



The Guiding Principles on Access to Healthcare: From Aspiration to Action

Status Report

November 2014



About This Report

This synthesis was written by Laura Gitman, Smruti Govan, Stacy Kotorac, Jonathan Morris, and Cecile Oger with support from the corporate members of BSR's Healthcare Working Group.

The report provides an overview of some of the approaches undertaken by the signatory companies of the [Guiding Principles on Access to Healthcare](#) to advance access to healthcare. It analyzes and evaluates case studies submitted by the companies in order to determine key insights, challenges, and recommendations for companies in expanding access to healthcare. The report is primarily based on the analysis of 31 case studies submitted by the Guiding Principles on Access to Healthcare (GPAH) signatory companies as listed in the report. The authors would like to thank the signatories for their review of this report for accuracy. Any errors that remain are those of the authors.

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Contents

Executive Summary.....	4
Introduction	5
Objectives	5
Report Writing Process	7
How to Read this Report.....	7
Part 1: Context.....	8
Access to Healthcare: Unfinished Business	8
An Evolving Landscape	9
Introducing the Guiding Principles on Access to Healthcare.....	10
Part 2: Illustrating the Principles.....	12
Background.....	12
Key Figures.....	13
The Principles in Action	14
Part 3: Key Findings	28
What Do the Case Studies Tell Us about Access to Healthcare?	28
What Do the Case Studies Tell Us about the GPAH?	32
Conclusions	34
Looking Forward.....	35
Appendices.....	36
Glossary.....	36
References.....	39

Executive Summary

Access to healthcare is fundamentally important to society's ability to address unmet medical needs, combat global poverty, and spur economic development. While the Millennium Development Goals (MDGs) have in years past provided a blueprint for the world's countries to meet the needs of the poorest populations, access to healthcare remains a complex issue linked to myriad challenges. Moreover, the landscape of growing inequalities, competition for natural resources, and impacts from the financial crisis continue to raise the stakes and threaten basic entitlements to healthcare.

Within this context, member companies from BSR's Healthcare Working Group convened with healthcare stakeholders in 2011 to create a common, clear definition and commitment to what "access to healthcare" encompasses, forming the [Guiding Principles on Access to Healthcare \(GPAH\)](#). In 2013, 13 CEOs of major healthcare companies signed onto the principles to underscore the industry's approach to reducing the global burden of disease and improving global health outcomes.

In this report, we take a closer look at how signatory companies address access to healthcare by evaluating a sample of initiatives. Reviewing 31 projects under way by signatories and comparing them to the Guiding Principles on Access to Healthcare, this report informs the reader on companies' efforts to address access to healthcare and related opportunities.

Our initial analysis has uncovered a number of cross-cutting key findings from the case studies, which together represent success factors that future access initiatives can leverage:

- » Access is a fragmented issue and requires many types of innovative approaches.
- » Collaboration and partnership are critical to creating long-term solutions.
- » Technology enables and enhances access.
- » Clear links to global health agendas help paint a picture of collective progress.
- » Measurement is and will continue to be key in access initiatives.
- » Making clear links to business value helps drive systemic-level change.

This review also reflects on the guiding principles themselves one year post-launch, resulting in four main lessons: The principles are innately interconnected and interoperable; the GPAH succeeds in providing a collective view on industry efforts; sharing case studies is important for learning and replication; and the groundwork has been laid for a framework to analyze progress.

We conclude by reemphasizing that access to healthcare remains an unfinished challenge, one that requires a group of stakeholders working together to drive real systemic change.

We finally ask readers, healthcare companies and companies from other sectors, as well as global health stakeholders to help answer questions about what specific actions can be taken to advance access, what role GPAH should play to further drive impact, and how this report can be leveraged to better analyze progress on access to healthcare in the future.

Introduction

In December 2013, Jim Yong Kim, president of the World Bank, announced ambitious targets on access to healthcare in recognition of its important role in “combating poverty and spurring economic development.”¹ Earlier that same year, the CEOs who signed the Guiding Principles on Access to Healthcare (GPAH) acknowledged that all healthcare system stakeholders must work together to seek sustainable solutions to improve access. One year after the GPAH’s release, we examine how the signatories put their commitment into action.



This report provides an overview of the types of projects under way and an understanding of new ways of thinking about and innovative approaches to providing access to healthcare. We have written it to help the industry and external organizations and stakeholders assess progress and identify opportunities for further enhancing access to healthcare.

Objectives

We have developed this report to fulfill these key objectives:

- » To illustrate the five principles that constitute the GPAH through a varied sample of initiatives that the GPAH signatory companies are working on as individual organizations.

¹ BloombergBusinessWeek news, 2013.

Interested in Learning More?

Read these in-depth sources:

- » [Guiding Principles on Access to Healthcare](#)
- » [BSR's Healthcare Working Group](#)

Explore the [case studies](#) discussed in this report.

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- » To establish a framework that will subsequently be used to address and evaluate progress on access to healthcare.
- » To identify overall trends in how companies address the challenges of access to healthcare in addition to highlighting individual companies' recent practices and approaches.
- » To identify opportunities for companies to further advance their access to healthcare efforts as individual companies and collectively.

This GPAH report supplements various other sources on how healthcare companies address access to healthcare including, among others:

- » Individual companies' websites, corporate responsibility reports, or information disseminated by companies through other external communication channels.
- » The International Federation of Pharmaceutical Manufacturers & Associations' (IFPMA) Developing World Health Partnership Directory, a repository of partnership initiatives that the GPAH signatories and other pharmaceutical and healthcare companies work on.²
- » The Access to Medicine Index (ATMI), an initiative funded by the Bill & Melinda Gates Foundation and the U.K. and Dutch governments, which independently ranks the efforts of pharmaceutical companies (the majority of which are GPAH signatories) to improve access to medicine in developing countries.³
- » The Global Health Progress website: This initiative seeks to bring research-based biopharmaceutical companies and global health leaders together to improve access to medicine and healthcare in the developing world, identifies best practices for programs that address healthcare needs, and facilitates partnership and research and development efforts to fight neglected diseases in the developing world.⁴
- » The website of Uniting to Combat Neglected Tropical Diseases,⁵ a collective of healthcare companies and international organization invested in, interested in, and dedicated to fulfilling the London Declaration on Neglected Tropical Diseases 2020 Goals.⁶

We intend to provide the reader with an increased understanding of the type of initiatives and progress made by the GPAH signatories, along with the many other players they partner with, but also to make the reader aware of the challenges that remain and opportunities that exist to further advance access to healthcare.

