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Industry-Led Access-To-Medicines Initiatives In Low- And Middle-Income Countries: Strategies And Evidence

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Abstract

Global biopharmaceutical companies are increasingly establishing access-to-medicines (AtM) initiatives in low- and middle-income countries. We reviewed the initiatives of twenty-one research-based global biopharmaceutical companies to assess their strategies for improving access and the quality of evidence on the impact of their initiatives. The number of operating initiatives increased from 17 in 2000 to 102 in 2015. Of the 120 different AtM initiatives identified, 48 percent used a medicine donation strategy, and 44 percent used a price reduction strategy. While companies have frequently claimed that their initiatives have had

positive impacts, we found published evaluations for only seven initiatives, and nearly all of the evaluations were of low (62 percent) or very low (32 percent) quality. It is clear that the biopharmaceutical industry has increased its commitment to improving access to medicines in low- and middle-income countries. However, companies should do more to generate high-quality evidence on their initiatives, and the global health community should do more to assist the developing of evidence about the initiatives.

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The international community is increasingly recognizing that the biopharmaceutical industry must play a leading role in improving access to medicines in low- and middle-income countries. The industry's role was first articulated explicitly in Target 8.E of the Millennium Development Goals, which stated, "In cooperation with pharmaceutical companies, provide access to affordable drugs in developing countries."[1] Building on the Millennium Development Goals, the United Nations Special Rapporteur Paul Hunt concluded in a 2008 report to the UN General Assembly that while "states have primary responsibility for…enhancing access to medicines," it is also true that "pharmaceutical companies… have human rights responsibilities in relation to access to medicines."[2] The recently published Sustainable Development Goals reinforce the need for industry engagement in improving access to medicines.[3]

There are signs that the biopharmaceutical industry has responded to the UN declarations and expanded its efforts to increase access to medicines in low- and middle-income countries. Several large access-to-medicine (AtM) initiatives have been established by companies in recent years, including Pfizer's International Trachoma Initiative, which provides mass administration of donated azithromycin; Merck MSD's Mectizan Donation Program, which provides mass administration of donated ivermectin; and Novartis Access, which provides a portfolio of medicines for noncommunicable diseases at reduced prices. What appears to be missing, however, is a commitment by companies to measuring and reporting the impacts that these initiatives have on access to medicines. As stated in the aforementioned 2008 UN report, existing reporting systems "do not usually monitor, and hold a company to account, in relation to its human rights responsibilities to enhance access to medicines."[2]

Efforts are currently under way to improve reporting and accountability for industry-led AtM initiatives. Soon after the 2008 UN report came out, the Access to Medicine Index published its first ranking of biopharmaceutical companies based on their efforts to improve access to medicines in low- and middle-income countries.[4] Now funded by the Bill & Melinda Gates Foundation and the UK and Dutch governments, the index has since come out with updated company rankings every two years and appears to have created an incentive for expanding AtM initiatives, as well as for more transparent reporting.[5] However, the index's ranking methodology does not include a rigorous review of the evidence on the impact of companies' initiatives. Such a review would constitute an important next step

toward holding companies more accountable for improving access to medicines in low- and middle-income countries.

In this article we review industry-led AtM initiatives in low- and middle-income countries and assess the reporting and quality of the evidence available on the impact of these initiatives. Our aim is not to draw conclusions about whether AtM initiatives are effective, but rather to understand the quality of evidence being produced that would allow such conclusions to be drawn. We conclude by suggesting reasonable steps that could be taken to increase the production of rigorous evaluations of industry-led AtM initiatives.

