted in Ekstrand, Maria, Lisa Garbus, Elliot Marseille. *HIV/ AIDS in India*. California. AIDS Policy Research Centre, University of California. 2003

[35] World Bank. *India: policies to reduce poverty and accelerate sustainable development: Chapter 2- improving health and infrastructure for the poor* January 31, 2000 Quoted in Ekstrand, Maria, Lisa Garbus, Elliot Marseille. *HIV/ AIDS in India*. California. AIDS Policy Research Centre, University of California. 2003

To date, a majority of ART has been provided at full cost to patients. Some NGOs have had *ad hoc* arrangements to provide ART at subsidised rates, while other NGOs have fairly organised arrangements for their provisions.

In the light of India's earlier-mentioned proposal to the Global Fund for AIDS, TB and Malaria (GFATM) approved in January 2003, the government has reached an agreement with four pharmaceutical manufacturers, who will participate in a graduated cost recovery programme[36].

The ART programme will initially involve four model institutions:

1. AIDS Research and Control Center (ACORN), Mumbai (which will administer the GFATM's ART component.
2. YRG Care, Chennai
3. Freedom Foundation, Bangalore
4. Freedom Foundation, Hyderabad

Under this GFATM funded programme, PLHA will be able to avail of ART monitoring at these institutions at a subsidised rate of US$12, as opposed to the full costs for ART and monitoring they had to pay earlier. Four Indian generic drug manufacturers have agreed on a sliding-scale pricing mechanism based on the patient's income.

This proposal does not, however, address the numerous constraints noted earlier in this study in the largely unregulated private healthcare sector that will affect the provision of ART, and monitoring and adherence issues[37].

Soon, the Government of India will emerge as the biggest purchaser of medicines from the pharma companies who make generic ARVs. This will however include only the five molecules that are used to treat WHO Stage IV infections. At the same time it must also be remembered that these molecules, which are mostly for first-line treatment, will be rendered out of use when more efficacious second-line options become available. The cost to government therefore may be driven up substantially when that occurs. As yet, however, it is not very clear from where these extra resources will be generated.

Practitioners also fear that to access drugs with better efficacy during a product patent regime may encourage the emergence of a thriving grey market of drugs of uncertain provenance, in poor storage facilities with unassured supply and at uncontrolled prices. These are also expected to be non-reimbursable and at full cost to the patient[38].

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[36] India GFATM Country Coordinating Mechanism. Proposal to the GFATM: Expansion of Effective Public and Private Sector Interventions in HIV, TB, and Malaria Prevention and Treatment in India. New Delhi, September 24, 2002 http://www.globalfundatm.org/fundingproposals/indiauk.pdf.

[37] Ekstrand, Maria, Lisa Garbus, Elliot Marseille. *HIV/ AIDS in India*. California. AIDS Policy Research Centre, University of California. 2003

[38] Report on CSM consultation on *Corporate Responsibility and Economic Development in India – Pharmaceutical Sector: focus on HIV medication*, April 6, 2004. Delhi

## 10. CHALLENGES TO HIV MEDICATION SEGMENT IN POST-2005 PERIOD

Indian pharmaceutical firms are currently manufacturing generic versions of ART and selling them at less than US$1 a day. The manufacture of generic ART drugs was an essential element in the drastic reduction of drug prices. However, in 1994 India signed the Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPs) as part of its obligations as a member of the World Trade Organisation in (WTO). As a result, Indian patent law was scheduled forchange on January 1, 2005. This will block the option of Indian firms being able to manufacture additional ART drugs. This particularly affects on-patent drugs used in second-line therapies and future new ART agents that may be developed.

Therefore, as noted earlier, India's domestic ART options have stayed within the existing 11 molecules currently being used by medical practitioners. But even the current prices need to be revised to ensure better access to ART, for which partnerships may be the best method. There are also other hurdles to medication, which can and should be addressed with active participation from pharma, and which may be done according to certain parameters.

### 10.1 Poor Levels of Awareness

In India, a further problem is the general lack of awareness. Sensitisation to medicine consumption issues at the community level is extremely poor. In Kerala, where the state government has announced provision of free medical treatment for all those living with HIV/ AIDS in the state, including provision of free ART, PLHA say there is still a high level of stigma and discrimination in the medical field, especially government hospitals. Different doctors give different prescriptions and communities have alleged that exploitation by doctors is very high (often charging double for the medicines).

The case of the Council of People Living with HIV/ AIDS in Kerala (CPK+), where only 30 out of 462 members were taking medicines, illustrates this. People who took medicine did not have correct information regarding the medicines, their side effects, correct combination, and the chances for developing resistance if the medicine is stopped. Lack of information led many people to stop taking medicines and suffer thereafter.

An additional dilemma is that in resource poor settings like Churachandpur, even access to hospitals that treat HIV patients does not ensure access to medicines. The Affected and Infected Women's Associate (AIWAC), for example, said that even after medicines to treat full-blown AIDS cases were provided in Manipur for free from April 1, they would not be in a position to use these medicines as they do not know how to manage the side effects.

The World Bank estimates that HIV/ AIDS may reduce productivity growth by up to 50 per cent in the private sector of the most affected countries. Besides erosion of human capital and loss of skilled

workers, this will result in a mismatch between labour requirement and labour availability in the private sector[39].

10.2 Gender Discrimination

As in many other walks of life, women face an extra set of problems with regard to accessibility. Men are often reluctant to get their spouses tested – although early detection always helps in treatment. In many cases, antiretrovirals are not started on women due to resistance within the family. Overall, the number of women on ARVs is very low[40]. Many self help groups bear testimony to the fact that women members are unable to afford medicines, and therefore go without[41]. The International Alliance for HIV/ AIDS has found that when both a husband and a wife are infected with HIV/ AIDS, men routinely receive care ahead of their wives[42]. Also, resource constraints and having to travel long distances for treatment are additional problems[43].

Dr Suniti Solomon, who diagnosed the first case of HIV in India at Madras Medical Centre and is the director of the YR Gaitonde Center for AIDS Research and Education in Chennai, analyses the social construct of gender in India, which renders women highly vulnerable to acquiring HIV and other sexually transmitted infections.

Dr Solomon responded to various questions and a special survey conducted by this study. Comparably, at an international conference she noted that in addition to biological vulnerability:

*"The lack of opportunities for young women to receive sex education and HIV information leads them to accumulate unverifiable myths. Social norms only encourage "innocent" women, e.g., who is sexually naive until marriage, does not seek pleasure from sex, one who would willingly and actively participate in sex only for the pleasure of her husband. Women's economic dependence on men causes poor health-seeking behaviors. Reproductive tract infections are not promptly treated increasing their susceptibility to HIV. Women with poor social and job skills feel inclined to offer sexual services or to offer sex in return for social support. These women are more likely to stay within a marriage no matter how vulnerable they are to infection. Motherhood, no doubt noble, also enslaves women. Fertility forces women to abandon caution*

[39] World Bank. HIV/ AIDS and Development. *World Bank* [On-line fact sheet]. Available at: http://www.worldbank.org/ungass/factsheet.htm

[40] In response to a CSM questionnaire, The Naz Foundation, a Delhi-based NGO that has been treating HIV patients since 2000 through its clinic, found that a comparison of compliance rates for ARVs between men and women cannot be done because there is a discernible difference in the number of men and women on retro-virals, because the number of women on ARVs is very low. They also noted that there is resistance from male family members to access services when the person infected and requiring care is a female

[41] *Enabling Women to Fight HIV/ AIDS*, ActionAid India publication

[42] International HIV/ AIDS Alliance. *Improving Access to HIV/ AIDS-related Treatment: A Report Sharing Experiences and Lessons Learned on Improving Access to HIV/ AIDS–related Treatment*. London: June 2002 http://www.aidsalliance.org/_docs/_languages/_eng/_content/_3_publications/download/Reports/Access_To_Treatment_Report.pdf/

[43] Alfred DSS, Vijaya S, Alfred RSS, et al. "Women beyond the accessibility of treatment: the social, cultural and family barriers in accessing services in the rural parts of AP." Abstract no. WePeF6651. XIV International Conference on AIDS, Barcelona, July 7-12, 2002.

*when having sex with a known HIV-infected partner. Marriages are saved at the cost of HIV. Women are taught to accommodate and be resilient in the face of violence. They pride in being able to live in the midst of violence. Violence directly enhances one's vulnerability to HIV. Submission to violence encourages men to engage in irrational and unchallenged behaviors such as having concurrent multiple partners. The impact of HIV on a woman is much greater than that on men. In most societies, women play the nurturing role, in predominant cases, naturally and voluntarily. However, when she is HIV infected, which may imply an infected partner, her burden doubles[44]."*

The woman, who is the primary caregiver for an ill and dying husband, is left vulnerable to many social evils if she outlives her husband, as is often the case[45]. There is a huge amount of documented evidence that even if she goes back to her family, she may not always be accepted. Very often, such women are forced into prostitution[46]. That in turn reinforces the swifter progress of the disease.

10.3 Cost of medicines

Doctors and NGOs are unanimously of the opinion that the cost of medicines still remains high, particularly protease inhibitor (PI)-based medicines, which has clear immunological, virological end-points, but which most patients cannot afford. Furthermore, even certain opportunistic infection drugs such as anti-fungals remain very costly. The cost of second-line drugs also continues to remain very high and often results in doctors looking only at short-term goals[47].

NGOs who provide medicines at a subsidised cost have so far been able to negotiate discounts with the pharma companies. However, even after the discount, providing sustained ARV support to patients is very limited, as this is a lifelong commitment. This constrains the resources available for purchase of medicines and cannot guarantee adherence to prescription schedules.

As Solomon and Ganesh have pointed out in a seminal study, "When HIV infected persons attain a good quality of life, usually after about 6 months of initiating therapy, the rich take a break and the poor run out of money"[48]. Besides, the cost of diagnostics is also very high.

To sum up, for the healthcare providing community cost is still the biggest constraint, although certainly not the only inhibiting factor in providing quality healthcare.

10.4 Infrastructure facilities

The essential elements of good healthcare infrastructure are doctors, paramedics, intensive care units (ICUs), ventilators, biochemistry services, drugs for opportunistic infections. In public hospitals and

[44] Solomon S. "Stopping HIV Infection Before it begins in Women". Abstract no 114. 10th Conference on Retroviruses and Opportunistic Infections, February 10-14, 2003, Boston. Quoted in Ekstrand, Maria, Lisa Garbus, Elliot Marseille. *HIV/ AIDS in India*. California. AIDS Policy Research Centre, University of California. 2003.
[45] *Enabling Women to Fight HIV/ AIDS*, ActionAid India publication
[46] *Enabling Women to Fight HIV/ AIDS*, ActionAid India publication
[47] CSM interviews with doctors.
[48] Solomon, S and A K Ganesh, *HIV in India*. Vol 10 Issue 3. 2002. Topics in HIV Medicine, International AIDS Society, USA.

private clinics, in addition, there may be voluntary counseling and testing facilities, state-of-the-art laboratory, support services, scale-up and drug centre.

India's public health infrastructure is vast, comprising 600 district hospitals, 4000 community health centers, 25,000 primary health centers, 137,000 sub-centers, and 160 medical colleges. But its public health facilities also suffer from poor quality service, paucity of funds and poor management[49].

Fundamentally, quality control issues are not adhered to in the public health sector. For example, there is often a paucity of reagents and a host of other factors. In their study[50], Solomon and Ganesh found that:

*"The majority of the laboratories in India do not take part in quality-assurance and quality-control exercises for HIV testing, and poor techniques are commonplace. HIV test results are often inaccurate for several reasons: test kits are used after the expiration dates; kits are not stored at the correct temperature; electricity is shut down at night; air-conditioning for the testing equipment is erratic; poor-quality water is used; and tubes, tips and other equipment are often recycled. With makeshift laboratories that have scant respect for quality control or assurance, patients cannot necessarily be sure of their test results, especially when these laboratories do not provide their patients with an opportunity to discuss their lifestyles and risk histories with a counselor who could help them place the result within that context".*

Among the primary necessities in putting a patient on viable anti-retroviral therapy (ART) is pre- and post-medicine counselling. Since ART is a lifelong commitment, it has to be compulsorily accompanied by counselling services, so that the patient understands the implications of stopping the medicine, as well as come to terms with his/her condition. In the absence of quality adherence counselling, both the rich and the poor are not adherent.

In their response to our survey, YRG Care referred to the importance of counselling as a key element of not just treatment but empowerment and added:

*"From our organisation's point of view, empowerment means enabling an individual (who has been tested HIV +ve) to accept his/ her condition and help him/ her cope with the disease physically, mentally and socially to lead a better quality of life".*

In our experience, it is apparent that there is a lack of understanding at government hospitals that counselling is an important tool for empowerment. Doctors at government hospitals who do understand it complain of a lack of resources. Regrettably, experience shows that in these cases the chances of non-adherence to the medicine regimen is also very high.

