

**Chapter 8.1: Public-Private Partnerships for Neglected Diseases  
Opportunities to Address Pharmaceutical Gaps for Neglected Diseases**

Priority Medicines for Europe and the World  
"A Public Health Approach to Innovation"

Background Paper

**Public-Private Partnerships for Neglected  
Diseases:  
Opportunities to Address Pharmaceutical Gaps  
for Neglected Diseases**

By Elizabeth Ziemba, JD, MPH

7 October 2004

# Chapter 8.1: Public-Private Partnerships for Neglected Diseases

## Opportunities to Address Pharmaceutical Gaps for Neglected Diseases

### Table of Contents

8.1.1	Summary of Public-Private Partnerships.....	3
	A. Definition of Public-Private Partnerships for Neglected Diseases .....	3
8.1.2	Definitions and Economic Factors Relating to “Rare”, “Orphan”, and “Neglected” Diseases .....	4
	A. Legislative Definitions of “Rare Diseases” and “Orphan Drugs” .....	4
	B. Definitions of “Neglected Diseases” .....	5
	C. Factors Contributing to the Rise of PPPs.....	7
	D. Summary of Major Public-Private Partnerships for Health.....	9
8.1.3	Funding Public-Private Partnerships .....	11
	A. Estimated Cost of Drug Development.....	12
	B. Current Financial Investments in PPPs .....	15
	C. Non-Financial Contributions .....	18
8.1.4	Outlook for Public-Private Partnerships.....	18
8.1.5	Conclusion.....	22
	References.....	23

#### Case Studies and Needs Assessment of Four Public-Private Partnerships (See [Annex 6.1.3](#)) (separate documents):

1. [Medicines for Malaria Venture \(MMV\)](#)
2. [Drugs for Neglected Diseases \(DNDi\)](#)
3. [Global Alliance for Tuberculosis Research \(TB Alliance\)](#)
4. [International AIDS Vaccine Initiative \(IAVI\)](#)

### List of Figures

Figure 8.1.1	Number of public-private partnerships created between 1986 – 2003.....	8
Figure 8.1.2	- Stages of the Drug Development Process .....	12
Figure 8.1.3	Total grants awarded by the Gates Foundation from 1994 to January 2004 .....	15

### List of Tables

Table 8.1.1	Number of Partnerships with Associated Disease or Issue.....	10
Table 8.1.2	- Summary of Public-Private Partnerships for Product Development.....	11
Table 8.1.3	Summary of Drug Development Costs by Stage of the Process .....	13
Table 8.1.4	Summary of Estimates of Drug Development Timelines by Development Stage.	14
Table 8.1.5	Summary of Funding Pledged and Funding Needed for Drug Development.....	14

### [Annexes](#)

## **Chapter 8.1: Public-Private Partnerships for Neglected Diseases Opportunities to Address Pharmaceutical Gaps for Neglected Diseases**

### **8.1.1 Summary of Public-Private Partnerships**

Every year, approximately US \$70 billion is spent in health research but only about 10% of funding is targeted to the diseases that account for 90% of the global disease burden. The unavailability of medicines to people in developing countries results in enormous human and economic costs.<sup>1</sup> The disconnect between disease burden and the medicines available is largely due to the fact that there is little or no economic incentive for the for-profit pharmaceutical and biotechnology industries to research and develop medicines for people in poor countries where there will be no return on the substantial financial investment required to bring a drug to market. Legislative initiatives such as “Orphan Drug” statutes have been ineffective in developing medicines for the “neglected diseases” of people in developing countries.

Public-private partnerships are an innovative approach to close the medicines gap between wealthy and poor nations. Entities in both the private and public sectors in different combinations of partners are working together to combine financial and non-financial resources to create or provide urgently needed medicines to developing countries.

Among these, a new breed of public-private partnerships, focused on product development for neglected diseases, has emerged. These partnerships link public sector goals with private sector know-how to accelerate drug, diagnostics, and vaccine development targeting diseases such as HIV/AIDS, malaria, and tuberculosis as well as other diseases such as leishmaniasis and human African trypanosomiasis that are unknown in developed countries but that take an enormous toll on life and health in developing countries.

Public-private partnerships are filling the gaps where current economic incentives have failed. The political and social will to support these organizations is growing. The European Union has provided little support for these initiatives. Now it is time for financial and institutional support to match the efforts of these partnerships to respond to the health crisis in developing countries.

#### **A. Definition of Public-Private Partnerships for Neglected Diseases**

During the past ten years, the global health community has identified gaps in research and development of medicines to prevent or cure diseases that are primarily associated with extreme poverty and its attendant lack of access to clean water, adequate nutrition, and basic sanitation.<sup>2</sup> While diseases such as malaria, tuberculosis and others that are even less well known are rampant in developing countries; they are virtually unheard of in developed countries<sup>3,4,5,6</sup> There is little or no economic incentive to develop pharmaceutical products<sup>7,8</sup> for these diseases as well as other issues including: “distribution challenges in countries with poor infrastructures and lack of awareness about these diseases in more developed countries”<sup>3</sup>, “liability considerations, inadequate science base, and underestimation of the disease burden”<sup>9</sup>. As a consequence, a minimal amount of research has been conducted. To address this enormous and widening gap in availability of medicines, an innovative approach to solve this problem has been created in the form of Public-Private Partnerships for Neglected Diseases (PPPs).<sup>10</sup>

## **Chapter 8.1: Public-Private Partnerships for Neglected Diseases**

### **Opportunities to Address Pharmaceutical Gaps for Neglected Diseases**

PPPs bring together skills, knowledge, and resources from a variety of sectors including academia, non-governmental organizations, philanthropists, not-for-profit organizations, government and intergovernmental agencies, as well as members of the for-profit private sector such as pharmaceutical and biotech companies to create a unique approach to solving a global health issue. From 1986 when the first PPP for health was created until the end of 2003, 91 such partnerships have been instituted, 78 of which are still in existence.<sup>11</sup> Each partnership has its own separate legal status, broad range of goals, combinations of partners from the public and private sections, management structures and strategies.<sup>11</sup>

The spectrum and mix of public and private entities involved in any one partnership can range from an organization such as Drugs for Neglected Diseases Initiative which has no representatives of the private sector on its Board of Directors<sup>12</sup> to the Pharmaceutical Security Institute whose members are companies that are research-based for-profit multinational pharmaceutical firms.<sup>13</sup> For example, the International Trachoma Initiative is comprised of a for-profit entity, a private foundation, national governments, other private foundations, non-governmental organizations, and the World Health Organization.<sup>14</sup> Many partnerships reflect a mix of representatives from the public and private sectors on their Boards of Directors some of whom represent a particular institution while others sit in an individual capacity; however, it remains unclear which model is optimum for ensuring success.

The nature, variety, and individuality of public-private partnerships make definition difficult.<sup>15,16,17</sup> For a working definition, Public-Private Partnerships for health can be defined as “arrangements that innovatively combine different skills and resources from institutions in the public and private sectors to address persistent global health problems”.<sup>18</sup>

#### **8.1.2 Definitions and Economic Factors Relating to “Rare”, “Orphan”, and “Neglected” Diseases**

The terms “rare diseases”, “orphan diseases” and “neglected diseases” have been used interchangeably generating confusion when discussing diseases and programs associated with them. These terms have been defined with varying degrees of specificity and usefulness in statutory or legislative terminology or informally as used by organizations and institutions in public health.

##### **A. Legislative Definitions of “Rare Diseases” and “Orphan Drugs”**

The terms “rare diseases” and “orphan drugs” are given specific statutory or regulatory meanings in developed countries including the United States, Japan, Australia and the European Union. Singapore and Korea also have “orphan drug” policies. (See [Annex 8.1.1](#) for regulatory details including legislative definitions). For each of these countries, the term “rare disease” is tied to the concept of the number of people within a population who have a particular disease (disease prevalence) within each geographical area. In the United States, the Orphan Drug

## Chapter 8.1: Public-Private Partnerships for Neglected Diseases

### Opportunities to Address Pharmaceutical Gaps for Neglected Diseases

Act (P.L. 97-414), as amended, defines “rare diseases and conditions”. A numeric prevalence threshold is set out in the legislation as well as an economic condition to be met:

“The term rare disease or condition means any disease or condition which (a) affects less than 200,000 persons in the U.S. or (b) affects more than 200,000 persons in the U.S. but for which there is no reasonable expectation that the cost of developing and making available in the U.S. a drug for such disease or condition will be recovered from sales in the U.S. of such drug”.