Study Data And Methods

Review Of Initiatives And Strategies

We systematically reviewed the health initiatives of the twenty-one research-based global pharmaceutical companies listed in the Access to Medicine Index.[4,5] First, we developed a list of each company's health initiatives by reviewing the Health Partnerships Directory of the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA).[6] Information from the directory was supplemented with information from reports published by the Access to Medicine Index and annual and corporate social responsibility reports for Gilead and Novo Nordisk, companies that are not IFPMA members. At this stage, we included all initiatives that aimed to improve the health of patients and populations through efforts that go beyond traditional drug production and sales and that were implemented in low- and middle-income countries (according to the World Bank's definition).[7] We extracted from the sources mentioned above key information for each initiative, including the company

or companies involved, disease focus, target population, program countries, and years of operation.

In the second stage of our review of initiatives, we labeled each initiative according to the strategy or strategies used, applying a taxonomy we developed specifically for this review. The taxonomy contained three groups, each with a series of strategies (for definitions, see online Appendix 1).[8] In the first group are access-to-medicines strategies that aim to reducing access barriers to medicines directly. These strategies include price reductions, medicine donation, licensing agreements, and supply chain strengthening. In the second group are health service strategies that aim to improve service delivery, including service sponsorship, infrastructure investment, provider training, and awareness campaigns. In the third group are indirect support strategies that aim to improve population health indirectly. These strategies include financial support, community development, and research and development.

We labeled all health initiatives with at least one of these strategies and labeled several initiatives with multiple strategies. We then categorized initiatives labeled with at least one access-to-medicines strategy (price reduction, medicine donation, licensing agreement, or supply-chain strengthening) as AtM initiatives.

Review Of Evidence

After completing the review of initiatives and strategies, we reviewed AtM initiatives to identify the available evidence on their impact. We searched several sources for published reports and peer-reviewed journal articles. First, we systemically searched PubMed for articles related to each initiative. We applied a

consistent algorithm that included the name of the initiative, name of the company, focus disease, and focus countries. Second, we searched Google Web and Google Scholar using the same algorithm that we used with PubMed. Third, we reviewed each initiative's web page on the IFPMA Health Partnerships Directory. The directory is the primary source for information on industry-led health initiatives, and companies have incentives to keep it up to date. Links to publications are also frequently included.

In the second stage of the review of evidence, we read the abstracts of the publications we had identified to determine whether they constituted evaluations of the initiatives. We used a broad definition of *evaluation*, and we included in our analysis any article that attempted to measure outcomes or impacts using a clear research design. Publications that only described initiatives or reported inputs or outputs (for example, money spent or pills distributed) were excluded. Also excluded were efficacy trials that tested the impact of a medicine used in an initiative rather than the impact of the initiative itself. An example is the study by Simon Cousens and coauthors that examined the impact of annual dosing with ivermectin.[9]

Concurrent with the review of evidence, we reviewed AtM initiative resources to identify claims made related to impacts, so that these claims could be compared to the available evidence. For this, we searched initiative web pages on the IFPMA Health Partnerships Directory, as well as annual reports and corporate social responsibility reports for Gilead and Novo Nordisk.

Assessment Of Evidence Quality

Three of us read the full text of each published evaluation that we included and independently determined the quality of evidence rating using the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) system.[10] This system is recommended by the Cochrane Collaboration for use in grading the quality of evidence and the strength of study recommendations. In the GRADE system, study design is a strong determinant of whether the quality of evidence is high, moderate, low, or very low. The quality of evidence from a randomized controlled trial is initially graded as high, while the quality of evidence from an observational study is initially graded as low. The initial quality grading based on study design is then raised or lowered as appropriate based on other key aspects of the study—for example, how well a randomized controlled trial is implemented and its results reported.

We assigned an overall quality rating of high, moderate, low, or very low to each article based on consensus or a majority among the three independent author ratings. Descriptive information was also extracted from each publication, including the aim of the evaluation and the study design.

Limitations

This review had several limitations. First, we relied primarily on reports by pharmaceutical companies and the IFPMA to identify initiatives. However, companies have strong reputational incentives to report all of their initiatives, so the risk of missing data should have been minimal.