Further, we hope this report will be an opportunity to learn what drives successful efforts in order to replicate effective access to healthcare initiatives at GPAH signatory companies and beyond.

² IFPMA, 2014.

³ Access to Medicine Index, 2013.

⁴ Global Health Progress, 2014.

⁵ Uniting to Combat Neglected Tropical Diseases, 2014.

⁶ London Declaration 2020 Goals, 2014.

Report Writing Process

In the process of drafting this report, signatory companies were asked to submit up to three case studies in March 2014 to demonstrate that their efforts were consistent with the GPAH. These cases represent only a small fraction of companies' efforts in the access to healthcare space but are indicative of current approaches and help identify significant lessons across the companies.

The method used to develop the report included:

- » Desk-based research on global trends regarding access to healthcare to shape the global health context and further evaluate implications for the GPAH's future.
- » The review of the 31 case studies from GPAH signatory companies to identify key themes and lessons.
- » Input from signatory companies and key external stakeholders on expectations and key themes for this report.

How to Read this Report

Part 1: Context sets the context in which global healthcare companies operate and in which the GPAH were developed. It also reviews the genesis of the principles, including why and how they were developed.

Part 2: Illustrating the Principles examines each principle using the case studies to illustrate some of the work that the signatory companies are conducting. This section identifies common traits and trends in the way that signatory companies address access to healthcare.

Part 3: Key Findings summarizes the key findings through conclusions that cut across the full set of principles, including trends that emerged in company approaches to improve access, as well as common challenges and areas that need improvement.

Conclusions and Looking Forward offers our initial conclusions as well as high-level thoughts on avenues that the GPAH signatories may explore to further the impact of their collective initiative.



Part 1: Context

Access to Healthcare: Unfinished Business

Global health and the global burden of diseases have been at the forefront of international discussions for decades. In 2000, the Millennium Development Goals (MDGs) provided a blueprint for the world's countries to meet the needs of the poorest populations. Many elements of the 2015 goals spoke to the challenges facing the healthcare sector (healthcare companies and their stakeholders, such as NGOs, governments, etc.), including the areas of access as noted in bold:

- » Goal One: Eradicate extreme poverty and hunger.
- » Goal Two: Achieve universal primary education.
- » **Goal Three: Promote gender equality and empower women.**
- » **Goal Four: Reduce child mortality.**
- » **Goal Five: Improve maternal health.**
- » **Goal Six: Combat HIV/AIDs, malaria, and other diseases.**
- » Goal Seven: Ensure environmental sustainability.
- » **Goal Eight: Develop a global partnership for development** (specifically Target 8.E, in cooperation with pharmaceutical companies, provide access to affordable essential drugs in developing countries).⁷

As stated in a recent discussion paper from the World Health Organization (WHO), the MDGs have been a real force for change, resulting in impressive progress over the past decade in healthcare, particularly in the areas of child and maternal mortality, AIDS, tuberculosis, and malaria.⁸ Collaboration among healthcare companies and with other critical stakeholders (such as NGOs and governments) has contributed significantly to this progress.

Yet, 6.6 million children still die every year before age five from a lack of access to quality healthcare, far from the target of “under 4 million” by 2015.⁹ Noncommunicable diseases (NCDs) are still on the rise as shown by the 350 million people suffering from diabetes worldwide (a tenfold increase from 35 million in 1985), and an estimated 100 million people slip into poverty every year because they cannot afford their expensive medical care.¹⁰

In many parts of the world, access to healthcare remains a very complex issue linked to myriad challenges, such as lack of access to clean water and sanitation, general poverty and geographic isolation, inadequate infrastructure, weak healthcare capacity, limited availability of trained healthcare providers and pharmacies, lack of awareness and/or skepticism, cultural norms restricting uptake or mobility, and other indirect costs such as travel or waiting time.

Long-term, systemic, innovative solutions to address current and future unmet medical and healthcare needs must be formulated—and much needs to happen beyond 2015. World leaders and civil society have called for an ambitious, long-

⁷ UN, 2013.

⁸ WHO, 2012.

⁹ WHO, 2013.

¹⁰ International Diabetes Federation, 2009.

term post-2015 sustainable development agenda that builds on the momentum generated by the MDGs.¹¹ Being developed in consultation with many stakeholder groups (including businesses) and expected to be adopted by UN member states in September 2015, this agenda must be ambitious to tackle the many remaining issues, such as poverty and hunger, climate change, education, and, of course, health.

Additionally, and to respond to increased rates of NCDs, another important global scheme is the 66th World Health Assembly endorsement of the WHO¹² 2013–2020 Global Action Plan for their prevention and control. This plan provides a road map for member states, the WHO, UN, and international organizations, as well as the private sector, which—when implemented collectively between 2013 and 2020—will attain a set of voluntary global targets, including a 25-percent relative reduction in premature mortality from NCDs by 2025.

An Evolving Landscape

As expressed by the WHO, the context of growing inequalities, competition for natural resources, and impacts from the financial crisis threaten basic entitlements to health care. New political, economic, social, and environmental realities are shaping our world and health globally:¹³

- » **Changing demographics** around the world, including growing and aging populations, impact and shift the global burden of disease,¹⁴ with, for instance, close to two-thirds of all deaths caused by NCDs.¹⁵
- » **Economic fluctuations** are expected to further decrease public spending in an era in need of increased public spending.
- » **Inequality** is expected to deepen poverty and increase gaps in health outcomes. Medicines are estimated to account for between 20 and 60 percent of health spending in low- and middle-income countries, compared with 18 percent in Organisation for Economic Co-operation and Development (OECD) countries. The WHO estimates that up to 90 percent of the population in developing countries purchase medicines through out-of-pocket payments, which results in the steepest expense for families after food.
- » **Rapid urbanization:** By 2050, 70 percent of people across the world will be living in towns and cities, which presents its own toll of opportunities (access to better healthcare) and risks (increased health risks and new hazards).¹⁶
- » **Technology and social media** keep transforming our daily lives, with incredible opportunities, on one hand, that can be leveraged to improve patients' lives, but on the other hand, increased stakeholder expectations and pressures on healthcare companies.
- » **Water and resource scarcity:** Renewable and nonrenewable resources (energy, water, land, and minerals) are in ever-higher demand.¹⁷ Competition for access to these key resources is expected to lead to geopolitical conflicts and trade issues.