Under this statute, any drug that is approved to treat the “rare disease or condition” is designated an “orphan drug”.<sup>19</sup> Through usage, “rare diseases and conditions” are commonly referred to as “orphan diseases”.<sup>19</sup>

The concept of low prevalence and associated lack of economic incentive to develop medicines for the small potential population has been adopted by other developed countries. Applying these standards, “rare diseases” in one developed country may not be a “rare disease” in another. Among the four countries with legislative definitions of “rare disease”, degrees of prevalence set by each definition varies.

#### Orphan Drug Prevalence Criterion

Australia	Japan	United States	European Union
1 / 10,000	4 / 10,000	7.5 / 10,000	5 / 10,000

Source: [www.europarl.eu.int/stoaa/publi/167780/chap5\\_en.htm](http://www.europarl.eu.int/stoaa/publi/167780/chap5_en.htm), accessed 16 February 2004.

Through the development of “orphan drug” legislation, governments have set economic incentives to overcome market failures and to encourage industry to develop medicines for diseases of low prevalence in developed countries.

#### B. Definitions of “Neglected Diseases”

None of the statutes and regulations created by these governments use or refer to the term “neglected disease”; however, the term is used in the public health field in discussions about diseases that afflict millions of people in developing countries but for which there are no or few medicines available. “Neglected diseases” may share the two major characteristics of “rare diseases” in that they have zero or low prevalence in developed countries and there is no economic incentive to develop new or improved methods of prevention or treatment. Unlike “rare diseases” that have a universal low prevalence, “neglected diseases” only have zero or low prevalence in developed countries but have millions of sufferers globally, primarily in poor countries.

Organizations such as Public-Private Partnerships dedicated to global health issues frequently use the term “neglected diseases” when referring to a group of diseases affecting developing countries. To redress the imbalance in availability of medicines

## Chapter 8.1: Public-Private Partnerships for Neglected Diseases

### Opportunities to Address Pharmaceutical Gaps for Neglected Diseases

to developing countries, PPPs are used as a means to gather resources and funding to be applied to solving this problem.<sup>12</sup>

According to the Drugs for Neglected Diseases Initiative<sup>20</sup>, “neglected diseases” can be characterized as diseases that:

- Kill millions each year, primarily in the poorest areas of the developing world, such as malaria and tuberculosis.
- Seriously disabling or life threatening for which treatment options are inadequate or do not exist such as leishmaniasis and Chagas’ disease.
- Could be cured or prevented with the currently available science and technology, but for which research and development has ground to a standstill.
- Do not constitute a valuable enough market to stimulate adequate research and development of new medicines.
- Governments have failed to redress market failure.

The International Federation of Pharmaceutical Manufacturers Association (IFPMA) calls for a clear distinction between those infectious diseases for which treatment is available such as leprosy or onchocerciasis but for which delivery systems and infrastructure within developing countries hamper the efforts for drug access, and diseases such as Chagas disease, leishmaniasis, and African trypanosomiasis that are “truly neglected” diseases because no cure or treatment is available.<sup>21</sup>

An initial attempt by the MSF/DND working group sets out a framework and formula to identify “neglected diseases” and focuses on three areas of analysis: (1) existing disease treatment and/or diagnostic test; (2) disease burden; and (3) complimentary factors.<sup>22</sup>

The MSF/DND analysis looks first at the question of whether a treatment exists and whether that treatment is safe, effective, affordable, and easily applicable in the field. A similar analysis is suggested for diagnostic methods. Second, what are the disease burdens in terms of geographic distribution, disease magnitude, and disease severity? The final set of factors to be considered are: number of new chemical entities marketed in the past 25 years; number of drugs under clinical development; cost of complete drug treatment per patient; number of publications discussing new causative pathogen; number of people working on the target disease; and targeted research and development initiatives such as public-private partnerships.

Much work remains to be done to hone a definition of “neglected diseases” that will be universally accepted. Focusing on prevalence, existing or potential economic incentives, and disease burden provides a framework for evaluating potential solutions to categorizing various diseases as “rare”, “orphan”, or “neglected”.

Technically, neglected diseases qualify for “rare disease” status in the United States and Europe but the economic incentives built into this type of legislation have not benefited diseases for which there is no paying market.<sup>4</sup> Defining a disease as a “rare disease” allows policy makers to create economic incentives for research and

## **Chapter 8.1: Public-Private Partnerships for Neglected Diseases**

### **Opportunities to Address Pharmaceutical Gaps for Neglected Diseases**

development of medicines for diseases of developing countries as the low prevalence rate and market based lack of incentive classifies many of the diseases of the developing world as “rare” in developed economies. Despite the artificial economic incentive created by Orphan Drug legislation, this mechanism has not been used to develop medicines for neglected diseases.

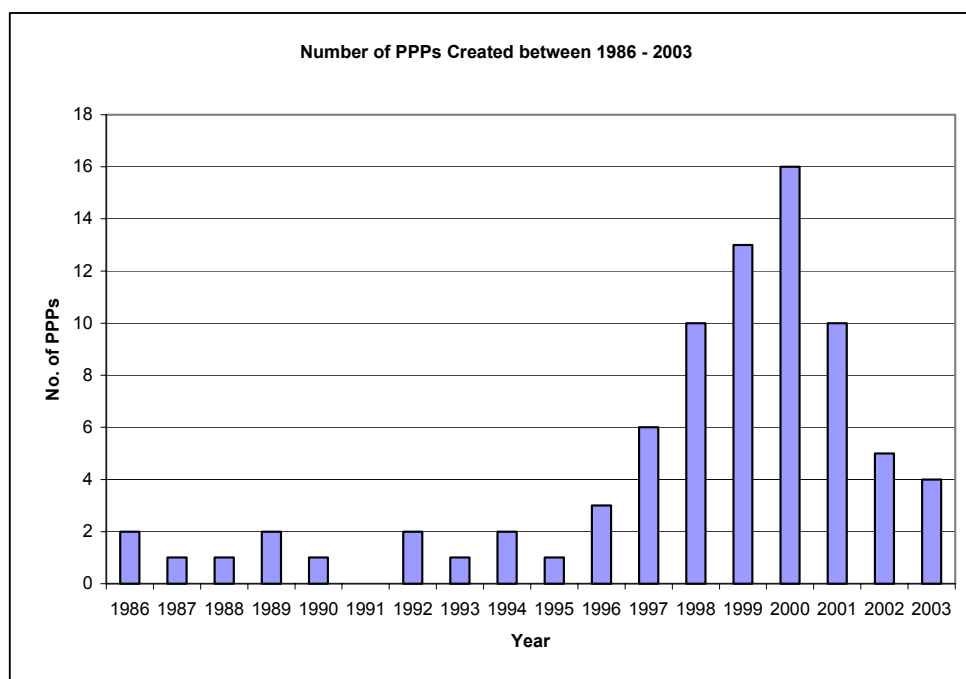
#### **C. Factors Contributing to the Rise of PPPs**

Public-private partnerships have existed in the United States and United Kingdom for several decades in areas such as criminal justice, transportation, energy, and more, with the Federal government as a leading partner.<sup>23,24</sup> Until the late 1970’s, little collaboration existed between the private and public sectors in health research; however, by the early 1980’s, changing attitudes enabled broader relationships to be formed with international agencies looking for a greater role for the private sector.<sup>4</sup> By the 1990s, both the private and public sectors acknowledged that “a pure market mechanism generally does not work”<sup>15</sup> where medicines are involved and new approaches needed to be developed. Public attitudes as championed by consumer, environmental, and other civil society groups encouraged the participation of the private sector by demanding corporate responsibility and accountability.<sup>16</sup> The private sector responded to public pressure and entered into new arrangements with the public sector as part of the business strategy of “pharmacophilanthropy”<sup>15,25,26,27</sup>

The vast majority of PPPs were formed in the past seven years as illustrated in Figure 8.1.1. Research into the reasons for this spike in PPP formation is beyond the scope of this paper.

