Partnerships for Developing World Health: Decision and Management Issues for Pharmaceutical Companies
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Decision and Management Issues for 
Pharmaceutical Companies

Report of a Meeting Organized by 
INSEAD Business School and the 
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Abbreviations

ABPI   Association for British Pharmaceutical Industries
ACHAP  The African Comprehensive HIV/AIDS Partnerships
ACOSHED African Council for Sustainable Health Development
ARV    Antiretroviral
DAI    Drug Access Initiative
DNA    Deoxyribonucleic Acid
DNDi   Drugs for Neglected Diseases Initiative
EDM    Essential Drugs and Medicines
EMEA   European Agency for the Evaluation of Medicinal Products
EU     European Union
FDA    Food and Drug Administration
GATB   Global Alliance for TB Drug Development
GSK    GlaxoSmithKline
IAVI   International AIDS Vaccine Initiative
IFPMA  International Federation of Pharmaceutical Manufacturers Association
INSEAD Institut Européen d’Administration des Affaires
IP     Intellectual Property
IPPPH  Initiative on Public-Private Partnerships for Health
J&J    Johnson and Johnson
LDC    Least Developed Country
MIRH   Center for the Management of Intellectual Property for Health Research and Development
MMV    Medicines for Malaria Venture
MRC    Medical Research Council
MSF    Médecins Sans Frontières
MSH    Management Sciences for Health
NDC    National Development Council
NGO    Non-governmental Organization
NHS    The National Health Service
NIH    National Institutes of Health
OECD   Organization for Economic Cooperation and Development
PPP    Public-Private Partnership
PQMD   Partnership for Quality Medical Donations
R&D    Research and Development
TDR    UNDP/World Bank/WHO Special Programme for Research & Training in Tropical Diseases
WHO    World Health Organization
At the end of June, 2003, approximately three dozen representatives of the pharmaceutical industry, non-governmental organizations (NGOs), educational institutions, philanthropic organizations, public health departments and multilateral organizations (in particular different instances of the WHO) met for two days at the Institut Français des Relations Internationales in Paris to discuss decision and management issues for pharmaceutical companies involved in public-private partnerships (PPPs). While industry and WHO representatives were most numerous, it can fairly be said that no one group dominated the ensuing discussions.

The first order of business for participants¹ was taking stock of where the PPP movement is at the present – its current initiatives, issues and prospects. It was immediately agreed that PPPs have probably permanently altered the landscape of health project funding and drug development and distribution in developing countries. Yet this shift has been so rapid that questions such as the best means of program evaluation remain open, while new issues, such as whether R&D is always the best possible industry contribution (and if not, what those other contributions might be), are emerging in the wake of previous successes.

This report, rather than adopting a chronological approach to the subjects evoked, is organized thematically. In other words, rather than merely following a discussion which often looped forward or back, I have grouped related comments and issues under distinct headings. Readers who wish to read a fuller summary may skip ahead to the Conclusion. Those interested in a particular aspect of PPPs are urged to see if it is listed under the title headings in the Table of Contents.

The main messages of this workshop² can be simply stated:

- PPPs have altered the landscape of drug development and delivery in the developing world, though this evolution remains incomplete.
- In the process, they have transformed the means available to public and multilateral institutions, and to some extent their management methods and issues. However, major problems of evaluation (and in particular of impact assessment) remain for all partners.
- While conflicts of varying intensity remain between the pharmaceutical industry on the one hand and its critics and partners (who are sometimes one and the same) on the other, elements of common analysis and understanding are beginning to appear in more than one place simultaneously, notably where the divisive issue of pricing is concerned.
- Outside the industry, there is growing demand for industry skills beyond R&D, which the industry advances as its most logical and necessary contribution.
- The success to date of PPPs, as well as their growing ambitions, are obliging partners to confront issues for which they are not yet fully prepared, notably in terms of health systems reforms at the national level, and hence of interfaces with the political sector. Addressing those challenges may well involve widening the circle of PPP partners and allies, notably among political actors.
- Nonetheless, PPPs which focus on improving access to existing products for neglected diseases are making a significant contribution to address such public health problems. Contrary to expectations, they do not appear to distort national health priorities (based on the IPPPH evaluation in Uganda).

¹ The organizational affiliation of participants is given in parentheses the first time that their names appear in the report.

² All quotes and summaries of quotes were checked with participants before publication.
1. Background and Present State of the PPP Movement

A. Key drivers behind the emergence of PPPs

There was absolutely no disagreement at the workshop that public-private partnerships (PPPs) represent what Robert Ridley (WHO) called “a new area in the neglected diseases or tropical diseases sector.” While at least one PPP among the 83 partnerships represented on IPPPH’s website (a list that is not definitive) has existed since the 1970s, participants agreed that the movement is widening in more ways than one—not only more partnerships, but more ambitious partnerships, operating across industry, NGO, multilateral and academic sectors, in theatres ranging from the local to the international.

Why did they arise? Frans van den Boom (IAVI) believes that PPPs attempt to “overcome market and government failure.” For example, the public sector has not succeeded in creating adequate infrastructure for clinical trials in developing countries (an issue of repeated concern at the workshop), despite “investments in development co-operation for over 40 years. More could have been done.” For pharma companies, PPPs indicate a renewed interest on their part in the health needs of developing countries. Besides a potential long-term strategic gain—namely, that investing in global health may help to create “new” markets (the “health-wealth paradigm”)—PPPs are an expression of social responsibility or corporate citizenship.

Conversely, via pharma companies, PPPs provide expertise in R&D, process development and manufacturing “which the public health sector doesn’t have.”

Michael Reich (Harvard Center for Population and Development Studies) concurred: PPPs “arise from a number of different institutional failures or weaknesses—market failures, government failures, distribution failures, NGO failures. PPPs seek to address a number of these failures by bringing together the strengths of different kinds of organizations.”

The goal of many PPPs is to accelerate the timeline of drug discovery, development and distribution. However, it is important to note that PPPs focused on R&D, and partnerships aimed at improving access to medications, are not always identical and often face different challenges. In particular, the accessibility issue touches on drug pricing and affordability as well as delivery systems, key objects of discussion throughout the meeting. I will argue below that the workshop indicated growing pressure to widen the goals of discovery/development/distribution to other subjects, but they remain fundamental. There was general agreement that PPPs are meeting these goals more successfully than previous models, at least where the public sector is concerned. Said one participant (concerning neglected diseases):

“The public approach to creating new drugs for the future has never worked. The private approach has not worked for 30 years. The PPP approach is there. A tool we can use. I know the public sector will never produce a drug—it lacks coordination, also technique, but mainly the coordination. These are from the private sector. The PPP is an improvement over the previous models, which don’t seem to work.”

Michael Reich identified three classes of reaction to these partnerships: Enthusiasm, skepticism, and conditional acceptance.

Médecins Sans Frontières (MSF), while allowing that “there is room for them [PPPs],” embodies skepticism: “PPPs must not be a smoke screen. Brundtland (WHO) popularized the concept. But her budget was limited, she needed money. So people from the private sector were interested. They get a lot of PR,” said Pierre Chirac of MSF.

Lilian Dudley (Health Systems Trust), self-described as being “from a country [South Africa] that is “cautious about pharmas,” symbolized...
conditional acceptance of the PPP concept in the public sector. Previously, she was not convinced about the sustainability and long term benefits for health systems of PPPs. Now, she recognizes a role for PPPs, though she noted that from a public health perspective, “a different language is involved.”

Jeffrey Sturchio (Merck & Co. Inc.) described some basic ground rules and assumptions of successful PPPs:

1. The complexity of the issues is beyond the ability of any single organization or country to tackle alone.
2. They work best when the people directly affected and involved are in the lead.
3. Integrating programs into existing initiatives and public health priorities is the best way to have lasting impact.
4. Clear objectives, shared targets and complementary expertise in partners.
5. Coordination of efforts and continual communication among partners are critical.

This last point, it appeared, is increasingly present for participants, as a direct consequence of the success to date of PPPs. In the next section we collect their comments on the matter.

B. As PPPs evolve, issues of coordination at global/national/local levels become more critical

Lola Dare (ACOSHED) pointed out that “the relevance of global issues [and global actors] to national agendas” is becoming a more important factor. All partners are obliged to “recognize diversity” – to confront their a priori assumptions re: capacities, systems and cultures, “paying insufficient attention to constraints or partners at the national level”.

The growth of PPPs leads to the realization that global priorities, national priorities and local priorities may not always be identical. To put it another way, as PPPs focus their efforts on delivery to the patient, the importance of local factors and actors assumes a new prominence.

Workshop participants from both WHO and industry made plain that connections between global, national and local actors are not always made. Justine Frain (GSK) wondered: “When a new partnership is announced, do African ministers groan? Do we have a consensus we’re going in the right direction?”

