

# The IFPMA Health Partnerships Survey: A Critical Appraisal



Panos Kanavos PhD, Tony Hockley, Caroline Rudisill

**LSE Health & Social Care**  
**London School of Economics & Political Science**



**Report Commissioned by the IFPMA**

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## Abbreviations

<b>AAI</b>	<b>Accelerating Access Initiative</b>
<b>FSS</b>	<b>Federal Supply Schedule</b>
<b>GAELF</b>	<b>Global Alliance for the Elimination of Lymphatic Filariasis</b>
<b>GAVI</b>	<b>Global Alliance for Vaccines and Immunization</b>
<b>GFATM</b>	<b>Global Fund to Fight AIDS, Tuberculosis and Malaria</b>
<b>GHP</b>	<b>Global Health Partnership</b>
<b>IFPMA</b>	<b>International Federation of Pharmaceutical Manufacturers and Associations</b>
<b>ITI</b>	<b>International Trachoma Initiative</b>
<b>IVSITF</b>	<b>Influenza Vaccine Supply International Task Force</b>
<b>MDG</b>	<b>Millennium Development Goal</b>
<b>MDP</b>	<b>Mectizan Donation Programme</b>
<b>MMV</b>	<b>Medicines Malaria Venture</b>
<b>MSF</b>	<b>Médécins Sans Frontière</b>
<b>NGO</b>	<b>Non Governmental Organisation</b>
<b>NHS</b>	<b>National Health Service</b>
<b>ODA</b>	<b>Overseas Development Assistance</b>
<b>PHI</b>	<b>Positive Health Initiative</b>
<b>PEI</b>	<b>Polio Eradication Initiative</b>
<b>R&amp;D</b>	<b>Research and Development</b>
<b>RBM</b>	<b>Roll Back Malaria</b>
<b>UNAIDS</b>	<b>United Nations Programme on HIV/AIDS</b>
<b>WAC</b>	<b>Wholesale Acquisition Cost</b>
<b>WHO</b>	<b>World Health Organisation</b>

## **Executive Summary**

1. During 2005, the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) conducted a survey on the overall scale of the pharmaceutical industry's commitment to the achievement of the UN Millennium Development Goals (MDGs). As is the case in many industrial sectors, individual initiatives are well documented and reported, often with dedicated websites, but it is almost impossible to obtain an overview of an industry's total contribution towards the MDGs, to set alongside the contribution of other global partners such as the World Bank, World Health Organisation (WHO) and other agencies and organizations. Through this survey, the IFPMA gathered data on the relevant activities of the research-based pharmaceutical companies in order to provide such an overview of the industry's contribution to the MDGs. In order to provide an opinion on the validity of the published figures, IFPMA provided LSE Health and Social Care with access to the confidential data provided by each company, as well as access to the IFPMA researchers involved in the survey and to relevant company contacts.

2. Overall, the IFPMA Health Partnerships Survey achieves three important outcomes: first, it does provide a reliable, conservative and cautious basis for assessment of the pharmaceutical industry's overall contribution to the UN Millennium Development Goals. This is done by defining the number of "Positive Health Interventions" in developing countries and attaching a monetary value to these. Second, it sets a very useful benchmark for future reference against which the industry's efforts can be judged on a consistent basis, over the next ten years towards the MDG deadline of 2015, and beyond. And, third, it sets a standard to which other important industries might aspire, in demonstrating their global commitment to the developing world.

3. Whilst only the first of these outcomes was a clear intention on the part of the authors of the IFPMA Survey, it would certainly be valuable if the Survey has both future and wider uses.

4. The IFPMA's definition of a "Positive Health Intervention" seems to us to provide a reasonable unit of measurement, but it is nevertheless conservative inasmuch as it takes no account of the third-party effects of many of the interventions included.

5. Companies and other partners do directly control the amount of financial investment that they make in health partnership programs, and are often able to put a monetary value on these investments. Assessing the value in terms of outputs is, however, fraught with difficulty, although some of the programs included in the Survey do include systems to monitor their impact. Without direct follow-up studies after an initiative has been administered, it is difficult to monitor intervention impact. However, the number of individuals reached by interventions can be extrapolated in some cases. Future survey work could aim at encouraging more of an understanding of how to estimate interventions rather than underreporting initiative impact as measured by interventions. Additionally, the total monetary value of a partner's financial contribution is often understated. This issue arises from the inevitable difficulty of hypothecating some in-kind costs, such as training costs associated with product donations.

6. Differences in reporting time-periods are problematic, because some programs have been in existence for quite long periods of time before the time-period of the Survey or the MDGs. This can lead to an underestimation of a company's contribution to a particular cause, although it does, of course, more accurately reflect their commitment as it relates directly to the achievement of the MDGs since 2000.

7. Companies do appear to be generally cautious in reporting contributions if they are unable to attribute them.

8. The IFPMA Survey on Health Partnerships provides a realistic picture of the pharmaceutical industry's contribution towards achievement of the health MDGs. It is, however, a partial picture given the exclusion of R&D initiatives and the exclusion of a large amount of investment that cannot be accurately reported and the wider societal aspects of the initiatives.

9. As far as we could discern the Survey represents a first attempt by any industry to provide a global estimate of the industry's role in the partnership to achieve the MDGs and may lead other industries to benchmark their roles in assisting progress towards the relevant MDGs.

10. The IFPMA should maintain the Survey as an up-to-date record of the industry's overall commitment to the MDGs, using a consistent and robust methodology in order to ensure its ongoing validity. Using a consistent, validated survey on an annual basis could facilitate data gathering. The template method of returning data is a reasonable way to start a reporting process by which companies become used to filling in the same data on a regular basis. Whilst such a template places constraints on reporting each program, it does have benefits in terms of maintaining a consistent approach and easing the burden on respondents as they become increasingly familiar with its requirements. Qualitative data that might be omitted due to this approach is usually published in other contexts.

## 1. Introduction

During 2005 the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) resolved to gather data on its members' contributions as part of the global effort since 2000 towards achievement of the Millennium Development Goals (MDGs) by the target date of 2015. Based on the evidence submitted, the IFPMA published estimates at the end of 2005<sup>4</sup> suggesting that the industry had contributed some US\$4.4 billion to relevant projects, and in terms of patients reached its contribution had resulted in 539 million "Positive Health Interventions"<sup>i</sup> to date. These figures are intended to exclude any (hypothetical) lost revenue due to the low prices of products supplied under preferential pricing arrangements, responses to natural disasters such as the Asian Tsunami, programs to assist underprivileged patients in developed countries and R&D programs for neglected diseases.

In order to validate these estimates and make any necessary refinements the IFPMA asked LSE Health & Social Care, to investigate the methodology and results of the survey. This analysis was undertaken between December 2005 and January 2006, and is presented in this report. Respondents to the IFPMA survey were given the option to ask for the specific data that they provided to remain confidential, which enabled the IFPMA to secure widespread participation across the industry. The confidential data was provided to LSE Health & Social Care (LSEHSC) in a spreadsheet, with the remit to examine the methodology used and validate the figures produced by the Survey. The report first provides an overview of the main health MDGs and describes the methodology used by the IFPMA to collect and verify data from participating companies. It subsequently presents our findings and conclusions, and finally provides a summary of each of the ten case studies randomly selected from the overall sample.

### Box 1: Principal MDG Health Targets

- 5 Reduce by two-thirds, between 1990 and 2015, the under-five mortality rate
- 6 Reduce by three-quarters, between 1990 and 2015, the maternal mortality ratio
- 7 Have halted by 2015 and begun to reverse the spread of HIV/AIDS
- 8 Have halted by 2015 and begun to reverse the incidence of malaria and other major diseases
- 17 In cooperation with pharmaceutical companies, provide access to affordable, essential drugs in developing countries

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<sup>i</sup> The IFPMA definition of a Positive Health Intervention is given in full in section 3.2.



## **2. UN Millennium Development Goals (MDGs) and the Contribution of the Pharmaceutical Industry**

The MDGs were agreed by world leaders at the Millennium Summit in 2000. They include eight goals, 18 targets, and 48 indicators. Three of the goals, eight of the targets, and 18 of the indicators relate directly to health<sup>5</sup>. The five targets that are most relevant to the intervention of the pharmaceutical industry are listed in Box 1.