## Chapter 8.1: Public-Private Partnerships for Neglected Diseases Opportunities to Address Pharmaceutical Gaps for Neglected Diseases

Figure 8.1.1 Number of public-private partnerships created between 1986 – 2003



**Source:** Extracted from data found on the website for Initiative on Public Private Partnerships for Health, [www.ippph.org](http://www.ippph.org). Accessed week of February 16 – 20, 2004.

Traditionally, the primary actors in the research and development of medicines and vaccines were the public research institutions and private pharmaceutical companies in developed countries.<sup>15</sup> Public researchers at universities contributed primarily to the early stages of drug research while development, production and commercialization would be handled by the private sector.<sup>4 29</sup>

Prior to the intervention of PPPs, economic factors were the primary driving forces behind the decision making process as to which products were to be developed within the private sector. If insufficient markets existed to allow the company to make a profit, then private companies did not pursue medicines that could be used to treat diseases endemic in developing countries, i.e. malaria, tuberculosis, or leishmaniasis.<sup>4</sup> People in developing countries are too poor to buy the medicines needed to cost justify the expense of research and development of new medicines.

A huge gap in research developed and exists between diseases of rich and poor countries. According to the Global Forum for Health Research, “Every year more than US \$70 billion is spent on health research and development by the public and private sectors. An estimated 10% of this is used for research into 90% of the world's health problems. This is what is called ‘the 10/90 gap’”.<sup>28,29</sup>

During the first part of the 20<sup>th</sup> century, the discovery and development of the majority of current tropical medicines were driven by the needs of the colonial



## Chapter 8.1: Public-Private Partnerships for Neglected Diseases

### Opportunities to Address Pharmaceutical Gaps for Neglected Diseases

countries.<sup>30</sup> Lack of sufficient financial returns for medicines to treat or cure “tropical diseases”<sup>1</sup> has caused a sharp drop in the number of medicines available. From 1975 to 1999, only 1% of the 1,393 new chemical entities marketed were registered for tropical diseases and tuberculosis despite the fact that these diseases account for 11.4% of the global disease burden.<sup>31</sup> In addition, “because of the timing of industry disengagement, research into tropical diseases has missed out on the substantial advances in drug discovery technology brought about by the developments in molecular and structural biology, medicinal chemistry and robotics in the 1980s and 1990s”<sup>29</sup>

Impelled by the knowledge that millions of people globally die or become disabled from diseases for which there are no or inadequate medicines and seeing that the free market has no incentive to develop such medicines, PPPs have been created to fill this void.

#### D. Summary of Major Public-Private Partnerships for Health

According to the Initiative for Public-Private Partnerships for Health,<sup>2</sup> 91 public-private partnerships for health were formed between 1986 and 2003. Of this total, 78 are still in existence and active. Please refer to [Annex 8.1.2](#) for summary background and financial information for each partnership. These partnerships reflect the diversity of purpose, collaborators, and goals that reflect the number of global health issues requiring urgent attention as well as the flexibility of the partnership model. Please also refer to the Spreadsheets in Appendices [8.1.2.1](#), [8.1.2.2](#), and [8.1.2.3](#) as well as Annex [8.1.2.4](#) for Summary information for partnerships.

In general, public-private partnerships are formed for one of three basic purposes: (i) product distribution; (ii) product development; and (iii) policy or health systems issues.<sup>32</sup>

i. Certain PPPs are designed to assist people in developing countries by improving distribution of medicines or medical products to prevent or treat diseases. For example, the Mectizan Donation Program sponsored by Merck Pharmaceutical focuses on distributing its medicine, ivermectin, to treat onchocerciasis.<sup>33</sup>

ii. The majority of partnerships focus on the development of medicines, vaccines or products for use in the treatment or prevention of neglected diseases.<sup>34</sup> The diseases that have the most number of PPPs currently working on developing medicines or preventative tools are HIV/AIDS, malaria and tuberculosis. The Medicines for Malaria Venture (MMV) was created to “fund and manage the discovery, development, and registration of new medicines for the treatment and prevention of malaria in disease-endemic countries”<sup>35</sup>. The Development of Autodestruct Syringes

---

<sup>1</sup> As defined in the paper “Drug Development for neglected diseases: a deficient market and a public-health policy failure”, tropical diseases are: malaria, African trypanosomiasis, Chagas’ diseases, schistosomiasis, leishmaniasis, lymphatic filariasis, onchocerciasis, intestinal nematode infections, leprosy, dengue, Japanese encephalitis, trachoma, infectious diarrhoeal diseases, and tuberculosis.

<sup>2</sup> The IPPPH, based in Geneva, has two primary aims: to monitor, analyze and facilitate the exchange of information on PPPs; and to foster the development of new partnerships. [www.ippph.org](http://www.ippph.org).

## Chapter 8.1: Public-Private Partnerships for Neglected Diseases Opportunities to Address Pharmaceutical Gaps for Neglected Diseases

partnership was formed to create and produce single-use, self-destructing syringes for use in immunization programs in developing countries.

iii. The third type of PPP concentrates on health policies and systems as they relate to global problems. The partnership, Pharmaceutical Institute, focuses on the issues of counterfeit and substandard drugs as they may be manufactured or distributed worldwide as well as in developing countries.

Of the 78 active partnerships, the number of partnerships that focus on certain diseases or health policy issues is set out below in Table 8.1.1. Categorization is not an exact science as partnerships may deal in any combination with product distribution, product development, and/or policy and health systems issues between or among various diseases.

**Table 8.1.1 Number of Partnerships with Associated Disease or Issue**

13 + 1*	-	HIV/AIDS (See Global Fund below)
12 + 1*	-	Malaria (See Global Fund below)
8	-	Health policies and systems
7	-	Chagas, leishmaniasis, trypanosomiasis, lymphatic filariasis – individually or in combination with each other
6	-	Microbicides
5 + 1*	-	Tuberculosis (See Global Fund below)
5	-	Vaccines of the poor
4	-	Onchocerciasis and/or trachoma
3	-	Micronutrients/Vitamin A
3	-	Reproductive health
2	-	Dengue
1	-	Communicable diseases – prevention through hand washing with soap
1*	-	The Global Fund to Fight AIDS, Tuberculosis and Malaria
1	-	Guinea Worm
1	-	Hookworm
1	-	Lassa fever
1	-	Leprosy
1	-	Meningitis
1	-	Polio
1	-	Schistosomiasis
1	-	Tetanus

**Source:** Extracted from data found on the website for Initiative on Public Private Partnerships for Health, [www.ippph.org](http://www.ippph.org), accessed 26 February 2004.

For information on selected specific neglected diseases, please see Section 6.9.

Sixteen public-private partnerships have been established specifically for product development (PD-PPPs). The PD-PPPs are identified in the following table.

## Chapter 8.1: Public-Private Partnerships for Neglected Diseases Opportunities to Address Pharmaceutical Gaps for Neglected Diseases

Table 8.1.2 - Summary of Public-Private Partnerships for Product Development

### PD-PPP Endeavor Addresses Some of Top Global Killers

Disease target	No. of people killed annually by disease*	Number new cases annually*	PDPPP	focus	Committed dollars raised to date*
HIV / AIDS	2.8M	5.5M	IAVI	Vaccines	\$350M
			SAAVI	Vaccines	\$45M
			IPM	Microbicides	\$95M
			MDP	Microbicides	\$27M
TB	1.6M	8.0M	TB Alliance	Drugs	\$42M
			Aeras	Vaccines	\$108M
			FIND	Diagnostics	\$30M
Malaria	1.2M	300 – 500M	MVI	Vaccines	\$150M
			EMVI	Vaccines	\$18M
			MMV	Drugs	\$97M
Dengue Fever	19K	20M	PDVI	Vaccines	\$56M
Hookworm	3K	N/A	HHVI	Vaccines	\$18M
Leishmaniasis	51K	1.0-1.5M	DNDi / IOWH	Drugs	\$10M (IOWH)
Chagas	14K	16-18M	DNDi / IOWH	Drugs	\$30M (DNDi)
Other			RoADIP/PnADIP	Vaccines	\$60M
<b>Total</b>	<b>5.7M</b>	<b>351-553M</b>			<b>\$1.1B</b>

Source: WHO 2002. \* “B” = Billion, “M” = Million and “K” = Thousand

Sander, A, Widdus, R. The emerging landscape of public-private partnerships for product development, IPPPH workshop “Combating Diseases Associated with Poverty: Strategies for Produce Development and the Potential Role of Public-Private Partnerships”, April 15-16,2004, London, England.