¹¹ UN, 2014.

¹² WHO Global Action Plan, 2013.

¹³ WHO, 2012.

¹⁴ World Bank, 2007.

¹⁵ WHO, 2012.

¹⁶ WHO Urbanization and Health, 2010.

¹⁷ World Economic Forum, 2014.

- » Finally, **climate change** is expected to negatively affect social and environmental determinants of health: clean air, safe drinking water, sufficient food, and secure shelter. According to the Intergovernmental Panel on Climate Change (IPCC),¹⁸ climate change is expected to increase global heat and humidity, resulting in more food-, water-, and vector-borne diseases and related deaths.

Vulnerable populations¹⁹ (counting the world's poorest citizens at the bottom of the pyramid, BOP), many of whom are targeted by access initiatives, are expected to be affected by diminished food productivity and risks from lost work capacity.

Beyond these key trends that are shaping the world, events like the current Ebola outbreak that highlight the weaknesses of local health systems and consequent difficulty of the global health community and governments to help contain it remind the global community of the challenges that lay ahead.

Many different players—from international health authorities (such as the WHO and various UN agencies) to NGOs to various industries, including the healthcare sector—are addressing these challenges at several levels. The complexity of the challenges means that each player can contribute in different, useful ways.

Introducing the Guiding Principles on Access to Healthcare



The [Guiding Principles on Access to Healthcare](#) (GPAH, or Principles) were formed within this context. During a 2011 engagement between BSR's Healthcare Working Group (HCWG) member companies and a group of healthcare stakeholders, it emerged that there was no common and clear definition and understanding among stakeholders and the pharmaceutical sector, as well as within the healthcare sector itself, of what "access to healthcare" encompasses. Different companies and different organizations had different views and definitions of access to healthcare. It became clear that a common definition and framework was needed.

In the following months, BSR acted as a convener and gathered BSR members and stakeholders to discuss access to healthcare. BSR and the HCWG members began drafting a definition that would complement and align with existing initiatives undertaken by stakeholders and individual companies. Eventually, through a thorough process that included extensive discussions and stakeholder consultation, the HCWG formulated the GPAH, a set of principles to help frame and position the healthcare industry's approach to reducing the global burden of disease and improving global health outcomes.

CEOs from 13 companies signed the GPAH to demonstrate their companies' commitment to expanding access to healthcare and to promoting new thinking and a comprehensive approach involving all stakeholders of a particular healthcare system.

With the principles, the signatory companies have provided consistent terminology for the industry to define and understand the complexity of its role in expanding access to healthcare.

¹⁸ IPCC, 2014.

¹⁹ World Bank, 2005.

The Five Principles

The principles encourage, and thus far have driven, increased collaboration to address companies' shared responsibility for expanding access to healthcare.

1. **Collaboration:** Expanding access to healthcare is complex and requires the participation and cooperation of numerous diverse stakeholders, with complementary responsibilities and capabilities, to solve systemic challenges.
2. **Research and Development:** R&D is the primary mechanism through which [the signatory companies] seek to meet unmet health needs.
3. **Availability:** The results of the [signatory companies'] innovations are only of value to patients if they are available and accessible. Approaches need to be market appropriate and reflect adherence to globally recognized compliance guidelines.
4. **Health System Resources:** Quality healthcare rests on the strength and capacity of local health systems.
5. **Human Rights:** Respect for human rights is at the foundation of the signatory companies' activities.

The GPAH Signatories

The GPAH signatories are 13 of the world's major healthcare companies with global leadership in pharmaceuticals, vaccines, diagnostics, and other medical technology. Together these signatory companies represent more than 60 percent of the 2013 global sales²⁰ for the top 25 pharmaceutical companies.

- » **Astellas**
- » **Bristol-Myers Squibb**
- » Eisai
- » Eli Lilly
- » **GlaxoSmithKline**
- » **Johnson & Johnson**
- » **Merck & Co.**
- » Merck KGaA
- » **Novartis**
- » **Novo Nordisk**
- » **Roche**
- » **Sanofi**
- » **Takeda**

GPAH
signatories

represent **60%** of
the global sales for the
top 25 pharmaceutical
companies

The founding signatories (in bold) are the BSR HCWG members who initiated and developed these principles. Organizations may become signatories of these principles, whether or not they were involved in their initiation and development.

²⁰ PMGroup, 2014.

Part 2: Illustrating the Principles

This section examines some of the approaches that signatory companies are taking by analyzing case studies. We do not intend to describe each case study in detail but rather use them to identify lessons and demonstrate what specifically companies can work on under each principle.

Background

In March 2014, BSR asked signatory companies to provide up to three case studies that illustrate their current access initiatives.

For each case study, we asked a company to provide:

- » The name of the initiative
- » The GPAH principle that the initiative focuses on, acknowledging that most initiatives address more than one principle
- » A description of the initiative and its objectives, stating the overarching goals and how these goals drive progress on the principle
- » Thoughts about lessons learned (key insights generated, how the program has or could evolve, etc.)
- » Results to date for one to five quantitative data points and an accompanying qualitative narrative

We also asked companies to provide details:

- » Scope (whether it is a single- or multi-country program)
- » Geographic focus (global, Africa, Asia, Australia, Europe, the Middle East, North America, or South America)
- » Market profile (developed, emerging market, or least developed countries, LDCs)
- » Disease type (communicable or noncommunicable)

In total, we received and analyzed 31 case studies for the purposes of this report.

Key Figures

The figures below provide key information about the scope and impact of the GPAH signatories' initiatives reviewed in this paper.

94%

take place in emerging markets and LDCs.

31

case studies were reviewed and analyzed for this report.

GPAH signatories represent

13 of the top 25

pharmaceutical companies.*

Sample Case Study Locations

50%

address neglected diseases.