The 2005 review of progress towards the UN Millennium Development Goals (MDG), five years after their adoption, revealed that current efforts to achieve the MDG health targets fall well below what is required<sup>6</sup>. The review found, for example, that no region of the developing world is on track to meet the child mortality target, and that the lack of progress on maternal mortality has been the worst in the countries where the need for improvement has been greatest.

Analysis by the World Health Organisation (WHO) of the 2005 data led the organization to argue that success in meeting the targets will depend upon improvements that go well beyond the health sector, and across the wide range of government activities.<sup>7</sup> The WHO Director-General commented:

*“We have the treatments: the technology is known and affordable. The problem in many countries is getting the staff, medicines, vaccines and information to those who need them on time and in sufficient quantities. In too many countries the health systems to do this either do not exist or are on the point of collapse”.*<sup>8</sup>

The Survey may also prove to be a useful resource for small and medium-sized pharmaceutical firms around the World, offering ready access to information on the types of programs that are already underway, thus encouraging their emulation. There is, of course, a risk that the huge size of the aggregated data may deter smaller firms from engaging in similar activities, due to a perception of a limited ability to have a noticeable impact<sup>9</sup>, in addition to limited corporate awareness of the MDGs amongst smaller firms. This deterrent effect may be worsened by a tendency to focus attention on the health programs with the largest value and impact, such as the Accelerating Access Initiative (AAI)<sup>10</sup>, Merck’s Mectizan® Donation Program<sup>11</sup> (MDP) and the Medicines for Malaria Venture (MMV)<sup>12</sup>, and it may prove to be

helpful to balance this with increased attention on some of the many small programs contained within the Survey.

The IFPMA Health Partnerships Survey provides the first global measure of the pharmaceutical industry's contribution to achieving the MDGs. There are, of course, significant difficulties and complexities involved in gathering comparable data from companies and initiatives around the globe. At its launch in December 2005 the IFPMA reported that the Survey included 126 health partnerships<sup>ii</sup>, providing up to 539 million positive health interventions to individuals, on which it put a nominal value of US\$4.38bn.<sup>13</sup>

The pharmaceutical industry, however, will only ever be one small but crucial player in the partnership to achieve the health MDGs. For example, UNAIDS has estimated that a comprehensive strategy of prevention, full coverage of support for orphans and children affected by AIDS, and universal access to treatment globally by 2010 will require US\$14.9bn during 2006, rising again in 2007, and reaching US\$22.1bn in 2008. In addition to this, around US\$2.9bn is needed annually to scale up malaria control interventions, with an estimated number of annual cases as high as 500 million,<sup>14</sup> with no evidence of progress in reducing its incidence. It is estimated that the total required to achieve all eight MDGs, including the health goals, could rise to US\$195bn by 2015.<sup>15</sup>

IFPMA member companies lack the resources, expertise and mandate to strengthen health system infrastructure in the developing world, and are confined to individual programmes where they can identify an opportunity to make a tangible difference. Nevertheless, the assessment that IFPMA members have been responsible in recent years for more than 500 million health interventions that support achievement of the MDGs provides a demonstration of what can be achieved by global partnership in pursuit of common goals. It certainly sets an example that other industries may be urged to follow.

Achievement of all of the MDGs, including the health targets, will require the global effort to be redoubled. The partnerships that are necessary to do this have evidently taken time to develop, and this may partially account for the very slow start.

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ii In some cases several partner firms reported on a single partnership, so that the number of entries in the Survey exceeds the number of initiatives. The Survey included 134 entries reporting on 126 partnerships

### 3. The IFPMA Methodology

#### 3.1. Process and objectives

The IFPMA used the data available to it on known initiatives, and questionnaire responses from its member companies, to obtain an overview of the research-based pharmaceutical industry's contribution so far towards achievement of the health MDGs.

The development of such a survey is a significant task given the global nature of the industry and the diversity of the projects, set against the need to compile simple and universal questionnaires that readily capture the most relevant data, and answer the basic question: "*What is the pharmaceutical industry's contribution to the MDGs?*"

The IFPMA used two forms of the questionnaire, both of which were hosted on a password-protected website, designed and operated by an external firm, to which respondents could return to update their entries as necessary. The first form was a specific one for each of the known industry initiatives, on which some data was publicly available. IFPMA researchers completed these themselves with any publicly available data and then requested the relevant companies to verify, amend and add to the data as necessary. The online format allows several people within a company to access the questionnaires relevant to their initiatives through use of a weblink, login ID and password. The second form was a generic questionnaire which could be used by companies to report on initiatives of which the IFPMA was either unaware or for which the IFPMA researchers had found no publicly available data.

The introduction to the online questionnaires described the purpose of the research as being to:

- *more effectively communicate the impact that the pharmaceutical industry as a single entity has on the developing world;*
- *create an overall vision for industry activities in addressing developing country needs, backed by concrete data and examples;*
- *build a central depository that identifies parties interested and active in various disease areas and geographic regions that can be used to create new collaborations and partnerships.*

The online survey was open not only to IFPMA member companies, but to all major research-based pharmaceutical companies and IFPMA country associations' member companies. Respondents were invited to provide data for the five years from the launch of the MDGs to 2005 on currently active projects, and they were also invited to submit data and information on any projects in the previous 10 years that would be relevant to the MDGs. For each question where this was appropriate, the respondents were required to state whether the answer should be treated as confidential. No other company or the public would be given access to confidential data. The survey was live online between June and August 2005, and, in the final quarter of 2005, IFPMA researchers engaged in follow-up discussions with respondents on the data that they had been provided with. The 17 companies that completed surveys themselves do appear to encompass the best-known health partnership initiatives. The company responses were supplemented with those that came through the involvement of IFPMA country associations.

### **3.2. Data sources**

The main units of measurement decided upon to provide a global measure of the industry's contribution comprise both an assessment of cumulative financial value and an assessment of the number of positive health interventions achieved. In order to achieve a robust and consistent basis for these measures the IFPMA asked those completing the questionnaires to use wholesale acquisition cost (WAC) to value donated products, as the closest to an industry-standard "wholesale list price". They adjusted data on the number of beneficiaries to comply with their own definition of a positive health intervention<sup>iii</sup>, relating either to delivery of sufficient medicines or vaccines to cure one person of one disease, or to manage or prevent a disease for a year. In addition, in order to include public health measures, a proven program of health education for one person was also assessed as a single positive health intervention.

LSEHSC have had access to two spreadsheets containing the survey data. The first was provided in October 2005, and the final version dates from December 2005. Companies were given the option of providing data on their programs in confidence, and most decided to do so, so that the IFPMA could only publish the aggregated totals. The spreadsheets were, therefore, provided to LSEHSC in confidence for

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<sup>iii</sup> The full definition is given in section 3.4.

critical appraisal and validation, although access to a demonstration of the survey methodology can be provided by LSE upon request. Requests for program-specific information may be addressed to IFPMA.

In addition to the data from the survey, the spreadsheets also provided basic information on the validating work undertaken by the two full-time researchers on the IFPMA staff who worked on the Survey during 2005. The researchers intervened when there were possibilities of double-counting in the process of compiling the Survey. Double-counting could easily arise, for example, when several companies are involved in a single partnership program, or when a company lists a cash or in-kind contribution under more than one heading. The IFPMA also sought to exclude initiatives that are not directly linked to the MDGs, so that industry responses to natural disasters, such as the Asian Tsunami or Hurricane Katrina, and other short-term programs were not included in the Survey. The data available to LSEHSC does reveal a considerable effort by IFPMA researchers over a period of two months to work with company respondents to validate the data for final inclusion, and make any adjustments to transform the figures for the numbers of beneficiaries into a number of positive health interventions.