Second, we were able to identify only evaluations that had been published and made accessible to the public. While we might

have missed relevant publications, the ease of finding reports is itself a key aspect of accountability.

Finally, we were unable to draw any conclusions from our analysis as to whether the increase in AtM initiatives since 2000 has on the whole been a positive development. We were able only to conclude that not enough evidence has been produced to say one way or another.

Study Results

We identified 385 health initiatives across the twenty-one companies reviewed (Exhibit 1). Of these, 120 (31 percent) were categorized as AtM initiatives. Novartis had the most initiatives (fourteen), and Sanofi was second with thirteen. Twenty-one initiatives were multiple-company partnerships. Most of the 120 AtM initiatives used either a medicine donation strategy (57 initiatives, or 48 percent) or a price reduction strategy (53 initiatives, or 44 percent). Fewer used licensing agreements (26 initiatives, or 22 percent) or supply chain strengthening (13 initiatives, or 11 percent).

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Exhibit 1

Health initiatives, including access-to-medicines (AtM) initiatives, by company, 2016

The number of operating AtM initiatives has increased steadily over the past fifteen years, from 17 in 2000 to 102 in 2015

(Appendix 2).[8]

Eighty-eight percent of the 120 AtM initiatives focused on infectious diseases, including neglected tropical diseases (33 percent) and HIV (22 percent) (Appendix 3).[8] Fifty-two percent focused on noncommunicable diseases, including hypertension and diabetes. Finally, 33 percent focused on women's and children's health, and 16 percent focused on general health.

Several AtM initiatives targeted specific populations (Appendix 4).[8] Sixty-eight percent targeted populations in poverty, 62 percent targeted children, and 58 percent targeted women or mothers.

There was a clear concentration of initiatives in sub-Saharan Africa, with many countries in the region home to more than twenty-four initiatives (Exhibit 2). A few countries in Southeast Asia, including India and Bangladesh, also had a large number of initiatives, as did Brazil. We identified at least one AtM initiative in every low- and middle-income country in the world.

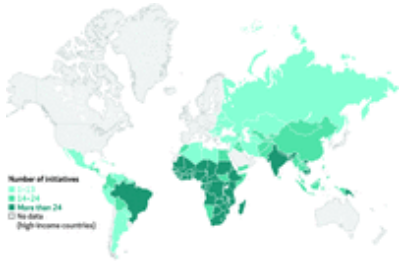

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Exhibit 2

Geographic distribution of access-to-medicines initiatives in low- and middle-income countries, 2016

SOURCE Authors' analysis of data for 2016 from the Health

Partnerships Directory of the International Federation of Pharmaceutical Manufacturers and Associations. NOTE High-income countries were excluded from the analysis.

We found claims of impact for 70 (58 percent) of the 120 AtM initiatives, but we found published evaluations for only 7 (6 percent) initiatives (Exhibit 3).

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Exhibit 3

Impact claims and published evaluations for access-to-medicines (AtM) initiatives, by company, 2016

Exhibit 4 summarizes the strength of the evidence available for the seven AtM initiatives with published evaluations. Overall, we found forty-seven articles that met our inclusion criteria for evidence, and all of them were published in a peer-reviewed journal (summary information for each article is provided in Appendix 5).[8] Merck MSD's Mectizan Donation Program had the most articles (seventeen), while the Global Alliance to Eliminate Lymphatic Filariasis, a partnership including several pharmaceutical companies, was second (fourteen articles).

