International Treatment Preparedness Coalition

ITPC

World CAB 4

Community Advisory Board
Meeting with the Indian Generic Drugs Industry

New Delhi, India
April 23–24, 2008

World CAB: Community Advisory Board
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Snehansu Bhaduri	AHF India Cares
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Industry Participants

Aurobindo	Sharadd Jain, General Manager, Formulation International Marketing
Matrix	Anirudh Deshpande, Vice President, Business Development
Ranbaxy	Arun Kumar Purohit, Vice President and Head, Global Therapy Management
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ITPC World Cab 4: Foreword

In April 2008, twenty-five treatment activists from sixteen countries met in Delhi, India, with representatives of three Indian manufacturers of generic antiretroviral (ARV) drugs. The Indian generic drug industry is a major supplier of affordable ARVs to treatment programs in Africa, and their impact has facilitated placing nearly two million people on lifesaving treatment.

This is the fourth World Community Advisory Board (World CAB) meeting sponsored by the International Treatment Preparedness Coalition (ITPC).

So much has changed since 2004, when ITPC decided to bring activists from all regions of the world to sit down with drug companies at the first World CAB meeting in San Francisco. Treatment activists in the United States and Western Europe have been meeting with pharmaceutical companies for more than two decades to discuss drug pricing, clinical research and clinical trials, drug development, and drug approval. The San Francisco World CAB was the first time people living with HIV and their advocates from Africa, Asia, Eastern Europe, South and Central America, the Caribbean, North America, and Western Europe came together in one place with industry to make this conversation between the community and industry truly global.

The first World CAB was historic. It was a contentious meeting on drug pricing with Roche, GlaxoSmithKline, and Boehringer Ingelheim. Many of the participants had never met each other before and most had never met with high-level drug company executives. We've had two more World CAB meetings since then with generic manufacturers in Mumbai in 2005 and with brand-name companies again in 2006, until the fourth World CAB this year, 2008, with Matrix, Aurobindo, and Ranbaxy in New Delhi.

What was striking from our meeting in India this year is how far we've come as a community. The group assembled in New Delhi had more experience and expertise than that first group that met four years ago in San Francisco, as shown by the sophistication of the discussions and the debate among ourselves and with the companies. We've also made tremendous progress in expanding access to treatment—this year the World Health Organization is set to announce that approximately three million people in resource-poor countries are on antiretroviral therapy (ART). Though three years late—the WHO had set a target of three million people on treatment by 2005—this is a success, particularly when only a few years ago some said that provision of ART in developing countries couldn't be done at all.

You'll see from the report from World CAB 4 that there are many challenges ahead in terms of access to better first- and second-line therapies, difficulties in drug registration, lingering high prices on key medicines, and patent and trade barriers.

However, we face greater challenges in 2008. The consensus that people with HIV and their advocates helped to forge in the late 1990s, which put access to AIDS treatment for people in the developing world high on the global agenda, is being chipped away by people pitting HIV prevention against treatment, and AIDS against other health conditions and diseases. We need to keep our focus and build a stronger movement so that the gains we've made are not reversed. We say the choice is not between HIV prevention or treatment; there is no contest between care for AIDS . . . or TB . . . or diarrheal disease . . . or any other pressing health need. It's all those AND more. What we demand is comprehensive health care for all who need it around the world.

Gregg Gonsalves
Cape Town, South Africa
May 2008

ITPC World CAB 4
Generic Drugs & Universal Access

Achieving the goal of universal access to antiretroviral drugs throughout the world by 2010 will depend on vastly increasing supplies of drugs made available at significantly lower prices than are now offered. The Indian generic pharmaceutical industry is responding to this demand yet faces challenges from inefficient regulatory systems at the country level, looming patent law restrictions in India, tightenting trade barriers around the world, and shrinking margins as ARVs become commodities.

Background

More than 25 million people around the world are living with HIV, with an additional four million becoming newly infected each year. In low-and middle-income countries, more than five million people living with HIV/AIDS (PLWHA) are now in urgent need of antiretroviral therapy (ART), and more than three million of these individuals have no access to HIV treatment. In Asia and the Pacific only 19 percent of people who need ARV treatment are receiving it, with access rates even worse in some African countries.

Global HIV treatment access is increasing rapidly. Each year, the World Health Organization (WHO) estimates that an additional 600,000 people gain access to first-line ART. However, as the HIV epidemic accelerates and matures, millions of additional people will need treatment, and tens of thousands who are currently on treatment but experiencing drug resistance now require access to second- and third-line regimens.

There is an urgent need for PLWHA leaders and advocates to engage in the process of drug development and access, from research on new agents all the way to the point where pills appear in clinics, hospitals, and pharmacies. This means PLWHA and advocates must know about clinical trials, pharmacology, medicinal chemistry, intellectual property, drug pricing, procurement, tariffs and duties, supply chain management, and more. Armed with this knowledge, PLWHA and advocates must engage with pharmaceutical companies, researchers, national health and trade officials, and UN agency representatives to ensure that communities gain access to the drugs they need to save their lives. The past decade has provided a valuable lesson: that despite the presence of good people and good intentions within some national governments, multinational organizations, pharmaceutical companies, and global philanthropy, advances in global access to treatment must frequently be driven by the advocacy of PLWHA and advocates. Training is needed, therefore, to ensure that PLWHA have accurate information about the forward-looking challenges and opportunities for treatment access in their countries and communities. A core mission of ITPC is to ensure that HIV-positive individuals and their healthcare providers and advocates have a high degree of treatment literacy and are empowered in their interactions with the health care system and in their decision making related to health and HIV treatment, and that all who need treatment are able to access it in affordable manner.

To facilitate this global training and advocacy, ITPC established the World Community Advisory Board (World CAB) in 2004 to meet with multinational and generic drug companies on issues of access, affordability and availability of AIDS drugs and clinical research on new agents. World CAB has convened four times since its inception, from its first meeting with brand-name pharmaceutical companies in February 2004, to the second with generic manufacturers of AIDS drugs in January 2005, to the third with brand-name makers again in 2006.