48%

address NCDs.



35%

focus on children's health.

20%

specifically address women's health needs.

16%

focus on HIV/AIDs.

*Note: In terms of global sales. Source: PMGroup, 2014.

The Principles in Action

In the following pages, we undertake a retrospective analysis of ongoing initiatives led by GPAH signatories.

The examples shared in this report represent a wide range of solutions developed and led by signatory companies, including approaches to enhancing the capacity of healthcare workers, transferring knowledge and technology, adapting product formulations for different markets, improving and influencing local policy and regulations, or even working to strengthen healthcare infrastructure.

Initiatives (case studies) are listed under the principle they best represent and then in alphabetical order by company name. For each initiative (case study), we provide the name of the company and initiative and basic information that relates to its nature. Detailed information for each case study is available on the [GPAH website](#).

Table 1: Key for the Case Studies Tables

CATEGORY	DESCRIPTION	KEY
Country Focus	Single-country program	
	Multicountry program	
Geographic Focus	Global	
	Asia	
	Africa	
	Middle East	
	North America	
	South America	
Market Profile	Least developed country	
	Emerging market	
	Developed market	
Disease Type	Communicable	
	Noncommunicable	

The variety of initiatives, reach, objectives, and means demonstrate the complexity of the topic and the need for varied solutions. As we demonstrate throughout the report, most initiatives address more than one principle.

This section is structured around the five principles. We first redefine the principle, then list the case studies used to illustrate it, and finally provide key findings to help you understand the type of activities and initiatives that are conducted in regard to it.

Principle 1: Collaboration

Definition of the Principle (as stated in the GPAH)

Expanding access to healthcare is complex and requires the participation and cooperation of numerous diverse stakeholders, with complementary responsibilities and capabilities, to solve systemic challenges.

Collaborators: Positively impacting access to healthcare requires the industry to work together with other stakeholders—including governments, patient groups, healthcare providers, NGOs, multilateral organizations, payers, regulators, and other organizations. We recognize that each stakeholder brings its own commitment, expertise, and resources to improve development, deployment, and availability of medicines, vaccines, diagnostics, and other medical technology, while respecting areas of expertise and legitimacy.

Case Studies

Astellas, Eisai, and Takeda	Global Health Innovation Technology Fund (GHIT Fund)	
<p>The GHIT Fund is a Japanese-led initiative established with the government of Japan, five Japanese pharmaceutical companies, and the Bill & Melinda Gates Foundation. It aims to advance the development of new drugs, vaccines, and diagnostics for infectious diseases in the developing world.</p>		
GlaxoSmithKline	Save the Children Partnership	
<p>GSK and Save the Children have formed a long-term strategic global partnership, combining expertise, resources, and influence to help save the lives of 1 million children. This partnership includes developing child-friendly medicines, widening vaccination rates, and increasing investment in healthcare worker training.</p>		
Merck & Co.	Mectizan Donation Program	
<p>This donation program aims to eliminate river blindness (onchocerciasis). To facilitate the donation, Merck & Co. established a multisectoral partnership involving the WHO, the World Bank, UNICEF, ministries of health, NGOs, and local communities. The program has been extended to include the prevention of lymphatic filariasis (LF) in African countries where this disease coexists with river blindness.</p>		
Merck & Co.	Merck for Mothers	
<p>This 10-year initiative aims to reduce maternal mortality, by addressing postpartum hemorrhaging (bleeding after childbirth) and preeclampsia or eclampsia (hypertensive disorder). Merck for Mothers works closely with governments, international organizations, health experts, and advocacy groups.</p>		
Merck KGaA	Merck Access Dialogues	
<p>The Access Dialogue Series is a multistakeholder cross-sectoral platform for sharing information and best practices and discussing collaborative action around barriers to overcoming access challenges with public and private stakeholders.</p>		
Novartis	Power of One with Malaria No More	

In 2013 Novartis, together with the global charity Malaria No More and other partners, launched the Power of One campaign to engage the general public in fighting malaria and contributing to closing the treatment gap in Africa, with an initial focus on Zambia. Novartis will match up to 1 million treatments funded by the public annually through 2015.

Takeda

Takeda-Plan Healthcare Access Program



Takeda-Plan Healthcare Access Program promotes a range of measures aimed at giving children in Thailand, the Philippines, Indonesia, and China (where Takeda operates) access to healthcare services.

Key Highlights

- » Companies engage with most categories of key local and global stakeholders (NGOs, government, multilateral organizations, peer companies, etc.).
- » Collaborations are not simply one on one; each initiative listed under this principle involves multitudes of partners leveraging many different skills.
- » Innovative types of collaboration include ambitious long-term partnerships with NGOs, as well as cross-sector or peer collaborations.

The GPAH signatories are engaging and involving key stakeholders to share expertise in order to break down the complexity inherent in advancing access. Overall, collaboration among companies and stakeholder groups is addressing access issues as diverse as increasing the speed of innovation in new health products and technologies (Astellas—GHIT Fund project), bringing healthcare products to remote communities, donating a product until the disease is eliminated (Merck & Co.—Mectizan Donation Program), and leveraging core capacities and platforms to spread information about access to affected populations (Merck KGaA—Access Dialogues).

In the shared cases, the initiatives involve collaboration with at least five organizations—mainly government institutions, multilateral organizations, local and global NGOs, and foundations, but also with other stakeholder groups, such as patient organizations, health experts, and advocacy groups. We saw two main types of approaches and strategies when it comes to collaboration and partnership—local and global, both complementary:

- » Some of the cases include collaboration with local NGOs who often provide important knowledge about local needs and culture. Working with groups, such as healthcare professionals (Merck—Merck for Mothers), or local governments (Takeda—Takeda Plan Healthcare Access Program) brings in additional, necessary expertise, capacity, and knowledge to accurately target populations and deliver medicines to the patients in need. In addition, having strong local relationships also improves the effectiveness of information delivery and best practice exchange,²¹ such as reaching remote areas and patients, and advocating public health issues to the appropriate local audiences. As an example, Roche partnered with the national government and Ministry of Health of Saudi Arabia and the Saudi Cancer Society to better inform their work with individuals at the local level.