Out of 134 entries in the Survey, 52 list no financial value at all for one of the following reasons: first, because it would be double-counted elsewhere in the Survey;<sup>16</sup> second, because data is not available, or, third, because it is not possible to put a meaningful figure on the project. In the column for the number of beneficiaries, some 59 list no value, most often because the assistance has been channeled through an NGO and it would not be possible to make an accurate assessment of the number of beneficiaries directly attributable to a company's contribution to the partnership.

### **3.3. Defining Value: Wholesale Acquisition Cost for drug donation, and direct Cash or In-Kind contribution costs**

The survey questionnaires made clear that respondents should use the Wholesale Acquisition Cost of a product when stating a value for donated products, or to make it clear when this was not the case. Only 30 entries actually listed any value for donated drugs. Two of these stated that the value stated was "at cost", and one of these made it clear that this was done because the product in question had no commercial market, and, therefore, no WAC. Another has stated that they have used the manufacturing cost which, if correct, should be below WAC, and another has used

a “preferential price” and is excluded from the value assessment of the Survey. In the case of vaccines some respondents have listed a reduced price, in one case below the declared manufacturing cost of the product.

Wholesale Acquisition Cost (WAC) (previously known as Net Wholesale Price) represents the manufacturer's published *catalogue* or *list* price for a drug product to wholesalers. WAC does not represent actual transaction prices and does not include prompt pay or other discounts, rebates or reductions in price. From this perspective, it could be argued that it is a fictitious price, but one that may be easily accessible and usable. One alternative to WAC would be to use a basket of national public prices, for instance, the US Federal Supply Schedule (FSS)<sup>17</sup>, the UK National Health Service (NHS) price<sup>18</sup>, the German public price quoted in the Red List<sup>19</sup>, the French public price quoted in the Vidal database,<sup>20</sup> etc. The caveats with using such a basket are, however, threefold: first, an agreement on the basket of countries would need to take place, and before doing so, a list of criteria would need to be set up for this purpose on which countries to include; second, prices in the basket countries would reflect supply and demand conditions in specific environments at specific points in time; and, third, in order to use such a basket, appropriate weights might need to be constructed, all of which would result in a process which can be very laborious.

### **3.4. Measuring Impact: Positive Health Interventions (PHIs)<sup>21</sup>**

The other dimension measured in the IFPMA Survey was the number of Positive Health Interventions (PHI). The IFPMA defines a PHI as:

- (a) The delivery of sufficient medicine to cure one person of one disease;
- (b) The provision of a course of therapy sufficient to manage one disorder in one person for one year;
- (c) The provision of sufficient vaccine to immunize one person against one disease for at least one year; and
- (d) The delivery of a proven program of health education to one person.

It may be tempting to translate positive health interventions into “beneficiaries” or “people treated” although this is not actually the case. The IFPMA press release at the launch of the Survey in December 2005 mentioned “*enough*

*interventions to help up to 539 million people*". Although this may, in principle, be true, in practice the actual number of *people* helped cannot be measured with accuracy. The number of people helped by an intervention can extend beyond the sole recipient of a vaccine or drug into that individual's household or even community, particularly in light of the public health nature of the initiatives tracked in the Survey. Consequently, the impact of positive health interventions may be significantly underestimated and does not include the broader community or societal benefits.

The clarity in the IFPMA's PHI definition alleviates any uncertainty about the extent of positive outcomes that this survey accounts for. Whilst other definitions are certainly possible, the IFPMA's use of a positive health intervention is conservative, and does attempt to strike a reasonable balance between measuring products that might require just one or two doses provided to an individual in order to be effective, and others that might require a daily delivery of a combination therapy, with clinical support, in perpetuity.

There will, of course, also be overlap between the beneficiaries of several programs, so that the number of interventions would be greater than the number of individual patients benefiting from the industry's partnership programs.

Point (d) of a PHI as it relates to health education is the most contestable of the four, because it relies on *proven* programs of health education, but, as yet, entries in this category are few and have little bearing on the overall results. However, this definition may warrant an early review in order to determine a less subjective definition. This might be achieved simply by omitting the word "proven", given the difficulties of proving the effectiveness of health education initiatives, or, alternatively, focus narrowly on those interventions which have a proven track record or evidence base. Nevertheless, the first three points of a PHI used by IFPMA are useful and should be retained as the Survey develops in order to provide consistency. Revision of point (d) should not affect the figures already published to any appreciable extent, thus enabling them to remain useful for future comparison.

As already discussed, where the link between a company and beneficiaries of a program is indirect, IFPMA has tended to exclude any assessment of PHIs.

## 4. Validation Methodology

The IFPMA provided access to the data supplied in confidence by respondent companies relating to their own initiatives, and we constructed a sample from these. We subsequently analysed the sample against a set of endpoints.

### 4.1. Sample selection and sample size

The sample was developed (a) to reflect the wide range of initiatives in the Survey; (b) to maximise the relevance of the sample to a validation exercise by focusing on those initiatives which have the greatest impact on the results of the survey in terms of their reported value and number of positive health interventions, including the largest direct drug donations and “in-kind” donations; and (c) to include a spread of companies, in case reporting practices varied between them. A large project was also included for which IFPMA decided to include neither a financial value nor a PHI figure in its published totals.

As a result, the sample examined in this report comprised 10 initiatives reported by 10 different companies, albeit with a degree of overlap in some participating companies because some of the initiatives involve two or more of them. The initiatives in the sample are listed in **Table 1**.

<b>Initiative</b>	<b>Company</b>	<b>Value</b>	<b>Impact</b>	<b>Disease/Use</b>
Access to HIV Care	Abbott	n/a	25.5m tests	HIV/AIDS
MDR-TB Partnership	Eli Lilly	US\$70m	n/a	MDR-TB
Mectizan® Donation Program	Merck	US\$174m pa (2001)	452m treatments since 1987	River Blindness
Global Alliance to Eliminate Lymphatic Filariasis (GAELF)	GSK Merck	US\$1bn	235m treatments (2000-2004)	Elephantiasis
Global Polio Eradication Initiative (PEI)	Sanofi Pasteur	n/a	120m doses of vaccine (since 1997)	Polio
International Trachoma Initiative	Pfizer	n/a	10m doses	Trachoma
Glivec International Patient	Novartis	n/a	10,000 patients treated	Cancer



Assistance Program				
BMS Donations to Américas <sup>2</sup>	BMS	US\$220m (since 1982)	n/a	Various (e.g, respiratory infections in Mexico)
Wyeth Partnership to provide oral contraceptives (OC) to the developing world	Wyeth	n/a	1.5bn cycles of OCs (sold at discounted prices since 1968)	Contraception
Viramune® Donation Programme	Boehringer Ingelheim	n/a	634,000 doses	HIV

**Notes:** <sup>1</sup> Headline values from published sources.

<sup>2</sup> A US-based non-profit disaster-relief and humanitarian aid organisation.

**Source:** Published information referenced in individual Case Study summaries (pp 27-36)

The sample represents 7.5 percent of the 134 entries in the Survey. By reported value, however, the sample covers 52 percent of the reported total, and by the number of positive health interventions some 88 percent. While the case study methodology allows for a robust examination of the quality of the IFPMA survey totals, it automatically means that many initiatives were not examined in as close detail as the selected case studies. Some of the remaining 116 initiatives included in the Survey may present difficulties upon examination for a variety of reasons. First, some contributors may not have submitted data to IFPMA, despite being involved in initiatives in developing countries and making contributions; second, there may be no public information about PHI or contribution values to use for validation purposes; and, third, either PHI or contribution values can be validated but not both.

With regards to the first point, there were 15 initiatives that contributed no data to the Survey but for the most part contributed a paragraph to the IFPMA outlining the general principles of their initiative or at least a website for further information. This was due to one of the following reasons: (a) attribution of contributions was too difficult to make due to the involvement of several parties in the initiative, for instance, an NGO implementing the programme, and many companies being simultaneously involved in the initiative and (b) the nature of the initiative making attribution of contributions difficult. For example, the IFPMA Influenza

Vaccine Supply International Task Force (IVSITF) incorporates both of these points as it involves multiple pharmaceutical companies and has some aspects to it that are difficult to attach a monetary value. This initiative aims to assist vaccine companies in ensuring that there is adequate production and distribution of influenza vaccines and assist health authorities in making policy to ensure adequate vaccine use and delivery. Thus, this initiative serves many functions, for some of which it is difficult to put a figure on for attribution purposes. Strategy planning advisory capabilities are more intangible than direct donations of pharmaceuticals, especially when multiple companies are involved in performing the task. For this reason, some companies have not submitted contribution data for this initiative. Consequently, the (financial and/or PHI) impact of these fifteen initiatives remains unaccounted for in the total reported figures. This most likely led to an underestimation of the industry's total contribution to the MDGs and the developing world.