[49] Ekstrand, Maria, Lisa Garbus, Elliot Marseille. *HIV/ AIDS in India*. California. AIDS Policy Research Centre, University of California. 2003

[50] Solomon S, Ganesh, A Ekstrand, M et al. *High HIV seropositivity at an anonymous testing site at Chennai, India: client profile and trends over time.* AIDS Behav. 2000; 4: 71-81. Quoted in Solomon, S and A K Ganesh, *HIV in India*. Vol 10 Issue 3. 2002. Topics in HIV Medicine, International AIDS Society, USA

Government hospitals have a paucity of trained counsellors, and even when present they are in short supply. Counselling means empowerment through guidance and care, and is of fundamental importance if the government's ART scale up programme is to succeed.

Counselling should also include therapy counselling, a new concept in addition to the medicine counselling, which is needed to ensure adherence and therefore effectiveness of the medicines.

It will take some time to implement NACO's plan to work with the Confederation of Indian Industry (CII) and put in place a network of public-private diagnostic services like CD4 cell count facilities, from existing laboratories. This is intended to be accessible to institutions/ hospitals where such counting facilities are not available. The cost for patients is an important part that has yet to be worked out.

Besides, patient monitoring will continue to remain difficult. The human resource and infrastructure support (research officer, counselor, record keeper, computer) stipulated in NACO's ARV programme implementation guidelines indicates little about the actual costs likely to be incurred by a hospital with an ARV unit. A quick look at the allocations suggest that at least some of this cost will have to be generated internally[51] by the hospital. This will place an extra demand on the already constrained the resources of the state's budget and its public health system.

Not only this, there are only 25 public health facilities for testing CD4 count of patients in the whole of India and no public hospital has a viral load facility. Diagnostics are crucial for monitoring the patient, but NACO's programme says CD4 will be done for free when the treatment is started, implying that before starting treatment, the first CD4, which is vital to start treatment, will have to be done at full cost to patient. Absence of any subsidy in this area may be a problem.

There are also no more than two resistance testing facilities in India – monitoring and documenting viral resistance has to be done at one stage or another. Only one out of these two laboratories has started standardising for resistance studies. Foreign countries that have expertise in this kind of testing are willing to collaborate with NACO in this area, but, as Dr Alaka Deshpande, one of the country's leading AIDS physicians, noted in her contribution to our research: "Unfortunately, our very stringent rules and bureaucratic hurdles are coming in the way of this facilitation".

The country also has to have in place biochemical laboratories to monitor biochemical parameters of the patient, along with the other parameters like CD4 and viral load. These laboratories, which are at present lacking, are equally important if the ART programme has to succeed. More importantly, infrastructure is an area where partnerships with pharma are vital to ensure that the efficacy of existing drugs are preserved.

[51] See programme implementation guidelines for a phased scale-up of access to anti-retroviral therapy http//: www.naco.nic.in/

### 10.5 Affordability vs access to treatment

Doctors and NGOs alike in the field of HIV care are of the opinion that affordability, though one of the important factors, does not guarantee access to treatment. Dr Alaka Deshpande mentions the other essential requirements as:

*"low cost diagnostics to monitor patient compliance (follow-up with CD4 and viral load every three months is not affordable), lower costs of PI and supportive therapy. It is necessary to have trained physician, a therapy counselor and a sustained support for the patient".*

The consensus among healthcare providers is that lower prices of medicines may increase accessibility, but price is not a guarantor for adherence. Better systems of disbursement, trained medical personnel and programs to promote adherence and commitment among the healthcare team delivering ART are needed.

An attendant issue here is the stain of stigma and discrimination, which can prevent patients from coming forward for proper check-up and treatment.

### 10.6 Lack of trained doctors

HIV is a disease that requires skilled management, no less than what the premier business schools teach us. However, there is a paucity of trained doctors in government hospitals and a high level of ignorance among the medical fraternity about HIV/ AIDS. In a country where only a small portion of physicians have willingly learned about HIV infection and its management, finding a competent opinion on treatment options may therefore not be quite straightforward[52].

HIV is an infectious disease. A physician is best placed with knowledge of the pharmacology of the drugs, their side effects, complications and management. But in the absence of prescription auditing, the drugs are prescribed by doctors from any discipline ranging from sexually transmitted diseases (STD), to Obstretician-Gynaecology, TB, Ayurveda and Homoeopathy[53]. On the ground, the majority of the government hospitals HIV is handled by STD units. Ideally, however, HIV treatment should be provided by a team comprising specialists such as physicians, STD specialists, chest physicians, gynaecologists, paediatricians and surgeons[54].

For an appropriate scale-up of anti-retroviral therapy, greater sensitisation of doctors is needed not just from the public sector, but also from the vastly unregulated private sector practitioners where the reluctance to treat HIV patients is very pronounced. This is especially so since NACO's scale-up proposal is strongly predicated on public private partnerships, and pre-empts the need for continuous doctors' training, as the knowledge about disease management continually increases.

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[52] Solomon, S and A K Ganesh, *HIV in India*. Vol 10, Issue 3. 2002. Topics in HIV Medicine, International AIDS Society, USA.
[53] Doctors' responses to CSM questionnaire
[54] Feedback on CSM consultation *Corporate Responsibility in India in the Pharmaceutical Sector: Focus on HIV Medication*, April 6, 2004, Delhi

## 10.7 Adherence and resistance

In resource poor settings where government hospitals lack diagnostic facilities and private laboratories have very high charges, there are no ways of knowing if molecular resistance has set in. However, in places where there is quality lab support, such as at the YR Gaitonde Centre for AIDS Research and Education, one of the premier AIDS research and care setups in the country, ART resistance in the naïve population is 20% with protease inhibitors – major mutations – and 19.6% with reverse transcriptase (RT) inhibitors. However, the basis for this calculation is not known, and the scientific validity of this claim has to be tested against the fact that less than 1% of patients are given antiretroviral therapy[55].

Poor adherence levels leads to poor clinical outcomes and transmission of drug resistant viral strains, thus lowering the effectiveness of the ART in the infected population. Studies on resistance suggest fears are particularly pertinent in India due to the generic triple drug formulations include so-called non-nucleoside reverse transcriptase inhibitors (NNRTI) like nevirapine. Research has found that an easily acquired single point mutation can confer resistance to all the agents in the NNRTI class when the virus becomes resistant to nevirapine alone[56].

Increasingly, stakeholders are underlining the importance of efforts to improve infrastructure, so that those targeted with ART intervention can get the maximum benefit. As Dr Sanjay Pujari of Ruby Hall Clinic, Pune, Maharashtra puts it, "A good infrastructure to deliver drugs is needed, then it may even be provided free".

A multicenter study led by Grant Medical College and GT Hospital in Mumbai[57] on the causes of ART therapy failure in India found that only 10% of patients were counseled prior to initiating ART. Adherence was observed only in 10% of cases and all were on (sub-optimal) PI-sparing regimens. In over 90% of the cases, the long-term goal of therapy was not determined, and dual-drug regimens were used in 70% of cases and monotherapy in 23%. In 61% cases, ART was used without treating underlying opportunistic infections. The authors found that initiation of salvage regimens from among the scant number of currently available drugs gave indications of improvement in 30% of the previously failing cases. The study recommended that only specially trained doctors should prescribe these drugs.

## 10.8 Unregulated private sector

Entrusting ART to the private sector without adequately equipping them to do so would be disastrous, particularly since they fall outside the purview of regulatory control. Many doctors and government officials say this would lead to faulty prescription practices, setting the stage for drug resistant HIV strains to emerge[58].

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[55] CSM consultation on *Corporate Responsibility in India in the Pharmaceutical Sector: Focus on HIV Medication*, April 6, 2004, Delhi

[56] Anitori A, Zaccarelli M, Cingolani A, et al. "Cross-resistance among non-nucleoside reverse transcriptase inhibitors limits recycling efavirenz after nevirapine failure". *AIDS Res Hum Retroviruses* 2002 Aug 10; 8(12): 835-38. Quoted in Ekstrand, Maria, Lisa Garbus, Elliot Marseille. *HIV/ AIDS in India*. California. AIDS Policy Research Centre, University of California. 2003

[57] Saple DG, Vaidya SB, Kharkar RD, et al. "Causes of ARV Failure in India." Abstract no WePeB5860. XIV International Conference on AIDS, Barcelona, July 7-12, 2002.

[58] Mudur, G. "India must change health priorities to tackle HIV." *BMJ* 2002 Nov 16; 325 (7373): 1132

A study led by Grant Medical College & Sir JJ Hospital in Mumbai on family physicians and consultants examined the knowledge and practices of physicians in three low-prevalence and three high-prevalence states. Among its findings were that in low prevalence states, 70% of family physicians were unaware of the HIV ELISA test, and 80 per cent unaware of ART except AZT. CD4 and viral load monitoring facilities were non-existent, and counseling concepts unknown. In the high-prevalence states under study, 85% of family physicians knew of ELISA and Western Blot tests. Elementary counseling concepts were known but hardly practiced. Parameters to initiate therapy, drug regimes, drug combinations and patient monitoring are poorly known. About 5% of family physicians attempt ART use, with AZT and 3TC the most frequently used regimen. Monotherapy is also common. Other branches of medical practitioners like internists, chest physicians and dermatologists/ veneriologists also practice HIV medicine, of whom 60% know of HIV/ AIDS drugs and regimens. However, their knowledge of patient selection criteria and monitoring, including CD4 and viral load, is vague, and over 90% are not familiar with salvage therapy[59].

In light of these constraints to providing ART more extensively in the public sector, it becomes apparent that merely lowering the cost of drugs is not the only issue that ensures access to the product. Public health infrastructure, costs of monitoring and adherence levels, better-trained doctors and para-medics and a raft of other issues need to be addressed when businesses attempt to understand the implications of measuring the impact of their activities from a broader economic development perspective.

### 10.9 Prescription auditing

Poor prescription auditing can be one of the biggest threats that brings on resistance. But so far no audits have been done of prescription practices for ARVs in India. In his submission to us, Dr Pujari of Ruby Hall Clinic noted that: “Most cases only come to light when patients change doctors”.

While standard guidelines make it clear that ART can begin only after a patient’s CD4 counts and where possible viral loads have been monitored, some doctors fear that ARV drugs are used like antibiotics. “There appears to be a haste in prescribing anti-retrovirals without appropriate communication with patients about the need for lifelong treatment and risks,” Dr Pujari said[60]. This is also borne out by Dr Deshpande, who speaks of “irrational prescription, irrational combinations and inadequate dosages,” which is a substantial hurdle to appropriate treatment.

### 10.10 Nutrition

Another complication is that it will be impossible to tackle HIV without controlling issues of nutrition, a fact borne out by NGOs working in this area. According to Anjali Gopalan, CEO of the Delhi-based Naz Foundation, “Unless nutritional issues are tackled while administering ART, we are gunning for failure”. This is a potential area for partnerships with pharmaceutical companies like GlaxoSmithKline, which has nutritional products that can be used through a transparent distribution partnership. However,

[59] Vaidya SB, Deshpande AK. “Anti-retrovirals (ARVs) in India – a challenge with two edges.”
[60] Mudur, G. “India must change health priorities to tackle HIV.” *BMJ* 2002 Nov 16; 325 (7373): 1132

as CSM's pharmaceutical sector consultation in April 2004 found out, there is considerable nervousness about working in such partnerships.

### 10.11 Lack of advocacy efforts

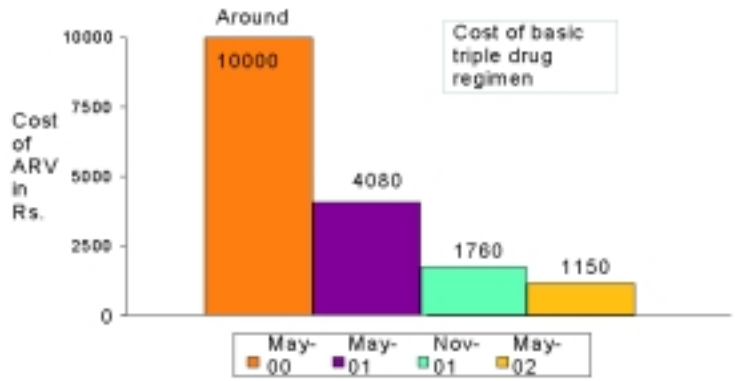
Advocacy is crucial for awareness raising around ARV consumption issues, whether it is a rigid public health programme such as the government ARV programme, or other issues around ARV consumption. Advocacy is needed for both administrators, such as heads of medical colleges (India's public health system has always remained completely separate from the medical education system) as well as politicians (so as not to misinterpret the programme) and the end-user of the medicine itself: the patient whose life depends upon competent provision. In this regard, training PLHAs can prove to be very effective, as they can be a good support group. If they are trained and involved to make ART programmes sustainable with available options and understand the toxicity and side-effects of the medicines, then there are better chances that the efficacy of the present limited options can be sustained[61].