*Leveraging
a multitude of
skills to advance
access*

²¹ BSR, 2012.

- » The remaining case studies demonstrate partnerships developed between signatories and global NGOs or foundations with global outreach in an effort to contribute to larger, multicountry efforts that reach more patients—often in several regions or countries. Examples include the long-term global partnership between GSK and Save the Children; Astellas, Eisai, and Takeda partnering with the Gates Foundation in the GHIT Fund project alongside several other Japanese companies; Merck & Co. partnering with the WHO, UNICEF, the World Bank, ministries of health, and NGOs in the race to eliminate river blindness; and Novartis partnering with the global charity Malaria No More to engage the general public, using social media, in the fight against malaria.

Several initiatives demonstrate collaboration with peer companies. For instance, Merck KGaA's Merck Access Dialogues promotes continuous, creative dialogue and exchange among all stakeholders on priority access topics and challenges and incorporates private partners, including GPAH signatory companies Novo Nordisk, Roche, and Sanofi, as well as Eli Lilly and Astra Zeneca.

Another interesting example of collaboration with peers and government is the GHIT Fund, which advances the development of new health technologies. This organization is a joint partnership among the government of Japan, the Gates Foundation, and five Japanese pharmaceutical companies, including GPAH signatories Astellas, Eisai, and Takeda. Its establishment represents the first time that a group of pharmaceutical companies in Japan has joined forces to facilitate and advance global health R&D. The GHIT Fund builds on the strong ties and trust that pharmaceutical companies in Japan have developed (as a unified body) with the Japanese government over the last few decades, in their common goal of making healthcare a national priority. The fund's role is strongly aligned with government policies, to enable the country's technology, innovations, and insights to have an impact (in this case on reducing health disparities between the rich and poor). The fund's mission and vision are also aligned with the priorities of Japan's pharmaceutical companies: to enable access to needed medicines, while increasing awareness of the commitment of the Japanese government and these five companies to addressing global health needs.

Finally, several examples emerged (as expected) that will have long-term, sustainable impacts. These case studies shared a few important characteristics: Objectives are correlated with a time, either a qualitative or quantitative target (eliminating river blindness by 2025 for Merck & Co.'s Mectizan initiative and helping save the lives of 1 million children for GSK, for instance) that reinforces the impact that the company is having. In some instances (such as GSK and Save the Children), they also demonstrate an alignment with business strategy, which means that the company is acting in an area that it is familiar with and possesses the expertise and infrastructure to effect positive change.

Principle 2: Research and Development

Definition of the Principle (as stated in the GPAH)

R&D is the primary mechanism through which we seek to meet unmet health needs.

- » **Developing and adapting products:** We invest in R&D across a broad range of disease areas to address prevention, detection, diagnosis, and treatment of diseases (communicable, noncommunicable, and neglected) and work to expand the applicability of medicines and medical products.
- » **Promoting innovation and intellectual property rights:** We depend on R&D to promote innovation, and we support a variety of approaches, such as clear patent policies, and, when appropriate, voluntary licensing and collaborative models to increase access to our products. We believe that appropriate intellectual property protection enables innovation and creates the necessary conditions to make our R&D sustainable and enhance innovations over time.
- » **Clinical trials:** We are dedicated to increased transparency of our clinical trial results, while respecting a company's proprietary information and a patient's personally identifiable information, as well as ensuring the safety, dignity, well-being, and legal rights of participants. We only perform clinical studies in countries that are in compliance with international guidelines and in countries where we intend to make the product available.
- » **Building local R&D capacity:** We support the development of R&D capabilities, for example, through the transfer of technology, clinical trials, and skill building.

Case Studies

Astellas	NTDs Drug Discovery Research Consortium	
<p>A collaborative drug-discovery research program for the treatment of neglected tropical diseases (NTDs). This research is supported by the Drugs for Neglected Diseases initiative (DNDi), three Japanese universities, the High Energy Accelerator Research Organization (KEK), and the National Institute of Advanced Industrial Science and Technology (AIST).</p>		
Astellas and Merck KGaA	Pediatric PZQ Consortium to Treat Schistosomiasis	
<p>The Pediatric Praziquantel Consortium is an international, nonprofit public-private partnership, aiming to develop, register, manufacture, and launch a pediatric formulation of praziquantel (PZQ), suitable for preschool age children (younger than 6), including infants and toddlers, to treat schistosomiasis. Partners contributing expertise include Merck KGaA and Astellas, as well as Swiss TPH, TI Pharma, Farmanguinhos, and Simcyp.</p>		
GlaxoSmithKline	Achieving a Key Milestone in the Development of a Malaria Vaccine	
<p>A public-private partnership with the PATH Malaria Vaccine Initiative (MVI), supported by grants from the Gates Foundation to develop the world's first vaccine against the main malaria parasite.</p>		

Key Highlights

- » Collaboration, partnership, and innovative thinking are present in all the R&D initiatives.
- » Enhancing access through R&D offers many avenues that can be explored at various stages of a drug's development, from the early research phases to its reformulation to better fit local needs.

All the examples shared under this principle incorporate partnership or varying degrees of collaboration with stakeholders in order to enhance their respective R&D capacities, such as:

- » Advancing drug development to address unmet medical needs: For instance, through the Pediatric PZQ Consortium involving Merck KGaA and Astellas, partners are progressing toward the elimination of schistosomiasis by developing a new formulation to treat preschool age children
- » Leveraging open innovation, new technologies, and collaboration with industry, academia, and governmental organizations, such as in the Astellas NTDs drug-discovery consortium to jointly research antiprotozoan and antidenque drug candidates.
- » Determining how to quickly move a product through the process of research, registration, and manufacturing (such as in the GSK malaria vaccine example).
- » Determining different business models to generate revenue to better support local R&D (as seen in the GSK malaria vaccine initiative) and more effectively respond to a community's most critical needs for treatment.

Combining *open innovation, new technologies, and collaboration*

The power of collaboration in R&D is illustrated by the case studies on the Pediatric PZQ Consortium to treat schistosomiasis by both Merck KGaA and Astellas. Initiator Merck KGaA is responsible for leading it and also provides necessary expertise and support, including various resources (chemical and manufacturing, preclinical, clinical, and regulatory). Astellas brings innovative technology to help improve drug compliance and functionality, while also working to reduce the medicine's bitter taste and provide expert advice on clinical development in children, pharmacokinetic modeling, and health access. This partnership and collaboration within the consortium cross-fertilizes company expertise and shares risks and resources in order to deliver an innovative pediatric product for very young children.