World CAB 4 was divided into two sessions. The first session focused on capacity development and training of PLWHA leaders and treatment advocates from around the world on second-line ARV access. This involved learning about the drugs and factors that influence access to these agents, including trade, health, and local drug pricing.

The second session of World CAB 4 was a meeting with generic pharmaceutical companies Aurobindo, Matrix, and Ranbaxy. The meeting provided a platform for initiating a dialogue between global treatment activists and generic companies on achieving universal access to AIDS drugs by 2010 and the Millennium Development Goal of halting and beginning to reverse the spread of HIV/AIDS by 2015. Key to this dialogue was a discussion about the role of generic drugs in expanding and sustaining AIDS treatment over the long term and the threats to generic drug access.

Antiretroviral Drug Access
Then and Now

What has happened to the cost and availability of HIV drugs in low- and middle-income countries between the World CAB meeting in January 2005 and the meeting in April 2008?

	2005	2008
Cost of first-line regimen per year (NVP/d4T/3TC)[1]	$159	$99
Cost per year of EFV/TDF/3TC[2]	$780	$350
Role of tenofovir in WHO guidelines	Tenofovir reserved for second-line therapy	Tenofovir preferred for first-line therapy
Number of people on ARV treatment in low- and middle-income countries	970,000	2–2.8 million
Number on second-line treatment	<40,000	<200,000
Number of WHO prequalified ARVs	50	120
Number of FDA approved ARVs	1	66
Number of FDA approved pediatric formulations	0	9
Number of ARVs on the market in the U.S.	25	30

[1] nevirapine/stavudine/lamivudine
[2] efavirenz/tenofovir/lamivudine

In April 2008, twenty-five treatment activists from sixteen countries met in New Delhi, India with representatives of three Indian manufacturers of generic antiretroviral (ARV) drugs. The Indian generic drug industry is a major supplier of affordable ARVs to HIV treatment programs in Africa, and their impact has facilitated placing nearly two million people on lifesaving treatment.

Aurobindo and **Matrix** are both producers of bulk quantities of ARVs and are relatively new to the production of finished formulations. **Ranbaxy** does not manufacture bulk drugs, but purchases bulk supply from Matrix and produces a wide range of individual and combination drug tablets.

Despite success with stavudine- and nevirapine-based drug regimens, international treatment guidelines now call for a switch to newer, safer drugs. But these drugs, such as tenofovir and efavirenz, are more costly to make and deliver. Second-line drugs—for use when resistance has rendered first-line choices ineffective—are also too expensive. The activists of the International Treatment Preparedness Coalition's World Community Advisory Board (**ITPC World CAB**) were keen to understand how the Indian generic drug makers were planning to respond to the need for more affordable second-line drugs and to the challenge of switching to next-generation first-line drugs.

Abbreviations

Drugs

3TC: lamivudine
ABC: abacavir
ATV: atazanavir
AZT or ZDV: zidovudine
EFV: efavirenz
FTC: emtricitabine
LPV/r: lopinavir/ritonavir or Kaletra or Aluvia
NVP: nevirapine
RTV: ritonavir
TDF: tenofovir
TMP/SMX: trimethoprim/sulphamethoxazole or co-trimoxazole or Bactrim

API: Active pharmaceutical ingredient (bulk quantity of drug)
ARV: Antiretroviral (class of drug)
CAB: Community Advisory Board
FDA: United States Food and Drug Administration
FDC: fixed dose combination (pill)
IP: intellectual property
LDC: least developed country
NACO: National AIDS Control Organization (India)
NCE: new chemical entity (a novel drug)
NGO: nongovernmental organization
PAHO: Pan American Health Organization
PEPFAR: United States President's Emergency Plan for AIDS Relief
PLWHA: person or people living with HIV/AIDS
TRIPS: Trade related aspects of intellectual property rights (World Trade Organization)
WHO: World Health Organization

Registration

Nearly every country has a drug regulatory authority that decides which medications can be sold in that country. A drug company submits data about its drug to the regulatory authority for evaluation. If the regulator approves, the drug is registered and can be distributed and sold. Some countries have strict registration requirements and others automatically register drugs that have been registered in neighboring countries. Sometimes a country does not require registration for drugs imported by NGOs and will issue a waiver. However, registration for all drugs is recommended to prevent interruptions when waivers are withdrawn.

There are 210 countries in the world, and none without HIV.

AUROBINDO

Lorena: In which countries are your ARVs registered?

Aurobindo: We supply to 65 countries but not all require registration. The importance of registration varies. Registration is not necessary if supplied through the Clinton Foundation or PEPFAR, or if the purchaser has a waiver or imports it via diplomatic pouch.

In Africa, registrations are generally extremely important, though some small countries are not so strict. Eighty percent of Aurobindo's ARV business is in Africa. Registrations are not so important in the Caribbean but important in Brazil. We market through PAHO in Latin American countries and it supplies to Guatemala and other places without registration. If countries are strict, then we need registration, but if your documents are complete then it is not a problem to get registration.

Lorena: What is your strategy for serving small markets?

Aurobindo: NGOs may make a purchase, then distribute the drugs among several small countries. NGOs are a very important part of the distribution system. If the customer is not a big institution then we use small agents to handle the deal.

The private market is very small but anyone who wants the medicines can buy them. We will even fill a $100 order. We will go for registration in a small market if the hurdle is not high. We have translators who prepare labels and materials for new markets. If we can't give you product in the Viet language, then we give you a package insert in Viet. In the next month we will have

MATRIX

Sudin: Where are your ARVs registered?

Matrix: We register everywhere we have to. This includes small market countries—Togo, Benin—but we don't think about that; we do it because that is our business. And some small countries don't require registration. Soon we will get into Central and South America, but we are not there yet. We have local agents in most countries that are responsible for acting with the governments to get registrations done. We pay them a fixed fee. But we have no agents in the distribution picture.

Sudin: What challenges do you find in registering?

Matrix: Many challenges. Registration guidelines are aligned with WHO, but there are deviations. Some countries want to follow their own regulations. In Kenya they say they need to have two-year stability data. WHO accepts six months and FDA accepts six months, but Kenya wants two years. This means newer products will not get into Kenya. It means a two-year real-time lag. The patients are suffering.