[61] Report on consultation on Corporate Responsibility and Economic Development in India – Pharmaceutical Sector: focus on HIV medication, April 6, 2004. Delhi

## 11. INDIAN ARV PHARMA COMPANIES: AN OVERVIEW

Cipla was the first Indian generic manufacturer to attempt to capture the African market by selling to Uganda in 2000, and subsequently to Medicines Sans Frontieres in 2001. The epidemic being the severest in sub-Saharan Africa, Cipla enjoyed a first mover advantage in ensuring its presence as a supplier in many African countries, as well as in South Asian nations[62]. In India too, this advantage remained with Cipla, where in the beginning, Cipla was the only manufacturer of anti-retrovirals. Prices of international brands came down from around Rs 25,000 to Rs 30,000 in 1997 for a month's supply for a triple drug combination, to about Rs 10,000 in 2000[63] in India.

When Cipla started manufacturing generic ARVs for the Indian market, prices came down even further, to approx Rs 4000 in May 2001, and the number of patients affording the treatment gradually began to rise. This was followed by the launch of ARVs by Genix (subsidiary of Hetero Drugs). In April 2001, Cipla was confronted with competition by the Imunus division of Aurobindo Pharma which entered with more options than other players in the market. Of the big four, Ranbaxy, the number 1 pharmaceutical company in India, was the last to launch its products. With these options competing in the market, prices were revised to more affordable levels[64]. Finally, in February 2002, the Government of India slashed import duties on all ART drugs. This helpful policy decision brought down the prices of drugs to all-time lows. This progression can be traced in the following diagram:




Source: Imunus Aurobindo

In 2001, no industry player knew about the actual size of the market. It was thought to be around Rs 120 crore, on the basis of the sales at the retail level[65]. Owing to the stigma attached to AIDS, however, numbers could be gleaned only from indirect sources[66]. Now though, after successive price revisions,

[62] The MSF website http://www.accessmed-msf.org/ clearly states that generic companies did not always make their internationally publicised prices available at country level. This was the case in Cambodia for most Cipla drugs, which forced the MSF team to import the drugs from the manufacturer.
[63] These were the prevailing price levels of international brands like Glaxo and a few other companies when Cipla came on the scene.
[64] With the entry of competition, Cipla had revised prices downwards thrice in the three consecutive months of May, June and July 2001.
[65] Subbu, R. "Pharma companies bet on African market for their anti-AIDS drugs". *The Hindu*, May 14, 2001.
[66] Ibid

the market stands at approximately Rs 40 crore per annum, with an ARV consumption base of between 20,000 and 25,000 at any given point of time. Cipla has a share of about 70% of the market by virtue of being the first mover, while all the others have 10% each[67]. This does not of course take into account the transactions that companies might have with NGOs or self help groups, which are examples of informal networking.

In terms of overall market potential, the western India markets have the highest value. The average monthly sales of ARVs is approx Rs 60 lakh, giving a yearly return of Rs 7.2 crore. The shares of individual companies in the western India markets are not known. Ranbaxy claims on its website that in 2003, it emerged second in the anti-retrovirals market, while Imunus and Genix Pharma were third and fourth respectively, but it does not publish any figures. On being asked about market share in the questionnaire for this study, Ranbaxy declined to divulge details. (For a clearer idea of the maximum retail price offered by each company [prior to discount], please refer to annex 2.)

Prior to the emergence of domestic competition, Cipla followed a successful marketing model of eliminating all intermediaries and directly liaising with doctors only for distributing its product information and continually updating doctors on the latest medical information. But when Imunus Aurobindo entered the market, its value-addition was a human resources approach of service to doctors and patient, whereby it pioneered the practice of networking with NGOs and like-minded people to trim the distribution channels. This enabled Imunus Aurobindo to carve out a new entry-point and access a new patient base while at the same time drawing down domestic level prices. Subsequently, this model of networking was taken up by other manufacturers as well.

The total number of molecules available for treating HIV in India is 11, and all the companies offer all these options. Initially, Cipla offered 6 options, which expanded with the entry of competition. Cipla is also credited with having introduced a drug cocktail of the existing three-drug combination into a single pill, which reduced the pill burden of the patients. This practice, which is not prevalent in any other part of the world, was tested for bio-equivalence by WHO and approved subsequently. This move has been very successful in India.

Marketing anti-retrovirals is very different from marketing of other pharma products, because of the severe stigma attached to the HIV disease. The product demands a consistent level of after-purchase service, because adherence is critically important in maintaining the sustained well-being of a patient. Pharma companies have to provide extra service to both doctors and patients as part of product servicing, at no extra cost. For example, due to India's poor public health surveillance system and lack of record-keeping capacity at hospitals[68], ARV companies often maintain information about the patients – their regime information, the starting date for the medicines, the due date on which the next course has to start – and give this information service to the doctor whenever required.

[67] Figures provided by Citadel Aurobindo Biotech Ltd

[68] Doctors from government hospitals interviewed by CSM have borne testimony to lack of record keeping facilities. In many government hospitals, there is no computer support for record maintenance.

After-purchase service in HIV care can also extend to informal counseling of the patient. Since a life-long commitment to medication is needed, a relationship of trust may develop between the patient and the representative in say, the positive people's networks. Anecdotal evidence suggests that this is sometimes helpful in ensuring adherence[69].

Timely payments are a problem in this medication segment where the patient's income may be very constrained. Many patients afflicted with the disease are attached to positive people's networks or to NGOs who liaise with the pharma companies on behalf of low or middle-income groups. Often, as in the case of NGOs who subsidise the cost of medicines to the patients from their own resources, there are difficulties in making bulk payments.

The ARVs have a shorter shelf life compared to many other pharma products – only one to one-and-a-half years. An across-the-board practice is to offer deep discounts on the shorter course medicines among these, while they are usable.

These factors, along with a consumer base that has not significantly expanded, make ARVs a low-volume, low return business, which contributes a very small portion to the total domestic earnings as a proportion of the total business of any manufacturer. Given this, these manufacturers have turned more to the export markets, notably sub-Saharan Africa, where they may not have a full corporate presence in all the countries where their medicines are sold. But now, with the domestic market set to expand and the Government of India emerging as the single biggest buyer, market dynamics are likely to undergo some major changes. This makes it all the more necessary to consider the impact of medicines on a community's economic development, and make a case for companies to participate in measuring this impact.

From a consumption perspective, ARVs are a unique product. It is an established fact that a large number of consumers who are HIV positive also belong to the lower income bracket and would benefit greatly if prices of products were lowered. The practice, however, is that if a patient has started using a particular brand of generic medicine, they prefer to adhere to that brand, even if it is not the cheapest available option in the market[70]. For companies that have come to the market after Cipla, their target is to build on a new patient base, keeping price as the prime basis for competition and after purchase service as a value added where possible. And since treatment of this disease is a personalised process which only uses prescription-based medicines, doctors are the key contact points for the generic pharmaceutical manufacturers.

One additional drawback of the existing medical information system to doctors is that physicians may not always gain complete knowledge of the medicine they use to treat patients. Very often the only source of knowledge these physicians have is based on the monographs supplied by the drug companies.

[69] Personal communication with Citadel and Ranbaxy managers in Kolkata

[70] This has been the case with most Cipla medicines, which are most often the highest priced among the existing generic brandnames

These physicians are often unaware of the basic requirements of vital information, technical and socio-economic issues surrounding the initiating of ARV drugs, counselling and guidance on the drugs, the cost, the length of therapy, side effects, the monitoring of treatment and cost of investigations[71]. The detailing given by medical representatives to doctors often do not include any insight regarding parameters on the basis of which treatment has to be started, the issues of adherence, issues of therapy counseling and the issues of long-term follow-up[72].

The WHO, which recognised early on the dangers of irrational use of drugs, has a strategy in place for rational drug use and monitoring. But it is up to the national government and pharma companies in those countries to implement them. Too often, continued education in good prescribing is unavailable. If it is, such education is often dominated by promotional messages from pharmaceutical companies rather than from independent sources. Most prescribers are not trained to evaluate such information critically. This situation is not helped by the increasing blurring of the boundaries between commercial and independent information[73].

Prescribing in the private sector has its own dangers, such as poor knowledge of medicines, little or no training in ARV treatment, and can result in many undesirable outcomes. These include ARV prescription for HAART therapy on proxy, without a baseline test or a CD4 or viral load or now geno-typing for resistance, or bizarre prescriptions like mono therapy of AZT or other strange prescription modalities[74].

Such acts can only speed up the onset of resistance, and drive up the costs of therapy. For example, experience has shown that second-line treatment for malaria may be 50-90 times as expensive as the original drugs, while one year's treatment of multi drug resistant tuberculosis (this is the commonest HIV co-infection) costs US$ 8000 to 12,000, compared with about US$ 40 for the first line of treatment. Rampant and indiscriminate use may not only help drive up the number of resistance cases, but also spread the resistance virus, rendering these life prolonging drugs useless, or even harmful[75]. To avoid this, the training of doctors by pharma companies should be considered essential.

There are also other quality control issues like accurate number of medicines in monthly packs, which may sometimes be missing, and good quality packing, which is a must for these medicines.

The general rules and regulations for companies manufacturing other standard kinds of medicinal products apply here also. But ARVs are a specialty product, and very often, various malpractices are

[71] http://www.procaare.org/

[72] CSM consultation report on *Corporate Responsibility in India in the Pharmaceutical Sector: Focus on HIV Medication*, April 6, 2004, Delhi

[73] World Health Organisation strategy on rational medicinal use. http://www.who.int/medicines/strategy/rational_use/strudmon.shtml

[74] Experiences exchanged by healthcare professionals on the electronic board of Programme for the collaboration against AIDS and related epidemics (Procaare), http://www.procaare.org/. Doctors' responses to the CSM questionnaire also made similar observations.

[75] http://www.procaare.org/

found in this sector such as changing the prescription of patients (not equally true in all parts of India) by the chemists who get a commission from the pharma companies. It has even been alleged that pharma companies have encouraged doctors to sell ART from their clinics[76].

In the light of the government's decision to reach out to a larger cross section of the population in high prevalence states with anti-retroviral therapy, pricing patterns are set to change in the near future. The literature available so far indicates that while there has been a steadily growing body of research on the economic viability of the government providing ART at an international level, studies done in India have been relatively few[77].

In this highly competitive sector, services are an important value added. Such services are in very high demand, considering the socio-economic background of the affected people, and the fact that the role of monitoring is so strong in treatment of the disease. In the light of this specification, this study has chosen three companies for industry best practice studies in India viz Citadel Aurobindo Biotech Ltd. (carved out of Aurobindo Pharma), Ranbaxy Laboratories Ltd and GlaxoSmithKline Pharmaceuticals India Pvt Ltd.

The rationale for studying these three companies is clear. In the light of the available literature, it is clear that Cipla contributed significantly to the international debate about pricing and access to medicines, but a fresh study is unlikely to contribute significantly to existing knowledge. On the other hand, competition from Aurobindo Pharma (now CABL) helped to bring down Cipla's prices in the domestic scenario. At present, Citadel Aurobindo Biotech Ltd offers more competitive prices than Cipla in terms of Maximum Retail Price (MRP). At the same time, Ranbaxy also enjoys a strong presence in the global anti-retroviral market, especially in the poorer countries, and its CR practices merit closer study. In contrast, GSK India is a multinational company that does not have a presence in the Indian ARV market, but has a well-structured CSR policy in place. Internationally, GSK was at the centre of a controversy regarding prices and access to HIV medicines in poor countries and disadvantaged communities.

Of all the three companies approached for case studies with the questionnaire, Citadel Aurobindo Biotech Limited gave the most detailed, considered responses, and was willing to come on board with the maximum information about the markets and the challenges faced by it. In contrast, the response of Ranbaxy, the largest pharma company in India, was the briefest and the company was reluctant to disclose market share details in the anti-AIDS segment.

[76] Doctors' communication to CSM questionnaire.

[77] Mead Over, Peter Heywood, Sudhakar Kurapati, Julian Gold, Indrani Gupta, Abhaya Indrayan, Subhash Hira, Elliot Marseille, Nico Nagelkerke, Arni S R Srinivasa Rao. *Integrating Anti-Retroviral Therapy HIV Prevention in India: Costs and Consequences of Policy Options*. Draft 2 Washington DC: World Bank, March 26, 2003

## CASE STUDY 1 - Citadel Aurobindo Biotech Ltd, Imunus Division

The Imunus division was originally launched as a generics specialty division of Aurobindo Pharma, the largest bulk drug manufacturer in April 2001 in India. This division, along with other specialty divisions Indus and Argus, was hived off into a joint venture called Citadel Aurobindo Biotech Ltd. (CABL) in May 2002. In the same month, Aurobindo Pharma transferred its identified branded formulation lines to Citadel Aurobindo Biotech Limited (CABL) and formed a 50:50 marketing joint venture with Citadel Fine Pharmaceuticals Limited (CFPL). CABL markets products that are under licence from Aurobindo Pharma, a Rs 1000-crore (USD$219 million) player in segments such as semi synthetic penicillins, cephalosporins, antivirals and certain lifestyle disease drugs. It ranks among the top five pharmaceutical companies in India and exports to 70 countries. In 2002-03, the company's profit after tax was Rs 100 crore (USD$22 million). Citadel Aurobindo Biotech Ltd is a privately-owned company. Details about Citadel's ownership, internal structure and governance are unavailable currently.

As is standard practice in India, the pharmaceutical industry only reports on traditional economic performance and environmental impact. Citadel's reporting details are unavailable at present.