At the partnership level, a consequence of the disconnect between global, national and local actors is growing awareness of (and sometimes impatience with) governance issues. As Penny Grewal said: “Sometimes you create complex governance, and you spend money on discussing issues in the abstract that are best solved at the country level.” In an ironic reference to the energy and resources absorbed in building partner relationships, instead of defining and meeting objectives, she asked: “Does it matter at the partner level if you’re on good terms?”

Likewise, Janneke van der Kamp (INSEAD) reported that, “The feeling is maybe we talk too much [about governance], there’s not enough action.” Her finding correlated with the critical observation, voiced by several participants from different perspectives, that partnership issues (including delivery of drugs and services) are most urgent at the field level:

- Denis Daumerie (WHO): “The problems are simple – you just have to solve them a thousand, a million times. They can only be solved at the local level. We were wasting time discussing global partnerships. You can’t improve practices from on high.”
- Nevio Zagaria (WHO): “A partnership is valuable when supporting a program on the ground responding to local health needs. PPPs are often decided at a global level, merging resources and contributions from different institutions focusing on a common goal. NGOs have a lot to offer in delivering health interventions to populations in need. Sometimes NGOs play more an administrative rather than an operational role. The channeling of the funds is not always done with the full involvement of the local national health authorities.”
- Alain Aumonier (Aventis): “I’m happy with the relationship with people in the WHO headquarters – how can this kind of partnership be developed at the regional and country level?”

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4 Dudley was alluding to an issue that surfaced several times, though indirectly, during the conference: Namely, that the different perspectives of industry, NGOs, and the public sector are expressed in sometimes distinct vocabularies, or in particular ways of using shared terms. The question of whose vocabulary is employed, and in which contexts, therefore impacts on matters ranging from communication within partnerships to the influence of given partners (in the sense that the way a problem is defined partly determines the solution).
2. The Role of the Public Sector

A. PPPs have altered the scope and scale of public initiatives

Rob Ridley’s Programme at WHO (research and training in tropical diseases - TDR) is emblematic of the opportunities and challenges for the public sector that arise from PPPs: Created 27 years ago because of a lack of R&D – basic, field, academic and product R&D – it has subsisted on a relatively small budget and initiated several successful drug development projects through public private partnership. During this period other organizations (e.g. the Wellcome Trust, EU, NIH and others) have contributed to a “huge increase” in basic sciences funding. In the late 1990’s interest in product R&D was further developed and, with TDR support, led to the establishment of independent PPPs such as MMV, GATB and the Drugs for Neglected Diseases Initiative (MSF).

Through PPPs, says Ridley, the scope and scale of public sector operations is altered: “We have experience of individual partnerships in R&D for over 25 years and how to manage these through appropriate legal agreements and memoranda of understanding. What’s new is the extent, breadth and amount of money.” Hence public sector management “is becoming more professionalized and mainstream.” However, there’s still “a huge lack of resources for product R&D in the neglected diseases and tropical diseases sector – more is required of both the public sector and the private sector, to solve the problem.”

B. The public sector assumes a “gatekeeper” role

The public sector, and WHO in particular, has apparently assumed a gatekeeper role in PPPs – here meaning that, while WHO does not control participation in initiatives, it frequently serves as intermediary or matchmaker between companies, NGOs and countries.

Examples of this role abounded:

- Alain Aumonier noted that Aventis “had very lengthy discussions with WHO before acting, but this was a necessary preliminary.”
- Boris Azais (IFPMA) commented that one of his organization’s key functions is to serve as a channel and a facilitator between WHO and the pharmaceutical industry on an ad hoc basis for partnerships and joint initiatives. For a variety of reasons, past experiences show that the level of interest in working in partnerships with the pharmaceutical industry varies between different clusters in WHO.
- Nevio Zagaria reported that WHO has interacted with and supported NGOs that are capable of delivering health services, particularly in countries in experiencing civil unrest in areas that are not under Government control.

Some of the reasons that WHO has adopted this role, and that industry accepts WHO in this role, were evoked by Penny Grewal (Novartis Foundation), in explaining why Novartis and the Novartis Foundation collaborate with WHO:

- No worry (for recipients, stakeholders) about “getting involved with Big Pharma” (i.e., credibility is assured).
- Health ministries perceive the tropical disease programs as local, and “the programs fit with local priorities” (i.e., countries are empowered).
- WHO provides vital country level support and technical guidance.
- “Crucial: there are no tariffs, no barriers, when drugs are supplied through WHO.”
C. The visibility of public sector influence: Two examples

The public sector can to some extent impose its criteria on partners, as Loretta Foran (INSEAD) suggested: “For the public sector, scale and experience is not a requirement in partners, but it’s a definite plus. They like larger partners.” With smaller companies (notably biotech), she added, “Public interest partners have to monitor more.”

Likewise, noted Foran, the public sector may take a different view on drug efficacy standards: “When do you decide a drug is good enough? So far, [pharma’s] regulatory concerns focus on the developed world. The public sector may want to push forward before the private companies, [who] don’t want to be criticized for having double standards.”

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1 This element appears in “virtual R&D” – wide scale funding to industry and academia – a procedure which “enables the public interest partner to monitor the [R&D] process.”
Overview: A “sea change” in corporate involvement

A “probably irreversible sea change” has occurred in industry, in part through its growing involvement in PPPs, said Michael Reich: “Ten years ago you wouldn’t have seen CEOs of Big Pharma sitting and wondering how to improve health care in the world’s poorest countries.”

One sign of that shift is a startling rise in pharma contributions to developing world health needs. Trevor Jones (ABPI) cited investments of $564M in research on drugs for developing world diseases in 2001, and Boris Azaïs said that annual drug donations from the ten biggest pharmaceutical companies rose to $812M in 2002. He also noted that 95% of those donations are related to long-term development projects (PQMD data).

Equally important, the mission of pharma has changed via PPPs, said Alain Aumonier: “Pharma was asked to provide treatments to individual people, and is now asked to help populations.” Jeffrey Sturchio agreed: “Partnership must be viewed as a way toward improving population health, not as an end in itself.”

However, the implications of this shift were not the object of a consensus among participants. In fact, comments indicated growing divergence of opinion about the role of industry in PPPs. Interestingly, this divergence was visible not only between industry and other partners, but between different industry participants. The most salient aspect of this trend, so far as the workshop showed, concerns the industry’s primary (though not exclusive) focus on R&D as its principal contribution. Different aspects of this issue arose throughout the workshop, and are grouped in the rest of this section.

A. The industry’s R&D focus: Consensus and conflict

1. “Our primary role is to invent new drugs”

The majority of industry participants argue that their role in PPPs is R&D, aimed at “specific diseases in specific contexts,” noted Aumonier. Industry contends (and, significantly, many participants agreed⁶) that it is uniquely equipped for this task:

- Gill Samuels (Pfizer Global Research and Development)(Pfizer): “The one thing you learn in the industry is how you make a molecule ‘druggable’ – you need expertise and kit that academic institutions and government don’t have. You can’t just take public money and find who’s doing the work.”
- Boris Azaïs: “Our primary role is to invent new drugs.”
- Trevor Jones: “Our real role is discovering and developing products… We need new medicines, that’s what we’re doing.”

2. Points of tension around the industry position

Despite this near-consensus among industry participants – nearly all of whom, significantly, represent R&D-oriented companies – there are several points of tension re: the primacy of R&D in PPPs, both within industry and between industry and other participants.

a. Using PPPs to support the industry’s business model

It is clear that by assuming the role of lead researcher, the industry seeks in part to justify its business model at a moment when it is under

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⁶ However, Michael Reich points out that “some people might argue that industry’s main contribution should be its products or its money, not its focus on R&D.”
severe and unrelenting attack. From the industry’s perspective, it is faced with a profound (and unjust) irony: At the same time that the importance of its discoveries for public health are recognized, the fact that it profits from its discoveries is used against it. As Roy Widdus (IPPPH) noted, “The R&D based industry was regarded as part of the problem, not part of the solution.”

The industry portrays its R&D skills and the profits it makes from them as keys to the solution – because without the profits, there would be no resources to develop the skills. Thus Trevor Jones argued that R&D on drugs that can be deployed in both the developed and developing world is “in our interest commercially as well as humanly. I make no apologies for that. We’re in business to make money.” The point applies in a different way to biotech companies, according to Loretta Foran: “PPP is a source of funding for them – they didn’t have resources or scale, and saw virtual R&D as a way to advance their work.”

The industry’s argument is accepted by participants like Joelle Tanguy (Global Alliance for TB Drug Development): “If major drug companies don’t find the [business] model attractive, they won’t contribute technically.” But it nonetheless leaves openings to critics, such as one ironically defined by Denis Broun (MSH): “Are we discussing PPPs, e.g. partnerships, or mechanisms that provide money to private entities to develop? That’s called contracting, and that’s not the same thing.”

b. Can PPPs be justified by the bottom line?