We want to register TDF/3TC in Nigeria but they want us to do a clinical study on a black population. We can't do a large clinical study. Meanwhile they are buying the same drugs through the Clinton Foundation.

On fixed-dose combinations we have some small issues with WHO, where they want six-month stability data when we already have the single products and APIs approved with six-month data.

RANBAXY

Aaron: Have you registered in countries with small markets?

Ranbaxy: There are 210 countries in the world and none without HIV. We sell in 60–70 countries, so we don't sell in every one. We go out to make maximum impact. It took a long time to get to where we are. We started with a few key registrations and continued adding more.

When Vanuatu got their first consignment of ARVs from us no registration was required. We gave them minimal paperwork and they accepted it. It was a WHO prequalified product and it was used in neighboring countries, so they accepted it.

The general problem with registration is that, even if you have a WHO prequalified or FDA approved product, the country wants to look at it from scratch. And if it's an ARV, they want to look at it even closer so they put a special team on it. But because of the detail they go slower than normal. This is true of most countries. Registration for ARVs requires six months to three years, and the average is one-and-a-half years. We would like to see WHO prequalification become sufficient for registration.

Aaron: Any special issues with registering FDCs?

Ranbaxy: We don't have any particular problems registering FDCs. Zimbabwe had a problem with a lower strength FDC that did not have specific bioequivalence studies, and we had to do a special study for Zimbabwe, so there was a delay and it cost us. We could have introduced another product for what we spent on that study.

AUROBINDO (cont.)

product for Angola in Portuguese. But Libya, Niger, and Egypt don't do much with ARVs.

Kon: The Clinton Foundation had a waiver in Kyrgyzstan. When that ended the government took over importation but the drugs were not registered. Do you commit to registration after the waiver is over?

Aurobindo: This recently happened in Senegal. The government asked for registration after the waiver, so we did it. Even Benin wants registration. If the government says we have to do it, we do it. We are in the ARV business, so we do it.

Lorena: Where do you find problems with registration?

Aurobindo: Every few years you have to pay renewal registration fees for each product and the fees are going up. Registration fees have gone up in Nigeria and are very high in Zimbabwe—$2,000.

MATRIX (cont.)

Bob: Are the registration fees an increasing burden?

Matrix: There are registration fees for a plant audit, and fees for a five year registration, and there are renewal fees, which are good for different periods in different countries.

Russia is now charging $50,000 inclusive of travel and translation. But I can get any language translated in Europe for $2,000. In general, though, we are not seeing registration price increases; it is not a problem.

Kon: Do you register after a waiver has ended?

Matrix: Import waivers are a short-term accommodation but we still have to register for the long term. Waivers are allowed for donations, but not often for commercial sales.

Carlos Moreno moderates discussion with Sharadd Jain of Aurobindo.

Quality & Prequalification

Prequalification is certification by an internationally recognized drug regulatory body that a medicine has been produced according to good manufacturing practices and is of high quality. Prequalification may involve testing the medications, inspecting the factories, and assuring that raw materials are pure. Many countries require prequalification before a drug can be registered, and many NGOs and government treatment programs will only purchase prequalified drugs. The WHO performs quality testing and prequalifies ARVs submitted to it by the manufacturer. The U. S. FDA also evaluates drugs submitted to it and issues temporary approvals that allow generic drugs to be purchased by the U.S. PEPFAR program. Each of these processes offers a strong assurance of quality to funders, prescribers, and consumers.

AUROBINDO

Andy: Which of your drugs have WHO prequalification status?

Aurobindo: All are WHO prequalified drugs and FDA approved. We have nine FDA-approved products and there are 11 products pending. FDA takes only six months to approve but WHO can take two years. WHO wants six months of stability data. But we say if the API is approved, then why do you need another five months for the final form?

Andy: What about expired drugs?

Aurobindo: Expired drugs have nothing to do with quality. It means the shelf life is over. A classic case is Nigeria where Global Fund funding stopped and expired drugs were used. Our policy is to make drugs with two years minimum shelf life; then they have 19 to 24 months remaining when shipped.

MATRIX

Vladimir: What is the status of WHO prequalification for your products?

Matrix: If it does not prequalify or meet FDA approval, we will drop it.
We have filed 21 dossiers with each: eight are FDA approved and two have been prequalified by WHO. We only started a year ago.

Certain antibiotics, if you manufacturer them correctly, don't require prequalification. It costs to prequalify, so if it is not necessary, why do it?
The WHO system has problems. They have little manpower. They only work for three months at a time. If there is a query you have to wait for the next sitting.

Our objective is to access the PEPFAR fund. The U.S. FDA will not give final approval for a drug until the patent expires. But I can access PEPFAR.

Dorothy: Do you have a way to track problems with drugs in the field? (pharmacovigilence)?

Matrix: Pharmacovigilence is a new division with us. The drug regulatory agencies are insisting that they want this information; it is not mandatory, but they want it. The Clinton Foundation is helping us.

Dorothy: What is your policy on expiry?

Matrix: Most tenders require that you must supply at least 85 percent of shelf life. I have not come across any African tenders with shorter shelf lives.

RANBAXY

Snehansu: What is the prequalification status of your ARVs?

Ranbaxy: Thirteen are WHO prequalified and six to eight more are pending. Our policy is to go for WHO prequalification for everything because it gives assurance throughout the world and the funding agencies look for it.

WHO prequalification used to be faster but is slower now. We have six to eight drugs in the pipeline.

Paul: Do you do pharmacovigilence?

Ranbaxy: In developing countries pharmacovigilance is in a very early state. We have our own program and it is rolling out slowly over time. Our internal quality safety committee oversees this. In South Africa and a few big places people are paying attention to this.

Paul: What is your expiry policy?

Ranbaxy: Most tenders specify the expiry period as 80 percent of shelf life and we comply with that.