Second, in some 40 cases, there was no information in the public domain against which to validate confidential IFPMA Survey responses for either PHI or the value of contributions. In these cases, companies would be involved in an initiative but would not publicly report their donation activities. This was more often the case for smaller companies donating to an initiative or an initiative itself being small in value or scope of activity. For example, if an initiative run by a company was not part of a larger initiative such as the International Trachoma Initiative (ITI) that operates its own website, press and public reporting of information about that initiative would tend to be limited. For companies operating multiple initiatives over the survey time, programs taking place prior to the survey and perhaps reducing activity during the survey time could result in less coverage in the press and in a company's annual report as new initiatives receive highlighted attention. Figures for such initiatives could not be validated from any other public sources, but were self-reported by the companies involved. To the extent that these self-reported figures form parts of company annual reports we assumed them to be truthful and realistic representations. In some cases it is known that figures were validated by external auditors at the behest of the contributing companies, which further supports their validation.

Finally, there were an additional 21 entries where either the PHI or the value of contribution Survey figures could be validated in the public domain but both figures could not be validated. This can happen in cases where a company typically

reports press information about their initiative either in the form of contribution values or PHIs and calculated the alternative form of contribution valuation solely for the purpose of the IFPMA survey. Again, the particular figure that could not be validated using publicly available data was self-reported and assumed by ourselves to be a realistic picture of a company's involvement in an initiative.

Excluding those for which no value is included in the Survey totals, the declared financial value of the individual initiatives in the sample range from less than \$10 million to more than \$1 billion, and by the number of positive health interventions from 10,000 to several million patients.

#### **4.2. Data sensitivity and analysis**

The initiatives in the sample were then reviewed using both the confidential data available to us from the IFPMA and any publicly available data. Where necessary, we also contacted the companies and the IFPMA for clarification of specific issues, for instance when the public and confidential data do not match. Summaries of each of the 10 case studies are appended to this paper, as these provide practical examples of the variety of initiatives and types of issues that have arisen in compiling and validating the Survey. The summaries do not divulge confidential data provided to the IFPMA, but do seek to show how we have used published data in order to assess the validity of the entries in the IFPMA Survey. Further information on each of the initiatives is available on the websites listed in each summary. As most of the data in the Survey is sensitive for the companies concerned, the creation of the Survey has, therefore, been bound by the requirements of commercial confidentiality, which means that only the aggregated totals for “value” and “impact” are published. For the purposes of validation we were given access to spreadsheets containing the company-specific data from the survey, which also included a summary record of issues raised by the IFPMA researchers in their correspondence with company respondents. This revealed some of the validation questions that had already been covered. We were, therefore, able to investigate the survey responses, the decision on whether to include them in the survey totals, and the calculation of the extent to which they were included in the totals.

### 4.3. Endpoints

In assessing validity, we sought to identify whether the data are robust, and whether they are consistent with the IFPMA definitions. We have assumed that the main purpose of the validation is to ensure that the IFPMA has not overstated the pharmaceutical industry's contribution to the MDGs. In assessing the case studies therefore, we have paid particular attention to ways in which the reported data could be inflated. This could have arisen from: (a) the inclusion of spending that is not related to the achievement of the MDGs in developing countries; (b) the inclusion of periods of time beyond the time-frame of the MDGs; (c) the inclusion of contributions from other organizations, or, (d) the results of others' contributions, or from confusion between the reporting of doses and courses of treatment. In addition, we have used other sources of evidence, which may refer to the activities of Global Health Partnerships (GHPs) and the contribution of pharmaceutical companies to these efforts.<sup>22</sup> Such activities, include, among others, the Polio Eradication Initiative (PEI),<sup>23,24</sup> Roll Back Malaria (RBM),<sup>25,26</sup> Stop TB,<sup>27</sup> The Global Alliance for Vaccines and Immunisation (GAVI),<sup>28,29</sup> The Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM),<sup>30</sup> and Global Alliance to Eliminate Lymphatic Filariasis (GAELF).<sup>31,32</sup>

Wherever possible we have used published information to check against the figures included in the Survey totals. For example, in some cases we have been able to make basic calculations from published data on the number of doses delivered, to assess whether the reported figures for the number of PHIs appear reasonable. In others, we have used published figures on total spending or planned spending over a number of years some of which are outside the time-limits of the IFPMA Survey, to assess whether the declared level of spending within the time-limits is reasonable given the nature of the initiative.

The questionnaires asked respondents to declare whether they had used WAC to report the value of donated products, and to comment where this was not the case. These comments provided useful insights into the use of WAC as the unit of measurement and difficulties that might be associated with this.

In some cases, public information on financial contributions and PHI impact data was not available for the entire survey period. There are two types of cases in particular to highlight. First, some initiatives started before the survey time period

and have effectively been winding down over this time. This means that the survey time period may not account for the cumulative impact of a program's entire life with the given survey period of 2000-2005. This is much more of an exception case as most initiatives either began during or started at the beginning of the time period included in the Survey. As the Survey went live in the summer of 2005, the timing could also have led to companies not having yet completed their compilation of 2004 and/or 2005 data thus underreporting overall contributions for the period 2000-2005.

Second, there are cases where the publicly available numbers to use for validating against Survey figures describe differing time periods. For example, for an initiative that has been operational since September 2001, there could be a public figure for cash contribution for the program start up until September 2004, whereas the Survey figure would include data for 2005, in which case there would be a mismatch. With an understanding of the objectives of this program, such as if the end of 2004 and the year 2005 are times of increased funding and activity or periods of slow-down, the figure in the Survey could be assessed against known initiative progress. Any estimates about additional months or years were always performed to err on the side of being conservative. Where necessary, our methodology included linear extrapolation calculations to determine if numbers appearing in the Survey followed along expected figures as available in the public domain. Any calculations were always performed with an understanding of the objectives of an initiative and would take into account qualitative factors and developments such as an initiative being introduced in additional countries or reducing cash contributions but increasing drug donations in certain years.

## **5. Summary of Findings**

### **5.1. Robustness and comparability**

The main focus of our validation has been to ensure that the survey data are only included in the headline totals when they fully comply with the IFPMA definitions for value and impact. To make this assessment we not only investigated the data as provided by respondents for the initiatives within our sample, but we also compared this with any published data on the initiatives. In addition, the spreadsheet containing the data also included comments on the data from respondents and the IFPMA researchers, which sometimes provided useful insights. Overall, the sample

demonstrated that the IFPMA had taken a conservative approach towards inclusion of the initiatives' value and impact in the survey totals. There is clear evidence that when there has been any doubt about the quality of the available data then the relevant data has been excluded or not accounted for.

As most of the programs are partnerships, there can be considerable difficulty in assessing each partner's contribution in terms of health interventions given that the link is indirect. For example, many of the partnerships receive funding not only from one or more pharmaceutical companies, but also from a range of other sources including the World Bank and the Gates Foundation. Some of these are major programs. For example the Global Alliance to Eliminate Leprosy includes the WHO, the World Bank and the Nippon Foundation amongst its partners, and the Accelerating Access Initiative is a co-operative endeavour between UNAIDS, the WHO, UNICEF, the UN Population Fund, the World Bank, and seven pharmaceutical companies. Donations to NGO and official aid programs can amount to very large sums for a single company, but the individual donor can often only estimate the number of beneficiaries directly attributable to their own involvement. For these cases, a monetary value attached to contributions can be readily attributed to a company, but only an estimate of interventions can be made as an NGO actually operates the initiative. This is evidently the case for a number of major initiatives covered by the Survey.