Each of these sixteen PD-PPPs use private sector approaches to face research and development challenges, primarily target one neglected disease, and use a portfolio management approach to pursue their goal of filling a public health rather than commercial need by developing a product specifically for use in developing countries.<sup>36</sup>

These sixteen PD-PPPs represent more than \$1.1 billion in committed funding which includes funding received as well as funding that is pledged in the future.<sup>36</sup>

Tremendous variety exists among the public-private partnerships in terms of focus, management, size, donor base and other factors. No single way has emerged as the “winning combination” and each partnership should be viewed on its own distinctive merit.

### 8.1.3 Funding Public-Private Partnerships

According to DiMasi, it can cost more than US \$800 million to bring a medicine or vaccine from the research to distribution stage<sup>37</sup> and can take 10 to 12 years to develop. Annual sales of at least US \$200 million for a single drug are required to justify the level of investment from the private sector.<sup>38</sup> Rather than finance the entire drug development process, PPPs look to “invest strategically, to establish new discovery projects, to jump-start stalled or shelved projects, and advance the field of science in the specific diseases”.<sup>4</sup> By using this opportunistic strategy, PPPs hope to spend less than the industry average for product development and shorten the development time but, at this time, this strategy has yet to be fulfilled.

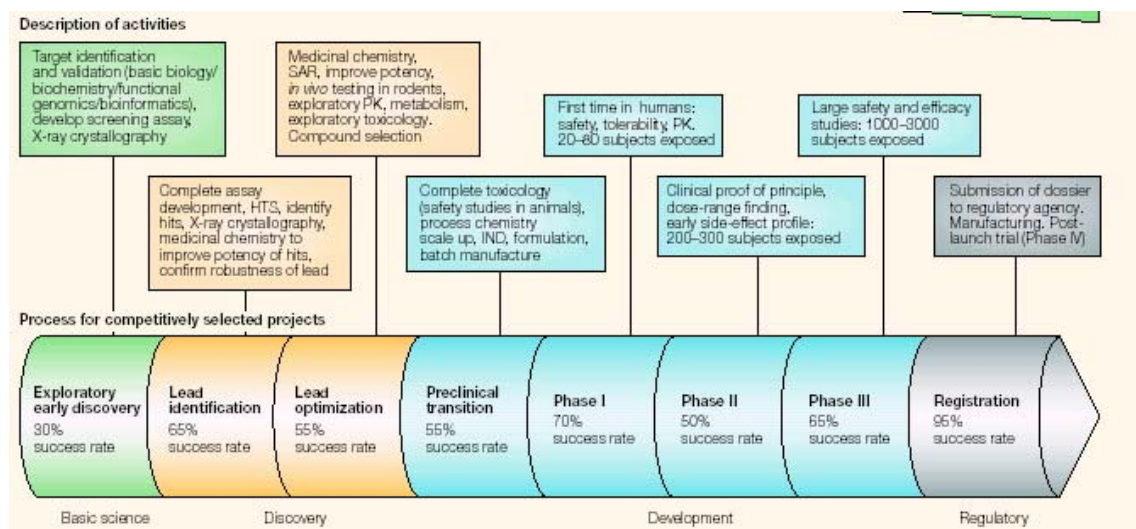
## Chapter 8.1: Public-Private Partnerships for Neglected Diseases Opportunities to Address Pharmaceutical Gaps for Neglected Diseases

### A. Estimated Cost of Drug Development

The cost of developing a novel medicine and bringing it to market is a significant financial undertaking. While there is much debate about the true actual cost, an often-cited estimate is \$802 million US dollars.<sup>37</sup>

The drug development process comprises several basic steps which break down into four major stages: (1) Exploratory basic discovery; (2) Lead identification and lead optimization; (3) Preclinical transition plus Phase I, Phase II and Phase III of clinical trials, and (4) Registration:<sup>29</sup> Stage 1 typically occurs at colleges and universities conducting basic research while Stages 2-4 are developed in the private sector.

Figure 8.1.2 - Stages of the Drug Development Process



Nwaka S, Ridley R, Virtual drug discovery and development for neglected diseases through public-private partnerships, *Nature* November 2003; Volume 1: 919-928, 924.

These steps exclude the post-discovery costs associated with delivering and distributing the product in the market.

In order to develop and sustain a partnership with developing countries to reinforce clinical capacity for the development of new tools to fight HIV/AIDS (See [Annex 8.1.4](#)), malaria and tuberculosis, the European and Developing Countries Clinical Trials Partnership (EDCTP) was created in 2003.<sup>39</sup> The EU and national programmes have committed 400 million Euros to support clinical trials and clinical trials capacity in developing countries including 200 million Euros for new funding through EDCTP.<sup>39</sup> The activities of EDCTP include: fostering cooperation and networking of European NPs accelerating clinical trials of new and improved existed products, in particular drugs and vaccines in developing countries; ensuring that research effectively addresses the needs and priorities of developing countries; helping to develop and strengthen capacities in developing countries; encouraging the participation of the private sector; and mobilizing additional funds to fight these diseases.<sup>39</sup>

## Chapter 8.1: Public-Private Partnerships for Neglected Diseases Opportunities to Address Pharmaceutical Gaps for Neglected Diseases

The estimated development costs by stage of four PD-PPPs are compared with the same estimated costs of development costs of the major pharmaceutical companies:<sup>40</sup> The for-profit pharmaceutical information is based on the DiMasi article which examines the cost of drug development (MMV, TB Alliance, DNDi) as opposed to vaccine development (IAVI).

**Table 8.1.3 Summary of Drug Development Costs by Stage of the Process**

	MMV	TB Alliance	DNDi	IAVI	DiMasi et al.
<b>Total discovery and pre-clinical</b>	8.33	18.6	16.2	20.0	26.0
Phase I	1.58	0.6		7.0	15.2
Phase II	1.15	3.4			23.5
Phase III	9.5	22.6		30.0	86.3
<b>Total clinical</b>	12.23	26.6	24.2	37.0	125.0
Other	1.5	8.0		50.0	5.2

Towse A., Renowden O. Estimates of the Medium Term Financial Resource Needs for Development of Pharmaceuticals to Combat Neglected Diseases, IPPPH workshop "Combating Diseases Associated with Poverty: Strategies for Produce Development and the Potential Role of Public-Private Partnerships", April 15-16,2004, London, England. Modified from page 14.

Variations in the estimated costs may be due to several factors including number of clinical trials, lengths of clinical trials, numbers of patients per trial, cost per patient per trial as well as variation by disease as well as development of medicines as opposed to vaccines.<sup>40</sup> Estimates of drug development timelines among these five entities vary somewhat and it should be noted that the DiMasi article refers to medicines rather than vaccines:<sup>40</sup>

## Chapter 8.1: Public-Private Partnerships for Neglected Diseases Opportunities to Address Pharmaceutical Gaps for Neglected Diseases

**Table 8.1 4 Summary of Estimates of Drug Development Timelines by  
Development Stage**

	MMV	TB Alliance streamlined	DNDi	IAVI	DiMasi et al.
	Months	Months	Months	Months	Months
Discovery and preclinical	96	-	60	30	52
Phase I	12	19	60	30	12
Phase II	12	24			26
Phase III	24	36		36-48	34
Approval	12	6			18
<b>Total clinical</b>	<b>60</b>	<b>85</b>	<b>60</b>	<b>72</b>	<b>90</b>
Years	5.0	7.1	5	6.0	7.5
<b>Total</b>	<b>156</b>	<b>-</b>	<b>120</b>	<b>102</b>	<b>142</b>
Years	13	-	10	8.5	11.8

Towse A., Renowden O. Estimates of the Medium Term Financial Resource Needs for Development of Pharmaceuticals to Combat Neglected Diseases, IPPPH workshop "Combating Diseases Associated with Poverty: Strategies for Produce Development and the Potential Role of Public-Private Partnerships", April 15-16, 2004, London, England. Modified from page 16.