ARVs: Production & Pipeline

Better 1st- and 2nd-Line Drugs

Despite the success with the current drug regimens, international treatment guidelines are now calling for a switch to newer, safer drugs. But these drugs, such as tenofovir and efavirenz, are more costly to make and deliver. It is critical to understand how the generic drug makers are planning to respond to the need for more affordable second-line drugs. Although protease inhibitors are used as first-line therapy in the United States and Europe, they are strictly reserved for second-line treatment in the developing world. One problem with drugs that require "boosting" with ritonavir is that Abbott Laboratories, the original producer of ritonavir, only makes a soft gel capsule, which tends to melt in tropical heat. However, the Indian generics have leapfrogged this problem and are the first to offer heat-stable ritonavir.

AUROBINDO

Snehansu: What is the status of tenofovir in fixed-dose combinations (FDC)?

Aurobindo: Tenofovir will be in an FDC of tenofovir/FTC/efavirenz. Tenofovir was submitted to the FDA in February and we need another three months to get FDA approval. The FDC was filed in March. We have completed the exhibit batch for stability and bioequivalence studies. It will be another 6–8 months for the FDC.

Snehansu: Are you planning to produce other second-line drugs?

Aurobindo: FDA approval of lopinavir/ritonavir (LPV/r) is expected by June. We have also filed for a pediatric formulation. We have didanosine in a chewable tablet and in an enteric coated tablet.

Bob: What process is used to make the LPV/r tablets heat stable?

Aurobindo: We use the melt-extrusion process (meltrex) to make heat-stable LPV/r. It is the same process as in Abbott's Aluvia. We buy the equipment from the same supplier.

Gregg: How about atazanavir and darunavir?

Aurobindo: We will do atazanavir (ATV) alone first, but copackage it with ritonavir. We will be the first with

MATRIX

Matrix: We have the first generic approval of a second-line drug. We have filed for tenofovir/FTC and tenofovir/3TC. We see no difference between the two and the cost is better for 3TC, but we are applying for both and should get approval in a few months. We have filed and the registration dossiers should be going out to the countries soon.

Kon: What plans are there for other, newer drugs?

Matrix: Our LPV/r has been filed for WHO prequalification. We are supplying it to the Clinton Foundation. We have gotten registration approval in Uganda and Zambia.

We use a different process for heat-stable LPV/r. Meltrex is not a simple process. Abbott made proprietary changes in the design of the machines that they are not willing to pass on. Time was running out, so we didn't use that process. We used a process where we dry the drugs at a premix stage, then tablet them. We will eventually switch to Meltrex and the machines are now being modified. There will be pressure from Abbott, and the U.S. will apply stringent requirements.

Ramya: Do you have licenses with major pharmaceutical companies?

Matrix: We have a license with Gilead and use that license to make all of the tenofovir combinations. We are

RANBAXY

Ranbaxy: We have several formulations of tenofovir under development. We are filing for everything you can think of multiple, creative combinations. They should all be filed by later this year. We don't talk about the products we are working on. It is for competition reasons that we don't reveal specifics about our pipeline.

We have a large range of second-line products in our pipeline and the bulk should be done by later this year. We are working on LPV/r along with the other second-line drugs. Newer drugs like integrase inhibitors have patent protections.

Our company has a very strong drug delivery team—we have licensed processes to big pharma. The Meltrex process is capital-intensive because it depends on the machines. Our formulation scientists have come up with other processes that may be applicable and we are exploring them too. We are considering all three processes.

AUROBINDO (cont.)

heat-stable ritonavir. A FDC of ATV/r will come later. The shift to second line is not creating a big market yet. We will finish this wave of second-line products before making newer drugs like darunavir.

Asia: How are you planning to handle the transition to tenofovir?

Aurobindo: There are 1.89 million people currently on treatment. The target is ten million by 2010. It will take three or four years for the shift to happen. You can't shift them all at once, especially when the current drugs are working for them.

There are not many generic manufacturers of tenofovir currently, so it is a costly product. It is a big jump from stavudine. But we don't do this on a small scale; we don't just buy the API from China and make pills.

MATRIX (cont.)

negotiating to get a license with BMS to make atazanavir. We have developed the atazanavir-based products and should soon have a fixed-dose combination, boosted atazanavir tablet. BMS has been good. They haven't given a license but give assurances.

Matrix: The pressure to make heat-stable ritonavir is that you can not give atazanavir without ritonavir. And everybody knows why Abbott is not selling heat-stable ritonavir. [Documents revealed in a court case show that Abbott intended to restrict access to ritonavir to protect its market for Kaletra—ed.]

Kon: Integrase inhibitors—have you talked with Merck about raltegravir?

Matrix: Not yet. We are taking the stand that we are going to develop them. It will take a year or two. We have a relationship with Tibotec and are developing one of their intermediates. This is all in an early state. We are preparing and will see what is the best deal we can get with them.

But we may also decide that something may not be a useful or superior product and we may skip over certain molecules.

Developing the drug is one thing, but developing in volume is another. All of our APIs are done in-house. Volumes have grown enormously. We are looking to scale-up tenofovir in a big way, going to ten tons a month.

Anirudh Deshpande of Matrix with moderator Andy King.

Non-ARVs: Production & Pipeline

Quality HIV care depends on several non-ARV drugs to prevent and treat opportunistic infections. Tuberculosis (TB) is the most common killer of people with AIDS, yet the basic TB regimen has not improved over several decades. Treatments for drug-resistant TB are expensive. Better TB drugs are urgently needed.

AUROBINDO

Snehansu: What about drugs for opportunistic infections (OIs) and tuberculosis (TB)?

Aurobindo: We do TMP/SMX for HIV—however, there are restrictions in manufacturing it because a lot of pollution occurs as a by-product. We manufacturer it for Health Canada and they give it to Zambia.

We have nothing for hepatitis C. We are not doing TB drugs because they require a separate facility for manufacture.

Our management policy is clear: We do our own APIs, and that is a long process. TB drugs must be made in a separate facility, so it is not practical for us.

MATRIX

Kon: Will you be making OI drugs or TB drugs?

Matrix: Our parent company, Mylan, has some of these products in the portfolio and is acquiring other generic companies. So we are in the process of coming out with a list of drugs. We have some of these drugs but have not targeted these markets.