A second issue, which it can be safely predicted will grow in importance, is that because pharma companies have shareholders, they will be required to publicly justify their PPP activities in R&D in terms of the bottom line. We will return to this issue in more detail later. Here, let us consider two points:

• First, bottom line requirements can mean, as Loretta Foran noted, that pharma companies may be “supply driven: They have a compound, they carry it through.”

• Second, the industry is already, and will increasingly be, called on to justify its investments in these programs as strategic. GSK’s Tres Cantos lab in Madrid is one example. While GSK “does not expect any commercial return” from the lab’s activities, according to its director Federico Gomez de la Heras, GSK nonetheless plans to “be among the leaders in the field.” The facility thus has real strategic importance to GSK, on several grounds – new development processes, creation of products for marginal markets, etc.

c. Is pharma doing R&D in the most effective way?

A third issue, expressed by two participants, concerns the way in which pharma conducts R&D. Joint projects like MMV (discussed in greater detail below) have not eliminated the perception that companies are more concerned with proprietary discoveries than sharing knowledge to combat diseases. One participant said, “I’d have liked more commitment from more companies. One or two out of ten could have opened labs a bit more.” Denis Daumerie commented: “I was shocked by the way pharma addresses R&D for neglected diseases. Instead of competing in a corner, cooperate.” Both these remarks were, in effect, appeals to industry to collaborate more on specific diseases, particularly those for which resources are already short, rather than pursuing separate efforts.

B. Is R&D the fundamental need?

A further issue, omnipresent throughout the workshop, is whether drug R&D is the most effective way of addressing developing world health needs. It came up from both industry and public sector participants.

One concern is that the focus on R&D obscures needs such as product development.

The problem is not particular to the pharma industry, noted Roy Widdus: 95 percent of funding from public entities in this sector now goes to R&D, and only 5 percent to product development – that is, the transformation of a scientific discovery into a packaged and deliverable treatment.

A broader question is whether R&D, no matter how brilliant, can compensate for shortcomings in existing health systems.

• Lola Dare (ACOSHED) asked: “Africa will not solve its problems if we keep doing what we’re doing” – i.e., concentrating on...
the discovery of medicines, rather than reforming the systems that deliver them. Underlining the point, she challenged the group: “Should the initiative be investing in systems, or in R&D?”

- Likewise, Yves Champey (DNDi) declared: “Most of present drugs and vaccines innovation organizations do not answer to the issue of how to deal with the needs of poor patients in poor countries.”

- Boris Azaïs remarked: “Because the research-based industry is around the table, that increases the focus on research as a means of addressing the source of the problem or the potential solution. In fact, increasing access to existing essential drugs and therapies (most of them off-patent and inexpensive) may have a greater public health impact in LDCs than additional innovation.”

The growing involvement of pharma in public health makes such issues unavoidable, but their resolution, as Ethan Kapstein (INSEAD) noted, is often, and in some major ways, beyond pharma. One prominent example is education. As Kapstein remarked, “Primary education is the best health investment. Some countries do spend on education – few on primary, almost none on girls.” Scott Ratzan (Johnson and Johnson) agreed that health education is “the best investment for health, especially for mothers,” but pointed out that “many companies have no competence at the system level for investments in education.” Moreover, a danger for pharma companies that undertake such initiatives is the possibility, evoked by Kapstein, that partnership programs may be perceived as biased toward dominant social or ethnic classes. Despite these obstacles, some companies are investing in such initiatives:

- According to Scott Ratzan, “Johnson and Johnson has invested significantly in education throughout the world. So J&J has a variety of competencies including education, training, capacity building as well as health sector investment.”

- Jeffrey Sturchio reported on Merck and Co.’s work with the Bank of Uganda in 2000 on a workplace program for employees with HIV. It was the first such program in Uganda, and among the first in the banking sector in Africa. Merck also helped to sponsor the Uganda Business Coalition on HIV/AIDS, mobilizing business on HIV issues.

C. A growing demand for other pharma skills beyond R&D

Industry’s focus on R&D has one other consequence, which participants repeatedly alluded to: It obscures the fact that additional industry capabilities are in high demand. One of the most crucial, referred to by Gill Samuels, is the simple fact that industry has deep experience in the management skills required for alliances and partnerships, “not confined to developing countries – active collaborations with academia, institutions.” These skills include focus on delivery, clear responsibility and accounting ability, transparency in accounting and reporting, and defining and achieving milestones.

Likewise, Frans van den Boom pointed out that “vaccine development partnerships have three players: Developers, industry (process and manufacturing skills), and clinical/scientific groups in developing countries. Managing these partners demands different skills for different groups.”

For example, he noted, managing academic partners involves getting them to focus on product development instead of basic science issues. When it comes to industrial involvement, IP and technology transfer issues have to be addressed. Technology transfer to developing countries has to take into account the lack of capacity and expertise in those countries. Involving scientific groups in developing countries must consider recruitment, training/retraining, and retention of staff. In general, trust and responsibility levels must be established and maintained.

7 In correspondence following the workshop, Jeffrey Sturchio commented on the relationship of such sector-specific programs to the issue of poverty: “With a per capita income of around $300 (last time I checked), Uganda qualifies as a poor country – arguably any PPP that helps to improve healthcare in Uganda is ‘helping the poor.’ The IPPPH study presented in Paris by Louisiana Lush [see below] reaches the conclusion that the health programs they explored [including Merck’s] were making a difference in the lives of the poor. Finally, the best way to improve population health in Uganda or other developing countries is to implement a variety of initiatives, each designed to solve a particular problem for a specific population. The sum of these interventions – if designed effectively – will add up to ‘making a difference in the lives of poor people,’ as well as other economic strata. Single programs should not be viewed in isolation.”
Janneke van der Kamp suggested that “something like internships” between pharma and NGOs could serve to further mutual understanding of skills and issues among partners from different sectors, but noted that internships would not suffice to transfer industry capabilities: “There are things like clinical trials and regulatory affairs that require a whole machinery, not just someone with a half-year experience.”

A similar point was made by Federico Gomez de la Heras, who was asked if GSK trains scientists in the Third World, as Intel does in Costa Rica. He replied, “To take full advantage of pharma R&D training in developing countries you need a whole support structure.” The implication was that such structures are beyond the means of any one pharma company.

Other industry capabilities that are in growing demand include packaging, manufacturing and process control, issues management, general management, and evaluation skills:

- **Re: packaging,** Louisiana Lush noted that in Uganda, “New blister packs and dosages for local conditions have made a huge difference,” while Penny Grewal agreed that “innovative packaging and information is crucial to proper use of our drugs.”

- **Re: issues management,** Lilian Dudley commented: “If one can identify system problems up front, one can start to leverage health system development at ministries, and define roles and responsibilities. We’re not saying pharmas should provide human resources – but they can leverage governments and other resources to address the shortcomings.”

- **Likewise,** Janneke van der Kamp (INSEAD) wondered why the industry does not make more use of its “enormous political clout” to focus government attention on the need for more health resources.

- **Raj Thamotheram** (Universities Superannuation Scheme) pointedly counted “using their political influence” among the things pharmas “do best” but highlighted that this raised issues about whether such influence was being used wisely.

- **Dudley** also appealed for **general management skills transfer:** “Another major problem is capacity – human capacity at management and service delivery. There are major expertise gaps, from the developing to the developed world. I would like to see more done by pharmas to support development of human capacity – not just donations.”

- **Re: manufacturing and process control,** Frans van den Boom reported, “In order to bring a product to market, we need the process and manufacturing skills of Big Pharma.”

- **Re: evaluation skills:** Armelle Armstrong pointed out that corporations have long experience in designing performance metrics, and asked how corporate partners could help measure success and impact in PPPs. The issue is crucial, and we will return to it later in this report (see “Evaluation of PPPs”).

How much and how many of these skills can pharma safely transfer to developing countries, and under what conditions? The workshop did not address these issues. But participants’ interest in them clearly suggests that they will soon be more urgent.

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8 All of these issues are familiar in some form to industry alliance and partnership managers. However, these managers are not the ones involved in PPPs, so far as this workshop indicated. We will look at this issue again under the heading of “Ownership Within Companies.”

9 Dr. Lush’s comments were based on her recent study (with K. Caines, J. Bataringaya, G. Murindwa and H. N’jie, “Impact of Public-Private Partnerships Addressing Access to Pharmaceuticals in Low Income Countries: Uganda Pilot Study” (IPPPH, 2003). The study, presented during the workshop, was considered by participants as one of the first and most comprehensive country-level assessments of the effectiveness of PPPs.