On a positive note, the case studies illustrate most of the R&D subprinciples (see the definition above for details). The most common is that of developing and adapting products (Astellas NTDs drug research consortium and the joint efforts of Astellas and Merck KGaA in the pediatric PZQ schistosomiasis consortium). And while no case studies explicitly claim to work on promoting innovation and intellectual property rights, several (including Bristol-Myers Squibb's agreement with the MPP about atazanavir and Janssen's global HIV medicines program, shared under other principles) address this R&D subprinciple. Such overlap reinforces the notion of the principles' intertwined nature and that certain elements are closely related, which in turns reflects the complexity of access to healthcare.

Principle 3: Availability

Definition of the Principle (as stated in the GPAH)

The results of our innovations are only of value to patients if they are available and accessible. Approaches need to be market appropriate and reflect adherence to globally recognized compliance guidelines.

- » **Pricing:** Individually, we seek appropriate pricing strategies that recognize the value of innovation while addressing barriers to access. Strategies may include value-based pricing and differential pricing where price is a barrier and there is a strong commitment to expanding access to healthcare in a sustainable manner.
- » **Registration:** We support the broad, timely, and efficient registration of high-quality medicines through appropriate regulatory frameworks.
- » **Commercialization:** We support exploring new business models, which may include innovative financing and distribution mechanisms, to expand access in a manner that remains supportive of long-term commercial viability.
- » **Policy:** We contribute to shaping policy that expands sustainable access to healthcare and that supports the development, registration, distribution, and monitoring of health innovations.

Case Studies

Bristol-Myers Squibb	Agreement with Medicine Patent Pool	
<p>The Medicines Patent Pool (MPP) and Bristol-Myers Squibb signed a licensing agreement to increase access to a key HIV medicine, atazanavir, in 110 developing countries where approximately 29 million people are living with HIV/AIDS. The agreement includes a technology transfer package to facilitate manufacturing.</p>		
Janssen (Johnson & Johnson)	Global HIV Access & Partnerships Program	
<p>The program works toward providing sustainable, not-for-profit HIV medicine access to patients with a high HIV-burden and economic vulnerability in resource-limited countries. It focuses on product availability (including generic licensing agreements), priority registration, reduced pricing, and medical education.</p>		
Merck KGaA	River Ambulance–Narmada Samagra, India	
<p>The River Ambulance expands access to health services and solutions to underserved tribal and local populations along the Narmada River. Merck supports the NGO Narmada Samagra with funding and provides medicines and products.</p>		
Novartis	Arogya Parivar	
<p>Arogya Parivar (Hindi for “Healthy Family”) is a for-profit social initiative aimed at reaching the underserved living at the bottom of the pyramid in rural India. The program expands access to affordable products, improved healthcare infrastructure, and community education. Similar business models are being rolled out in other countries including Vietnam and Indonesia.</p>		

Novo Nordisk	Base of the Pyramid Project	
<p>In 2010, Novo Nordisk established the Base of the Pyramid Project to identify successful business models that could lead to an integrated approach to diagnose, treat, and control diabetes among the working poor at the base of the pyramid (BoP).</p>		
Roche	Differential Pricing in Egypt	
<p>In 2007, Roche partnered with the Egyptian government to establish a national project for treating chronic hepatitis C. Part of the project included introducing a second brand of hepatitis treatment (packaged locally), introducing differential pricing, and including diagnosis and treatment monitoring. In 2013, this project was replicated in oncology.</p>		
Sanofi	Sanofi Pasteur Endgame Polio Eradication Effort	
<p>Sanofi Pasteur and the Bill & Melinda Gates Foundation have developed a joint price support mechanism that allows Sanofi Pasteur to offer inactivated polio vaccines (IPV) in the world's poorest countries as part of the Global Polio Eradication Initiative (GPEI) polio endgame strategy.</p>		
Sanofi	StarBem	
<p>In 2013, Sanofi launched StarBem in Brazil to support patients in the treatment of diabetes. The platform, together with Sanofi's existing initiatives for people with diabetes, provides a wide range of services, including assistance for insulin use, support from call centers, a pharmacy network, etc.</p>		

Key Highlights

- » Synergies and complementary skills are again essential. All case studies used to illustrate this principle include partnerships.
- » The case studies shared under this principle demonstrate innovative thinking and the development of new holistic approaches and models (licensing, pricing, distribution, reinvestment, involving local players, etc.).
- » Addressing the local context and developing solutions that are adapted to local circumstances are essential to developing successful initiatives and bringing about long-term impact.

The case studies for this principle all include partnerships, and the majority are also being implemented within multiple countries, with a focus on emerging markets. Notably, a clear majority illustrated initiatives around commercialization, followed by new pricing models. One strategy, pursued by Roche and Sanofi, is to collaborate with either government or global philanthropy organizations to offer a product to specific patient segments at a lower price.

These case studies display interesting business models, particularly those that are localized, featuring innovative commercialization and pricing approaches for increased access. Roche, for example, in its differential pricing project in Egypt combines pricing and commercialization by promoting the medicine under a different brand using a local manufacturer and offering it to the government at a reduced price, thereby increasing the number of public patients who can be treated. Others, such as Novartis in its Arogya Parivar project, reinvest a portion of profits into affected communities, thereby increasing both the market for these products and the capacity of individuals in a particular community to purchase

*Adapting
to local
context to meet
local needs and reach
long-term impact*

them. Similarly, the agreement between BMS and the MPP requires the latter to reinvest the full royalty into HIV programs in the few countries where a royalty is indeed collected.

Many case studies under this principle demonstrate innovative thinking. A great example is the Merck KGaA River Ambulance initiative in collaboration with NGO Narmada Samagra, which combines the use of a local transportation mode (a river boat) to ferry doctors and medicine for periodic checkups and help transport emergency patients to a local city for treatment. The River Ambulance is part of Merck KGaA's focus on strengthening supply chains and developing localized health solutions. Two other projects address BOP patients and demonstrate innovative thinking and flexible, adaptable solutions: the Novartis Arogya Parivar and Novo Nordisk BOP projects.