## **5.2. Use of PHIs**

The use of PHIs as the unit of measurement for the impact of industry initiatives, means "individual" PHIs, thus any third-party effects are excluded. However, the latter can be very significant in the context of infectious diseases. The WHO estimates, for example, that each person with MDR-TB will pass the infection to 20 others, thus the economic and social value of prevention extends much further than the benefits to each treated individual. A TB program in China treated more than 1.5 million patients over 10 years at a total cost of \$130m, preventing 30,000 TB-related deaths annually and averaging less than \$20 for each life saved. But each dollar invested in the program generated \$60 in the form of savings on treatment costs and the increased earning power of healthy people. It is also estimated that investment in the control of river blindness in sub-Saharan Africa, will generate \$3.7bn from improved worker and agricultural productivity.<sup>33</sup> These figures are indicative of the

societal impact of industry initiatives, which remain completely unaccounted for through the use of individual PHI.

### **5.3. Treatment of R&D activities**

During the process of developing the Survey, IFPMA excluded R&D activities from the survey results entirely. The rationale was that the availability of only a very small amount of data, given the commercial sensitivity of R&D costs, could not provide a meaningful reflection of the industry's contribution. The lack of R&D data is a shortcoming, as it does not allow for a detailed account of activities and initiatives that otherwise are to the benefit of furthering research in neglected diseases. Nevertheless, information on some of these activities is available. For instance, we do know that company contributions to the Medicines for Malaria Venture (MMV) are publicly reported to be worth around \$25m annually;<sup>34</sup> that AstraZeneca's capital outlay in the Bangalore Research Institute amounted to \$10m, with \$5m a year running costs;<sup>35</sup> and that the Novartis Institute for Tropical Diseases in Singapore reflects a \$122m investment.<sup>36</sup> These initiatives are supporting the development of centres of excellence in pharmaceutical research within developing countries, with long-term implications for the availability of new medicines for the diseases that most affect them. Over time these initiatives will begin to provide access to new medicines and would then be reported in the Survey once they begin to produce PHIs.

We would hope that the omission of R&D programs from the Survey might be corrected in future, in order to provide a fuller picture of the industry's contribution towards tackling the diseases of the developing world, although many of them are covered in general terms in other IFPMA publications<sup>37</sup>. The reasons for the decision to omit R&D are, however, obvious to us following our research into several R&D projects.

### **5.4. Overall assessment**

The Health Partnerships included in the IFPMA Survey provide up to 539 million (individual) PHIs, on which a nominal value of US\$4.38 billion has been placed. These figures are substantial. Indeed, the number of interventions that have taken place is equivalent to two-thirds of the population of Sub-Saharan Africa<sup>38</sup>. The total cumulative value is larger than the 2004 net Overseas Development Assistance (ODA) budget of Canada or The Netherlands, and almost three times the Swiss net ODA budget.<sup>39</sup> As a further example of the scale of the estimated pharmaceutical

industry contribution, the *combined* annual aid spend of Oxfam, Médecins Sans Frontières (MSF) and Save the Children is currently around US\$650m.<sup>40</sup>

It is important to bear in mind, however, that the philanthropic activity captured in the IFPMA database as PHIs does not include the millions of PHIs that occur as a result of the industry's pharmaceutical sales as a part of standard business operations. Additionally, the industry contributes to the training of health professionals regarding medicine usage thus furthering their contribution towards achieving the MDGs. As this Survey only includes those donations and other charitable efforts either performed or reliably attributable to pharmaceutical companies' activities aimed at achieving the MDGs, it means that the Survey does not represent pharmaceutical companies' total efforts made towards achieving these goals.

Our research certainly did not demonstrate conclusively that these definitions were universally adopted by company respondents to the survey, although the IFPMA may be able to ensure that this is the case as the Survey matures. Nevertheless, analysis of our sample suggests that underestimation of the value and impact of the programmes is more probable than overestimation. This is due largely to the earlier work of IFPMA researchers to verify the data received and delete or amend items that were either not meaningful or which could be unreliable. This is particularly the case in the common circumstances where there is an overlap between individual programmes.

Our assessment of the case studies was often hampered by a lack of published data on the initiatives, or external assessments of them. Much depends on the design of each initiative and the nature of the partnership. The Mectizan® Donation Program, for example, has a very clear structure and operating system, and now publishes annual reports on its operations and achievements. In addition, it has recently been the subject of a series of papers published in a supplement to the *Journal of Tropical Medicine and International Health*<sup>41</sup>. The majority of the initiatives in our sample, however, had very little of their data in the public domain and with insufficient time to enter into substantive discussions with the companies concerned we were often limited in the detail of our assessments. Nevertheless, it appears that the IFPMA Survey is the first of its kind across industrial sectors. Indeed, within the context of this exercise, we have also sought to identify examples of other sector-wide efforts to



produce similar data, but it does appear to be the case that the IFPMA Health Partnerships Survey is the first attempt to measure an industry's overall contribution towards achievement of the MDGs. In particular, we searched for similar exercises in the water and food sectors, given their direct relevance to many of the MDGs. Whilst there are many programs by individual multinational firms, and groups of firms, there did seem to be no aggregated data for either of these sectors. It is possible, therefore, that the IFPMA Survey will not only serve as a useful tool to monitor the commitment of the pharmaceutical industry to achievement of the MDGs, but also that it will serve to promote the development of similar tools for other important industrial sectors.

## **6. Conclusions**

The IFPMA Survey is undoubtedly a welcome addition to the discussion on the MDGs, and the role of business in the global partnership to achieve them. It sets a benchmark against which the pharmaceutical industry's contribution to the MDGs can be judged during the coming years. It also presents a challenge to other important industries to follow suit.

The IFPMA's definition of a "Positive Health Intervention" seems to us to provide a reasonable unit of measurement, but it is nevertheless conservative inasmuch as it takes no account of the third-party effects of many of the interventions included.

Monetary values are under the control of companies, whereas the implementation of partnership programs is often in other hands, hence companies are usually more able to provide reliable financial data than data on positive health interventions. The exceptions to this are the programs whose design ensures that the outputs are measurable and trackable. Amongst our 10 case studies this is, for example, the situation with the International Trachoma Initiative. Furthermore, the overall monetary contribution is often underestimated because of the difficulty in hypothecating some in-kind costs, such as training costs associated with product donations, which would be admissible in the survey if they could be calculated.

Differences in reporting time-periods are problematic, because some programs have been in existence for quite long periods of time before the time-period of the Survey or the MDGs. This can lead to an underestimation of a company's

contribution to a particular cause, although it does, of course, more accurately reflect their commitment as it relates directly to the achievement of the MDGs since 2000.

Companies do appear to be generally cautious in reporting contributions if they are unable to attribute them.

The template method of returning survey data is a helpful way to start a process where responsible individuals at the companies will become used to filling in the same data every reporting cycle, thus reducing misinterpretations and mistakes in returns. If the necessary expertise is maintained by the IFPMA, whether in-house or not, so that the current methodology can be used with consistency, then the task of maintaining an up-to-date survey and reporting its results on a regular basis would be greatly eased.

In conclusion, it does appear from this brief review of the IFPMA Survey on Health Partnerships that the figures presented provide a realistic picture of the pharmaceutical industry's contribution towards achievement of the health MDGs. It is, however, a partial picture given the exclusion of R&D initiatives and the exclusion of a large amount of investment that cannot be accurately reported and the wider societal aspects of the initiatives.

## Case Studies

### Case Study 1

<b>Initiative</b>	<b>Access to HIV Care</b>
<b>Company</b>	<b>Abbott</b>

#### Background

Abbott Access to HIV Care was launched in 2001 and provides the rapid diagnostic test Determine® HIV-1/2, and Abbott's two protease inhibitors, Kaletra® and Norvir®, to 69 developing countries, including the whole of Africa. Abbott says that the program *“is available to any organization or institution that provides products to patients as part of a sound and sustainable program of care”*. As part of a 5-year, \$100 million commitment to fight HIV/AIDS in the developing world, Abbott makes its two antiretroviral drugs available at a loss to the company, at a price of \$500 per patient-year, and the Determine® HIV test is made available at a no-profit price of \$0.80.