We are not going to do hepatitis C. We are going to do TB and malaria first. We want to go into newer drugs that not many companies have attempted.

RANBAXY

Raoul: Any plans to make malaria or TB drugs?

Ranbaxy: We do not have a malaria product currently, but we are working on an artemisinin product, which will take a few years. We want to have a WHO product. We don't have a TB product at present.

Kon: Do you have any plans to conduct drug trials on drug-resistant TB?

Ranbaxy: We might consider it in the future when we move in this direction. We would be interested in a good NCE [new chemical entitiy] lead in this market. We would work with a public/private-funded project and we might be a good partner for a global company. Our research people are looking for leads, too.

API: Production & Capacity

A drug's active pharmaceutical ingredient (API) is produced in very large quantities, then mixed with certain inactive ingredients and pressed into tablets to make finished formulations. Only a few companies make APIs.

AUROBINDO

Dorothy: Which APIs are you producing?

Aurobindo: We generate all of our APIs. We are basically known as an API company. We have only been making formulations for the past five years. We have production contracts with GlaxoSmithKline to make bulk Combivir. We recently had ARV production capacity of six tons per month and that is going to 12 tons. The demand is much larger than our current capacity.

MATRIX

Matrix has been doing ARV APIs for the last six years and we produce more tonnage than any other company. We are also contracted to make intermediates for lamivudine for GlaxoSmithKline.

We supply APIs to Brazil for the government pharmaceutical companies. Brazil is not enforcing a patent on tenofovir but the license we have prevents supplying Brazil. We are talking to Gilead and if they can't supply Brazil, they would want one of their licensees to supply them.

All APIs are made in our facilities; nothing is outsourced. Some of the intermediates come from Indian sources and we have a subsidiary in China.

RANBAXY

In the late 1990s we acquired a company that made APIs for ARVs then later sold it and later it became Matrix. So we understand the chemistry and APIs of ARVS.

In early 2001 we decided to get into finished form ARVs. Before that we only sold raw materials. We have stayed competitive because we know how APIs are made. Now we don't make the API, but we buy it from Matrix. Because of our cost efficiencies, we are able to reach the lowest prices.

Local Production & Technology Transfer

Some countries are interested in establishing factories to manufacture ARVs domestically. Technology transfers would provide technical assistance in setting up these factories to produce high-quality product locally.

AUROBINDO

Paul: If I buy an API for a factory in my country, how do you assure quality in the final product that I make?

Aurobindo: Our department will visit the plant and decide if you have the ability to manufacture a quality product. We get proposals to supply local manufacturing in Africa, but we discourage that.

Paul: If you find an acceptable partner in Africa will you sell them API?

Aurobindo: We would, or we would sell tablets and let them package it, but we have not found one yet. We will help in planning the plant if we can count on having a long-term relationship. But prices will not come down if you produce locally: the volume is too limited and it is too costly to hire the right people.

MATRIX

We will share technology with other generics but I can still offer them drugs cheaper than they can make them. Down the line more countries will want to have sustainable drug supplies and we will help them if we can't sell to them.

Many governments write us seeking investment. But it rarely seems feasible because they don't produce APIs.

RANBAXY

We can look at technology transfer with developing countries. If an important opportunity arises and there is mutual benefit, we are not opposed.

Among generic companies we have a very different business model. We have subsidiaries in many countries; we manufacture in 11 countries. Compare that with other generics that are based in India and simply export. Ranbaxy sells in both emerging and developed markets. Unless there is a rationale, it will be more costly to manufacture locally. We talk to governments all the time and in the end they decide they will buy from us. We are not opposed to local production but it requires government subsidy to run. You would treat fewer patients with that money than you could if you bought cheaper drugs from us.

Moderator Ramya Sheshadri with Arun Kumar Purohit and Sandeep Juneja of Ranbaxy.

Patents & Intellectual Property

The Indian patent system is the key that allows its generic drug industry to copy and distribute affordable, high-quality versions of ARVs that are patented in the United States and Europe. However, restrictive new protections for intellectual property (IP) threaten this system. Until recently, Indian patents could only protect the process by which a drug is made—not the final product. This allowed generic makers to copy a drug as long as a different manufacturing process was used. But recent changes in the law may grant patent protection to drugs invented after 1995. Activists in India are fighting these changes.

AUROBINDO

Kannikar: What relations do you have with major pharmaceutical companies?

Aurobindo: We have voluntary licenses with Bristol-Myers Squibb for stavudine. We had a tie-up with Merck for efavirenz in South Africa. They give exclusivity for certain countries. Sometimes we pay a small royalty.

Kannikar: Do you own patents?

Aurobindo: We have process patents for how the drug is made.

Asia: Do you think about challenging patents to get around evergreening [extending monopoly with new patents for minor product modifications]?

Aurobindo: No, it is a waste of money.

Kannikar: But a lot of patents are weak.

Aurobindo: That is a different department. We have an intellectual property division. Under Indian law, we have to make the drug using a different process. If we can do that, we will go for it. If we are not confident we can, we will not. The penalties for violations are huge. If not we have to wait for patents to expire.

Kannikar: Would you apply for a compulsory license?

Aurobindo: Give me a proposal. Last year Brazil threatened a compulsory license . . . then orders came to Ranbaxy and us.

MATRIX

Loon: What would happen in India if tomorrow Gilead lost the tenofovir patent?

Matrix: Gilead is supporting us and we have a good relationship. I would go to them and dialog and if we didn't move forward then we would take a stand and break the patent.

But the Gilead agreement stands no matter the outcome with the patent situation in India. Going forward we think they would want to cooperate. I'm not worried about the royalty cost.

Ramya: Do you have voluntary licenses with any other companies?

Matrix: Not yet. We are working with Bristol-Myers Squibb on atazanavir. We have a joint venture with Aspen, so we have decided not to get into South Africa. We supply APIs to Aspen but not finished products.
Aspen uses Gilead's technology and they are bound by Gilead's price restrictions. We developed our own tenofovir API, so we are not bound by price restrictions on API. There are some conditions, but we talk to them when there is a problem.
We have filed in Thailand for tenofovir and when registered we can sell it there because we have a license in Thailand. We also have a compulsory license in Thailand for LPV/r.