Based on current funding levels for four of the PD-PPPs, there is an implied funding shortfall between the amount pledged and the amount of funding needed to successfully bring a drug to market for the targeted neglected diseases.<sup>40</sup>

**Table 8.1.5 Summary of Funding Pledged and Funding Needed for Drug  
Development**

\$ mn	Cumulative funding pledged to 2007	PPP estimate of cumulative required resources to 2007	Implied shortfall
IAVI	174	1,036	862
TB ALLIANCE	35.75	249	213
DNDi	0	255	255
MMV	97	152	83
<b>TOTAL</b>	<b>306.75</b>	<b>1,692</b>	<b>1,413</b>

Towse A., Renowden O. Estimates of the Medium Term Financial Resource Needs for Development of Pharmaceuticals to Combat Neglected Diseases, IPPPH workshop "Combating Diseases Associated with Poverty: Strategies for Produce Development and the Potential Role of Public-Private Partnerships", April 15-16, 2004, London, England. Modified from page 19.

There is a large gap between the current available funding and the finances needed to bring the products to market. Donors and PPPs need to improve their understanding of the size of the funding gap and measures to be taken to bridge it.<sup>40</sup>

## Chapter 8.1: Public-Private Partnerships for Neglected Diseases Opportunities to Address Pharmaceutical Gaps for Neglected Diseases

### B. Current Financial Investments in PPPs

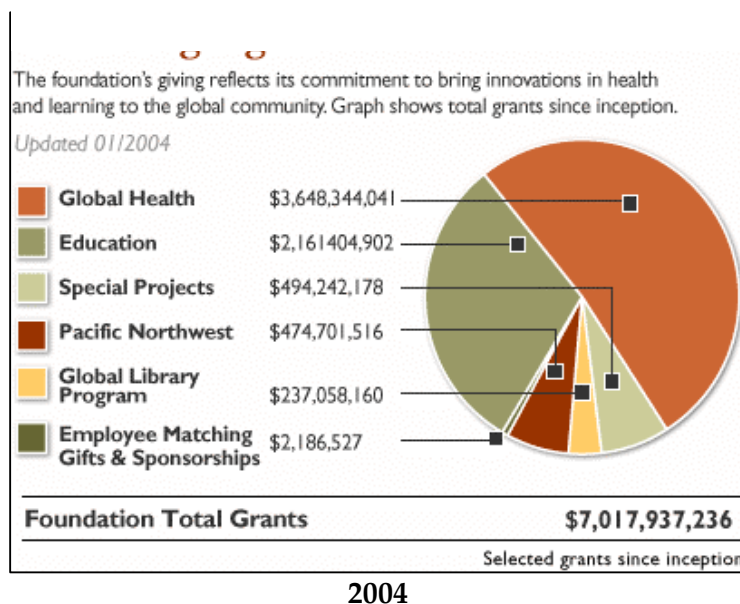
Funding for PPPs come from six major sources: foundations; government bilateral aid agencies; other government funding; multilateral agencies; non-governmental organizations (NGOs); and business.<sup>41</sup>

Foundations are the major funding sources for PPPs. The largest amount of funding in terms of real dollars allocated and number of PPPs funded is the Bill & Melinda Gates Foundation.

According to The Foundation Center, the Gates Foundation is the largest US foundation in terms of total assets with approximately \$24 billion as of December 31, 2002, as well the largest giver in 2002 spending in excess of \$1.1 billion.<sup>42</sup>

From 1994 to January 2004, the Gates Foundation has awarded grants in the amount of \$7,017,937,236.00 with \$3,648,344,041.00 committed to global health projects.<sup>43</sup> The generosity of the Gates Foundation has supported the increase in funding available to PPPs and may be a contributing factor in the growing number of PPPs, especially those committed to developing vaccines for diseases in developing countries. Total foundation giving from its inception to January 2004<sup>44</sup> is set forth in Figure 8.1.2.

**Figure 8.1.3 Total grants awarded by the Gates Foundation from 1994 to January**



Source: The Gates Foundation website.

<http://www.gatesfoundation.org/Grants/default.htm?showYear=2002>, Accessed 26 February 2004.

The Gates Foundation has primarily concentrated its giving to PPPs involved with development of vaccines including: IAVI, IPM, MMV, TB Alliance, AERAS, FIND, IOWH, PDVI, HHVI, Rota ADIP and Pneumo ADIP.<sup>45</sup> Its awards tend to be in multi-year pledges, allowing for easier financial planning and more economic stability for

## Chapter 8.1: Public-Private Partnerships for Neglected Diseases

### Opportunities to Address Pharmaceutical Gaps for Neglected Diseases

PPPs. (See [Annex 8.1.2.2](#) illustrating the partnerships selected for grant funding by the Gates Foundation, year funding was awarded, amount of funding, funding period and major purpose of funding).

The Rockefeller Foundation is an active supporter of PPPs providing funding to such partnerships as IAVI, IPM, MMV, TB Alliance and PDVI.<sup>46</sup> The Rockefeller Foundation has total assets of \$2,801,471,403 as of December 31, 2003 with \$149,159,867,000 in total awards as of December 31, 2002.<sup>47</sup>

The second largest donor category in terms of funding support for PPPs is government bilateral agencies from countries including Canada, Denmark, Ireland, Netherlands, Norway, Switzerland, Sweden, United Kingdom and United States. These agencies generally provide funding on a year-to-year basis rather than on a multi-year pledge basis.<sup>48</sup>

Multilateral agencies including the European Union, UNAIDS, UNFPA, WHO and the World Bank have provided funding for various PPPs.<sup>49</sup> The Government of South Africa and USAID have contributed to SAAVI.<sup>49</sup>

The NGO, Médecins Sans Frontières, has provided a five-year grant to establish and fund the new partnership, Drugs for Neglected Diseases Initiative (DNDi).<sup>49</sup>

Contributions from the business community have come from pharmaceutical companies as well as other industries.

Major pharmaceutical companies are partners in PPPs that are involved all three types of PPPs for product distribution; product development; and systems and issues relating to health.<sup>15</sup> For example, the Mectizan Donation Program was started as a product donation program and continues to be funded by Merck Pharmaceuticals to donate and distribute its product, Mectizan, to combat onchocerciasis in developing countries.<sup>50</sup>

A pharmaceutical industry program for medicine development, training of medical personnel in developing countries, and distribution of products is the Eli Lilly Multi-Drug Resistant Tuberculosis (MDR-TB) Partnership. The collaboration between Eli Lilly, multilateral agencies, teaching hospitals and universities is designed to increase the number of trained personnel and medicines available to treat MDR-TB.<sup>51</sup>

Other industries have supported PPPs for health including ExxonMobil and DaimlerChrysler.<sup>52</sup>

In looking closely at the sixteen PD-PPPs, half of them are funded by a single donor while the other half has 3 or more donors. This fragmented donor base represents more than 60 donors from more than 15 countries.<sup>37</sup>

The European Commission has provided funding for one PD-PPP, the European Malaria Vaccine Initiative. Please refer to Table 8.1.6.