10 He added: “At this point IAVI is collaborating with different vaccine companies testing different vaccine approaches (DNA, bacterial and viral vectors).” Likewise, Alain Aumonier reported that Aventis is on the way to having its sleeping sickness drugs manufactured by local companies in developing countries.
4. Ownership of Partnership Programs: A Double Issue

Participants discussed ownership – who gets credit and power, and what is done with it – in two distinct ways. The first, explicit way was in terms of control of programs. The second, tacit sense concerned ownership within companies: Who is driving the program, and who else buys in? Both forms of ownership have direct current impact on PPPs.

A. Ownership of programs among the various actors

Industry participants held strong views about program ownership. One position – that ultimate ownership should reside with public authorities – can be described as idealistic. Its outlines were clearly defined by Penny Grewal:

“ It should be government responsibility; health is a public good. I have a problem with creating parallel structures – it’s not sustainable. We could have gone through parallel structures. Our preference was to go through governments. It works. Ownership should be with governments, and that means WHO [is involved]. You have corrupt governments, but you have corrupt NGOs as well. NGOs have a role, but the framework has to be set by governments.”

She added that in terms of program beneficiaries, ownership is perceived as residing with the end of the delivery chain: “As soon as you have high quality care available, the local health worker is empowered, and gets credibility in the community.”

Louisiana Lush (London School of Hygiene and Tropical Medicine) reported that this ideal has in fact been put into practice in Uganda, so far as her recent study of PPPs in Uganda could determine: “All initiatives seen were run as national disease elimination programs. All the people we spoke with agreed these programs fit with national priorities.” Significantly, drug company donors were credited for their products: “People said, ‘These are diseases of concern, the drugs help us do something.’”

However, participants agreed that in practice, ownership issues are increasingly draining, in fairly direct proportion to the number of partners involved.

- Denis Daumerie commented: “A lot of unnecessary time is wasted to solve emotional issues among partners – visibility, ownership.”
- Alain Aumonier suggested that these issues are often related to internal struggles within each partner, such as competition or conflict between headquarters and legal affairs (for example, over IP issues): “We have to face our own complexities, and so does WHO.”

Focusing on action in the field – on delivery of a drug or health service to patients – was perceived as the best remedy. It also serves as a test of whether partners are serious. Said Penny Grewal, “If you trust [each other] you’re looking for solutions, not problems.” Denis Daumerie agreed: “If you say, ‘Ownership is with the local people and government, we’re here to help, let’s discuss concrete issues’ – they’re easy to solve.”

B. Ownership within companies

1. The need for champions

Janneke van den Kamp reported that most companies don’t have a standard process for joining PPP initiatives: “It was mainly resulting from a push by individuals, at any level from R&D to CEO.” In other words, within companies, champions are needed. Eric-Marie Dupuy (Sanofi-Synthelabo) drew a portrait of the constituencies that he has to convince and handle, within and outside the firm, in order to successfully implement an “access to treatment” program. The list was fairly long, and the
particular interests of its members were more or less congruent.

It was significant that at least two industry representatives at the workshop (Jones and Samuels) are themselves research scientists. Samuels noted that “one thing that incentivizes the research scientist is the knowledge that the medicine will ultimately get to the patient.” Alain Aumonier seconded her point: “Many feel a greater personal reward in developing a treatment for malaria than for acne.”

If this workshop was an accurate indication, key champions within companies are currently drawn mainly from scientists and external affairs. It is worth asking if this partially explains the observable bias of pharma companies toward partnerships focused on R&D, as well as their desire for partnerships that deliver rapid, reportable successes.

2. The necessary involvement of top management

The role of top management in supporting PPPs was seen as critical for industry involvement, in two different ways.

- On the one hand, as Loretta Foran noted, a company’s involvement in PPPs “often comes from [top] management saying “We want to do more.”

- Conversely, programs driven by managers below chief executive or board levels require top management support in order to get the attention of operational executives. Thus Alain Aumonier said that Aventis’s programs were decided “at the highest level, Board of Management. Involving them was not an easy task, but essential to have support in the company for day to day work.”

3. Operational managers: How to get buy-in?

Alain Aumonier’s allusion to the difficulty of obtaining “support in the company for day to day work” was echoed by Boris Azaïs. He commented that while programs are typically decided at the chief executive level, and viewed as a reputational or ethical investment, at lower levels programs may be originally seen as costs by commercial operations managers. Persuading line managers to participate whole-heartedly in such programs (for example, by ensuring that they are included in annual objectives) is a key factor of rapid implementation and success of the program.

Trevor Jones noted that at the individual level, managers must sometimes consider personal risks when getting involved in programs: “It’s not just about [how the manager uses the company’s] money, but persuading someone to do something that may not be good for their career prospects.”
A paradox was clear throughout the workshop: PPPs are an accelerating phenomenon, and apparently a durable one, yet there is still little knowledge of whether, when, and why they work. The workshop clearly indicated deep (and for some, urgent) concern with more reliably measuring the success of PPPs, as well as their effects on health systems.

This demand apparently reflects a turning point in the PPP movement, particularly on the pharma side. At least some partnerships appear to have been designed to serve “secondary” or “indirect” purposes vis-à-vis public health – to ameliorate corporate images, bolster political relationships (notably with the WHO), or counter criticism by NGOs. They are now refocusing on having a direct, measurable impact on specific diseases. Several distinct evaluation issues emerged in the workshop:

A. Evaluation before a program launches

The first often unanswered need is for evaluating needs and capacities at the global, country or district level, and the abilities of partners, before a program begins. There is little consensus on how this can or should be done, but there were numerous insights into different aspects of problems that could be measured.

• Iain Gillespie (OECD) pointed out that there are no measures to estimate the risks of developing a treatment portfolio as opposed to a single drug. Moreover, OECD does not have techniques or metrics to evaluate where marginal health dollars are best spent. He asked: “Does it matter?” The question for OECD was whether or not a PPP is the best vehicle for a given project.

• Hannah Kettler (Bill and Melinda Gates Foundation) countered that “as a funder”, evaluation of partner capabilities is essential before engagement.

• Joseph Saba (Axios Intl.) noted that some programs may not be addressing real needs when they place a request for products or donations: “There is little quantification of demands due to insufficient local infrastructure. We’ve seen this pattern with many programs. The problem is that programs in the same area don’t usually talk to each other. Even with the same government, we get requests from people who don’t talk to each other. We’re trying to get people together to talk about demands, quantification of needs at the country level.”

• Lilian Dudley underlined the missed opportunity costs: “If one can identify system problems up front, one can start to leverage health system development at ministries, in defining roles and responsibilities.” It would thus be interesting to know: “How much audit of country systems is done by partnerships? Is it one of the yardsticks [for participation]? If so, how is it applied?”

B. Evaluation during the program life cycle

1. Who should report to whom?

The question of what should be reported, and to whom, was raised repeatedly. On the one hand, participants were concerned that reporting requirements may become an increasing operational drain for PPPs. Louisiana Lush observed that in Uganda, “There were cases of burdensome reporting requirements, but these were WHO or national, not pharma [demands].” The necessity of obtaining useable and informative data about programs appears more salient at the present than concerns that there may be too much reporting.

A proposal by Cathy Garner (MIHR) was repeatedly cited by other participants: “Put in evaluators as part of the project. Instead of..."
mary evaluation, do formative evaluation as you go along, to see how you can improve. That can speed you up, allow good practice, help it work – not create blame and criticism.”

2. A demand for reliable, standard indices

Industry participants, in particular, were concerned that data from the field requires greater standardization. Alain Aumonier (Aventis) said that his firm’s program is “wondering how to achieve a greater consistency in what is reported from the field.” Along the same lines, Scott Ratzan (Johnson & Johnson) proposed using a measurement such as a health competence index, to gauge success of a program over time. Parameters would include system characteristics, workforce features, social and political environmental factors, uptake of services, etc.

3. A sense of missed learning

Participants were uniformly concerned that in the absence of accepted metrics, “We’re losing lessons retrospectively”, in Lilian Dudley’s phrase. If and when evaluation is done, the knowledge is not widely shared. Thus, said Lola Dare (ACO-SHED), there is “very little evaluation of what works in different settings” – that is, good or best practices. The scarcity of best practices knowledge may be one factor reinforcing separation or impeding networking between PPP programs.

C. An emerging consensual standard: the number of patients treated

Pharma industry participants repeatedly underlined that the success of a PPP is best measured in terms of the numbers of patients to whom medications are finally delivered. It is fair to say that such a metric satisfies not only the necessity for quantifiable results, but also carries a powerful emotional force (“we have saved X lives”), within and outside a program.

• Penny Grewal (Novartis Foundation) argued: “The outcome parameters are what happens at field level.”