An interesting characteristic is the focus on fitting within the local context and addressing its challenges. Most of the pricing case studies introduce different ways to make the products affordable to the local communities, such as Roche's initiative to develop different brands in collaboration with a local manufacturer and the Egyptian government, rather than donating products outright. While product donations remain essential for certain diseases or societal circumstances, they are not generally seen as a sustainable solution since they do not provide ownership and enhanced capacity to local populations. Addressing affordability, developing innovative financing mechanisms, and developing local capabilities are long-term solutions that can lead to more sustainable outcomes.

Truly sustainable models around the principle of availability should ensure that the product or resource remains available after the corporate initiative has ended. Each disease and/or local context may create a different set of challenges for a company to overcome in order to advance sustainable access and a product's availability.

In response, companies have developed different approaches to increase availability at the point where the product reaches the consumer, including:

- » **Developing pricing models that allow more patients to afford medicines by pricing them based on a person's ability to pay:** For instance, Sanofi employs a tier-pricing framework in its efforts to eradicate polio. This tiered structure aims to provide the lowest prices for poorest countries and affordable pricing for others. Another example is, yet again, the Roche differential pricing model in Egypt.
- » **Developing licensing agreements with institutional buyers to grant patients increased access to the medicine they need:** Several case studies mentioned licensing agreements or patent policies that enable greater development and distribution of drugs and health technologies. Janssen's Global HIV Access & Partnerships Program (GAPP) enables generic manufacturers to manufacture its HIV/AIDS drug darunavir by adopting a policy of not enforcing its patents for darunavir in sub-Saharan Africa and LDCs, as long as the generic version is medically acceptable and used only locally. Additionally, Sanofi has registered its antimalaria drug, ASAQ Winthrop, in 33 countries, most of which are in Africa. These examples represent efforts made to increase access to medicines through greater distribution.
- » **Collaborating with a foundation to increase access to life-saving medicine:** BMS's agreement with the MPP enables sublicensees to produce and sell low-cost versions of atazanavir, an HIV medicine, in 110 developing countries where approximately 29 million people are living with HIV/AIDS. Under the agreement, BMS also provides a technology transfer package to the licensed generic manufacturers.

- » **Enhancing education (as, for instance, in the Sanofi StarBem project) and infrastructure for a particular disease:** Many of the case studies that focus on commercialization include education and the transfer of skills to make the model more sustainable within the local community. This comprehensiveness reinforces the complexity of making products and health systems sustainable in new markets in developing countries; it further demonstrates the degree of overlap that can occur among the principles since education is arguably a more significant component of health system resources than of availability.

Principle 4: Health System Resources

Definition of the Principle (as stated in the GPAH)

Quality healthcare rests on the strength and capacity of local health systems.

- » **Capacity building:** We collaborate with key stakeholders to strengthen health systems through a variety of means, such as training health practitioners, advancing patient education, investing in health infrastructure, and improving supply chain efficiency and integrity.
- » **Detection, prevention, and awareness:** We support improvements in detection, prevention, and health literacy to build awareness and educate the public on ways to prevent and treat disease.
- » **Investing in our employees and suppliers:** We invest in our employees and suppliers through training programs and capacity building, which contributes to community development.

Case Studies

Bristol-Myers Squibb	Middle East Program in Health Economics and Health Technology Assessment	
A three-module program designed to educate decision-makers from various countries in the Middle East on the foundational principles of health economics and outcomes research (HEOR).		
GlaxoSmithKline	20% Reinvestment Initiative	
Since 2009, GSK has reinvested 20 percent of the profits it earns in LDCs into community programs to support the reduction of child and maternal morbidity and mortality rates. GSK works with Amref Health Africa in east and southern Africa, Save the Children in west and central Africa, and CARE International in Asia.		
Janssen (Johnson & Johnson)	eMedical Advisor Platform for sub-Saharan Africa	
Janssen eMedical Advisor (JeMA) Platform is a training tool designed to address the lack of on-demand product information resources for healthcare providers (HCPs) in Sub-Saharan Africa (SSA).		
Janssen (Johnson & Johnson)	ColaLife	
With the Johnson & Johnson Corporate Citizenship Trust and Janssen, U.K.-based charity ColaLife designed a holistic anti-diarrhea kit and delivery model based on learnings from the Coca-Cola supply chain to supply the BoP populations in rural Zambia with an emphasis on ease of use, affordability, and accessibility.		

Merck & Co.	Alliance to Reduce Disparities in Diabetes	
<p>This U.S.-focused alliance works toward minimizing disparities in diabetes outcomes and enhancing the quality of diabetes care by improving prevention and management services. The alliance consists of five organizations, located throughout the United States.</p>		
Novartis	e-Learning to Reduce Maternal and Child Mortality	
<p>The Novartis Foundation for Sustainable Development (NFSD) supports the WHO in developing an e-learning tool to improve health care for children and reduce mortality rates of children younger than five.</p>		
Novo Nordisk	Changing Diabetes in Children	
<p>Changing Diabetes in Children (CDiC) focuses on reducing childhood diabetes mortality rates. Its objectives are to improve health conditions and quality of life, develop the capacity of healthcare systems, and raise awareness of the prevalence of diabetes among children.</p>		
Novo Nordisk	Changing Diabetes in Pregnancy	
<p>This program aims to improve diabetes-related maternal health, ensure healthy pregnancies and adequate post-partum follow up, and promote awareness of and access to screening for and management of gestational diabetes.</p>		
Roche	Educating Healthcare Workers in Saudi Arabia	
<p>Project Outreach is an initiative among Roche, the Ministry of Health of Saudi Arabia, key opinion leaders, and national cancer associations. It aims at ensuring that people living in remote areas are properly diagnosed and referred to specialists early enough to receive treatment.</p>		
Roche	Strengthening Diagnostics in Africa	
<p>In 2012, Roche opened the Roche Scientific Campus in Johannesburg, South Africa, to address the lack of trained diagnostic workers and laboratory capacity by improving laboratory services and training pathologists. These efforts are being further supported through a five-year partnership with the United States President's Emergency Plan for AIDS Relief (PEPFAR).</p>		
Sanofi	ASAQ Winthrop Risk Management Plan	
<p>ASAQ Winthrop RMP is conducted in partnership with the Drugs for Neglected Diseases initiative (DNDi) to fight malaria. The RMP gathers data from clinical studies in 19 countries lacking efficient pharmacovigilance systems.</p>		
Takeda	Takeda Initiative	
<p>The Takeda Initiative is a 10-year grant program (running from 2010 to 2019) to support the Global Fund to Fight AIDS, Tuberculosis, and Malaria in developing the capacity of healthcare providers in Tanzania, Nigeria, and Kenya.</p>		

Key Highlights

- » Partnership and collaboration are, yet again, a fundamental element of the work being conducted under this principle.
- » The case studies shared under it, as for the availability principle, demonstrate interesting thinking and the development of new technologies to reach the increased access objective.