The reported turnover of the Imunus division of Citadel is around Rs 4 crore (USD$876,680), or close to 4% of the total turnover. Imunus has a presence in all the four high prevalence-HIV states in South India i.e, Tamil Nadu, Andhra Pradesh, Karnataka and Maharashtra. A profile of the sales of HIV treatments of the Imunus division in three Indian states is as follows:

| State | Average monthly sales (approx in Rs lakh) |
|---|---|
| Andhra Pradesh - High prevalence | 8 (USD$17,533) |
| Tamil Nadu - High prevalence | 8 (USD$17,533) |
| West Bengal - Low prevalence | 2 (USD$4,355) |

### Product range

Imunus was the third company to enter the market after Cipla and Genix Pharma but is credited as the first to have introduced more treatment options at affordable prices. Cipla entered the market with six treatment options. Within nine months of being launched, Imunus had introduced 11 treatment options. Now all the generic manufacturers of anti-retrovirals (ARVs) have all 11 treatment options available to them.

Imunus, while under Aurobindo Pharma, was the first to launch Efavirenz, the once daily Non-nucleoside Reverse Transcriptase Inhibitor (NNRTI) and a Protease Inhibitor (PI) Nelfinavir in August 2001 in the domestic market offering competitive prices compared to international brands. Other domestic companies then followed suit.

In February 2002, while Imunus was still a part of Aurobindo Pharma, the Government of India reduced

excise duty on all anti-HIV drugs. In an attempt to make prices even more affordable, Aurobindo Pharma successfully appealed to the concerned authorities to waive the sales tax at the central and state levels [78].

**Marketing and distribution**

Citadel's strategy has been to offer discounted (not donated) prices to capture volume sales, in bulk to NGOs, and in some states through retail.

Imunus pioneered the concept of service to patient and made efforts to trim distribution channels by reaching out to NGOs and positive people's networks and self help groups (SHGs) directly. It was the first generic manufacturer in India to target the informal sector and this has helped it gain a large customer base. Imunus is the only division among the generic HIV medicine manufacturers to solely deal with HIV products. Its HIV portfolio also includes two drugs for opportunistic infections. Overall, the margins are very low compared to other divisions. While the company has not disclosed the exact financial breakup, it has hinted that some amount of subsidisation from other business areas is required.

In West Bengal, where the purchasing power of patients is especially low compared to other states, partnerships with NGO networks has been essential to gain market share.

The TANSACS Pharmacy, attached to the Tamil Nadu State AIDS Control Society, offers company products at special discounts to patients, which are not available elsewhere in the state. Cipla has offered discounts on two of its products at the pharmacy, while both Citadel and Ranbaxy have given discounts on a range of products.

This distribution model has assured Citadel a steady monthly income and discounts at the pharmacy have been made possible by eliminating the middlemen. Citadel's monthly sales (figures unavailable) have been rising steadily in the process (see annex 5 for drug prices at TANSACS Pharmacy). TANSACS sales increased from Rs 80,000 (USD$1,739) in December 2003 (launched on December 15), to Rs 3.5 lakh (USD$7611) in March 2004. The average sales figure per day is approximately Rs 15,000[79] ($326). Citadel's income from TANSACS Pharmacy is around Rs 2 lakh (USD$4355) a month.

**Diagnostics**

Citadel has been working for a year with four doctors in two cities – Bangalore and Coimbatore – with about 25 patients. Citadel reimburses the cost of the diagnostic test (twice a year) to patients if they take Citadel medicines for six months, from the second diagnostic test onwards. The arrangement appears to be working well. (We have not explored potential treatment distorting effects, nor did we assess the consistency of this against local market regulations but this is clearly an important consideration

[78] Aurobindo Pharma's newsletter *The Aurobindo Times*, February 28, 2002

[79] Personal communication with Deputy director of Tamil Nadu State AIDS Control Society (TANSACS), Dr Palanachamy.

for companies). Selection criteria for doctors are two-fold: they should have genuine concern for patient welfare and they should have a reasonably large base of poor patients.

**Business Drivers**

Citadel has 10% of market share. The company seeks to make up for the low margins by targeting bigger volumes through innovative distribution partnerships and models.

The main challenge facing the company is its financial performance: i.e net sales, costs of production, debt, tax payments, dividend distribution, shareholder value, financial reporting and types of advertising and marketing regulation breaches. In addition, control of greenhouse gas emissions remains a challenge, as do product safety and health and safety of employees.

Aurobindo Pharma, the manufacturer of Imunus' product portfolio, has regulatory approval for manufacturing from US, UK, South Africa and Brazil. During 2000-2002, Aurobindo Pharma undertook a major modernisation of its production facilities to comply with US and European regulations, and in anticipation for intensified competition in global markets. Responsible manufacturing practices were seen as a critical element for global market access.

**Impact of programme**

A majority of the Imunus division's patients are middle-income earners, with a monthly average income of around Rs 6000 (USD$130). In West Bengal, the average monthly income is Rs 2000 (USD$43). In West Bengal, Imunus offers the most competitive prices after discounts, compared to all other generic manufacturers (see annex 3). This is inclusive of sales tax, which raises cost of medicine by 10% and has not been waived in that state. The price of the products varies according to the drugs and combinations prescribed. Treatment cost ranges from around Rs 1200 (USD$26) per month to around Rs 8000 (USD$174) per month depending upon the regimen. In Imunus' experience, the overall monthly sales from a given state depend on affordability, the standard of living, health awareness level of the general public and the willingness of the doctors to take up the medical management of the HIV afflicted, as well as the support extended by the family and the corporate sector.

**Lessons learnt**

Imunus, originally part of Aurobindo Pharma, was hived off along with two other divisions because Aurobindo Pharma found that niche marketing was a challenge as integrating manufacturing and marketing did not make good market sense for the company as a whole. So once Imunus was given the independence to raise its own profits, it shaped its business model on revising pricing and distribution models as the best way to improve market access.

Imunus' strategy of Responsible Competitiveness has been based on its core advantages of **price** and **innovative distribution partnerships** as well as a **well-motivated workforce**. Since inception it has used the slogan "Care for HIV Cause of Imunus". This has proved an important aspect of employee motivation and helped the division achieve its sales targets.

Imunus' **distribution models** have been continually evolving as the price of the HIV medicines continues to be high. The division has also learnt important lessons from its partnerships and models. For example, the division acknowledges that **partnerships** with NGOs have not always been very useful, especially when NGOs default on payments. This has often been the case in the state of West Bengal, and presented a concern as the state capital, Kolkata, happens to be Citadel's largest market. Imunus has therefore resorted to dispensing its products from a retail shop in Kolkata. The shop charges a service charge of 5% on sales, but provides assured payment to the company.

Imunus' **pricing policy** has not dramatically improved its market share. It recognises that since anti-retrovirals will always be prescription products, any company's sales will depend on its ability to liaise with and develop a relationship with doctors.

So far, the company's **modest profit margins** have been sufficient for salaries and overhead costs, but they have hindered better drug promotion efforts and limited the company's ability to deliver more quality education to doctors and patients on drug administration issues. Looking forward, it will be interesting to monitor for how long the company is able to sustain lower prices.

Nonetheless, there is a general absence of good multi-sector partnerships between the pharmaceutical companies, doctors, NGOs and People Living with HIV/ AIDS (PLHAs). As one consequence of this, the cost of medicines has not been driven down sufficiently to truly serve the vast population of afflicted patients.

Sources: Company responses to CSM questionnaire, www.aurobindo.com for annual reports, Report on CSM consultation on Corporate Responsibility and Economic Development in India – Pharmaceutical Sector: Focus on HIV medication, New Delhi, April 6, 2004.

The controversy over access to medicines in sub-Saharan Africa, where HIV/ AIDS has become a pandemic, had the effect of placing Cipla and the international pharmaceutical players on opposite sides. In an issue that had major market share implications for Cipla and other Indian generic manufacturers, 39 multinationals including GlaxoSmithKline unilaterally decided to drop their case against the South African government over the Medicines and Related Substances Control Amendment Act. The multinationals were clearly at the other end of the spectrum in the affordability debate, and their interpretation of what they considered their legitimate Intellectual property rights was pitted against the country's situation where HIV was developing into a major health crisis.

The case study of Glaxo, which does not have any ARV market share in the country but has been present for the last 27 years, illustrates an example of traditional corporate responsibility responses to the HIV situation in India.

**CASE STUDY 2: GlaxoSmithKline Pharmaceuticals Limited**

GlaxoSmithKline Pharmaceuticals Limited is the Indian arm of GSK India, a research-based pharmaceutical giant. GSK in India has a strong presence in vaccines, dermatology, respiratory, anti-infectives and nutritionals.

Other than pharmaceuticals, GSK has two businesses - Agrivet Farm Care (AFC) and Qualigens Fine Chemicals (QFC). AFC is the market leader in the animal health sector with an estimated marketshare of 10%. It has a significant presence in the cattle segment and also markets a range of specialized poultry products. QFC has an estimated market share of 29% in the laboratory chemicals market. It also has a big presence in the Diagnostics business (this does not include diagnostics for HIV). GSK has four manufacturing units in India, located at Thane, Nashik, Mysore and Bangalore. Glaxo's shareholding pattern is: Glaxo Group Limited, 40.93%; Eskaylab Limited UK, 7.90%; insurance companies, financial institutions and banks, 16.27%; UTI, 6.05%; FIIs, NRIs ad OCBs, 2.94%; Mutual Funds, 1.93%; Domestic Companies, 1.39%; Resident Individuals, 22.56%; Share in Transit, 0.03%.

**Description of programmes**

GSK makes its ARVs available at not-for-profit prices in 63 of the world's poorest countries in sub-Saharan Africa, but this does not extend to India.In India, GSK believes that access to medicines is not the only component for care of the HIV positive person. Infrastructure for constant testing i.e monitoring of viral load, treatment of opportunistic infections etc also include a high cost which needs to be looked at. These are as important for managing HIV as is the access to anti-retrovirals.

GSK Pharmaceuticals has a three-pronged strategy in place to deal with the HIV epidemic in India. This includes:
1) Initiatives for the general public including awareness and prevention messages and access to drugs
2) Initiatives with the medical fraternity
3) Initiatives for its own employees through workplace interventions

1) Public awareness initiatives
a) The company's social responsibility unit conducts community outreach programmes for the youth, women and sex workers on the subject of HIV, sexuality and adolescent issues. Eighteen such programmes were conducted during '03, which were attended by over 7600 participants.
b)The company also set up a 24-hour Helpline about HIV in 2000. Since then, the GSK HIV Helpline has handled over 50,000 calls from people who are either HIV positive or wish to avoid contracting the virus. The Helpline has generated a wealth of data on the disease, some aspects of which have been shared with the Union Minister for Health, Government of India.

c) The company also publishes informative books on commonly asked questions on HIV and AIDS in question-answer form. These booklets have been published in eight Indian languages, besides English. Over 3,00,000 copies of these booklets were distributed in 2003 at strategic locations such as food-joints on national highways.

2) Medical fraternity
GSK has helped draft medical communication to the doctors (medical updates for doctors i.e literature), including inputs from overseas experts.

3) Workplace interventions
GSK in India adopted the parent's global policy on HIV/ AIDS in 1995-96. This includes advocacy against testing for HIV status as a pre-requisite for employment, training and awareness programmes for the staff and supporting employees with serious illness, including HIV, by providing special leave with half pay for up to a year and a half and allowing for work adjustment.

**Learnings**
GSK India has concentrated on the philanthropy aspect of dealing with HIV and related problems in India. It has some programmes for donating its nutritional product, Horlicks. The company has not yet evolved a widespread distribution model to reach this product to the patients.

GSK India is positive about the Government of India's (GoI) recent initiative of making ARVs available in government hospitals for free for treating fully developed AIDS cases. GSK was appointed a member of the special task force on HIV of the Ministry of Health, in December 2003. It believes public private partnerships are the only method of better access to treatment, but are in their infancy in India.

Sources: Company response to questionnaire, Enterprises and HIV/ AIDS in India. ILO publication, 2002. GSK Corporate Social Responsibility Report 2002, GSK India website.

Ranbaxy, India's largest pharmaceutical generic giant with a global sales of $1 billion, entered the domestic anti-retroviral market after Cipla and almost simultaneously as Aurobindo Pharma, and at present enjoys a sizeable market share in the export markets.

**CASE STUDY 3 - Ranbaxy Super Specialties Divn, Ranbaxy Laboratories**

Ranbaxy Laboratories is India's largest generic pharmaceutical company with a global sales of USD$1 billion. It is present in 106 countries and has a sizeable market share of India's export profile. The company entered the domestic anti-retroviral market after Cipla and nearly at the same time as Aurobindo Pharma.

Ranbaxy Super Specialties is the division of Ranbaxy Laboratories Limited that sells HIV/ AIDS medicine, along with oncology and nephrology medicines. The company manufactures and markets branded

generic pharmaceuticals, bulk substances and intermediates. Ranbaxy also provides drugs to treat opportunistic infections and diagnostic solutions ranging from screening of HIV to tests for monitoring the infection.