• Likewise, Gill Samuels (Pfizer Global Research and Development) strongly argued for delivery of medicines as the goal of PPPs, and hence the criterion for success.

• Justine Frain (GSK) underlined that the number of patients treated is not yet a standard metric, but should be: “I don’t think we’ve got the reporting requirements for PPPs right. They tend to be discussed only in terms of financial contributions. We’ll be better off when reporting also includes the numbers of patients treated.”

Alain Aumonier added a qualifier to this standard: While acknowledging its importance, he said that “the number of patients treated was not our only goal. Also of crucial importance was the size of the population screened and diagnosed as well as better knowledge of the endemic areas.”

It is important to note that on the issue of measuring programs by patients treated, Médecins Sans Frontières (MSF) agrees in principle with industry. Though Pierre Chirac of MSF said that he hadn’t “seen the impact” of PPPs at field level, he did offer an explicit criterion: “How many patients will benefit?” This criterion can be applied independently of structural changes (such as price discrimination).

D. Concerns over the emerging standard

If the number of patients treated is a consensual and necessary condition for evaluation of PPPs, Nevio Zagaria (WHO) warned that it is shortsighted: “We have to address populations...Not [delivery] to patients, but to populations.”

Lola Dare likewise argued that more is involved than “the number of doses [delivered] and patients treated”. Questions included: Are other desired outcomes (including exit strategies) achieved? Are there unintended consequences for patients, the health system and public policy? Lush et. Al.’s Uganda study found no such effects, but others have.

Michael Reich argued that there is an unexplored “normative or ethical” aspect to the evaluation issue – namely, the values underlying these ventures:

“How do we think about good consequences? Once the ethical aspects have been decided, there are empirical questions to answer: How do we increase the likelihood of good consequences? It is important to deal with both the normative and the empirical dimensions of evaluating partnerships.”

11 Similar issues are raised under “Infrastructure and Networking” below. Note that “different settings” are characteristic of the conditions in which PPPs operate, and may have an impact on transfer of best practices, as Alain Aumonier suggested: “Obstacles to access to anti-malarials in Tanzania are different from those to access to ARVs in South Africa. Each time it’s a local problem.”
Infrastructure – whether phrased in terms of “capacity building,” “health systems,” “human resources,” etc. – was at once a dominant theme and a source of frustration for the workshop. As noted above, pharma companies do not feel competent, nor is it their role, to undertake systemic reforms in developing countries. Yet there is clear recognition that unless health systems evolve, other initiatives will have marginal impact.

A second, related concern was networking – or how diverse initiatives may combine their forces. Both issues involved several sub-themes, which we will treat separately.

A. An approaching bottleneck: clinical trials and approvals

As new drugs and vaccines aimed at tropical and neglected diseases move through the development pipeline, it is clear that **greater capacity for clinical trials will be needed, and that the need will grow if development is accelerated.** One participant commented that this is “a prerequisite for moving forward,” and added: “We need the cash to do that. Somebody has to fund it.”

Developing clinical trial capacity is also a way to reduce costs, noted Trevor Jones: “In MMV, it will cost some $100-200M to bring some of these [drugs] through [to approvals]. If you have the clinical infrastructure, you can bring these costs down.”

Jones added that the EU research councils are funding clinical research networks, and that the British Medical Research Council (MRC) has “hundreds of people” working on this issue in Gambia. However, **pharma companies must do trials to developed nation standards.** He clearly implied that trials standards must meet developed world criteria: “Could we turn [the Gambian network or similar initiatives] into a machine to do clinicals that will get data that will pass FDA standards? We can’t cut corners.”

Rob Ridley mentioned the “downstream” possibility that the European Agency for the Evaluation of Medicinal Products (EMEA) will develop a mechanism that might allow for an “approval status” to be given for certain drugs of value to the developing world, even though these drugs would not be marketed in Europe. WHO would be engaged in these discussions to help assess when this might be appropriate. J. Carl Craft (MMV) found the concept dangerous: “Never lower standards for developing drugs in the Third World. We’re giving them to uneducated people without health systems – standards must be high.”

Ridley also reported that WHO/TDR used part of its funding to build capacity for trials using local investigators, and to develop “a network of clinical trial investigators and monitors.” The challenge, he said, is to “move expertise from the front end of drug development so that we can have the whole spread from lab to clinic” operating in disease-endemic countries. He was effectively appealing for PPPs to dedicate part of their funding to this capacity.

Ridley also pointed out that not only clinical trials capacity, but also regulatory approvals capacity is crucial to speeding development. This capacity is extremely limited in many countries. Ridley noted that the principle that authorization for marketing approval of drugs must reside in a country, or (as in the case of EMEA) be negotiated through a regional approach, is “sacrosanct.” Thus attention is moving towards building the capacity of national regulatory agencies to handle approvals. “Building that capacity is equally important to developing R&D,” said Ridley. But he added, “It is not easy to get funding here.”

B. Does a “Manhattan Project approach” work?

Should the war against HIV/AIDS be fought like the Manhattan Project – the group of U.S.-based scientists who built the atomic bomb during...
World War Two – bringing together the best minds from different fields into a single, focused group? The question was explicitly raised, as we’ll see below. In a larger sense, to what extent can PPPs construct coordinated networks to fight specific diseases, or groups of diseases? Participants identified unmet needs as well as limits to the benefits of networking.

1. Skepticism toward an anti-AIDS “Manhattan Project”

Trevor Jones asked: “Isn’t it about time we made a Manhattan Project about HIV/AIDS, to pool intellectual and physical resources to find a truly effective vaccine, rather than handing cash to a few people and hoping they work it out?” The idea was widely rejected by the workshop.

- Ethan Kapstein replied: “You say we should have a Manhattan Project, throw money at it – any number of people in the World Bank say as much, only to find that money is being taken [i.e., stolen or wasted]. Given government problems in target countries, can we have effective progress?”
- Gill Samuels seconded: “I have a cynical view of Manhattan Projects – with academics who are over-optimistic about deliverables, and don’t have the same time frames that are beaten into us in industry.”

2. A distributed network approach to fighting AIDS

The IAVI, as described by Frans van den Boom, resembles a virtual or network type Manhattan Project, based on a scientific strategy that brings together all the concerned players. IAVI believes that in order to accelerate development and delivery of an AIDS vaccine, a business approach will do better than a classic academic approach. However, it is “an enormous and difficult task.” The challenges require a high level of management, and include:

- The desire for individual recognition.
- Institutional interests, and competition within and between academic groups and industry.
- Emphasis on basic science vs. product development.

3. Limits of research networks

a. Non-transferability of specific disease knowledge

A related issue, raised by Hannah Kettler (Bill and Melinda Gates Foundation), is the extent to which knowledge about specific diseases can be transferred to other diseases: “Is the network for malaria useable for other diseases, or just for malaria experts?” The consensus of the group appeared to be that while knowledge and skills required for building and managing projects or networks may be transferable, and are essential, knowledge required to develop treatments for specific diseases is far less transferable. As Trevor Jones said, “People in Thailand and South Africa really know malaria. It’d be hard to switch them suddenly.”

b. The need to involve southern researchers

Louisiana Lush warned: “[Research] Networks don’t seem to be including southern research institutions. They must be engaged.” Gill Samuels may have been referring to this when she warned that developed nations must not “keep wiping out infrastructure” – for example, by drawing scientists away from home – in the developing nations. Cathy Garner of MIRH said her organization was “keen to build a network” involving southern institutions, an implicit acknowledgement that the problem has yet to be addressed.

Frans van den Boom warned, “If you don’t involve the local [research] partner you might think you accelerate, but then it will slow you down.” Partners only commit if they are involved in defining the scope and content of the partnership agreement, which includes IP issues, as well as the design and implementation of trials.

c. The MMV model

The Medicines for Malaria Venture (MMV) clearly struck most participants as a model of how to accelerate research and development of treatments for a major tropical disease, involving compounds and personnel from most major pharma companies and some biotech firms, “working on a huge portfolio of target sites in the [malaria] parasite – 15 projects, with five therapies in the pipeline,” said Jones. “The single most comprehensive program of drug development in the world.”

While little detail was offered on the program, Federico Gomez de la Heras described the
MMV-GSK miniportfolio agreement: “We collaborate not on a single project, but on a portfolio of projects previously agreed by both MMV and GSK. If a single project goes nowhere, what do you do for a year, six months? If we identify that a project goes nowhere, we discontinue it and redirect those resources to a new project.” The portfolio is managed “jointly” with MMV. Gomez de la Heras considered this an important development innovation.

C. Integration with or support of existing systems?

How does a PPP fit into existing health systems, helping and not hurting it? In effect, there were repeated allusions to unwanted side effects of creating new programs. For example, Louisiana Lush argued that AIDS programs must “be seen in the context of broader development policies, so these programs don’t distract or subtract from what’s already going on.”