One potential is for us to manufacture and sell in a least developed country [LDC] like Bangladesh. That would address the barrier of patent restrictions, but we could still not sell in India. We are exploring moving to places like Uganda, an LDC, for production.

Ramya: What is your IP policy?

RANBAXY

We have certain agreements with pharma—since the patent laws have changed, we have more teams from international pharma visiting. I see a lot more activity since last year.

We have voluntary licenses for tenofovir and nevirapine. We have a local one in South Africa with GlaxoSmithKline for their products. We have asked Bristol-Myers Squibb for a license for atazanavir.

We will respect patents but we haven't said we will support evergreening, because that will affect our interests as well.

Loon: Will you oppose patents?

Ranbaxy: We opposed the tenofovir patent but then we got the license. We will file oppositions—sometimes the business group files and we don't even know. It helped in negotiations for the tenofovir license that we had an opposition filed.

Loon: Would you move to an LDC like Bangladesh that is not covered by the TRIPS agreement?

Ranbaxy: We have looked at that possibility. We are not oblivious to that and if the need arises we may consider it.

I would say, go for a voluntary license first, but if that doesn't work go for a compulsory licence, and only then go for an expensive plant in an LDC, because that plant must be qualified. Still, we would consider it if it became necessary to protect our interests.

Aditi: We think that the first line of defense is that only valid patents are granted.

Ranbaxy: We let our IP experts analyze

MATRIX (cont.)

Matrix: We don't have a standard IP policy. We would advocate—especially for HIV—that things should be more lenient. We think there should be protections where necessary and freedom where it is possible. It is necessary for research to be done; you need money to do research; and you need protections to make money.

We have not matured as a research company but we are strong in formulations. We are very strong in chemistry. We have filed many process patents in India. The technology transfer is now going both ways.

RANBAXY (cont.)

what is the best way to go. We are looking at collaboration for most of the newer products that are patented because they are not leaving any loopholes in the patents that we can work around.

Our team felt it was better to take a voluntary license rather than fight it out with tenofovir. We believed it would be better and faster to go that way. Our IP people are in the U.S. and they are the best in the business. Big pharma sees that we have a point and that we can beat them at it. But if it comes to that, we will apply for compulsory license or whatever is allowed by law.

Loon: Does Ranbaxy own patents?

Ranbaxy: Most of the patents we do are formulation patents. We are not working on new chemical entities [NCEs] in HIV. More generally, we are working on new drugs and we would patent them because that is an essential part of development.

Loon: Do you see your future in NCE research?

Ranbaxy: Generics are our core business. While we want to pursue NCE research, it is a long, drawn-out game. In our division we have not looked beyond 2012. Our vision statement says we want to be among the top five companies in the world. Generics are our bread and butter and will pay for expansion into NCEs.

Pricing

The low price of ARVs offered by the Indian generic drug makers was the enabling factor that allowed the drive to universal access for ARVs. In order for the planned expansion of ARV access to continue, prices must fall even farther.

AUROBINDO

Dorothy: How do you set prices, and how do they vary from region to region?

Aurobindo: The Clinton Foundation comes and negotiates with us. PEPFAR negotiates with us. The market drives the price. If there is a choice between two suppliers of the same product and they are both prequalified, the buyer will go with the lower price.

Dorothy: Does each NGO or government negotiate with you separately?

Aurobindo: If you buy small quantities the price is within 5 to 6 percent from one sale to the next. But the cost of the freight forwarding may be more than the cost of product. For the Clinton Foundation, they pick it up at our factory warehouse.

Dorothy: Can the cost of APIs be reduced?

Aurobindo: If I have better volume in APIs, then prices may go down. Clinton prices are setting the standard for prices. Prices are within 2 to 3 percent of the Clinton price for volume purchasers. Clinton is the lowest price. But Clinton is not very high volume; PEPFAR is higher volume. But we share technology with Clinton. This year Aurobindo has 80 percent of the Clinton business—although Clinton buys mainly pediatric formulations.

Asia: Do you charge different prices in LDC and middle-income countries?

Aurobindo: There is not much difference between prices in LDC and middle-income countries. If you charge more you will lose the order; the price is market driven—though freight costs may make prices higher in Latin America.

MATRIX

Simao: How will you price LPV/r?

Matrix: The biggest challenge we have is LPV/r. It is a very complex product to make. We are getting help from Clinton Foundation on technology. Clinton will announce new prices in the next few days.

The biggest challenge for LPV/r is to bring down the price. Now we only supply the Clinton Foundation at a small scale. If the scale goes up then price can come down. Costs are still high.

The best option is to move to ATV/r FDC—the dose is smaller and the API will be cheaper. We need BMS support and they want this, too.

Simao: How do you set prices among regions, NGOs, governments, the Global Fund?

Matrix: Our objective is not to charge someone who cannot afford it. We are compelled to sell below the ceiling price everywhere. We don't have a lot of reach yet, because we just started.

As a generic company, we want to sell at lower costs, but as a policy we can't do donations. We can't help it if big companies donate drugs, but it is not sustainable for us.

RANBAXY

Lorena: How are prices set?

Ranbaxy: Everything these days is tender-based. It is more like a commodity. Whatever the price of the last sale determines the price of the next sale; 99 percent is tender-based.

The key determinants for setting prices are initially cost recovery and making a little margin to keep the project going. But then the prices come down and we can no longer do that. These days prices have come way down and there is very little margin. Rationally we should not be doing this business but we have the blessing of senior management.

It is all economy of scale. The API cost is the prime driver of price and that does not come down until you have large demand and economy of scale. Up the supply chain there are people who make chemicals that go into many products, and they won't lower their price unless you buy in quantity.

Q: Who is your customer—the buyer or the consumer?

A: It is the buyer. This is a funded business. The buyer negotiates the price for all consumers who use it.

Local Prices & Agents

Pharmaceutical manufacturers sometimes contract with sales agents within a country to handle business functions such as dealing with the regulatory agencies, receiving imports through customs, and distribution to hospitals and pharmacies throughout the country. If the job provided by the agent is limited, he may work for a fixed fee. If the agent is responsible for distribution to a sales network, then the agent usually resells the drugs with a markup. Distributor markups can increase the price of a drug within a country considerably.