## Chapter 8.1: Public-Private Partnerships for Neglected Diseases Opportunities to Address Pharmaceutical Gaps for Neglected Diseases

Table 8.1.6 Funding Sources for Product Development Public-Private Partnerships<sup>36</sup>

### PD-PPP Funding Sources

Disease / product	HIV/AIDS vaccines		HIV/AIDS microbicides		Malaria drugs	Malaria vaccines		TB drugs	TB vaccines	TB/other diagnostics	Other regulated diseases					
	IAVI	SAAVI	IPM	MDP	MMV	MVI	EMVI	TB alliance	AERAS	FIND	DNDI	IOWH	PDVI	HHVI	Rota ADIP	Pneumo ADIP
<b>Foundations</b>																
• Bill and Melinda Gates Foundation	✓		✓		✓	✓		✓	✓	✓		✓	✓	✓	✓	✓
• Ellison Medical Foundation													✓			
• Rockefeller Foundation	✓		✓		✓			✓					✓			
• The Wellcome Trust					✓											
• Other foundations	✓															
<b>Government bilateral AID agencies</b>																
• Canadian Government (CIDA)	✓															
• Government of Denmark	✓		✓													
• Government of the Netherlands	✓		✓		✓											
• Government of Norway	✓		✓													
• Ireland Aid	✓		✓													
• Swiss Government					✓											
• Swedish Government	✓															
• U.K. Government (DFID)	✓		✓	✓	✓											
• US AID	✓				✓	✓										
<b>Other Government funding</b>																
• Government of South Africa		✓														
• National Institute of Health (NIH), USA		✓														
<b>Multilateral agencies</b>																
• European Commission							✓									
• UNDP																
• UNAIDS	✓															
• UNFPA			✓													
• WHO					✓			✓			✓					
• The World Bank	✓				✓											
<b>NGO</b>																
• Medicines Sans Frontiers (MSF)											✓					
<b>Business</b>																
• Pharma																
• Others	✓	✓			✓											

Source: IPPPH database

## **Chapter 8.1: Public-Private Partnerships for Neglected Diseases**

### **Opportunities to Address Pharmaceutical Gaps for Neglected Diseases**

#### **C. Non-Financial Contributions**

In addition to financial contributions, public-private partnerships are fueled and funded by contributions of goods and services.

Partnerships receive non-financial investments from industry sources, primarily the pharmaceutical and biotechnology sectors.<sup>4,53</sup> The contributions can be made outright or offered to the PPP for below market prices or at discount. This discussion does not include benefits that accrue to the private entity that is part of the partnership.

Generally, contributions are in two categories: goods and services. A third category of “value in excess of contribution” is an intangible part of the partnership process offering substantial benefits to the partnership.<sup>54</sup>

Goods can include: compounds; equipment, tools and technologies such as reagents; vaccine delivery techniques; compound libraries; or assays.<sup>54</sup>

Services include: advisory board participants; personnel time and expertise especially those involved in project management and clinical trials; technology services; access to proprietary data and information; functional or scientific expertise; and opportunities for an exit strategy.<sup>54</sup>

“Value in excess of contribution” can include benefits such as having access to a state-of-the-art core laboratory, access to expertise and training, product support, credibility, networks, and timesavings.<sup>54</sup> When subcontracting for paid research work, a partner implicitly offers overhead and the overhead may be viewed as “excess contribution”. These benefits are part of the partnership arrangement that result from working in tandem, are not contracted for specifically, and are difficult to value.<sup>54</sup>

Valuation of non-financial contributions may be useful to PPPs to support their decision to contract with private industry, and to leverage funding from sources. Industry may wish to value its non-financial contributions to demonstrate the full value of their participation in tackling neglected diseases.<sup>54</sup>

No survey of non-financial contributions to public-private partnerships has been done to date; however, the benefits derived from the contributions made to PPPs, both financial and non-financial are vital to the support and success of these ventures.

#### **8.1.4 Outlook for Public-Private Partnerships**

PPPs are an innovative approach to addressing the global health care crisis in developing countries. The preventable loss of life and disability suffered by people in poor countries is unconscionable and can no longer be ignored by countries with funding and resources including universities and institutes, technology and skills needed to discover and develop

## **Chapter 8.1: Public-Private Partnerships for Neglected Diseases Opportunities to Address Pharmaceutical Gaps for Neglected Diseases**

medicines for neglected diseases. PPPs are working to create solutions to save lives and reduce disability for the world's poorest.

A review of the funding sources for the 78 active PPPs for health clearly demonstrates certain facts: The major funding source for PPPs is private foundations, led by the Bill & Melinda Gates Foundation, but considerable support is provided by the Rockefeller Foundation and others. Among public health development agencies, the United States Agency for International Development (USAID) and the United Kingdom's Department for International Development (DFID) are actively involved with funding and supporting PPPs. International organizations such as the World Health Organization and various United Nations programs are involved with PPPs. What is equally clear is the lack of direct funding and support that the European Union has provided to PPPs

According to a review of the funding information available on the website for the Initiative on Public-Private Partnerships for Health, the European Union has provided financial support for only 5 out of 78 active partnerships: European Malaria Vaccine Initiative; Global Polio Eradication Initiative; International Partnership Against Aids in Africa; Roll Back Malaria Global Partnership; and Tropival.

The disappointing lack of direct participation by the European Union in public-private partnerships has several consequences:

1. The vast resources within the EU are not being applied to the extent to which they could be to correct the 10-90 gap, denying people around the world life and health. Millions of people die or are disabled every year because resources, financial and non-financial, are withheld from them in circumstances where help should be provided.
2. Opportunities are lost within the EU by failing to participate in the work done by PPPs. Basic science, research and development of medicines, technology in support of this research and other benefits fail to be achieved because the EU not as involved as other active participants in the race to develop and distribute life saving medicines. Basic science, research and development of medicines and technology produce economic benefits in and of themselves as they move towards the delivery of products for neglected diseases. Academic institutions and private sector entities in the US and the UK as well as other countries have benefited from their support of PPPs. Such benefits can be reaped in the European Union if it will increase its support of PPPs.
3. Global public health issues are international problems that demand the full and dedicated involvement of all governments. Protecting the health of the public is a fundamental duty of government. By failing to address problems of global health, governments are failing to perform an essential public function and are ceding their authority to the private sector. Regardless of the excellent direction, commitment, initiative, and funding brought to the problems of global health by the private sector,

## Chapter 8.1: Public-Private Partnerships for Neglected Diseases

### Opportunities to Address Pharmaceutical Gaps for Neglected Diseases

the problems cannot be solved without total political will to solve the complex, multinational challenges being tackled by PPPs.

4. The European Union has allowed the agenda and direction of global public health policy and possible solutions to be set by the private sector with support from US and UK development agencies. The EU has a major international political, economic and social role to play on the global health stage.

The EU has acknowledged the importance of neglected diseases in the Sixth Framework by supporting the funding for projects relating to these diseases. The commitment to addressing the problems associated with neglected diseases has been articulated but it is unclear why the benefits of this commitment have not been realized by PPPs.

The establishment in 2003 of the European and Developing Countries Clinical Trial Partnership (EDCTP) is a substantial commitment by the European community to building capacity in general and in developing countries in particular for the clinical trial phase of the drug development process. EDCTP focuses on HIV/AIDS, malaria and tuberculosis but does not specifically address other very neglected diseases such as trypanosomiasis and visceral leishmaniasis. While not specifically excluded from EDCTP, the question remains whether clinical trials for very neglected diseases is part of the scope of EDCTP.

The EDCTP is geared to provide services for Stage III of the drug development process and by its very existence assumes that there are sufficient chemical entities to be tested; however, pipelines for tuberculosis and malaria drugs as well as drugs for very neglected diseases are far from robust. Much support, financial as well as technical, is needed to bring entities from the research and development stage to the point where clinical trials are needed. If the chemical entities are not available to be tested in clinical trials, the EDCTP will be under utilized.

Conversations with several individuals active in PPPs were conducted confidentially to inquire about obtaining funding from the European Union. The comments received are summarized as follows:

1. The application process for obtaining EU funding is too cumbersome and burdensome. The PPPs operate with very small administrative staffs and the bulk of their spending goes towards scientific research and support. The PPPs could not commit the amount of administrative time and effort needed to apply for EU funding as the process currently stands. Larger organizations may hire consultants at many thousands of dollars to secure the assistance necessary to work through the application process but certain PPPs could not or would not budget money for this purpose. The PPPs directed their energy and resources to applying for funding from other sources where the process is not as time consuming, duplicative, and unnecessarily difficult to navigate.