Nevio Zagaria (WHO) was adamant on this point: PPPs must not seek to replace country systems, or to create “parallel” systems, but to bolster the systems in place:

“The challenge is not to integrate the partnerships into the health systems. [Through a PPP] we have something to reduce the burden [on a given system]. Integration between the partnership and the system is to support the health systems in increasing access to effective public health intervention.”

Are PPPs skewing national health care agendas? asked Lola Dare. “The Uganda study [which showed high correlation between PPP goals and national priorities] says no, but other studies say yes. Also, are they increasing inequities, within and between countries?”

The competition between vertically-structured PPPs and existing government programs for human resources is a specific area of general concern, defined by Denis Daumerie: “There is always a risk that vertical programs attract local health workers and recruit the best of them, sometimes at the expense of more comprehensive delivery of health care services.”

However, as Penny Grewal observed, at the present, “Most PPPs have to fit in with the existing structure of health services delivery. It is up to countries to choose how best to deliver health services to their populations, and not to a given partnership to dictate how this should be done. Jeffrey Sturchio underlined the importance of the human resources issue: “In Botswana, the President and Health Minister have said, ‘It isn’t a lack of money – the critical obstacle is a lack of trained nurses and physicians.’ So that’s one thing we focused on through ACHAP.”

D. Access, delivery and availability

Discussions indicated a strong linkage between three nominally distinct issues: availability of drugs, access to drugs, and distribution infrastructures that get them to patients. (In fact, when participants used the term “infrastructure,” they usually referred to distribution.) Unless drugs are available and can be delivered to patients, there is no access. (These issues appear less strongly linked to the question of drug pricing, which we will look at separately in section VII, “Pricing and IP Issues”.)

The pharma industry makes drugs available to Africa – to a large extent through donations, judging by the workshop discussions. The Uganda study indicated that those donations do reach patients, and that donors are appreciated by recipients.

However, the industry does not make drugs available within Africa. Said Trevor Jones, “We at MMV won’t get involved in delivery. It’s difficult enough to develop products, we need the right partners to deliver them. It is our responsibility to see they get into proper networks.” In practice, that means WHO or NGOs, notably MSF. Pharma companies do not have the infrastructure themselves, individually or as an industry, to assume that role, noted Lush: “There is very little presence of companies at the country level, so it’s a non-issue to talk about coordinating them.”

It is worth noting that this absence offers powerful legitimacy to pharma’s critics. Said Pierre Chirac, “If we launch a campaign, it’s because we

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13 How large was not defined at the workshop; the impression that donations are a majority of total distribution in Africa was questioned by Pierre Chirac, who asked: "Where are the data [to support the proposition that donations outweigh sales]?”
realize that on the ground the situation is unsatisfactory and worsening.”

*Creating delivery capacity cannot be done from the top down*, said Alain Aumonier: “Access to medicines is a global issue, but it’s a multitude of different problems. What are the factors of access? Where are the blockages? Access to anti-malarials in Tanzania raises quite different problems compared to access to ARVs in South Africa. *Each time it’s a local problem, a specific issue.*”

*In many places, delivery networks appear not to exist, despite initiatives to support access infrastructures*, notably by the Novartis and Bill and Melinda Gates Foundations. Louisiana Lush reported that “most Ugandans can’t reach places where drugs are available.” The WHO’s Drug Access Initiative – “essentially a catalyst to get ARVs in-country through a price and delivery system” – succeeded in reducing prices for some patients. But Lush concluded, “It’s difficult to see how DAI as set up could ever meet the needs of the poor.”

Denis Daumerie argued that the most important delivery issues involve training local personnel, logistics (including transport and security), and above all information: “If the community is informed they have the right to treatment, they move mountains. They move us. If you tell people they have the right to treatment low price or free, they ask for it.”

It is worth asking if the pharma industry, or another industry with deep experience in advertising, mass marketing and distribution can contribute needed expertise here. The point was suggested by Fleur van Bladeren (Dutch Partnership on Smoking Cessation): “Coca-Cola is all around Africa. Can’t we use that infrastructure for medicine?”
The single most divisive issue raised in the workshop – both within the industry and among its critics – was preferential or differential pricing and its corollaries, such as local manufacturing of drugs. Industry participants raised the issue early in the workshop, in a clearly defensive mode. However, as discussion progressed, two points of near-consensus emerged. The first is that many (though not all) participants agreed that while preferential pricing in some form is inevitable and/or necessary, it is not sufficient to assure access to drugs. Next, the industry is already looking at different aspects of a world in which preferential pricing exists – business models, leakage, IP protection, and possible grounds of compromise with pharma’s critics.

A. Pharma on the defensive

Trevor Jones, followed by several colleagues from the pharmaceutical industry, addressed the pricing issue from the beginning of the workshop. The essence of his stance was that it is both counter-productive and unfair to blame pharma pricing policies for lack of access to drugs:

“Sixty percent of sub-Saharan people don’t get the drugs on the WHO essential list, that cost pennies. The drug industry isn’t the world’s health service provider. The price is a barrier, but not the price per se. The debate is false – it’s not us ripping off the developing world.”

Jones identified corruption as a major contributor to inflating prices for African patients. Said Jones: “I’ve seen throughout Africa a ridiculous uplift in the price of drugs from the time they land till the time they’re sold. It has to stop.”

Boris Azaïs argued that other factors, such as customs and tariffs, local VAT, local wholesalers’ and pharmacists’ margins, have as much or more influence on drug prices for patients as pharmaceutical companies’ global pricing policies. He further argued that access to drugs is not only a poverty issue, but also a public policy issue: Vietnam has a GDP per capita one-fourth that of Brazil, but more than twice the rate of patient access to essential drugs, according to UNDP and WHO/EDM data.

Eric-Marie Dupuy contended that in the absence of control of delivery systems, preferential pricing can only be ineffective: “I would like to see the pricing issue and cost recovery system addressed from the distribution point, so as not to load the warehouse when you don’t know how the product will reach the patient at the lower price.”

However, the workshop suggested that pharma is losing this debate, and not only in the NGO and development communities. Raj Thamotheram (Universities Superannuation Scheme) declared that within the financial community, “It’s clear that people close to the [pharmaceutical] sector aren’t convinced [by the industry’s arguments on pricing]. KPMG thinks the sector has shown an inflexible approach that has weakened its position, socially and economically.”

Despite pharma’s initiatives, the AIDS epidemic in Africa still provides ammunition to its critics, particularly on the pricing issue. In terms of image, there is a negative heritage factor, as shown by Pierre Chirac’s reminder that “five years ago the cost of ARVs in Africa was $15,000 per person per year.”

Louisiana Lush’s study found that the availability of generic ARVs did more to lower prices of ARVs in Uganda than WHO access programs. She warned: “The pricing issue will get more complicated. Under DAI in November 2000, when generic ARVs first became available, prices
of branded ARVs for which there was a generic equivalent available dropped up to 80% in one month.” Moreover, she said, “The cheapest rather than the clinically most appropriate treatment is the treatment of choice.”

The pricing issue is more pointed for AIDS, compared to other tropical diseases, for several reasons, noted Lush:

- The drugs are new;
- They are very high-value drugs;
- Patents matter;
- And the market is global, including developed countries.

Pierre Chirac suggested that preferential (or differential) pricing would be an increasingly important condition criterion for MSF’s involvement in assessing PPPs. MSF, he said, is “not impressed” by PPPs or their effects, “when we see that Big Pharma is not interested in differential pricing.” His organization’s position is clear: “The pharma industry must propose price discrimination for essential drugs.” MSF sees preferential pricing as ordinary business: “We are not talking about philosophy. Price discrimination is a market law. [But] ‘Big Pharma’ doesn’t implement it.”

Representatives from WHO organizations and other participants took a wider view, expressed by Denis Daumerie: “Pharmaceutical prices will not solve access issues. Pharma has to change prices, but that’s not enough.” In particular, said Denis Broun (MSH), “The problem is that inequality and poverty have increased – so the poorest have less access.” Pierre Chirac allowed that pharma is not entirely responsible: “The fault is not only on ‘Big Pharma’. But companies must not set rules that worsen the situation.”

In sum, participants agreed that the industry’s pricing policies are not the sole barrier to increased access to drugs in Africa. But there is increasing and widening pressure for changes in those policies. The industry and other participants are already anticipating that shift, as we will see below.