AUROBINDO

Paul: Do you use agents or middlemen? How are they chosen?

Aurobindo: The role of the agent for ARVs is to primarily help us with local regulations. We choose the agent for our other products and he also has to do the ARVs. His most important role for ARVs is registration.

Zambia buys through ground agents. Some pediatric drugs come through the Clinton Foundation. PEPFAR sources from its own procurement agency, which adds 2 percent.

We can not control the private market. Even if funded and free, we can't control if a drug is ultimately sold. The only person who goes to the private market is someone who has money to buy. The distributor marks up those prices because he assumes the risk of taking a loss.

MATRIX

We have local agents in most countries that are responsible for acting with the governments to get registrations done. We pay them a fixed fee. But we have no agents in the distribution picture.

RANBAXY

Most often we have no agents. We operate in many countries ourselves. You need agents for the private market. But for the public tender market we usually do it ourselves. Sometimes you need an agent to get payment from the tender board because they deal with him all the time and they must pay him, whereas they may not feel they have to pay us. If we smell a problem we prefer to go through an agent but with the international donors it is not a problem.

We have an agreement that lays down how much a markup will be. The agent is only a supplier and does not market. With other pharma companies we have seen a dollar a day price become twelve-times higher on the ground due to the agent. The amount depends on the trade practices in the country.

The Future:
Opportunities & Threats

Finally, the three companies were asked to speculate about the future of their business in ARVs and to describe some of the challenges they face.

AUROBINDO

Aaron: What will the ARV market be like in the future?

Aurobindo: Funding will double in a few years. PEPFAR was $15 billion but will go to $30 billion.

Paul: You say the market is expanding. Does this only mean that there is more donor funding? Or are more people requiring treatment?

Aurobindo: Both.

Aaron: What are the major threats facing your business?

Aurobindo: Having to manufacturer so many regimens is confusing. We make regimens that no one wants. We went with emtricitabine (FTC) because people said they wanted it, so we produced it. Now they say lamivudine will be just as good. I wish they would settle on fewer regimens and not change them every year. It would be easier for us.

MATRIX

Sangeeta: What are your expectations for the ARV market in the future?

Matrix: The challenges we saw three to four years ago were in enrollment and infrastructure. Now that critical mass has been achieved and things have improved a lot. We are now ready to scale-up much faster than we were a year or two ago.

Second-line drug prices will be coming down significantly and will come down further in the coming years—the shift will begin happening significantly then.

The other challenge is how the Indian government goes about protecting patents. Anything happening in India will have an impact across the globe.

As long as we see business we will do business. But we are not only here to make money. I think to collaborate is good. We see in a partnership that we gain something and lose something. We gained a lot from the Clinton Foundation. They promote us everywhere we go. That helps us. We look at being here meeting with activists as a partnership.

World CAB 4 attendees in New Delhi prepare questions for representatives of generic drug companies.

RANBAXY

Ranbaxy: We are investing significant time and effort in developing the ARVs within the Indian patent situation. We are early in some areas and late in others, but we are not abandoning the ARVs.

Asia: What do you see as the threats and risks to your business in HIV?

Ranbaxy: In the past there has been a lot of focus on access. Most of the focus was on prices, which was good at that time. But we can see a shake-up coming. If prices and margins continue to fall, we could be headed in the direction of TB, where there were once a lot of good companies manufacturing products, but after the margins fell, the big ones left and now there are only small companies and one big one left in TB.

We have been thinking about the TB market because it is synergistic with our HIV business—but we cannot compete with the prices offered. In HIV you may see a few big players getting out and once they go it would be too difficult to get them back. We know of two big companies who considered getting into HIV and even hired people, but then backed out.

Intellectual property protections are another risk. Newer products coming along would be patent protected and as they replaced the older ones the big companies would be under pressure. The market would shrink and that would push up costs.

Currency fluctuations are another big risk. It is difficult to absorb the impact of these fluctuations.

The existing long registration timelines is an important threat. We cannot pull a batch together for testing on demand because they are too big and expensive to make. WHO prequalification is more expensive than FDA approval. WHO is more stringent than EU guidelines for approval; there are additional batching requirements.

ARVs in India

In 2005, Loon Gangte said, "I am proud to be Indian and proud that Indian companies make these drugs for the rest of the world, but I am paying $280 per year while people in other countries are paying $180 per year."

"Because of the intervention of some Westerner [the Clinton Foundation], other people are getting these drugs but our own people can't get treatment."

"Will I ever be able to buy drugs at the Clinton price?"

In 2008, Loon wanted to know what the Indian generic drugs industry was doing to help Indian people living with HIV.

AUROBINDO

In India, we supply 70 percent of the National AIDS Control Organization (NACO) tender with products we have. The price per patient for stavudine/lamivudine/nevirapine is about $80/year at the NACO price.

MATRIX

Loon: Would you sell to NGOs or buyers clubs in India? What price?

Matrix: We have no marketing structure in India. Maybe you could buy from Clinton? I have no problems if it could help more people.

Loon: What is your access price?

Matrix: We don't have an access price; it is all the access price. There is only one price.

NACO volumes are very, very small because there is very little second-line usage. We are looking to supply within four weeks of getting an order.

But NACO will tell you to send it to 300 different centers in small lots. We are not a distribution company. It is a big issue for us. We don't get paid for six to eight months from NACO. It is a big mess.

Any other country outside of India, you supply to a central facility and they distribute. India has that too, but NACO is independent. NACO is buying through the Clinton Foundation with a UNITAID donation.

RANBAXY

The private market in India is a very small part of the market. They pay a large part of the cost to the doctor for a fee and for diagnostics to the lab. We don't make a lot of money on the public market, and the private market price has fallen by half from what it was. But we have to make profit somewhere. We have to pay for the reps to talk to the doctors about the products and the older doctors are dependent on the pharma sales team to educate them. So that has to be paid for.

Loon: But second line is often only available through the private market and most people cannot afford to buy the drugs they need.