Ranbaxy employs 8000 people worldwide but has not provided a breakdown of the number of staff employed in India. The company's consolidated net profit in 2002 was Rs 6.48 billion ($141 million). Figures for 2003 were not available. Promoters hold 32.06% shares in the company.

Ranbaxy is committed to investing approximately 6% of its global sales in R&D. Between 1996-97 and 2002, the total outlay on R&D was Rs 5.46 billion (USD$118.6 million). HIV medicines are not part of this effort. Ranbaxy earns relatively little from its HIV medicines segment and does not appear to be focused on new product development in this area.

Ranbaxy won its first major international contract for USD$1.8 million from the Ministry of Health, Nigeria in 2001. Registrations have also been made in several countries with a high prevalence of HIV, notably Brazil, Cambodia, Peru and Vietnam. Ranbaxy's HIV products have been approved in 30 countries.

**Reporting and disclosures**

Ranbaxy has one of the most detailed profiles on disclosures in the Indian pharmaceutical sector. Reporting is mainly confined to financial issues. In common with other companies in the sector, Ranbaxy also provides information on its products, R&D projects, environmental performance and inventory.

**Description of Programmes**

**Agreement with Clinton Initiative**

Ranbaxy was part of a number of companies that signed an agreement with the Clinton Initiative in October 2003 to sell drugs to African and Caribbean countries. This initiative would reduce the cost of treatment from 80 cents per person/ day now to 36 to 38 cents per person/ day (USD$140 per person/ year). According to Ranbaxy, approximately 1.5 to 2 million patients are expected to benefit from this programme by 2008. However, there are no plans to offer such special prices in India.

**AIDS Awareness**

Ranbaxy Community Healthcare Society is a non-profit voluntary organisation and a registered society that carries out social initiatives. It has carried out a project funded by the Madhya Pradesh State AIDS Control Society (MPSACS). This was a targeted intervention programme for prevention of HIV/ AIDS among truckers and migrant labourers in the urban slum population of Dewas, Madhya Pradesh, where Ranbaxy has its manufacturing facility.

**Business Drivers & Challenges**

Ranbaxy's packaging method is its Unique Selling Proposition (USP). Medicine is packed in strip and blister packs, which impart stability to the product. The quality of products is thus ensured and the extra packaging cost absorbed.

Ranbaxy is, however, not the most competitive in terms of price. In fact, its prices are the second highest in the market after Cipla. Ranbaxy's website states that it is second in the domestic market in terms of market share, but gives no details. It claims to have performed better than Aurobindo Pharma and Genix Pharma in 2003.

The greatest challenge to the sale of Ranbaxy's products in both India and Africa relates to negative perceptions about the toxicity and side effects of its medications. This fear has frequently led to non-adherence to the regimen required and also boosted the market for alternative cures to HIV. Ranbaxy sees better doctor education programmes as a means of spreading greater awareness among patients on the need to adhere to drug regimens and says it continually carries out such programmes.

**Effect of Programs**

In terms of distribution, Ranbaxy is the only company that has retail licenses at the distribution centres from where the patients collect the medicines. This results in a cost reduction of 25 to 30%. The lowest cost range is Rs 1200 (USD$26). Ranbaxy gave no figures about the highest cost products.

**Lessons Learnt**

Ranbaxy has sought to maintain market share rather than adopt innovative strategies to help bring down prices for needy patients in India. It has focused its efforts on higher-earning, high-value exports, as opposed to price reductions in its own Indian context. In contrast to Citadel, it has not tried to enter into any novel partnership programmes with other stakeholders, or tried to engage them to bring down the cost of medicines to patients. Source: Responses to CSM questionnaire, Ranbaxy annual reports 2001 and 2002; and www.indiainfoline.com/news/news.asp?dat=37680

*The Economic Times* newspaper reported on March 24, 2004 that the Union Finance Ministry has cleared a $1.5 billion soft-loan package to help people affected by HIV/ AIDS in 27 low-income countries. This loan is expected to mean big business for companies like Cipla and Ranbaxy, by helping them seize a 20 to 25% share of the $6 billion-a-year African ARV market. The fund, whose size was finalized by an inter-ministerial group, would be disbursed over the next five years.

While the market implications of such a step are enormous, their impact on not just the financial bottom line but the economic bottom line remains to be seen. The government, having facilitated

both international and domestic market access to its generic manufacturers, is in a very firm driver's seat to ask pharma companies to address crucial issues like pricing, upgrading of health delivery systems and educating the health infrastructure around diagnostics and access to treatment and even nutritional issues. Such efforts will have to be through partnerships, and there is a broad consensus on this issue of partnerships being very necessary.

## 12. CSR ISSUES FOR PHARMA COMPANIES

Our research has underscored that public private partnerships are a must to reduce costs of delivery and ensure wise use of medicines to preserve their efficacy. This is of vital importance given the expected impact of TRIPs on generics as India's thriving generics industry will no longer be able to rely on a lack of law to protect their efforts at generic copying. NACO's ART programme is predicated on strong public-private partnerships, but there is no detail of the whys and wherefores of these partnerships. Partnerships are certainly important in order to bring down the cost of medicines and ensure better drug delivery. But more important, the parameters of these partnerships must be evolved in full public knowledge to ensure that both the pharma companies and the public at large benefit from their success. On the precautionary side, this is needed to prevent irrational use of medicines and onset of resistance.

In all areas, some donor support will be necessary to fulfill the goals that are set for pharma. All major HIV/AIDS donors including the World Bank, Bill and Melinda Gates Foundation, GFATM, DFID, USAID, Centre for Disease Control (CDC), National Institute for Health (NIH), UNDP, Japanese International Agency for Cooperation (JICA), AusAID, CIDA, GTZ and the EU, are present in India.

According to our research, the areas of where partnerships have to be forged include:

### Diagnostics

Diagnostics would include CD4 facilities, viral load monitoring laboratories, laboratories doing biochemical tests for patients, laboratories to monitor the opportunistic infections. In short, diagnostics partnerships are necessary to keep track of the patient's progress once ART treatment has started. At present diagnostics are nearly twice as costly as the medicines that have to be consumed. To better serve the target population, partnerships around the area of diagnostics are a must.

Further infrastructure includes more laboratories and testing facilities for monitoring patient performance equipped with the latest equipment. The state AIDS societies in high prevalence states, together with multilateral donors can encourage companies for a one-time participation in putting these in place. In India, Ranbaxy is the only company that has such a diagnostic facility in place, but many more facilities are needed, especially in high prevalence states. Once such a mechanism is in place in a state, the state AIDS society can together with NACO and the local chambers of commerce participate in a subsidised diagnostic treatment programme for patients.

### Better stakeholder engagement

Companies can together with community-based organisations (CBOs) and even faith-based organisations (FBOs) implement community treatment literacy and preparedness programmes in conjunction with ARV provision and supply. Both men and women need to be addressed separately and sensitively on this issue. But for this, there needs to be greater participation of community and

NGO representatives in advisory structures of pharma companies in relation to the provision of anti-retrovirals. Such a step will likely reduce dropout rates, and improve adherence. It may also help effectively counter the frustration of lifelong consumption of medicine.

**Awareness building**

This is a traditional area of serving the needs of the community that all ARV manufacturers typically seek to do. Primarily, the roles of government and private sector can add value to each other in educating the health infrastructure around diagnostics and access to treatment.

The option of targeting special outreach programmes for women may also be examined for awareness building. Empowerment through knowledge is one of the avowed goals of gender mainstreaming.

Government and pharma manufacturers can also help train PLHAs to oversee the success of the government's ART programme is a sustained manner.

**Private sector practitioners**

While the thrust of ARV activities at present is the public sector, overwhelming evidence exists of the need to involve the private sector practitioners in treating HIV/ AIDS and related diseases. Studies have shown that the majority of healthcare seeking population opt for private sector services, and the private sector is ill-equipped and often reluctant to treat HIV patients. Today, private sector prescribing poses one of the greatest risks in developing drug resistance. But it can be an extremely useful and even influential ally in spreading the reach of treatment. It is well known that this conforms with the goals and targets often set by major international donor agencies.

In 2001, the World Bank commissioned a study carried out by Imunus Aurobindo on those who were practising ART in each state. This helped identify both private and public practitioners. Another round of study is now in order, and the pharma companies through their representatives in various states can be the vehicles to conduct such a study. This can act as a useful data bank and help identify private practitioners. Such practitioners, as well as healthcare workers, can then be trained through public private partnership programmes with multilateral aid agency participation.

None of the above is to suggest that doctors practising in public hospitals should be excluded from training, but pharma companies already sponsor their continuing medical education and the focus now must be on the private sector given its greater use by the public.

**Training**

Regrettably, most of the training programmes conducted by the government are only for government doctors. If private practitioners are sensitised to this problem, there will be a good number of doctors who may be interested. This is another area where pharma companies can contribute. Activities to be taken up should be coordinated between the government, doctors, NGOs, pharma companies and

other like-minded people. The ideal would be to have a team of doctors from various disciplines and they be trained on ART, with proper training in prescribing medicines.

There should also be urgent training programmes for dealers and chemists on HIV medication issues.

**Nutrition**

Pharma companies who manufacture nutritional products as well – for example GlaxoSmithKline – and NGOs can partner on nutritionals. As there are issues of scale involved, big NGOs can partner with pharma for distribution of nutritionals. Partnering with small NGOs is a more difficult task – but if there is a network then this problem can be avoided by linking up with larger NGOs and more comprehensive and integrated care can be provided.

While the partnership areas can be clearly identified, the execution of these programmes will provide indicators of how well companies perform in these areas. Such an assessment is necessary to ascertain whether the goal of providing expanded access to ART is being achieved. For the government, it will mean addressing health sector imperatives, while for the pharma companies, it will mean better outreach to under-served communities and better markets.

## 13 PUBLIC POLICY ENABLERS

Public policy enablers, which are vital for health sector priorities to be met, are a must for the pharmaceutical sector to target traditionally under-served markets. Existing guidelines on anti-retroviral therapy and the ART programme implementation guidelines address the technical aspects of therapy and administration. However, this leaves unattended the crucial issues of partnerships, pricing and sustainability, to ensure the twin objectives of access to low cost treatment and preserving the efficacy of the current regimens used.

For this to happen, a number of steps are in order. These are:

### Procurement policy

The government needs to have a transparent procurement policy in place for buying medicines from the pharma companies. This way, there will be room for offering deep discounts on their products for bulk purchases, and the government will be able to negotiate the best price available.

### Prescription auditing

Prescription auditing for ARVs needs to be in place, to correct the huge amount of ignorance that exists about correct prescriptions for this disease. This has to be accompanied by hands on training for the doctors in treating HIV patients. These will go a long way in ensuring the success of NACO's programme. This can be done with the help of active co-operation from pharma.

### Incentives

The government needs to give incentives to those pharma companies that participate in infrastructure building efforts and partnerships in the area of building up diagnostic facilities. This way, there will be active involvement of pharma in a vital area.

Government may also incentivise responsible marketing of medicines. This is all the more vital in the current settings, for judicious use of the limited options at our disposal. It involves following the Ethical Criteria for Medicinal Drug Promotion as laid out by the World Health Organisation[80], as well as "responsible" marketing practices to reach out to the target community. This needs to be assessed in the context of the stigma attached to both HIV and its medication, as well as confidentiality issues. Responsibility entails supply of accurate unbiased information to the stakeholders on ARV issues. Company responses to the CSM questionnaire show that some of them perceive "responsible" marketing as their strength.

The government should also encourage pharmaceutical companies to have an HIV policy in place.

[80] http://www.who.int/medicines/library/dap/ethical-criteria/ethicalen.shtml

The International Labour Office (ILO) can provide technical help in this regard and the possibilities of mainstreaming a corporate responsibility agenda vis-à-vis HIV should also be explored.

**Doctors training**

Active role of pharma in targetting more private doctors for better training, like the ones available for public sector doctors under NACO programmes, should be encouraged. The training module should be devised on a mutual consultation basis.

**Partnerships**

All of the above points address both partnership and corporate responsibility issues. When these begin to be taken care of, a broad framework can be drawn up against which pharma companies can measure their impact on economic development.

Currently a lot of nervousness exists on all sides about partnerships. We have detected mutual fear and distrust among various stakeholders involved in HIV medication. However, evolving a framework of action that is mutually acceptable to different players is a necessity if the government's current goal of providing low cost access to treatment has to be addressed.

## 14. TOWARDS IMPACT ASSESSMENT: THE ECONOMIC DEVELOPMENT IMPERATIVE

A study on Business and Economic Development conducted by AccountAbility, Business for Social Responsibility and Brody Weiser Burns states that in 1970, 70% of the capital flows to the developing world were from the government sector and 30% were from the private sector. Today, the situation is reversed: 20% are from the government sector and 80% are from the private sector. Accordingly government, civil society and others concerned with economic development at home and abroad are focusing more and more on how corporations affect the economics of the communities they are involved with[81]. In a global economy, the corporate sector is increasingly the predominant driver of economic development and this can have especially profound effects on low-income communities.

Companies, especially those with operations across the globe, are increasingly realising that the economic impact of their activities leads to social and environmental outcomes, and understanding these impacts will enable better management. The more they seek to become accountable not just to their shareholders but also stakeholders the more imperative it will be to understand economic impact.