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Exhibit 4

Strength of evidence for access-to-medicines initiatives

The vast majority of the forty-seven evaluations used either a pre-post design without a control group (twenty-four, or 51 percent) or a post-only design without a control group (sixteen, or 34 percent). One study used an interrupted time series design, one used a panel analysis design, and one used a pre-post design with a control group. Nearly all of the forty-seven studies were assigned a GRADE rating of low (twenty-nine, or 62 percent) or very low (fifteen, or 32 percent) quality. Three studies (6 percent) had a rating of moderate quality,[11⇓-13] while none had a rating of high quality. The first of the three studies with a rating of moderate quality, which evaluated Merck MSD's Mectizan Donation Program in Mali and Senegal, carried out a baseline assessment and had a control arm.[11] The second study used an interrupted time series design to study the impact of access to malaria treatment in Tanzania.[12] The third study used longitudinal administrative data for a panel analysis to evaluate the International Trachoma Initiative in Tanzania.[13]

Discussion

We reviewed access-to-medicines initiatives in low- and middle-income countries from twenty-one large pharmaceutical companies to understand the strategies being used and the evidence available on the initiatives' impact. To our knowledge, this is the first comprehensive review of industry-led AtM initiatives. The Sustainable Development Goals make clear that the pharmaceutical industry has human rights responsibilities to improve access to medicines, and it is somewhat surprising how little has been published about the quality of evidence on industry-led AtM initiatives.

Our review produced four key findings. First, the number of AtM initiatives has grown substantially since 2000, when the Millennium Development Goals stated for the first time that pharmaceutical companies must play a leading role in improving access to medicines in low- and middle-income countries. Second, companies have adopted reduced pricing and medicine donation as the primary strategies for their initiatives. Third, many claims have been made as to the impact of AtM initiatives, but very few rigorous evaluations have been conducted and published. Fourth, the evaluations that have been published are generally of low quality, though three studies[11⇓-13] generated evidence of moderate quality.

Growth And Spread

We found clear evidence that the twenty-one biopharmaceutical companies we studied had responded in recent years to calls that they increase their commitment to improving access to medicines. Indeed, there is at least one AtM initiative in every low- and middle-income country. However, the processes that companies use to determine initiative strategies and set priorities are not transparent, which raises questions about whether the resources involved are being allocated in line with the countries' national priorities.

Strategies

For example, nearly half of the AtM initiatives we analyzed used medicine donation as their main strategy. It has previously been argued that such donations are unsustainable and might cause harm in the long term by distorting local market incentives for competition.[14] Therefore, local stakeholders might prefer alternative strategies to donations in some instances. We also

found that nearly all AtM initiatives in low- and middle-income countries included a focus on infectious diseases, while only half included noncommunicable diseases. Given the growing burden of such diseases in these countries,[15] an increased focus on access to medicines for them may be desirable.

What is clearly desirable is a more transparent and inclusive strategy and priority setting process that holds the industry more accountable to local stakeholders. As many low- and middle-income countries pursue efforts to achieve universal health coverage, assessing the contributions of AtM initiatives to these efforts—particularly those focused on coverage for populations in poverty—becomes more important.

Lack Of Evaluation

Despite frequently claiming that their AtM initiatives have had positive impacts, very few companies have evaluated the initiatives in any substantive manner. There are several plausible explanations for this finding. First, there are costs associated with evaluation, and companies might not have funds readily available for such efforts. Second, health system impact evaluation requires a degree of technical skill and research capacity that companies are unlikely to have. Third, evaluation presents a reputational risk for companies, in the event of a null or negative impact.

Nonetheless, the industry should not be excused for its failure to evaluate its efforts, and companies can take reasonable steps to ensure that future initiatives include an evaluation component. Costs can often be kept at acceptable levels by using quasi-experimental methodologies and data from existing administrative systems.[16] In some instances, it might also be

reasonable for companies to seek support for evaluations from traditional global health funders, who should welcome such partnerships. Companies can address constraints on technical capacity by partnering with academic institutions, as Novartis has done for an evaluation of Novartis Access in Kenya,[17] and as Merck MSD did for the evaluations of the Mectizan Donation Program.[18]

Finally, while the risks of evaluation to a company's reputation might be the most difficult deterrent to overcome, certain strategies seem promising. In particular, a shared commitment on the part of pharmaceutical companies to a standard and transparent evaluation and reporting system could ensure mutual accountability and place equal risk on all.[19] Relatedly, independent reviewers such as the Access to Medicine Index might create reputational incentives for increased evaluation. However, to do so effectively they must develop a process to measure companies' evaluation efforts. The analysis we present in this article could serve as a foundation for such a process.