The company reported that by the end of 2005 it had shipped 41.7 million tests through the Access to HIV Care program. Abbott's protease inhibitors reach approximately 25,000 patients. In May 2005 Abbott announced the sale of Determine® to Inverness Medical Innovations, but emphasized that this would have no effect of the Access to HIV Care program.

The request process for Abbott's programme is managed by Axios International, an organization that manages various other philanthropic initiatives from their offices in Paris and Kampala.

#### Discussion

The lack of public data on this program specifically related to what is measured through the IFPMA Survey limits our validation. Abbott does report on results of this Access program in its annual global citizenship report and on its website under the global citizenship section. It also communicates programme status at key international HIV/AIDS conferences. Although the available public data is limited at present, the scale of the figures included in the Survey, against the known quantity of rapid HIV tests that the company has shipped and the fact that it is operational in some 69 countries does suggest that Abbott have only included the cash costs of running the program, and not included any losses made on the provision of their medicines at preferential prices, thus meeting the requirement to exclude hypothetical costs in terms of lost revenue associated with preferential pricing arrangements. We have no means of confirming this conclusion. Abbott does not report a monetary value for the Access program but instead publishes health impact figures that amount to the volume of product provided as a result of the program.

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[www.accesstohivcare.org](http://www.accesstohivcare.org)

<http://abbott.com/citizenship/access/access.cfm>

[www.ifpma.org](http://www.ifpma.org)

[www.axios-group.com](http://www.axios-group.com)

<http://www.axios-group.com/en/news/default.aspx>

## Case Study 2

<b>Initiative</b>	<b>MDR-TB Partnership</b>
<b>Company</b>	<b>Eli Lilly</b>

### Background

In 2003 Lilly took the lead in a new partnership with the WHO and Doctors Without Borders to combat Multi-drug resistant TB (MDR-TB). The partnership aims both to train health personnel and increase the supply of drugs needed to treat MDR-TB sufficient to meet the WHO treatment goal of 20,000 patients treated annually by 2010. The company is working with manufacturers in China, India, South Africa, and Russia in order to develop local production of both capreomycin (Capastat®) and cycloserine (Seromycin®), active pharmaceutical ingredients and finished products-in high burden TB countries, as well as increasing its own manufacturing output. As part of this wide-ranging initiative, which includes technical assistance, training, surveillance, community support and evaluation, Lilly is distributing those two drugs “at a fraction of production cost” via the WHO’s Green Light Committee (GLC) to projects that meet the WHO’s criteria known as “DOTS-Plus”. Lilly has put the value of the discount at \$25m. Lilly puts its total financial contribution to the partnership at \$70m and states that from “2000 to the end of 2005, Lilly will have supplied close to 800,000 vials of Capastat, and nearly 3.7 million capsules of Seromycin”.

### Discussion

The timeline of Lilly’s commitment to the partnership means that part of Lilly’s total financial commitment to the project will take place outside the time limits of the current IFPMA survey, although within the time limits of the MDG targets, and it does appear that the IFPMA has made a proportionate reduction in the declared \$70m commitment to allow for this. This leaves scope for any additional investment to be properly included in any future updates to the Survey. Lilly’s declaration of the cost of its preferential pricing highlights the boundary issues that arise in drawing strict limits for inclusion in the Survey. Whilst in some cases companies may be giving preferential prices that are at or near cost, in others the prices will be substantially below cost. These discounts do constitute a donation to MDG-related initiatives, but are nevertheless excluded from the Survey.

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[www.who.int](http://www.who.int)

[www.ifpma.org](http://www.ifpma.org)

<http://www.usembassy-kazakhstan.freenet.kz/press-releases/pr-04-13-en.html>

### Case Study 3

<b>Initiative</b>	<b>Mectizan® Donation Program (MDP)</b>
<b>Company</b>	<b>Merck &amp; Co</b>

#### Background

Merck's Mectizan® Donation Program is the longest-running and one of the most substantial initiatives reported within the Survey. It was created in 1987, with a commitment to provide as much of the drug as needed, for as long as needed, for the treatment of onchocerciasis ("river blindness"). Merck reports that it has donated more than 1.3bn tablets by the end of 2004, reaching 40 million people a year in 34 countries, with a cumulative total of 452 million treatments since 1987. The Program continues to grow as more applications are received for community-based mass treatment.

In 1998 Merck extended the Program to the treatment of Lymphatic Filariasis, currently providing the medicine to 25 million people annually for the treatment of LF in 10 countries. As of December 2005, Merck has donated more than 1 billion tablets worth over \$1.5 billion in the past 15 years towards this Program.

#### Discussion

The scale of the Mectizan® Donation Program means that it is of considerable significance to the IFPMA Survey. Fortunately its scale also means that it is a very public program, with a large amount of published data and analysis. While the use of Mectizan® occurs in both the Mectizan® Donation Program and the Global Alliance to Eliminate Lymphatic Filariasis (LF) and there could be some potential for overlap in accounting for the donation of tablets, Merck clearly reports their donations separating to which initiatives donated tablets are allocated. The Survey makes clear that the figures for the Mectizan® Donation Program exclude donations to the Global Alliance to Eliminate LF thus removing any potential double-counting as a source of concern.

One of the MDP's strengths is the rigour with which applicant community-based mass treatment programs are screened by an independent expert committee to ensure that they can deliver their plans safely and effectively, and that the products are not diverted from their intended recipients. This, plus the general transparency of the MDP, makes it relatively easy to validate the data included in the IFPMA Survey as being realistic to the scale of the program.

#### Sources

[www.mectizan.org](http://www.mectizan.org)

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## Case Study 4

<b>Initiative</b>	<b>Global Alliance to Eliminate Lymphatic Filariasis</b>
<b>Company</b>	<b>GlaxoSmithKline, Merck &amp; Co.</b>

### Background

The Global Alliance to Eliminate Lymphatic Filariasis (GAELF), was created in 1998 as a public-private partnership with the aim of eliminating LF, commonly known as Elephantiasis, by 2020. LF is a parasitic infection spread by mosquitoes, which now infects more than 120 million people, of whom more than 40 million are incapacitated or disfigured by it. GlaxoSmithKline and Merck & Co have pledged all the albendazole and Mectizan® respectively that will be required to achieve the Global Alliance’s ambition.

The Global Alliance website reports that in 2004 the number of annual treatments under the Program doubled compared to the previous year, to 250 million treatments in 39 countries. In addition to their effect on LF, the treatments also eliminate intestinal worms, and the Global Alliance highlights reductions in hookworm and roundworm infections in children as an additional and immediate benefit.

### Commentary

The Global Alliance itself uses a definition that is similar in effect to the IFPMA’s “positive health intervention”, inasmuch as the data for the number of treatments represents the “number of individuals reported to have ingested anti-filarial drugs in the adequate dosage”, which the Global Alliance refers to as the: “At risk population covered by drug co-administration” in its datasets.

At first glance, the only potential cause for confusion in reporting this for the IFPMA Survey lies in the overlap with the Merck Mectizan® Donation Program (MDP): The WHO recommends that LF should be treated with a combination of either: albendazole plus DEC, or Mectizan® plus albendazole in African countries where river blindness and LF co-exist. The Survey makes clear that the MDP figures exclude Merck’s contribution to the Global Alliance to Eliminate LF, so that Merck’s contribution can be reported under the appropriate program without duplication. Merck has confirmed that their reporting mechanisms clearly allocate donated tablets between the Mectizan® Donation Program and efforts aimed at LF thus double-counting of Mectizan® donations is not of concern.

Over the life of GAELF to 2020 the total value of the companies’ drug donations is forecasted to exceed \$1bn. GSK reports that the value of donated albendazole reached \$26m in 2005, and 136m treatments. These figures are consistent with the four years reported in the Survey, taking into account the recent pace of growth in GAELF and the inclusion of Mectizan® donations in the reported totals.