What does this mean for Indian pharma companies? Indian pharma, including ARV manufacturers, are looking at domestic and global markets to find exciting economic opportunities. While the domestic market is expected to grow in double digits in the near future, the global generic market is expanding rapidly, with an estimated $50 billion worth of drugs going off patent in the next five years[82]. Indian companies have been actively looking at exploiting the international generic market as they enjoy a significant cost and innovation advantage over their peers in the developed world. They are also upgrading their manufacturing practices, quality standards and R&D capabilities to take advantage of expanding their operations across the globe.

Given these circumstances, learning to report on and manage their economic impacts on the markets they serve, especially under-developed markets will not only connect with accountability issues, it will also provide assurance to the investor community about the sustainability of their business in a given geographical territory. This report has found that overall, the reporting activities of companies is very much in the early stages.

In India, CSM has found in the course of its work in the pharmaceutical sector encouraging signs that companies are willing to assess more clearly their economic impacts, but no framework exists at present that will enable this. Once an independent, unbiased tool is in place, much of the current nervousness about partnerships in the HIV sector can be practically addressed and overcome.

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[81] *Business and Economic Development: The Impact of Corporate Responsibility Standards and Practices*. A report by AccountAbility and Business for Social Responsibility

[82] Ranbaxy Annual Report 2001.

## Corporate Responsibility standards

The Global Reporting Initiative adopts the triple bottom line approach of using social, environmental and economic indicators to measure sustainability in business. But as the BED report has found, the economic development aspect is not adequately addressed in this and other initiatives that admit its existence[83]. Some of the other international standards address economic development to some extent, like the Ethical Trading Initiative, the OECD Guidelines for Multinational Enterprises, Sigma and the United Nations Global Compact. But putting in place economic development indicators has not been attempted in a clear manner so far.

[83] The GRI Reporting Principles 2002 state: "While financial performance indicators are well developed, indicators of organisation-level economic performance as described in the previous paragraph are still evolving. The total economic impact of an organisation includes indirect impacts stemming from externalities that create impacts on communities, broadly defined. Externalities are those costs or benefits arising from a transaction that are not fully reflected in the monetary amount of the transaction. A community can be considered as anything from a neighbourhood, to a country, or even a community of interest such as a minority group within a society. Although often complex, indirect impacts are measurable. However, given the diversity of situations facing reporting organisations, GRI has not at this point identified a single, generic set of such indicators. Thus, each organisation should select performance indicators based on its own analysis of the issues.

## 15. MEASURING IMPACT

AccountAbility and BSR have developed the BED framework to help companies measure and manage their impact on community economic development. Termed as the Economic Impact Management Process, it espouses continual performance improvement through innovation and learning. The framework builds on contemporary corporate responsibility standards and links with other existing corporate policies and systems.

The impact management process has a five-step approach, and the key sequential elements are identify risks and opportunities, engage communities, define strategy to improve impact, develop indicators, manage and improve impact.

For Indian pharma, specifically for the HIV segment, direct impact management on the community may not be a feasible option, as there are strong confidentiality issues related to the target population i.e the HIV positive patients themselves. Any attempt by pharma for a direct interface with HIV positive people may draw criticism from the human rights advocates. Here, the economic impact assessment has to be indirect, and look for inputs from other stakeholders like NGOs/ CBOs at community level, doctors, social workers and self-help groups/ positive people's networks who consent to participate.

The steps involved in impact assessment would be:

- Identify the region-wise/ state-wise hurdles to ARV medication, after inputs from stakeholders and internal company staff
- Define strategy to improve reach and impact of ARVs
- Draw up practical steps to correct problem areas
- Assess reach and success of strategy

The practical steps involved would be determined by areas where the companies have a sizeable presence in the market and where they, after stakeholder consultation, would identify hurdles to medication, draw up steps to expand access to medicine and empowerment through awareness generation, devise novel methods and distribution partnerships to target the needy community, and finally improve impact and enhance possible beneficial effects. A good example of this last category would be the experiment of TANSACS Pharmacy, where public-private partnership proved to be a win-win combination in having a beneficial effect on the community.

Other parameters for impact assessment would include level of engagement of stakeholders in awareness generation, and improving the awareness of service providers like doctors and para-medics, who are an integral part of creating a positive impact on the target community.

Impact assessment will essentially remain a need-based corporate responsibility tool. It needs commitment from business to ascertain its success. However, the benefits of such social accounting has direct implications for business, at the community, stakeholder and even financial community level. This is so especially in the light of Indian generic pharma's global ambitions.

## 16. CONCLUSION

The sheer complexity of the pharma sector, and the nature and variety of its impacts on the community, both direct and indirect, pose a daunting challenge in presenting before pharma a case for economic development assessment using the BED model. However, an interesting part of HIV care is that the disease has a strong social aspect to it, and all the stakeholders – care and support NGOs, medical community and pharma companies themselves, have very well carved out social duties required of them in dealing with the disease.

It is unsurprising therefore, that many Indian enterprises like TATA Steel, Bajaj Auto, Mahindra and Mahindra, Employees State Insurance Corporation (ESIC), Larsen & Toubro Ltd, Steel Authority of India Ltd and TATA Tea have detailed workplace policies for HIV/ AIDS. These policies include no mandatory testing either pre-employment or during employment, awareness generation programmes, access to in-house diagnostic facilities, counselling services, condom distribution and so on[84]. There have also been initiatives at the level of the national chambers of commerce like the CII, through the Indian Business Trust for HIV/ AIDS. There have been initiatives by the FICCI Socio Economic Development Foundation, and also local chambers of commerce. The companies mentioned above, have very well structured workplace interventions. There are others who also have HIV policies in place, but just a few names are mentioned. This means that companies are ready and willing to commit resources to deal with HIV as they realise that it will ultimately affect workforce productivity.

The long and rigorous consultative process that the Centre for Social Markets undertook during its research into the pharma sector in India with reference to HIV medication has revealed what difficulty exists in assessing the specifics of economic impact as no framework currently exists for articulating or measuring this. There is however an appreciation by practitioners and users alike of the need for such a framework and transparency in the parameters included. These parameters should include adherence to good manufacturing practices, responsible marketing and drug promotion, better education of doctors, and greater stakeholder engagement at the core of their own decision-making structure on ARV issues. The study has not, however, suggested any specific quantification method.

In a field such as HIV medication where the element of care is so vital, it is not enough just to focus on the financial bottom line but also on the economic bottom line. Here the adoption of an appropriate sustainability framework can yield dividends. One clearly positive outcome of CSM's research and the allied advocacy process has been to affirm that the demand for such a sustainability framework exists and must be responded to[85].

An important aspect accompanying this demand has been the recognition of the centrality of partnerships to any holistic approach to treatment. This has been articulated in terms of product

[84] *Enterprises and HIV/ AIDS in India, 2002*. A publication by the International Labour Organisation
[85] Report on CSM consultation on *Corporate Responsibility and Economic Development in India – Pharmaceutical Sector: focus on HIV medication*, April 6, 2004. Delhi

pricing, improved health infrastructure, awareness-raising and training on HIV-related issues, nutrition and advocacy. Such an approach can help deliver both public health objectives and improve private sector performance. The research also revealed a broad understanding that partnerships themselves need to be evolved after much negotiation, and on the basis of an independent framework, so as to assist pharma companies in more positively managing their economic impact and contributing to overall community and national welfare.

# ANNEXURES

# Annex 1
# ARVs used internationally in the treatment of HIV

| Brand Name | Generic Name | Class of Medicine | Manufacturer Name | Approval Date | Time to Approval |
|---|---|---|---|---|---|
| Agenerase | amprenavir | PI | GlaxoSmithKline | 15-Apr-99 | 6 months |
| Combivir | lamivudine and zidovudine | NRTI | GlaxoSmithKline | 27-Sep-97 | 3.9 months |
| Crixivan | Indinavir, IDV, MK-639 | PI | Merck | 13-Mar-96 | 1.4 months |
| Emtriva | FTC, emtricitabine | NRTI | Gilead Sciences | 02-Jul-03 | 10 months |
| Epivir | lamivudine, 3TC | NRTI | GlaxoSmithKline | 17-Nov-95 | 4.4 months |
| Fortovase | saquinavir | PI | Hoffmann-La Roche | 7-Nov-97 | 5.9 months |
| Fuzeon | enfuvirtide, T-20 | FI | Hoffmann-La Roche & Trimeris | 13-Mar-03 | 6 months |
| Hivid | zalcitabine, ddC, dideoxycytidine | NRTI | Hoffmann-La Roche | 19-Jun-92 | 7.6 months |
| Invirase | saquinavir mesylate, SQV | PI | Hoffmann-La Roche | 6-Dec-95 | 3.2 months |
| Kaletra | lopinavir and ritonavir | PI | Abbott Laboratories | 15-Sep-00 | 3.5 months |
| Lexiva | Fosamprenavir Calcium | PI | GlaxoSmithKline | 20-Oct-03 | 10 months |
| Norvir | ritonavir, ABT-538 | PI | Abbott Laboratories | 1-Mar-96 | 2.3 months |
| Rescriptor | delavirdine, DLV | NNRTI | Pfizer | 4-Apr-97 | 8.7 months |
| Retrovir | zidovudine, AZT, azidothymidine, ZDV | NRTI | GlaxoSmithKline | 19-Mar-87 | 3.5 months |
| Reyataz | atazanavir sulfate | PI | Bristol-Myers Squibb | 20-Jun-03 | 6 months |
| Sustiva | Efavirenz | NNRTI | Bristol-Myers Squibb | 17-Sep-98 | 3.2 months |
| Trizivir | abacavir, zidovudine and lamivudine | NRTI | GlaxoSmithKline | 14-Nov-00 | 10.9 months |
| Videx EC | enteric coated didanosine | NRTI | Bristol-Myers Squibb | 31-Oct-00 | 9 months |
| Videx | didanosine, ddI, dideoxyinosine | NRTI | Bristol-Myers Squibb | 9-Oct-91 | 6 months |
| Viracept | nelfinavir mesylate, NFV | PI | Agouron Pharmaceuticals | 14-Mar-97 | 2.6 months |
| Viramune | nevirapine, BI-RG-587 | NNRTI | Boehringer Ingelheim | 21-Jun-96 | 3.9 months |
| Viread | tenofovir disoproxil fumarate | NtRTI | Gilead | 26-Oct-01 | 5.9 months |
| Zerit | stavudine, d4T | NRTI | Bristol-Myers Squibb | 24-Jun-94 | 5.9 months |
| Ziagen | abacavir | NRTI | GlaxoSmithKline | 17-Dec-98 | 5.8 months |

Source: compiled by Imunus division, Citadel Aurobindo Biotech Ltd

- PI – Protease Inhibitor
- NRTI – Nucleoside Reverse Transcriptase Inhibitor
- NNRTI – Non- Nucleoside Reverse Transcriptase Inhibitor
- FI – Fusion Inhibitor

# Annex 2: Comparative Price Chart of MRP of Generic ARV Drugs in India

(MRP)

| | COMPANY————> | IMUNUS | | | CIPLA | | | RANBAXY | | | GENIX | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| NO. | **COMPOSITION** | **Brand** | **Pack** | **MRP** | **Brand** | **Pack** | **MRP** | **Brand** | **Pack** | **MRP** | **Brand** | **Pack** | **MRP** |
| 1 | Zidovudine 100 mg | Zidovex 100 | 10 | 65.00 | Zidovir 100 | 10 | 77.00 | Viro-Z 100 | 10 | 63.00 | Zido-H 100 | 10 | 65.00 |
| | | N/A | | | Zidovir 100 | 100 | 700.00 | N/A | | | N/A | | |
| 2 | Zidovudine 300 mg | Zidovex 300 | 10 | 160.00 | Zidovir 300 | 10 | 215.00 | Viro-Z 300 | 10 | 160.00 | Zido-H | 10 | 180.00 |
| | | N/A | | | Zidovir 300 | 60 | 1140.00 | N/A | | | N/A | | |
| 3 | Zido 300mg + Lami 150mg | Zidovex L | 10 | 244.00 | Duovir | 10 | 274.00 | Virocomb | 10 | 244.00 | Zidolam | 10 | 198.00 |
| | | Zidovex L | 60 | 1464.00 | Duovir | 60 | 1495.00 | N/A | | | Zidolam | 60 | 1380.00 |
| 4 | Zido 300 + Lami 150 + Nevi 200 | Zidovex LN | 60 | 1816.00 | Duovir N | 30 | 900.00 | N/A | | | Zidolam N | 60 | 1880.00 |
| 5 | Lamivudine 150 mg | Lamivox 150 | 10 | 111.00 | Lamivir 150 | 10 | 117.50 | Virolam 150 | 10 | 101.00 | N/A | | |
| | | N/A | | | Lamivir 150 | 30 | 640.75 | N/A | | | Heptavir-150 | 60 | 635.00 |
| 6 | Stavudine 30 mg | Stavex 30 | 10 | 38.00 | Stavir-40 | 10 | 44.00 | Virostav 30 | 10 | 38.00 | Stag -30 | 10 | 38.00 |
| | | N/A | | | Stavir-30 | 60 | 240.00 | N/A | | | Stag -30 | 60 | 240.00 |
| 7 | Stavudine 40 mg | Stavex 40 | 10 | 45.00 | Stavir 40 | 10 | 49.00 | Virostav 40 | 10 | 43.00 | Stag- 40 | 10 | 43.00 |
| | | N/A | | | Stavir 40 | 60 | 267.00 | N/A | | | Stag- 40 | 60 | 280.00 |
| 8 | Stav30mg + Lami150mg | Stavex 30 L | 60 | 810.00 | Lamivir-S 30 | 60 | 827.65 | Virolis 30 | 10 | 135.00 | Lamistar-30 | 60 | 720.00 |
| 9 | Stav40mg + Lami150mg | N/A | | | Lamivir-S 40 | 60 | 881.00 | Virolis 40 | 10 | 144.00 | Lamistar-40 | 60 | 815.00 |
| 10 | Stav30mg + Lami150 + Nevi 200 | Stavex 30 LN | 30 | 786.00 | Triomune-30 | 30 | 801.00 | N/A | | | Nevilast -30 | 60 | 1385.00 |
| | | N/A | | | | | | Virolans-30 | 10 | 262.00 | N/A | | |