Quality Of Evidence

Overall, evidence on the impact of industry-led AtM initiatives is of low quality. Particularly striking is the lack of a control group in all but seven of the studies we reviewed. Most of these studies relied on retrospective administrative data, and the decision to conduct the evaluation seems to have occurred well after the initiative was implemented. AtM initiatives can be rigorously evaluated, as evidenced by the few strong studies we found. If a company commits to evaluation early, it should be feasible to collect baseline data and find an appropriate control group, as Lamine Diawara and coauthors did in their evaluation of Merck

MSD's Mectizan Donation Program in Mali and Senegal.[11] In situations where only administrative data are available, it is often possible to generate high-quality evidence using an interrupted time series design, as Sandra Alba and coauthors did in their evaluation of Novartis's malaria ACCESS program in Tanzania.[12] Longitudinal administrative data might also be used in panel analyses, as Anthony Solomon and coauthors did in their evaluation of the International Trachoma Initiative in Tanzania.[13] Strong study designs are necessary to determine the causal impacts of AtM initiatives. A baseline measurement is important, as is a control group. If an experimental design is not possible, a quasi-experimental design can still produce strong evidence of impact.

It could be argued that the nature of most AtM initiatives is such that no plausible confounding factors could explain observed changes in the outcomes of interest, making a control group or a rigorous study design unnecessary. For example, in the case of the International Trachoma Initiative, only the delivery of azithromycin through the initiative could have explained reductions in trachoma prevalence. However, such arguments are faulty and do not justify a poor study design. As Sheila West and coauthors recognized in their evaluation of the International Trachoma Initiative, by using a pre-post design without a control group, they could not "exclude other secular trends…[that] ideally…would be studied by comparison with populations in other villages that have had no intervention."[20]

The number of evaluations published about, and the relative consistency in findings from studies of, Merck MSD's Mectizan Donation Program and the Global Alliance to Eliminate Lymphatic Filariasis ease some concerns about the low quality of evidence

generated by individual studies. In terms of internal validity, it is unlikely that secular trends or other unmeasured confounders could account for the positive findings in all of these studies. In terms of external validity, demonstrating consistent impacts in multiple countries strengthens the generalizability of the evidence. However, according to the guidelines for systematic reviews published by the Cochrane Collaboration,[21] only the evaluation by Diawara and coauthors[11] would be eligible for a review of the evidence for these initiatives. Using a quantity-over-quality approach to evaluate AtM initiatives is inadvisable and inefficient.

Conclusion

The United Nations has made it clear that the pharmaceutical industry has a human rights responsibility to increase access to medicines in low- and middle-income countries. Overall, our findings suggest that current efforts to evaluate the impact of industry-led access-to-medicines initiatives are inadequate. Such initiatives may offer relevant lessons for improving access that ultimately improve population health and financial protection. However, uncertainty about the impacts of the initiatives limits the potential for including them within broader programs to strengthen health systems. At the global level, a variety of actors, including the United Nations Secretary-General's High-Level Panel on Access to Medicines[22] and the Lancet Commission on Essential Medicines Policies,[23] have called for an accountability framework that will hold all stakeholders accountable for their action (or inaction) on access to medicines. Such a framework would be effective only if evidence on the impacts of AtM initiatives were available. The Access to Medicine Index could facilitate the application of an accountability framework by

examining the quality of evidence on the impacts of industry-led AtM initiatives and taking this into consideration in their rankings. Companies must do more to produce evidence that they are meeting their responsibilities. However, the global health community should assist in these efforts with funding support, research expertise, and independent review.

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