Ranbaxy: Second line is now where first line was in 2001. At that time the head of NACO laughed at the idea of free treatment because it was too expensive.

We have not looked at the private market in India. There the price would be incremental cost without marketing support, since we have no sales force.

RANBAXY (cont.)

If I can get registration and approval all at the same time it would be much better because I could coordinate everything with one batch. But the countries want different amounts at different times and it makes planning very difficult. So harmonization is difficult, but it would be important for the industry.

We find that when the WHO prequalification happens there is no immediate demand because it has not yet been approved at the country level. Then an order finally comes in for 2,000 bottles. But we have the capacity to make 150,000 bottles. What do we do with the other 148,000? We don't know how to solve this problem of misaligned approval times.

I think countries will have to be rational and choose which second-line products they will use. If they insist on atazanavir their budgets will balloon, but if they choose lopinavir/r, which may not be patented, and they can live with the inconvenience of twice a day, they can get a much better price.

Regional Issues

Participants asked some specific questions about registration and product availability in their home regions.

Africa

Paul: What are the barriers to supplying products in Africa?

Aurobindo: There are not a lot of barriers to supplying in Africa. It is very open. The number of regimens is challenging. If you can group several country registrations together that would save time and money for us.

Asia

Ed: How are registrations going in Malaysia?

Aurobindo: It is in process. Thailand, Malaysia, Vietnam: all strictly follow patent laws.

We have only received one registration in Malaysia after five years and we have filed for 14. It takes a year and a half to register in Malaysia. In Africa it typically takes six months.

Matrix: We are looking at Malaysia. We have no license for tenofovir there, but if the government applies pressure maybe we can work something out.

Ranbaxy: We have registered in Myanmar; in Thailand we sell to the government. Bangkok has its Government Pharmaceutical Organization [GPO] and they block any other company from coming in. But we supply APIs to the Thai GPO. We have no direct business with Pakistan. I think Indian product goes into Nepal.

Aurobindo: China is a closed market and imports will not be allowed—only very small quantities are moved in China. We have a plant in China for intermediates and it is FDA qualified. Aurobindo has 8,500 employees in China.

Eastern Europe/Central Asia

Kon: Are you registering in Ukraine?

Matrix: Matrix is a subsidiary of Mylan Labs, a U.S. company. We are bound by a requirement that there be no patent restrictions, so Ukraine is a problem. We have not done a lot of work in Eastern Europe and Central Asia. We are filing in Uzbekistan.

Kon: The package insert you provide should include drug-drug interaction data with substitution drugs.

Sangeeta: This is also relevant for North India.

Latin America

Carlos: What are the barriers to registration in Latin America?

Ranbaxy: Generally, it depends on the regulatory guidelines in the country. We have an office in Sao Paulo.

Matrix: Our Latin American business was initiated this year. We are filing across all Central and Latin American countries. There are trade agreements on finished products in Argentina, but if they are FDA approved and are sold in U.S., it may be okay. You can sell API; there is no problem.

About the International Treatment Preparedness Coalition (ITPC)

A coalition of thousands of participants, led by people living with HIV, and funding more than two hundred grassroots projects throughout the world through its collaborative fund project, ITPC has proven itself capable and effective in mobilizing PLWHA and working on their behalf.

The International Treatment Preparedness Coalition (ITPC) is a worldwide coalition of people living with HIV and AIDS and their advocates. Since formation in 2003, ITPC has worked for universal access to HIV-related treatment, care, and support for all HIV-positive people and meaningful involvement of HIV-positive people in decisions that affect their lives. The ITPC is the primary international coalition of people living with HIV and AIDS (PLWHA) and their supporters dedicated to advocacy on HIV/AIDS treatment access. A coalition of thousands of participants, led by PLWHA, and funding more than two hundred grassroots projects throughout the world through its collaborative fund project, ITPC has proven itself capable and effective in mobilizing PLWHA and working on their behalf.

With advocates in more than 70 countries, ITPC:

- provides a network for many people working on treatment preparedness around the world to meet and discuss their work with each other, and to exchange up-to-date information and perspectives about the state of treatment access and preparedness on international and regional levels
- serves as a framework for PLWHA to create, maintain, and enhance local, regional and global treatment preparedness efforts; and provides an opportunity (through the Collaborative Fund) for foundations, international organizations, and other donors to directly support local and regional efforts for education and advocacy in the developing world
- closely monitors, through its regular *Missing the Target* report, the scaling up of treatment across the world and also identifies country-specific issues around treatment access
- provides, through its regular monthly updates, up-to-date information on the issues of treatment access and shares many inspiring activities carried out by PLWHA across the world

Objectives of World CAB 4

1. To build capacity among HIV-positive leaders and advocates on drug development and access issues, particularly issues around access to generic formulations of AIDS medicines.
2. To allow PLWHA leaders and advocates to share and learn from each other about how to advocate for access to treatment.
3. To build advocacy skills on issues related to access to essential medicines, including antiretroviral drugs, so that PLWHA leaders and advocates can be more effective in national advocacy efforts.
4. To create a platform to engage the generic pharmaceutical industry on issues of shared concern in terms of access to AIDS drugs.
5. To develop country specific strategies and action plans for greater access to second- and third-line ARV medicines.

Expected Outputs and Outcomes

1. Increased knowledge on second- and third-line AIDS drugs and the barriers to access including trade agreements and patenting issues.
2. Increased understanding of how to challenge restrictions on drug access, including countermeasures such as public mobilization/advocacy, public litigations and pregrant opposition
3. A draft strategy of ITPC and other PLWHA groups on securing access to second- and third-line ARV medicines.
4. Better dialogue and future communication strategies between PLWHA activists and generic pharmaceutical manufacturers.
5. A report from World CAB 4 that will be translated into several languages and distributed widely.

Participants

1. PLWHA leaders and advocates who have demonstrated substantial involvement in advocacy around treatment access from around the world.
2. Representatives of generic companies from developing countries.
3. Representatives from other NGOs, academic institutions, UN agencies, etc., with expertise on drug development and access issues.

ITPC World CAB 4, New Delhi, April 24, 2008

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