| COMPANY——————> | | IMUNUS | | | CIPLA | | | RANBAXY | | | GENIX | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| NO. | **COMPOSITION** | **Brand** | **Pack** | **MRP** | **Brand** | **Pack** | **MRP** | **Brand** | **Pack** | **MRP** | **Brand** | **Pack** | **MRP** |
| 11 | Stav40mg + Lami150 + Nevi 200 | Stavex 40 LN | 30 | 825.00 | Triomune-40 | 30 | 827.65 | N/A | | | Nevilast -40 | 60 | 1425.00 |
| | | N/A | | | N/A | | | Virolans-40 | 10 | 267.00 | N/A | | |
| 12 | Didanosine100mg | N/A | | | Dinex 100 | 60 | 1200.00 | N/A | | | Dinosin 100 | 60 | 900.00 |
| 13 | Didanosine250mg | N/A | | | Dinex EC 250 | 30 | 1335.00 | Virosin E 250 | 30 | 1250.00 | N/A | | |
| 14 | Didanosine400mg | N/A | | | Dinex EC 400 | 30 | 2130.00 | Virosin E 400 | 30 | 1950.00 | N/A | | |
| 15 | Efavirenz 200mg | Viranz 200 | 30 | 1076.00 | Efavir 200 | 30 | 1076.00 | Eferven 200 | 10 | 358.67 | Estiva 200 | 90 | 2700.00 |
| 16 | Efavirenz 600mg | Viranz 600 | 30 | 2915.00 | Efavir 600 | 30 | 2940.00 | Eferven 600 | 10 | 3000.00 | Estiva 600 | 30 | 2800.00 |
| 17 | Nevirapine 200 mg | Nevirex | 10 | 170.00 | Nevimune | 10 | 195.80 | Nevipan | 4 | 68.00 | Nevivir | 10 | 158.00 |
| | | N/A | | | Nevimune | 60 | 1068.00 | N/A | | | Nevivir | 60 | 890.00 |
| 18 | Indinavir 400mg | Indivex | 30 | 1035.00 | Indivan | 30 | 1076.00 | Virodin | 10 | 345.00 | Indivir | 90 | 3200.00 |
| 19 | Nelfinavir 250mg | Nelvex | 90 | 2520.00 | Nelvir | 100 | 2800.00 | N/A | | | Nelfin | 270 | 7550.00 |
| 20 | Ritonavir 100mg | N/A | | | N/A | | | N/A | | | Ritovir | | |
| 21 | Abacavir 300mg | N/A | | | N/A | | | Virol | 60 | 6500.00 | N/A | | |
| 22 | Abac 300 + Zido300 + Lami150 | N/A | | | N/A | | | Virol-ALZ | 60 | | N/A | | |
| 23 | Dida250 + Lami150 + Efa600 | N/A | | | Odivir 250 | Kit | 150.00 | N/A | | | N/A | | |
| 24 | Dida400 + Lami150 + Efa600 | N/A | | | Odivir 400 | Kit | 180.00 | N/A | | | N/A | | |

Source: Citadel Aurobindo Biotech Ltd

# Annex 3: Comparative Price Chart in West Bengal
# Antiretroviral Drugs

| | COMPANY——————> | IMUNUS | | | CIPLA | | | RANBAXY | | | GENIX | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| NO. | **COMPOSITION** | **Brand** | **Pack** | **MRP** | **Brand** | **Pack** | **MRP** | **Brand** | **Pack** | **MRP** | **Brand** | **Pack** | **MRP** |
| 1 | Zidovudine 100 mg | Zidovex 100 | 10 | 46 | Zidovir 100 | 10 | 66 | Viro-Z 100 | 10 | 52 | Zido-H 100 | 10 | 60 |
| 2 | Zidovudine 300 mg | Zidovex 300 | 10 | 115 | Zidovir 300 | 10 | 184 | Viro-Z 300 | 10 | 127 | Zido-H | 10 | 166 |
| 3 | Zido 300mg + Lami 150mg | Zidovex L | 10 | 185 | Duovir | 10 | 234 | Virocomb | 10 | 196 | Zidolam | 10 | 183 |
| | | | | | Duovir | 60 | 1270 | | | | | | |
| 4 | Zido 300 + Lami 150 + Nevi 200 | Zidovex LN | 60 | 1450 | Duovir N | 30 | 765 | N/A | | | Zidolam N | 60 | 1734 |
| | | | | | Duovir N | 60 | 1530 | | | | | | |
| 5 | Lamivudine 150 mg | Lamivox 150 | 10 | 80 | Lamivir 150 | 10 | | Virolam 150 | 10 | 88 | Heptavir-150 | 60 | 120 |
| 6 | Stavudine 30 mg | Stavex 30 | 10 | 29 | Stavir-30 | 10 | 40 | Virostav 30 | 10 | 32 | Stag -30 | 10 | 46 |
| 7 | Stavudine 40 mg | Stavex 40 | 10 | 33 | Stavir 40 | 10 | 44 | Virostav 40 | 10 | 34 | Stag- 40 | 10 | 51 |
| 8 | Stav30mg + Lami150 | Stavex 30 L | 60 | 600 | Lamivir-S 30 | 60 | 707 | Virolis 30 | 10 | 110 | Lamistar-30 | 60 | 664 |
| 9 | Stav40mg + Lami150 | Stavex 40 L | 30 | 300 | | | | Virolis 40 | 10 | 117 | | | |
| | | Stavex 40 L | 30 | 600 | Lamivir-S 40 | 60 | 749 | Virolis 40 | 60 | 702 | Lamistar-40 | 60 | 693 |
| 10 | Stav30mg + Lami150 + Nevi 200 | Stavex 30 LN | 30 | 580 | Triomune-30 | 30 | 682 | Virolans-30 | 10 | 208 | Nevilast -30 | 60 | 1280 |
| 11 | Stav40mg + Lami150 + Nevi 200 | Stavex 40 LN | 30 | 640 | Triomune-40 | 30 | 705 | Virolans-40 | 10 | 219 | Nevilast -40 | 60 | 1315 |
| 12 | Didanisine100mg | N/A | | | Dinex 100 | 60 | 1000 | N/A | | | Dinosin 100 | 60 | 830 |
| 13 | Didanisine250mg | N/A | | | Dinex EC 250 | 30 | 1134 | Virosin E 250 | 30 | 1029 | N/A | | |
| 14 | Didanisine400mg | N/A | | | Dinex EC 400 | 30 | 1810 | Virosin E 400 | 30 | 1547 | N/A | | |
| 15 | Efavirenz 200mg | Viranz 200 | 30 | 790 | Efavir 200 | 30 | 858 | Eferven 200 | 10 | 289 | Estiva 200 | 90 | 2490 |
| 16 | Efavirenz 600mg | Viranz 600 | 30 | 2200 | Efavir 600 | 30 | 2500 | Eferven 600 | 10 | 784 | Estiva 600 | 30 | 2674 |
| 17 | Nevirapine 200 mg | Nevirex | 10 | 130 | Nevimune | 10 | 167 | Nevipan | 4 | 56 | Nevivir | 10 | 146 |
| 18 | Indinavir 400mg | Indivex | 30 | 745 | Indivan | 30 | 858 | Virodin | 10 | 275 | Indivir | 90 | 2950 |
| 19 | Nelfinavir 250mg | Nelvex | 90 | 1803 | Nelvir | 100 | 2379 | N/A | 10 | | Nelfin | 270 | 6963 |

N B: For Stavex 30/ 40 dosages, Imunus, Cipla and Ranbaxy do not have 60s pack

Source: Personal collection of Soumen Bhattacharjee, Regional Manager, Imunus Division, Citadel Aurobindo Biotech Ltd

# Annex 4: Prices of International Brands

| No. | Class | Composition | Brand | Manufacturer | Pack | Price | Dose |
|---|---|---|---|---|---|---|---|
| 1 | | Zidovudine 100mg | RETROVIR 100 | GLAXO WELLCOME | 100 | 2000 | 2 TID |
| 2 | | Zidovudine 300mg | RETROVIR 300 | GLAXO WELLCOME | 60 | 4200 | 1 BID |
| 3 | | Lamivudine 150mg | EPIVIR 150 | GLAXO WELLCOME | 60 | 2100 | 1 BID |
| 4 | NRTI's | Stavudine 30mg / 40mg | ZERIT 30 / 40 | BRISTOL - MYERS SQUIBB | N/A | N/A | 1 BID |
| 5 | | Abacavir 300mg | ZIAGEN | GLAXO WELLCOME | 60 | 8100 | 1 BID |
| 6 | | Didanosine 100mg | VIDEX 100 | BRISTOL - MYERS SQUIBB | 60 | 3500 | 2 BID |
| 7 | | Zalcitabine 0.75mg | HIVID | HOFFMANN - LA ROCHE | 100 | 5100 | 1 TID |
| 8 | | Nevirapine 200mg | VIRAMUNE | ROXANE / BOERHINGER - INGLEHEIM | 60 | 5500 | 1 BID |
| 9 | NNRTI's | Efavirenz 200mg | SUSTIVA 200 | DUPONT PHARMACEUTICALS | 90 | 5100 | 3 OD |
| 10 | | Delavirdine 100mg | RESCRIPTOR | PHARMACIA & UPJOHN | N/A | N/A | 4 TID |
| 11 | | Nelfinavir 250mg | VIRACEPT | HOFFMANN - LA ROCHE / AGUORON | 270 | 11500 | 3 TID/ 5 BID |
| 12 | | Indinavir 400mg | CRIXIVAN | MERCK INC | 180 | 8900 | 2 TID |
| 13 | | Ritonavir 100mg | NORVIR | ABBOTT LABORATORIES | 84 | 8001 | 6 BID |
| 14 | PI's | Saquinavir Soft Gel 200mg | FORTOVASE | HOFFMANN - LA ROCHE | 180 | 4444 | 6 TID |
| 15 | | Saquinavir Hard Gel 200mg | INVIRASE | HOFFMANN - LA ROCHE | 120 | 14500 | 2 BID WITH RTV |
| 16 | | Amprenavir 150mg | AGENERASE | GLAXO WELLCOME | N/A | N/A | 8 BID |
| 17 | | Lopinavir (ABT 378+Ritonavir) | KALETRA | ABBOTT LABORATORIES | 180 | 24500 | 1 BID |
| 18 | 2NRTI'S | AZT + 3TC | COMBIVIR | GLAXO WELLCOME | 60 | 4900 | 1 BID |
| 19 | 3NRTI'S | AZT + 3TC + Abacavir | TRIZIVIR | GLAXO WELLCOME | N/A | N/A | 1 BID |
| 20 | NRTI'S | Tenofovir + DF 300mg | N/A | GILEAD SCIENCES | N/A | N/A | 1 OD |

# Annex 5: ART Drugs at TANSACS Pharmacy

| Name of Company | Name of drug | MPR rate Rs/month | Discount (%) |
|---|---|---|---|
| Citadel Aurobindo Biotech Limited | | | |
| | Stavex 30 LN | 1572.00 | 41.5 |
| | Stavex 40 LN | 1650.00 | 41.2 |
| | Stavex 30 L | 810.60 | 45 |
| | Stavex 40 L | 870.00 | 43.5 |
| | Zidovex L | 1464.00 | 34.4 |
| | Zidovex LN | 1816.00 | 30 |
| | Viranz 600 | 2915.00 | 35 |
| | Nevirex | 510.00 | 40 |
| | Indivex | 6210.00 | 40 |
| | Nelvex | 7560.00 | 30 |
| | Viranz 200 | 3228.00 | 35 |
| | Zidovex 100 | 1170.00 | 30 |
| | Zidovex 300 | 960.00 | 30 |
| | Lamivox 150 | 666.00 | 45 |
| Ranbaxy | | | |
| | Virocomb | 1464.00 | 28 |
| | Nevipan | 1020.00 | 28 |
| | Virodin | 6210.00 | 28 |
| | Virolans 30 mg | 1572.00 | 28 |
| | Virolans 40 mg | 1602.00 | 28 |
| | Virolis 30 mg | 810.00 | 28 |
| | Virolis 40 mg | 864.00 | 28 |
| | Virosine 250 mg | 1250.00 | 28 |
| | Virosine 400 mg | 1950.00 | 28 |
| | Efferven 200 mg | 3228.00 | 28 |
| | Efferven 600 mg | 3000.00 | 28 |
| | Virol | 6500.00 | 28 |
| | Virol ALZ | 7800.00 | 28 |
| Cipla Supra Care | | | |
| | Duovir N | 1800.00 | 22.72 |
| | Triomune 30 | 1602.00 | 39 |

Source: Citadel Aurobindo Biotech Ltd

# PHARMA MEETING REPORT

**CSM BUSINESS & ECONOMIC DEVELOPMENT SEMINARS**

THE PHARMACEUTICAL INDUSTRY, CORPORATE RESPONSIBILITY & ECONOMIC DEVELOPMENT IN INDIA

***Presentation of Results of CSM Research Project***

In association with AccountAbility & Business for Social Responsibility

TUESDAY, 6 APRIL 2004
INDIA HABITAT CENTRE
NEW DELHI

## 1. BACKGROUND AND OBJECTIVES

This meeting was organised by the UK- and India-based **Centre for Social Markets** (CSM) to share the preliminary findings of research we conducted on the subject in association with the UK-based Institute for Social & Ethical Accountability (**AccountAbility**) and the US-based **Business for Social Responsibility** (BSR). The meeting programme is attached. (Details on CSM's research activities can be found on our website: www.csmworld.org )

The meeting was an invitation-only event bringing together a small group of experts and practitioners active in the pharmaceutical sector with a particular interest in HIV medicines for the poorest segment of the sero-positive population.