### Sources

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[www.mectizan.org](http://www.mectizan.org)

<http://www.gsk.com/media/archive.htm> “Response to Global Disasters increases GSK’s giving by 16% to £380m in 2005” Press Release, 3 March 2006

## Case Study 5

<b>Initiative</b>	<b>Global Polio Eradication Initiative (PEI)</b>
<b>Company</b>	<b>sanofi pasteur</b>

### Background

sanofi pasteur is the longest standing corporate partner involved in the Global Polio Eradication Initiative. Founded in 1988, this initiative aims to eradicate polio worldwide through immunization of children. It conducts national immunization days in countries with endemic polio and polio outbreaks; monitors new cases and works to eliminate the spread of polio in areas where outbreaks continually occur. The initiative's total annual expenditure in 2005 was US\$ 620 million and about US\$ 600 million in 2004, for operations in 75 countries.

Since 1997, sanofi pasteur has donated 120 million doses of oral polio vaccine (OPV). The company pledged 30 million doses of OPV from 2002 to 2005. This particular donation covers all National Immunization Day needs and expected outbreaks in countries with armed conflicts such as Angola, Liberia, Sierra Leone, South Sudan and Somalia. Also, in March 2005, French regulatory authorities licensed sanofi pasteur's new vaccine called Monovalent OPV, and the company informed the WHO that it would be willing to produce the new vaccine for the Initiative. The Bill and Melinda Gates Foundation provided US\$ 10 million to purchase the vaccine from sanofi pasteur and Panacea Biotec, another mOPV1 manufacturer.

### Discussion

Because of the public health nature of this project, it is difficult to attribute sanofi pasteur's particular role in reaching patient audiences and others affected by the company's donations apart from those receiving vaccines. The discrete nature of vaccines, the number of courses of therapy involved with delivering the Oral Polio Vaccine (OPV) and the knowledge of how many vaccines sanofi pasteur has donated makes it possible to confirm that figures listed on the Survey accurately reflect the company's role in the initiative. The public section of the IFPMA website and other sources contain a figure of 120 million doses of OPV, which makes up the entirety of sanofi pasteur's contribution since 1997 to verify against the Survey figure. The way that information about sanofi pasteur's role in the initiative is reported in the survey reflects appropriately the impact of their vaccine donations.

The survey does make clear the fact that sanofi pasteur's role has been both in donating vaccines and providing vaccines at discounted prices.

### Sources

<http://www.polioeradication.org/>

<http://polio-vaccine.com>

<http://www.ifpma.org>

## Case Study 6

<b>Initiative</b>	<b>International Trachoma Initiative</b>
<b>Company</b>	<b>Pfizer</b>

### Background

In 1998, Pfizer and the Edna McConnell Clark Foundation founded the International Trachoma Initiative (ITI) to eliminate trachoma, the biggest cause of preventable blindness.

At the start of the ITI, Pfizer donated Zithromax® free of charge to five countries. As the initiative has expanded, Pfizer continues to donate Zithromax® to prevent the spread of active trachoma for all eleven countries now included in the ITI.

### Discussion

The number of patients receiving Zithromax® and the number of ITI surgeries performed as reported on the IFPMA Survey appears to accurately estimate the actual volume of antibiotics that have been distributed and surgeries performed by the initiative. Although it may be the case that some patients receive more than one course of Zithromax® treatment, it is intended to be a single-dose treatment. This simplifies calculations of the number of individuals impacted by the initiative. Even though some of the countries where the program has just commenced in recent years cannot yet be fully verified against publicly available data, figures submitted for the Survey are in line with expectations based upon verifiable data from 2000-2004.

The nature of Pfizer's role in the ITI program as the sole supplier of the single antibiotic used to fight trachoma makes Pfizer's contribution clear within the scope of the entire initiative. Given the stated objectives of ITI and published information regarding Zithromax® distribution, all countries involved in ITI received the antibiotic for patients with early infections and ITI surgeries for advanced stage patients. Assuming plans for expansion went successfully with appropriate infrastructure and goods in the locations where needed to continue and grow the program, figures present in the survey clearly state contributions to ITI.

The balance sheet in the annual reports released by ITI from 2003 onwards, include a note regarding the volume and value of Zithromax® donations for the year. According to these reports, the value of Zithromax® donations to ITI in 2002, 2003 and 2004 was \$64.0 million, \$86.0 million and \$268.36 million respectively. Against this, information appearing in the survey appears to underestimate the value of drugs donated. Without data in value by year for 2000, 2001, and 2005, this cannot be confirmed. Regardless, there is little reason to lack confidence in the value figure attributed to Pfizer's contribution in the survey.

### Sources

[www.ifpma.org](http://www.ifpma.org)

[www.pfizer.com](http://www.pfizer.com)

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## Case Study 7

<b>Initiative</b>	<b>Glivec International Patient Assistance Program (GIPAP)</b>
<b>Company</b>	<b>Novartis</b>

### Background

Novartis started the Glivec International Patient Assistance Program (GIPAP) in 2001 to ensure that patients lacking necessary financial resources and health insurance could have access to Glivec® for certain cancer diagnoses. The Max Foundation administers the program by registering qualified patients and physicians, and Novartis ships the drugs to approved treatment centers. Glivec® is not available through the GIPAP in countries where the drug is not approved for the specific indication required by the patient.

GIPAP operates in 74 countries. Since its inception, over 10,000 patients are reported to have been treated with Glivec® as a result of GIPAP.

### Discussion

Because of the nature of the GIPAP program, where Novartis is the single supplier of Glivec® to the initiative, attribution of Novartis' involvement in the program's operation is clear. GIPAP knows how many individuals are registered, the number of successful recipients of the drug, and the cost of the drugs provided.

The figures in the Survey for the number of patients reached as a result of the GIPAP program can therefore be validated adequately using publicly available information about the initiative. There is little cause for concern regarding the data submitted for the number of patients reached by the GIPAP.

### Sources

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[http://www.novartis.com/corporate\\_citizenship/en/2006\\_gipap.shtml](http://www.novartis.com/corporate_citizenship/en/2006_gipap.shtml)

<http://www.primezone.com/newroom>

<http://www.maxaid.org>

## Case Study 8

<b>Initiative</b>	<b>BMS Donations to Americares</b>
<b>Company</b>	<b>Bristol Myers Squibb</b>

### Background

Bristol-Myers Squibb (BMS) has donated pharmaceuticals to Americares since 1982 for both emergency and on-going operations. BMS pharmaceuticals have been sent to the Sudan and Chad, Haiti, various Caribbean countries during hurricane flooding and to Sri Lanka, India and Indonesia following the Tsunami in 2004. A particular partnership called “Cefzil para Mexico” provides the antibiotic Cefzil to patients with respiratory infections, especially children and young adults. The wholesale value of donations BMS has made to Americares since 1982 is US \$220 million while \$13 million of donations were distributed in 2004.

### Discussion

This initiative includes only BMS supplying drugs to Americares on an ongoing basis as well as when emergency needs arise. Because of the variety of drugs contributed by BMS to Americares, calculating a figure for how many positive health interventions have taken place is difficult. Additionally, the program is administered and executed through the NGO, Americares, creating difficulty in attributing what level of donations of what types of drugs, reached patients.

However, the attribution of contributions to BMS for supplies given to Americares is clearer in value terms because BMS would be able to assess the monetary value of its donations regardless of the role the NGO plays in their being put to use towards health interventions. The figures for the monetary values of contributed products create little cause for concern over their validity, but the inclusion of short-term disaster relief in the figures means that they cannot be included in the published totals from the Survey, and the IFPMA researchers have appropriately corrected for this.

### Sources

<http://www.bms.com/philanthropy/data/produc.html>

<http://www.ifpma.org>

## Case Study 9

<b>Initiative</b>	<b>Wyeth partnership to provide oral contraceptives to the developing world</b>
<b>Company</b>	<b>Wyeth</b>

### Background

Under this partnership initiative, Wyeth makes oral contraceptives available to organizations such as the US Agency for International Development (USAID) and international agencies at discounted prices, and contributes to related training and advocacy programs. The initiative is ongoing and has now reached 60 countries. Wyeth sees this as a contribution not just to stabilizing population growth but also improving the health of women and children in those countries where pregnancy can be associated with maternal death or long-term disability due to preventable causes. The company reports that 1.5 billion cycles of oral contraceptives have been sold to international agencies at discounted prices since 1968.