## Chapter 8.1: Public-Private Partnerships for Neglected Diseases

### Opportunities to Address Pharmaceutical Gaps for Neglected Diseases

2. Considering the time and expense incurred with the EU application process, the amount of funding awarded was modest and/or came with “too many strings” attached. In that most PPPs are nonprofit entities, they have a responsibility to budget carefully and exercise judgment as to the best use of limited resources. All things being equal, the commitment of time and resources was better utilized by working with other funding sources where the potential to raise substantial sums of money is greater.
3. PPPs were discouraged from applying for funding because their secretariats are located in Switzerland. Despite the fact that the PPPs interviewed all had non-profit and for-profit partners in Europe and despite the fact that Switzerland has entered into an agreement with the EU to allow Swiss entities to apply for funding, several Swiss PPPs report being told that they were not eligible for funding or should open an office in an EU country to have a legal entity in the EU. One third of all the PPPs have secretariats in Switzerland. By having a de facto policy of excluding Swiss - based PPPs, the EU is limiting its ability to support PPPs. It is at best impractical to suggest that a PPP go through the logistical and financial gymnastics required to “qualify” for EU funding. Further opportunities are lost to the EU and PPPs under the current application process.
4. Individuals associated with the application process must have a long-term perspective and be willing to enter into multi-year relationships with PPPs. By its very nature, the research and discovery process is time consuming and the projects involved will take years of commitment from the partners as well as funders. To benefit PPPs and make their investment of time and energy in the application process beneficial, funding should be made in multi-year commitments of substantial amounts. PPPs are willing to make their actions transparent and to be accountable to funding sources. Funding sources must invest human and other resources in PPPs to maximize the benefit of the relationship. Private funders are excellent at working with PPPs and the public sector must match the efforts of the private sector.

Based upon this information, it is clear that the EU funding process is not “user friendly” and may actively discourages PPPs from availing themselves of the resources available. Modifications to the current application process are needed. Support from the individuals involved with the funding process should be adequately trained and have the ability to work with applicants to ensure the quality and success of applications. If the EU truly wants to provide financial support for the problems of neglected diseases, then the commitment can be realized by revamping the application process.

The relative newness of the PPP concept means that the proverbial jury is still out as to whether or not PPPs will succeed with their ambitious agendas of discovering and developing new medicines for neglected diseases. Perhaps better methods will be implemented that will supplant PPPs in the future. At the present time, PPPs are the primary vehicle addressing many of these global health issues. As more partners join in, different synergies are created and are more likely to generate the solutions to these enormous problems.

## **Chapter 8.1: Public-Private Partnerships for Neglected Diseases Opportunities to Address Pharmaceutical Gaps for Neglected Diseases**

PPPs have done an impressive job of raising the level of awareness of the health disparities between the developed and developing countries as well as marshalling financial and non-financial support among the private sector. The public sector must match the political will of the private sector to ensure that lives are saved and people given the opportunity to live healthier lives – even if they aren't born in Europe.

### **8.1.5 Conclusion**

Public-private partnerships have changed the landscape of drug development for medicines for neglected diseases and the delivery of medicines in the developing world.<sup>55</sup> Stemming from market and government failures as well as ineffective legislative incentives, PPPs have brought together participants from all sectors in an attempt to maximize the skills and resources of those participants to tackle complex issues of drug development and distribution.

PPP-PDs are relatively new entities and have not yet brought a product to market so it remains to be seen if this innovative approach to drug development will succeed. They have introduced innovative and creative systems and processes for drug development outside the traditional for-profit pharmaceutical model. PPPs are challenging governments, industry, academia and non-profit organizations to face urgent public health issues.

PPP-PDs face the challenges presented by the risks inherent in the costly and time-consuming process of drug development especially for diseases where basic science and research has been dormant for decades. The cost of drug development is high and PPPs are optimistic that sufficient funding will be available as drug candidates move through each stage of the development process. It remains to be seen if the optimism is justified.

The role of the European Union in supporting PPPs is modest. The establishment of the EDCTP supports the clinical trials process and capacity building in developing countries but assumes that sufficient chemical entities exist in the pipeline to test in clinical trials. The pipeline for neglected diseases is far from robust with the possible exception of HIV/AIDS where many for-profit organizations are pouring substantial resources. Opportunities exist for the EU to support the activities in Stages I and II of drug development for medicines to treat neglected diseases.

EDCTP focuses on HIV/AIDS, malaria and tuberculosis – important diseases with millions of potential beneficiaries – however, EDCTP does not seem to support clinical trials for very neglected diseases. The most neglected diseases such as leishmaniasis and human African trypanosomiasis affect those people who have no financial ability to pay for medicines and the need for financial support is the greatest.

Currently, direct financial support of PPPs by the European Union is minimal. While the EU has provided direct financial support to a handful of PPPs, increased direct financial support is needed by these partnerships.

## Chapter 8.1: Public-Private Partnerships for Neglected Diseases Opportunities to Address Pharmaceutical Gaps for Neglected Diseases

Anecdotal information suggests that the process of accessing funding from the European Union is unduly cumbersome and out of reach of no-EU based PPPs who nevertheless see their mission as encompassing the needs of Europe and developing countries. A review of the process may enable PPPs to more readily obtain funding from the European Union.

Public-private partnerships are leading the way in addressing public health problems with consequences and opportunities for all governments. The European Union has the ability and resources to play a leading role in solving global health problems.

### References

- 
- <sup>1</sup> Davey, S Ed., *The 10/90 Report on Health Research 2001-2002*, Global Forum for Health Research, 2002, Geneva, Switzerland.
  - <sup>2</sup> Gwatkin DR, Guillot M, *The Burden of Disease among the Global Poor: Current Situations, Future Trends, and Implications for Strategy*, 2000, The World Bank, Washington DC.
  - <sup>3</sup> Wheeler C, Berkley S. Initial Lessons from public-private partnerships in drug and vaccine development, *Bulletin of the World Health Organization*, 2001; 79(8): 728-734. p.728.
  - <sup>4</sup> Kettler H, Marjanovic S, Engaging biotechnology companies in the development of innovative solutions for diseases of poverty, *Nature* February 2004: Volume 3: 171-176.
  - <sup>5</sup> Orphan Drugs, Abstract, STOA Study – European Parliament, [www.europarl.eu.int/stoa/publi/167780/default\\_en.htm](http://www.europarl.eu.int/stoa/publi/167780/default_en.htm), accessed 7 January 2004.
  - <sup>6</sup> Milne C, Kaitin K, Ronchi, E, Orphan Drug Laws in Europe and the US: Incentives for the Research and Development of Medicines for Diseases of Poverty, CMH Working Paper Series, Paper No. WG2:9.
  - <sup>7</sup> Biel PR Why is There No AIDS Vaccine?, *World Economics*, Oct.-Dec.2001: Vol. 2, No. 4, 1-16. p. 6.
  - <sup>8</sup> Orbinski J. Market enticements are not enough, In. Ridley R, ed. A role for public-private partnerships in controlling neglected diseases?, *Bulletin of the World Health Organization*, 2001, 79(8) 771-777, p.776.
  - <sup>9</sup> Milstein J, Widdus R. Facilitating Access to Vaccines: An Overview of Legal and Political Issues, *Pharm Dev Regul* 2003;1(2):101-116, p.111.
  - <sup>10</sup> Shretta R, Brugha R, Robb A, Snow RW. Sustainability, affordability, and equity of corporate drug donations: the case of Malarone, *Lancet*, May 13, 2000. Vol 355:1718-1720.
  - <sup>11</sup> Kettler H., Towse A. Public private partnerships, CHM Working Paper Series, 2001, Paper No. WG2:21, p.21.
  - <sup>12</sup> Interview with Dr. Bernard Pecoul, Executive Director of Drugs for Neglected Diseases Initiative, Geneva, Switzerland, March 1, 2004.
  - <sup>13</sup> The Pharmaceutical Security Institute is a non-profit organization with the mission of protecting public health by sharing information on counterfeit pharmaceuticals and initiating enforcement activities. ([www.psi-inc.org](http://www.psi-inc.org), accessed 2 March 2004).
  - <sup>14</sup> Reich M, Public-private partnerships for public health, *Nature Medicine*, June 2000, Vol. 6, Number 6: 617-620.
  - <sup>15</sup> Buse K., Walt G. Global public-private partnerships: part 1 – a new development in health? *Bulletin of the World Health Organization*, 2000, 78(4):549-561, p. 550.
  - <sup>16</sup> Reich M, Public-private partnerships for public health, *Nature Medicine*, June 2000: Vol. 6, Number 6: 617-620. p.618.