The meeting's objectives were as follows:

1. publicise the **findings** of CSM's research with a small peer group;
2. invite **feedback** from the peer group on the report to flag areas for further improvement;
3. discuss a possible **advocacy** strategy to take forward some of the recommendations contained in the report – particularly with the industry in question – in both the Indian and, where relevant, the international context; and
4. identify **next steps** – ideally in partnership with participating organisations.

## 2. SUMMARY OF MEETING & DISCUSSANTS PRESENTATIONS

In his introduction to the meeting, Chair Mr Julian Parr (Project Manager, BBC World Service Trust), made the point that no single segment of society could deal with HIV by itself. Partnerships among the various different players were needed to deal with the epidemic with its enormous socio-economic

and health impacts. However, experience has shown that it is very difficult to demonstrate to companies that they should consider the economic impacts of their business activities and not just their environmental and social impacts on effected populations. This report summarises the presentations made by discussants and the key points raised at the meeting.

**Discussant 1: Dr P Salil, Joint Director (Blood safety) National AIDS Control Organisation (NACO).** (Dr Salil also looks after the epidemiological aspect of HIV issues.)

Dr Salil agreed that partnerships are very important and that no party can go it alone. In fact, this was the pervasive sentiment in the seminar that partnerships are the key. Dr Salil noted that anti-retrovirals are not needed by the entire HIV population, but only by 10-15 percent. A major challenge is delivering to this population and partnerships are essential for this task. By and large, however, India remains an overall low prevalence country, with an adult prevalence rate of 0.8%, and the thrust of the NACO programme will thus always be prevention.

Response to the report:

***A) HIV estimates***: The report mentions that India's HIV estimates are based on sentinel surveillance data collected from public sites only. This, Dr Salil said was a comparable methodology with that of Center for Disease Control (CDC), which first reported the occurrence of this disease in 1981 – though CDC has a subset of non-public sites, it is the public sites that contribute to sentinel surveillance and then onto estimates of those that are infected. So if one is looking at countries and continents, then the NACO methodology is comparable. This has no significant implications for state level estimates, and the learnings that can be derived about market size by pharma companies at the state level are easily calculable from state-level data.

NB: Feedback from pharma company Citadel Aurobindo Biotech Ltd counters this view, stating that the state level estimates and their implications are more important not only in terms of the commercial aspect but also in terms of measuring the effect of the so called activities taken up by various state agencies, NGOs and others who are supposed to act in the area of awareness and care. Therefore information should always be extrapolated from micro to macro.

***B) Diagnostics***: This will be the most important area of intervention in the days ahead. HIV cannot be treated without monitoring, and expanding the lab facilities through public private partnerships is very very important – NACO is working with Confederation of Indian Industry (CII) in this direction, towards establishing diagnostics facilities.

***C) Tools of measurement***: Tools of measuring impact are very necessary, though it is beyond the scope of this research. They should be made available to the pharma sector for them to measure

the impact of their business on economic development. These tools are important if we have to carry the research further, and it would be appropriate to have such a tool in place.

**Discussant 2: Prof Dr Alaka K Deshpande, AIDS specialist. Head, Dept of Medicine, Grant Medical College and Sir J J Gr. Of Hospitals, Mumbai.** (Dr Deshpande is also a Padmashri awardee - one of the highest civilian honours given by the President of India)

***A) Monitoring***: It is important to monitor biochemical parameters, CD4 and viral load, as well as resistance, and more labs of good quality facilities are needed for biochemical tests, CD4 and resistance in patients initiated on antiretroviral therapy (ART). This is an area that needs active participation from pharma again. Also, there are western countries that have low-cost diagnostic facilities in place and are interested in collaborating with NACO, our government needs to partner with them for a successful monitoring set-up in our country.

***B) Limited options***: Both Prof Deshpande and Dr Salil agreed that limited options (only 11 molecules) are a problem. Since additional ART drugs will not be available for generic copying, and existing molecules will soon become out-of-use, there is a real danger of the grey market for drugs springing up, if these additional drugs are not easily available. Also, there will be no room for quality control. Even NACO will face problems in procuring and supplying these second-line, expensive drugs, which may have to be imported, Dr Salil pointed out. So wise use of existing drugs is important.

C) ***Therapy centers***: One way of encouraging wise use is by opening up therapy centers as done in done in Brazil. As with diagnostics, this is a key area that needs partnerships between govt and pharma. Without successful therapy counselling, efforts to scale up ART will fail.

D) ***Training of doctors***: This was a very hotly debated point at the meeting. By and large, the doctors' trainings conducted by pharma companies are of poor quality and it was agreed that there is a need to improve partnerships in this area. However, there was a point of dissension as NACO and pharma (Citadel and Glaxo) had diametrically opposing views on this. NACO was not ready to involve doctors at an early stage of deliberations on scale-up issues, while pharma companies thought that since the treatment is so heavily dependent on doctors, they should be involved early on. For HIV, a team of doctors rather than only physicians needs to be trained to scale up treatment.

NB: Pharma-sponsored medical trainings are a key concern. The quality of medical information imparted in such trainings, the resources they involve, and the lack of follow-up and outcomes are issues that the pharma sector needs to be aware of and guard against poor practice.

E) ***Prescription auditing***: This keeps a check on doctors for prescribing medicines in wrong dosages, and also keeps pharma companies under pressure to supply complete information about medicines

to doctors. This includes parameters such as the basis on which treatment has to be started, issues of adherence, therapy counselling and long-term follow-up.

F) ***Prioritisation***: The order of priority for treatment in NACO's free-ART to those in need in the high prevalence states is paediatric HIV, pregnant mothers and then full-blown AIDS cases. It should have actually been the reverse. Of course, this was a political decision.

G) ***Resistance***: CSM's draft report mentioned that in YR Gaitonde for AIDS Research and Care, a medical NGO in Chennai has seen roughly 20% resistance in its patients. Dr Deshpande (who is from the state of Maharashtra, which has the highest number of HIV + people in any single state) contradicted this, saying the % is very high – not too many people in India take anti-retroviral therapy (ART) and this cannot be true.

## 3. GENERAL POINTS RAISED

Other general points that emerged out of general discussion

A) ***Nutrition***: Anjali Gopalan of Naz Foundation (NGO) pointed out, without addressing nutrition issues, we are gunning for failure. In fact, this is an area where GlaxoSmithKline has a role to play as it is strong on nutritionals. The nervousness was about partnerships with NGOs. The meeting pointed out that once this partnering issue was sorted out, much more could be done in the area of nutrition.

B) ***HIV policy***: The International Labour Office (ILO) representative pointed out that HIV policy by pharma companies would help a great deal in building confidence in them. A better conversation between pharma and the general private sector on HIV issues and assistance in HIV treatment programmes in their respective organizations would be of help. For this, technical help was required, possibly by a body like ILO, to dispel some of the mistrust that existed, and help build up partnerships.

C) ***Insurance***: An area less discussed, but felt to be very important. Julian Parr pointed out during the wrap-up that some health insurance programmes in HIV were in place in Thailand, but none in India. But the insurance sector thinks that there would be lots of problems with definitions etc.

D) ***The Stock Exchange, Mumbai (BSE)***. Point of information: BSE has recently set up a CSR dept, and is putting together a CSR Policy in place, with help from Business and Community Foundation. In South Africa the Johannesburg Stock Exchange requires its members to have an HIV Policy in place.

## Report from Breakout Sessions:

There were two groups, both of which had the same set of three questions. For convenience sake, the answers have been clubbed into one whole of three questions and three answers.

The key questions/ challenges discussed at the meeting were as follows:

1) What should be done to enable pharma to target communities more successfully? What is the contribution of other stakeholders in this process?

2) How should other stakeholders build partnerships with pharma to address the issue of affordable pricing?

3) What is the role of public policy in creating an enabling environment for pharma and other stakeholders to bring down the cost to patients? Can there be a mechanism in place to measure the performance of the pharma sector in this area?

The primary responses to these questions can be summarised as follows:

A) ***Partnerships:*** There is much nervousness about partnerships between government & NGOs, between pharma & government and between pharma & NGOs, though the government's ARV programme is predicated on strong public private partnerships. Till now, partnerships have been forged on an informal basis only.

B) ***Role of NACO and public policy***: The National AIDS Control Organisation (NACO) is in a very good position to ask the pharma sector to address CSR issues while expanding ART coverage. Much remains to be done in this area, however, with special attention needed for resource-constrained situations. NACO has not explored much the prospect of partnerships on low-cost diagnostics – ART becomes far more possible in resource-constrained settings with low-cost diagnostics – and this could be an area for improvement.

C) ***Pricing:*** The more the burden on pharma to solely carry out training programmes for doctors and representatives, diagnostic management and even nutrition management, the more the effect on pricing. Partnerships need skilful management – especially with reference to monitoring and nutrition issues – and the challenge is how to dispel the existing nervousness among various stakeholders.

No tool to measure the performance of pharma in this area exists, but the good thing is that both the NACO representative and a pharma representative said that they were interested to see a tool in place.

## 4. CONCLUSIONS AND NEXT STEPS

The meeting concluded that as the example of Brazil shows, it is possible to manage with limited options (going by WHO guidelines) in resource-constrained settings. The pharma sector can play a much more effective role in the fight against HIV/AIDS with better partnerships with civil and other partners and adequate administrative and public policy support.

CSM's final research report will incorporate the above points raised at the consultation and suggest practical next steps to progress efforts in this area.

For more information, please contact:
Ms Dhruba Das Gupta
Researcher, CSM
Email: dhruba@csmworld.org

# PROGRAMME

**CHAIR:** Mr Julian Parr, Project Manager, BBC World Service Trust

| | | |
|---|---|---|
| 8.30 – 9.15 | Coffee & Registration | |
| 9.15 – 9.30 | Welcome & opening remarks | Mr Julian Parr, BBC World Service Trust & CSM Advisor |
| 9:30 – 9:45 | Introduction to overall research project on Business and Economic Development | Ms Helen Campbell<br>Overall Project Manager and<br>Senior Researcher, AccountAbility |
| 9.45 – 10.15 | Introduction to research & key findings | Ms Dhruba Das Gupta, CSM Researcher |
| 10.15 – 11.15 | Response by 2 expert discussants followed by open discussion | Dr P Salil, Joint Director (Blood Safety), National AIDS Control Organisation (NACO)<br><br>Dr Alaka Deshpande, Head, Dept of Medicine, Grant Medical College & JJ Group of Hospitals |
| 11.15 – 11.30 | Coffee/tea | |
| 11.30 – 12.45 | Break out sessions to discuss specific areas covered by report<br>§ Measuring Business Impact<br>§ Recommendations & Advocacy | |
| 12.45 – 13:15 | Report back by rapporteurs | |
| 13.15 – 13.45 | Discussion | |
| 13.45 – 14:00 | Concluding remarks | Mr Julian Parr, BBC World Service Trust & CSM Advisor |
| 14.00 – 14.30 | Lunch | |

**UK OFFICE :**

**Centre for Social Markets**
1, Trafalgar Avenue
London Se15 6NP
Tel/Fax: +44-20-7231 3457

**UK OFFICE :**

**Centre for Social Markets**
39, Hindusthan Park, Kolkata-700 029
Tel: +91-33-2465 5898, 2465 5711/12/13
Fax: +91-33-2465 5650