B. Pharma looks to the next step

1. Preferential pricing: a new business model?

Despite their repugnance to preferential pricing, it was clear that pharma representatives are not thinking only in terms of if preferential pricing will become general, but when and how. Justine Frain believes that “clearly ARVs are just the tip of the iceberg”:

“With preferential pricing, one point relevant to GSK, because we are the world’s biggest ARV supplier, is that the concept and design of preferential pricing is a difficult business model. We’re providing ARVs and antimalarials with no profit for 63 countries. We’re monitoring carefully, but there’s no way to plan that.”

In sum, said Frain, “Preferential pricing is not philanthropy – it’s a new business model.”

Similarly, Raj Thamotheram argued that involvement in developing world health issues can serve companies to define a sustainable business model at a moment when an industry shake-out is underway. The “survival” of companies may depend on that model, he suggested. Features of the new business model, he predicted, will include better relations with stakeholders (including NGOs), partnerships that can provide “lower value” care – that is, lower value in terms of shareholder return – and ways to recognize and satisfy the moral demands of knowledge workers, who will be in high demand among leading-edge firms across sectors. He added:

“My hypothesis is that NDCs and emerging markets are places where pharma companies can experiment with developing parts of a business strategy that will enable them to survive in their primary, developed markets. If some of that can be transferred to mature markets, we’d become a lot happier about pharma companies.”

2. The leakage issue

An issue of immediate concern to pharma companies is leakage – the illegal transfer of donated or cut-price drugs from developing to developed markets. Said Alain Aumonier: “If I discriminate on drugs sent to countries in need, where do they end up?”

The current scale of this problem cannot be determined (as is typical of any clandestine criminal enterprise). However, Lush observed in Uganda: “There were serious security problems, including while we were there – a scandal of drugs coming back into the UK.” She added: “I think it’s bizarre to imagine a flood of cheap ARVs from Africa to the EU. But it’s also local or regional – ARVs from Uganda will find their
way to Congo.” The problem has also appeared at the district level. The government has instituted anti-leaking measures, she reported, but the measures “have created confusion. [The Ministry of Health’s] director general has to sign off on every requisition.” In other words, in the name of security the director general has become the ultimate prescriptor, which is hardly the most efficient way to distribute these medicines.

3. Will IP be protected?

a. The industry sees IP protection as essential to incentivising R&D

IP issues are closely related to pricing, because from industry’s standpoint, as Boris Azaïs commented, “IP is a crucial guarantee for the industry that it can continue to invest in R&D and obtain reasonable returns on its past investments in R&D and manufacturing.”

Said Federico Gomez de la Heras: “The huge investment incentive to do new drugs has to come from governments – greater protection for IP, credits for investments in R&D.” As he sees it, governments must contribute to this effort by directly funding projects for diseases of the developing world, and by supporting the pharma industry’s efforts to discover and develop these drugs. That support may take the form of greater protection for IP, credits for investments in R&D, or other initiatives.

However, said Boris Azaïs, “A call to strengthen the IP regime by offering incentives may encounter resistance in the political arena. A group of people still believes that IP per se is not the solution, despite the fact that most pharmaceutical products in the market have been developed by the private sector thanks to the protection of IP rights.”

He nonetheless agreed that creating new incentives, such as the transfer of exclusive marketing rights, “may be one way to encourage research in poverty-related diseases.” Aventis and Eli Lilly, among other companies, are also experimenting with licensing drugs for production in developing countries.

Yet he pointed out that the belief that local manufacturing will suffice to solve the access problem is flawed: For example, while India has an estimated 20,000 pharmaceutical manufacturing sites, only 2,000 Indian patients receive structured treatment for AIDS.

b. IP protection can reduce the risk of counterfeiting

Boris Azaïs further argued that IP regimes with strong enforcement mechanisms are also a protection against drug counterfeiting, and that counterfeiting is not a small issue: “In some African countries, WHO estimates that half of all drugs are counterfeit – as a result, a sick person who may seek treatment, which is already a major public health achievement, has one chance out of two of buying a counterfeit. This is unacceptable.”

c. For some, patents remain an obstacle to drug production

However, said Frans van den Boom, “The current global system of patents has made it hard for low and middle income countries to produce essential generic AIDS drugs.” For that reason, said Pierre Chirac, “We are against a ‘one size fits all’ system of patents without flexibility and due exceptions.”

Yet van den Boom noted that even when a drug becomes available for free, this does not automatically lead to a fast or significant increase in uptake. He concluded: “Prices and patents are obstacles, but not the only obstacles.”

4. Elements of compromise

Frans van den Boom addressed pricing and IP issues as a multi-variable construct. On the one hand, he argued that participants must recognize that “we have to differentiate pricing for new AIDS vaccines.” On the other, “pharma does need guarantees of purchases.” Moreover, “investments for manufacturing will be enormous -- especially if we have massive doses, instead of a bell-shaped curve. Government should discuss these investments.” Conversely, he asked, “What will the public sector get back from the private sector for the huge investments in infrastructure [that will be required for delivery of new medications]?”

By unpacking these elements, we arrive at the parameters of a possible compromise:

- Pharma continues to invest in R&D.
- In exchange, governments provide IP protection and guaranteed purchases.
- Pharma allows differential pricing.
- In exchange, governments contribute to building infrastructure, capacity in manufacturing and distribution, and security against leakage at country levels.
Note that these elements are congruent with those contained in a “value strategy” for pharma companies proposed by Raj Thamotheram: flexibility on patents and pricing, quality of partners, active work with governments to ensure non-diversion of products, and wise use of corporate political leadership. In other words, similar ideas are emerging in more than one place.
8. Sustainability

A. At the project/country level

While Michael Reich suggested that the PPP movement (and the values it advances) may be irreversible, deep questions remained as to the sustainability of particular projects. There were two aspects of this issue at the country level.

1. Paradoxically, the first sustainability issue is termination.

Lola Dare put it simply: “What if Merck & Co. Inc. stops?”

Alain Aumonier suggested that projects or programs should not endure forever, and that this should be understood from the launch of a PPP:

“Companies have the habit and responsibility of working within defined timelines. Governments and institutions are made on longer timelines – companies can disappear or merge. So you have to have an agreement about duration of the contract and sustainability…. I know some programs were terminated because public partners were perceived as wanting a contract forever. A company can’t commit forever.”

However, he noted, “Sustainability can still exist if contracts terminate.” A program might be replaced by another, “second generation,” that carries the work forward, or another partner can be found.

That has not always been the case, reported Louisiana Lush: “There were examples where a disease got down to minimal levels, then there was a resurgence” after interest and funding dropped off.

2. How can successful programs scale up?

The second issue is that some programs have succeeded to the point where they should be expanded and rooted further. Beyond individual projects, said Nevio Zagaria, “There are neglected diseases for which we already have tools and strategies, and we cannot avoid talking about scaling up – we need PPPs to scale up at country levels.”

An underlying question here, once again, is the measure of success for different partners. Is the goal to generate positive PR or counter criticism, to develop and deliver a new treatment, to build capacity in different ways, or to eradicate a disease? Each of those goals implies a different time scale.

B. At the global level: widening the partnership circle

1. The missing political link

Workshop participants were unanimous that while PPPs can be useful tools, they are incapable of resolving the issues they are facing alone. Indeed, as Ethan Kapstein pointed out, the achievement of numerous goals discussed at the workshop will take PPPs and their partners from the health sector per se into a different realm: “When we think of helping populations, it’s political economy.”

From that perspective, a key missing link in the movement appears to be the political sector. Several participants, including Gill Samuels and Dya Eldin Mohammed Elsayed (Federal Ministry of Health, Sudan), remarked the absence of politicians at the table.

2. The inability or unwillingness of governments to contribute more

Yet politicians and governments were hardly absent from the debate. Repeatedly, the inability or unwillingness of governments (whether in developed or developing regions) to contribute appropriate resources to public health issues, at the national or international levels, was criticized.

- In the developing world, Alain Aumonier said: “We have invested with free drugs.
We hoped alleviating other structures from paying for them could allow funds to be reallocated to other programs and needs. This has not happened.”

• Lola Dare argued that in assessing partnerships and programs, it was crucial to “look at management not only at the global level, but also in the health care systems. How can political commitment be measured in this regard? When is a country committed to help?”

• Trevor Jones said that “we need governments from the developing world and governments of the rich world to put in cash and resources.” Only the U.K., Netherlands and Switzerland are supporting MMV – “a program that works, not for profit, and they’re not contributing.”

• Frans van den Boom said that a perspective shift is required in the North: “Funding countries give money in demand-driven, developed-country ways. We need a global approach – a demand-driven [Northern] country approach will not solve problems.”

3. The need for more unified lobbying

To involve politicians or simply get their attention, lobbying must be stronger and more unified, added Roy Widdus: “In the European Development Fund, expenditures on health are 2-3 percent. Not a priority. A lot of work has to be done to put health higher on the agenda. We have to sit together with PPPs and see how we can create synergies.”