## Chapter 8.1: Public-Private Partnerships for Neglected Diseases Opportunities to Address Pharmaceutical Gaps for Neglected Diseases

- 
- <sup>17</sup> Buse K, Waxman A. Public-private health partnerships: a strategy for WHO, *Bulletin of the World Health Organization*, 2001, 79(8) 748-754. p. 754.
- <sup>18</sup> Website for the Initiative on Public Private Partnerships for Health, ([www.ippph.org](http://www.ippph.org), accessed 24 February 2004)
- <sup>19</sup> The Office of Orphan Products Development is located in the office of the Commissioner, Food and Drug Administration, in the United States and administers the orphan products development program. ([www.fda.gov/orphan/progovw.htm](http://www.fda.gov/orphan/progovw.htm), accessed 7 January 2004).
- <sup>20</sup> Website for the organization Drugs for Neglected Diseases Initiative, ([www.dndi.org](http://www.dndi.org), accessed 18 February 2004).
- <sup>21</sup> *Neglected Diseases and the Pharmaceutical Industry*", IFPMA, December 2003: 1-6.
- <sup>22</sup> Depoortere E, Legros D, Torreele E, Developing a Needs-Based and Rational Approach to Identify Neglected Diseases and Select R&D Projects that Could Maximally Impact Treatment Options, MSF/DND Working Group.
- <sup>23</sup> Rosenau P, Linder, S. Mapping the Terrain of the Public-Private Policy Partnership. In: Rosenau P, ed. *Public-Private Policy Partnerships*, MIT Press, Cambridge, MA. 2000:1.
- <sup>24</sup> Lob-Levzt J. A donor perspective, In: Ridley, ed. A role for public-private partnerships in controlling neglected diseases?, *Bulletin of the World Health Organization*, 2001, 79(8) 771-777, p. 771.
- <sup>25</sup> Wehrein P. Pharmacophilanthropy, *Harvard Public Health Review*, Summer 1999: 32-39.
- <sup>26</sup> Stansfield S., Harper M., Lamb G., Lob-Levzt J. Innovative Financing of International Public Goods for Health, CMH Working Paper Series, 2000, Paper No. WG2 : 22.
- <sup>27</sup> Buse K., Walt G. The United Nations and Global Public-Private Partnerships: In Search of 'Good' Global Health Governance, Workshop on Public-Private Partnerships in Public Health, Endicott House, Dedham, Massachusetts, April 7-8, 2000.
- <sup>28</sup> The Global Forum's central objective is to help correct the 10/90 gap by focusing research efforts on diseases representing the heaviest burden on the world's health and facilitating collaboration between partners in both the public and private sectors. (<http://www.globalforumhealth.org/pages/index.asp>, accessed 26 February 2004).
- <sup>29</sup> Nwaka S, Ridlez R, Virtual drug discovery and development for neglected diseases through public-private partnerships, *Nature* November 2003: Volume 1: 919-928, 919.
- <sup>30</sup> Janssens PG, Kivtis M, Vuzlsteke J. Médecine et hygiène en Afrique centrale de 1885 à nos jours Brussels; Foundation Rio Baudoin, (1992) 590.
- <sup>31</sup> Trouiller P, Olliaro P, Torreele E, Orbinksi J, Laing R, Ford N. Drug Development for neglected diseases: a deficient market and public-health policy failure, *Lancet*, 2002: 359: 2188-94, p.2190.
- <sup>32</sup> Buse K., Walt G. Global public-private partnerships: part II – what are the health issues for global governance?, *Bulletin of the World Health Organization*, 2000:78 (5), p.700.
- <sup>33</sup> Colatrella B The Mectizan Donation Programme: Successful collaboration between the public and private sectors. *Essential Drugs Monitor* 2004 33 p27
- <sup>34</sup> The Initiative on Public-Private Partnerships for Health aims at increasing 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. ([www.ippph.org](http://www.ippph.org), accessed 2 March 2004).
- <sup>35</sup> Medicines for Malaria Venture Annual Report, 2000, p. 1.
- <sup>36</sup> Sander, A, Widdus, R. The emerging landscape of public-private partnerships for product development, IPPPH workshop "Combating Diseases Associated with Poverty: Strategies for Produce



## Chapter 8.1: Public-Private Partnerships for Neglected Diseases Opportunities to Address Pharmaceutical Gaps for Neglected Diseases

---

Development and the Potential Role of Public-Private Partnerships”, April 15-16,2004, London, England.

<sup>37</sup> DiMasi, J., Hansen, R., Grabowski, H. The price of innovation: new estimates of drug development costs, *Journal of Health Economics*, 22 (2003) 151-185, p.180.

<sup>38</sup> Hentschel C, Itoh M. The resurgence of Malaria and the role of the Medicines for Malaria Venture. MMV brochure.

<sup>39</sup> European & Developing Countries Clinical Trial Partnership, Joint Programme of the Action, Part A, Technical content and the overall work plan for the entire period of the Action, Annex I Part A, Final draft 13 November 2003.

<sup>40</sup> Towse A., Renowden O. Estimates of the Medium Term Financial Resource Needs for Development of Pharmaceuticals to Combat Neglected Diseases, IPPPH workshop “Combating Diseases Associated with Poverty: Strategies for Produce Development and the Potential Role of Public-Private Partnerships”, April 15-16, 2004, London, England.

<sup>41</sup> Extracted from information available in the partnership database section of the website for Initiative for Public-Private Partnerships for Health. ([www.ippph.org](http://www.ippph.org), accessed numerous times during February 2004).

<sup>42</sup> The Foundation Center mission is to support and improve philanthropy by promoting public understanding of the field and helping grantseekers succeed. ([www.fdncenter.org](http://www.fdncenter.org), accessed 19 February 2004).

<sup>43</sup> The Bill & Melinda Gates Foundation is committed to bringing equitz to global health and learning. ([www.gatesfoundation.org](http://www.gatesfoundation.org), accessed 24 February 2004).

<sup>44</sup>The Bill & Melinda Gates Foundation is committed to bringing equity to global health and learning. ([www.gatesfoundation.org](http://www.gatesfoundation.org), accessed 24 February 2004).

<sup>45</sup> The Initiative on Public-Private Partnerships for Health. ( [www.ippph.org](http://www.ippph.org), accessed 20 February 2004); The Gates Foundation ([www.gatesfoundation.org](http://www.gatesfoundation.org), accessed 18 February 2004).

<sup>46</sup> The Initiative on Public-Private Partnerships for Health ([www.ippph.org](http://www.ippph.org), accessed 20 February 2004).

<sup>47</sup> The Foundation Center ([www.fdncenter.org](http://www.fdncenter.org), accessed 19 February 2004); The Rockefeller Foundation ([www.rockfound.org](http://www.rockfound.org), accessed 19 February 2004).

<sup>48</sup> Interview with Roy Widdus, Director of IPPPH, Geneva, Switzerland, 19 February 2004.

<sup>49</sup> Extracted from information available in the partnership database section of the website for Initiative for Public-Private Partnerships for Health. ([www.ippph.org](http://www.ippph.org), accessed numerous times in February 2004).

<sup>50</sup> Website for the Merck Mectizan donation program. <http://www.merck.com/about/cr/mectizan/p2.htm>, accessed 24 February 2004.

<sup>51</sup> Website for Eli Lilly pharmaceutical company, [www.lilly.com](http://www.lilly.com), accessed 24 February 2004; website for Initiative on Public-Private Partnerships for Health, [www.ippph.org](http://www.ippph.org), accessed 19 February 2004.

<sup>52</sup> MMV Annual Report for 2002 and 2003.

<sup>53</sup> News Release: Neglected Diseases and the Pharmaceutical Industry, International Federation of Pharmaceutical Manufacturers Associations. [www.ifpma.org/News/NewsReleaseDetail.aspx?nID=235](http://www.ifpma.org/News/NewsReleaseDetail.aspx?nID=235), accessed 7 January 2004.

<sup>54</sup> Kettler H., White K., Jordan S., Valuing Industry Contributions to Public-Private Partnerships for Health Product Development, Initiative on Public-Private Partnerships for Health, Geneva, Switzerland, May 2003 p. 17.

## **Chapter 8.1: Public-Private Partnerships for Neglected Diseases Opportunities to Address Pharmaceutical Gaps for Neglected Diseases**

---

<sup>55</sup> Initiative on Public-Private Partnerships for Health, Partnerships for Developing World Health: Decision and Management Issues for Pharmaceutical Companies, Meeting Report 30 June – 1 July 2003, Paris, France.