### Discussion

A project entirely dedicated to offering oral contraceptives at discounted prices to the developing world requires some nuances in reporting for the purposes of the Survey, and the financial value of discounted sales cannot be included in the financial totals. The way the data has currently been reported takes into account the definition requested by the IFPMA for a positive health intervention, in this case meaning a sufficient course of therapy for one person for one year. The data reported appropriately reflects how many courses of oral contraceptive would be taken per woman per year.

Because of Wyeth's role in training and project support for this initiative, the attribution of Wyeth's total contribution appears underestimated. These types of activities are difficult to value and therefore are not included in calculating Wyeth's total contribution alongside the value of product contribution. This may result in an underestimation of Wyeth's total contribution.

Wyeth's total contribution in number of patients reached as result of the initiative and monetary overall contribution in the survey do not appear to cover the full time period of the survey, although the initiative has been in existence for much longer than this time period.

### Sources

[www.ifpma.org](http://www.ifpma.org)  
[www.wyeth.com](http://www.wyeth.com)

## Case Study 10

<b>Initiative</b>	<b>Viramune® Donation Programme</b>
<b>Company</b>	<b>Boehringer Ingelheim</b>

### Background

Since 2000, Boehringer Ingelheim has donated its antiretroviral drug, Viramune in over 50 countries. The drug is donated free-of-charge for Mother-to-Child Transmission prevention programs across the developing world. Viramune acts to reduce the transmission of HIV from mothers to children when both parties are given a single dose of the drug.

### Discussion

Because Boehringer Ingelheim donates Viramune to NGOs, charitable organisations and healthcare providers with appropriate specific mother-to child transmission HIV prevention programs, the company relies on the reports provided by these institutions with ad hoc site visits to monitor the information. Viramune is given as single-dose drug when used in prevention of mother-to-child transmission (pMTCT), and is provided to mother-child pairs, this makes reporting the number of positive interventions fairly straightforward to calculate. There is no apparent reason to call into question the veracity of reported data included in the Survey when checked against publicly available data, particularly as the Programme started well within the time-period of the survey.

No claim is made with regard to monetary value.

### Sources

[www.boehringer-ingelheim.com/hiv](http://www.boehringer-ingelheim.com/hiv)

[www.businessfightsaids.org](http://www.businessfightsaids.org)

[www.ifpma.org](http://www.ifpma.org)

[www.pmtctdonations.org](http://www.pmtctdonations.org)

## About IFPMA

Founded in 1968, the International Federation of Pharmaceutical Manufacturers & Associations is the global non-profit NGO representing research-based pharmaceutical, biotech and vaccine companies and national industry associations in developed and developing countries. The industry's R&D pipeline contains hundreds of new medicines and vaccines being developed to address global disease threats, including cancer, heart disease, HIV/AIDS and malaria. The IFPMA Clinical Trials Portal and the IFPMA Health Partnerships Survey help make the industry's activities more transparent. The IFPMA strengthens patient safety by improving risk assessment of medicines and combating their counterfeiting. It also provides the secretariat for the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH).

## About LSE

The London School of Economics and Political Science (LSE) is a world class centre for its concentration of teaching and research across the full range of the social, political and economic sciences. Founded in 1895 by Beatrice and Sidney Webb, LSE has an outstanding reputation for academic excellence. LSE is an unusual university. Few university institutions in the world are as international. The study of social, economic and political problems covers not only the UK and European Union, but also countries of every continent. From its foundation LSE has aimed to be a laboratory of the social sciences, a place where ideas are developed, analysed, evaluated and disseminated around the globe.

## About LSE Health and Social Care

LSE Health and Social Care (LSEHSC) - a research centre in the [Department of Social Policy](#) at the LSE - was established in 2000. As an international centre of academic excellence, the mission of LSEHSC is the production and dissemination of high quality research and policy analysis to contribute to the LSE's established world presence and reputation in health policy and social care. Bringing together a core team of researchers and academics, LSEHSC promotes and draws upon the multidisciplinary expertise of staff members, associated academics and a number of postgraduate students. Staff also contribute to a number of health MSc courses run by the LSE. The Centre is designated a collaborating Centre for Health Policy and Pharmaceutical Economics for the [World Health Organisation \(WHO\)](#). The major research areas within the Centre cover health policy, health economics and social care, with substantial overlap between these areas - emphasising the multidisciplinary assets of the Centre.



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## Notes

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<sup>4</sup> IFPMA News Release: *New IFPMA Survey highlights Major Contributions of Pharmaceutical Sector's Public-Private Health Partnerships in the Developing World* Geneva, 7 December 2005

[http://www.ifpma.org/pdf/ifpma\\_release\\_partnerships.pdf](http://www.ifpma.org/pdf/ifpma_release_partnerships.pdf)

<sup>5</sup> World Health Organisation "*Health in the Millennium Development Goals*" [www.who.int/mdg/goals/en/print.html](http://www.who.int/mdg/goals/en/print.html)

<sup>6</sup> [www.who.int/mdg/measuring\\_progress/progress/en/index.html](http://www.who.int/mdg/measuring_progress/progress/en/index.html)

<sup>7</sup> WHO Press Release: "*Building stronger health systems key to reaching the health Millennium Development Goals*" 22 August 2005 (Accessed online 24<sup>th</sup> November 2005) [www.who.int/mediacentre/news/releases/2005/pr35/en/index.html](http://www.who.int/mediacentre/news/releases/2005/pr35/en/index.html)

<sup>8</sup> Ibid.

<sup>9</sup> The World Bank Institute: *Business Action for the MDGs: Private Sector Involvement as a Vital Factor in Achieving the Millennium Development Goals* The World Bank, Washington DC, 2005

[http://siteresources.worldbank.org/CGCSRLP/resources/business\\_mdgs.pdf](http://siteresources.worldbank.org/CGCSRLP/resources/business_mdgs.pdf)

<sup>10</sup> [http://www.ifpma.org/Health/hiv/health\\_aai\\_hiv.aspx](http://www.ifpma.org/Health/hiv/health_aai_hiv.aspx)

<sup>11</sup> <http://www.mectizan.org>

<sup>12</sup> <http://www.mmv.org>

<sup>13</sup> IFPMA News Release *op cit*

<sup>14</sup> Data derived from UK Department for International Development factsheets 2005 [www.dfid.gov.uk/mdg](http://www.dfid.gov.uk/mdg)

<sup>15</sup> *Poor shooting at the Millennium Development Goals* The Lancet Infectious Diseases, Vol 5, September 2005, p529

<sup>16</sup> For example, several companies have an entry under some of the major initiatives, such as the Accelerating Access Initiative, but in such cases where the value of each company's own contribution is not available, the total value of the industry's investment in the initiative is either listed under one entry only or divided between each of them.

<sup>17</sup> <http://www1.va.gov>

<sup>18</sup> <http://www.emims.net>

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- <sup>30</sup> <http://www.theglobalfund.org/en/>, accessed 28 February 2006.
- <sup>31</sup> [http://whqlibdoc.who.int/hq/2005/WHO\\_CDS\\_CPE\\_CEE\\_2005.52.pdf](http://whqlibdoc.who.int/hq/2005/WHO_CDS_CPE_CEE_2005.52.pdf), accessed 28 February 2006.
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- <sup>34</sup> <http://www.mmv.org>
- <sup>35</sup> <http://www.astrazeneca.com/communityprojects.67.aspx>
- <sup>36</sup> <http://www.nitd.novartis.com>
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- <sup>40</sup> Sources: [www.oxfam.org.uk](http://www.oxfam.org.uk), [www.msf.org/source/actrep/2004/images/fin-income.jpg](http://www.msf.org/source/actrep/2004/images/fin-income.jpg), and [www.savethechildren.org/financial/index.asp](http://www.savethechildren.org/financial/index.asp)
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