4. A neglected priority for lobbying: International trade issues

Linkages to international trade issues were raised by Widdus and Lilian Dudley. She said, “Developing countries can’t buy drugs on open markets. I see no initiatives on international trade.” Said Widdus:

“Were always debating how to divide a limited pie. If you start factoring in trade protection and subsidies in the developed world, it becomes manageable – these two cost the developing world as much as health subsidies. If protection for inefficient farmers and industries was removed, there would be money for developing countries. INSEAD could make that case.”

C. Other potential new partners: Beyond pharma and NGOs

Can partners be drawn in from other sectors and industries, particularly to help resolve infrastructure issues? Pharmaceuticals are only one part of an effective health system, and perhaps not the dominant part. Gill Samuels remarked that medicines are only 12% of the U.K.’s NHS budget,15 and said: “Medicines are a drop in the bucket. Vastly greater resources are needed for a global health care program. A lot of things not discussed today will be expensive to implement and will require partnership.”

Multilateral organizations and the donor community were cited by Loretta Foran as possible partners. Roy Widdus observed that “we haven’t used peer pressure from existing funders onto new ones.” Promising projects must be identified and prioritized, “rather than spreading too thinly.”

15 Michael Reich notes that medicines make up a larger percentage of government health budgets in many developing countries. That said, Dr. Samuels’ argument that significant resources beyond medications are necessary for global health remains valid.
Several participants remarked that this workshop rendered visible a number of advances in the PPP movement, compared to only two years ago. This reporter was not present at the time, and so cannot draw detailed comparisons. However, judging from participants’ remarks, the following points can be advanced:

• PPPs have clearly contributed to the involvement of pharmaceutical companies in public health issues, as well as to the professionalization of the public sector and NGOs faced with the same issues. They are ceasing to be viewed as philanthropy, or as public relations, by numerous participants from industry and the funding community. Instead, in parallel with demands from the financial sector, they are globally evolving toward an exploratory venture in developing new business models and methods, as well as exploring new forms of distributed research and development. PPPs focused on drug donations have also contributed to disease control programmes at the country level and improved patients’ access to some treatments.

• Simultaneously, participants from outside industry are gaining appreciation for certain values of the pharmaceutical industry – notably its goals orientation and project and product management skills. By continuing to focus on R&D as its chief contribution, the industry may be missing an opportunity not only to share these valuable competencies, but in so doing, to gain wider acceptance and validation of the values behind them.

• While the confrontation between industry and other participants concerning issues such as pricing and IP remains vivid, an emerging critical mass (if not a consensus) is forming behind a compromise that would encourage industry to continue committing R&D resources in exchange for incentives and protection from governments. However, in the absence of government participation or interest in developing world health issues in general, and PPPs in particular, it is difficult to see how such a compromise could be enacted. Thus not only the pharmaceutical industry’s “political clout”, but also its ability to form policy alliances with multilateral organizations and NGOs, may be required.

• On the public sector side, the increased funding and resources made available through PPPs have enabled significant advances in certain programs. Yet there remain significant issues of evaluation, and of connections between international organizations and national or local authorities. These issues are now moving to the forefront of partnership management, and the public sector – in particular WHO, the leading “gatekeeper” – will certainly have to play a major role in addressing them. Significantly, the IPPPH evaluation in Uganda is the first evaluation of PPPs from the country perspective, and participants suggested that such evaluations should be carried out in other countries.

• Despite a troubling shortfall of evaluation metrics and methods, PPPs have acquired tremendous collective knowledge of program launch and management issues. However, that knowledge is not being widely enough shared. Some of this may be due to the competitive relations between industry partners, and another part may result from the limited scope of national or local initiatives. It is significant that organizations like the Bill and Melinda Gates Foundation, IAVI and the WHO are functioning, in effect, as “trusted third parties” within partnerships, enabling knowledge transfers that might not otherwise take place. Such knowledge sharing needs to be refined and accelerated.
A separate issue is whether there can be greater coordination and unity of purpose among partnerships (and not only within them, the principal subject of the workshop) – whether the particular challenge is to lobby politicians for greater investments in health, or to create secure conditions for the transfer of valuable drugs to developing countries, or to link dispersed efforts to discover and develop necessary medicines. While the PPP movement has succeeded in creating a nucleus that could contribute to such efforts, and has proven capable of cooperation among parties with different interests and values, it has apparently not found its place in a wider movement aimed at obtaining greater resources for public health. Moreover, though the question of how deeply PPPs should be involved in reforming or creating health systems, addressing the health of populations instead of patients, was raised directly and indirectly during the discussion, there was no consensus (and some significant conflict) around it. It may be too early to conclude that PPPs are being drawn or pushed toward partnerships and initiatives beyond the level of individual programs. But the plausibility, if not the feasibility, of such a shift is beginning to emerge.

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Annex 1: Agenda

Monday, 30 June 2003 (Day One)

2.45 p.m. – 3.00 p.m. Welcome and introductions
• Pierre Lepetit, Executive Director, IFRI
• Ethan Kapstein, Paul Dubrule Professor of Sustainable Development, INSEAD
• Roy Widdus, Project Manager, IPPPH

3.00 p.m. – 3.45 p.m. A Historical Perspective: Industry’s Contributions on Diseases Associated with Poverty
• Trevor Jones, Director General, Association of the British Pharmaceutical Industries

3.45 p.m. – 4.15 p.m. *** Break

4.15 p.m. – 5.45 p.m. PANEL:
The new corporate environment for pharmaceutical companies: Changing expectations
• Raj Thamotheram, Universities Superannuation Scheme Limited (USS Ltd)
• Pierre Chirac, Médecins Sans Frontières
• Frans Van den Boom, European Office, International AIDS Vaccine Initiative
• Boris Azaïs, Director of External Policy, International Federation of Pharmaceutical Manufacturers Association

Discussion

6.30 p.m. Visit to Genomics Laboratory, Institut Pasteur
7.30 p.m. Reception hosted by Institut Pasteur
— Introduction: Thierry de Montbrial, President, IFRI
— Remarks: Philippe Kourilsky, President, Institut Pasteur

End of day one
Tuesday, 1st July 2003 (Day Two)

9.00 a.m. – 10.30 a.m. **Panel:**
Engaging in programs to improve ‘access’ to pharmaceuticals:
Management issues

*Chair:* Lola Dare, African Council for Sustainable Health Development
(ACOSHED)
Nevio Zagaria, Acting Director, Control, Prevention &
Eradication of Communicable Diseases, World Health
Organization

- Overview – Janneke van der Kamp and Ethan Kapstein, INSEAD
- IPPPH Study of Access Partnerships in Uganda – Louisiana Lush, Lecturer in Health Policy, London School of Hygiene & Tropical Medicine
- Industry perspective – Jeff Sturchio, Vice President, External Affairs,
  Europe, Middle East & Africa, Merck & Co., Inc.
- Industry perspective – Alain Aumonier, Director, International Public
  Affairs, Aventis SA
- Industry perspective – Penny Grewal, Head, Health Care Sector,
  Novartis Foundation for Sustainable Development

Discussion

10.30 a.m. – 11.00 a.m. *** Break

11.00 a.m. – 12.30 p.m. **Panel:**
Engaging in R&D on health problems in developing countries:
Management issues

*Chair:* Gill Samuels, Senior Director, Science & Policy Scientific Affairs
  Europe, Pfizer
Robert Ridley, Coordinator, Product Research and Development,
  TDR/World Health Organization

- Overview – Loretta Foran and Ethan Kapstein, INSEAD
- Industry perspective – Gill Samuels, Senior Director, Science & Policy
  Scientific Affairs Europe, Pfizer
- Industry perspective – Federico Gómez de la Heras, GlaxoSmithKline

Discussion

12.30 p.m. – 2.00 p.m. *** Lunch

2.00 p.m. – 3.30 p.m. Roundtable discussion

*Chair:* Michael Reich, Dept of Population & International Health,
  Harvard School of Public Health

3.30 p.m. – 4.00 p.m. *** Break

4.00 p.m. – 5.00 p.m. **Future directions**

- Roy Widdus and Ethan Kapstein

5.00 p.m. Closure of meeting
Annex 2: List of Participants

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The aim of the Initiative on Public-Private Partnerships for Health is to increase the effectiveness of public-private collaboration, particularly by helping those seeking to develop health products, or to improve access to such products needed to fight neglected diseases and other health problems in developing countries.

Created in 2000 in Geneva, Switzerland, the Initiative on Public-Private Partnerships for Health is sponsored by the Bill and Melinda Gates Foundation, the Rockefeller Foundation and the World Bank. It operates under the aegis of the Global Forum for Health Research, an independent international foundation helping to correct the 10/90 gap in health research, from which it also receives support (www.globalforumhealth.org).

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