The majority of these case studies include partnerships. Roche, for instance, leverages both global and local partners by combining a partnership with an organization of global reach (the United States President's Emergency Plan for AIDS Relief, PEPFAR) with collaboration with a local organization (the African Society for Laboratory Medicine) along with local and international experts to increase the initiative's sustainability.

A majority of the initiatives we studied fall under capacity building and detection, prevention, and awareness. The latter takes a variety of forms, particularly with regard to educating patients. Five cases worked on both of these subprinciples simultaneously, and a majority worked on increasing the capacity of healthcare workers to deliver healthcare services, including detection and treatment.

Strategies range from Novartis and partners creating an e-learning tool to reduce maternal and child mortality to Roche having specialists travel among villages to spread information about cancer and its detection in Saudi Arabia. Three programs—Takeda with its eponymous initiative in Africa, Roche in Strengthening Diagnostic in Africa Project, and GSK with its 20% Reinvestment Initiative—shared the approach of training healthcare workers in developing countries and local communities.

Another case study shared by GSK under the principle of collaboration could have well illustrated what companies can do under the investing in our employees and suppliers subprinciple. In this case study, GSK leverages its employees' skills through its Save the Children partnership by inspiring and engaging its workforce to participate in fundraising initiatives. In addition, employees have the opportunity to undertake a three- or six-month volunteering placement with Save the Children and various other NGO partners through GSK's employee volunteering program.

Many of the GPAH case studies within health system resources work to increase infrastructure, including physical structure, at the local level, as well as establish the basics of healthcare intelligence within communities.

In creating sustainable resources, companies benefit from utilizing different corporate structures and private resources to enhance their initiatives. Janssen's use of Coca-Cola's infrastructure to more effectively reach its target communities demonstrates the power of effective corporate collaboration. Through this project, mothers can access antidiarrhea kits for their children from trained microretailers on average 2.5 kilometers from their homes instead of walking more than 7 kilometers, while also spending 20 percent of what they would to travel to a clinic.

Enabling
Innovation
and *out-of-*
the-box
thinking

Principle 5: Human Rights

Definition of the Principle (as stated in the GPAH)

Respect for human rights is at the foundation of our activities.

- ▶ **Respecting human rights norms:** We support principles that have their origin in the UN's "Guiding Principles on Business and Human Rights," the Universal Declaration on Human Rights (UDHR), and the Declaration of Helsinki.
- ▶ **Nondiscrimination:** We respect global human rights standards and support access to our products within communities, irrespective of differences.

Key Highlights

Although none of the signatories explicitly submitted any under the human rights principle, all of the case studies are arguably designed to promote it since they integrate at least one human rights norm as enumerated in the UDHR, the UN "Guiding Principles on Business and Human Rights," and the Declaration of Helsinki.

The pharmaceutical industry's human rights obligations naturally extend to the right to health,²² which is often described as the "right to the highest attainable standard of health."²³ It encompasses socioeconomic factors that are necessary for enabling underlying determinants of health, such as nutrition, food, sanitation, housing, and access to safe and potable water.²⁴ Additionally, the right to health encompasses equal access to quality healthcare without discrimination, as well as adequate healthcare for vulnerable populations, such as the impoverished, women, children, and persons with disabilities.²⁵

GPAH signatories are committed to supporting human rights principles and ensuring access in a nondiscriminatory manner. Equality and nondiscrimination are integral to promoting human rights with regard to access to healthcare, as these concepts coincide with the health concept of equity and emphasize the pharmaceutical industry's responsibility to provide lower income countries and vulnerable populations with access to drugs. As set forth in the introduction, one of the MDGs is to provide access to affordable essential drugs in developing countries in cooperation with pharmaceutical companies.²⁶

Promoting *equal*
access to
quality
healthcare
without discrimination

²² The right to health is recognized in various international conventions, including the UDHR; the International Covenant on Economic, Social, and Cultural Rights; the Convention for the Elimination of All Forms of Discrimination Against Women (CEDAW); the Convention on the Rights of the Child; the International Convention on the Elimination of All Forms of Racial Discrimination; and the Convention on the Rights of Persons with Disabilities. It is also codified in various national constitutions and regional treaties, such as the African Charter.

²³ See the preamble of the Constitution of the WHO.

²⁴ UN Economic and Social Council, General Comment 14 Right to the highest attainable standard of health.

²⁵ Almost all of the UN conventions and international human rights instruments emphasize the importance of the provision of high standards of maternal and reproductive health and child healthcare. See the UDHR; the International Covenant on Economic, Social, and Cultural Rights; the Convention for the Elimination of All Forms of Discrimination Against Women (CEDAW); and the Convention on the Rights of the Child.

²⁶ UN, 2006.

Given that 94 percent of the submitted case studies involve initiatives within emerging markets, LDCs, or both, the GPAH signatories demonstrated their commitment to increasing access to healthcare in a nondiscriminatory manner by addressing gaps within emerging markets and LDCs. Most of the case studies focused on Africa and Asia. Several initiatives also involve increasing the availability of medicines through pricing mechanisms or registration.

Implicit in the UDHR and the human rights norms of equality and discrimination is an emphasis on the health of vulnerable populations, who are often subjected to neglected diseases that typically do not affect other populations. The WHO, Centers for Disease Control and Prevention (CDC), and other organizations identify neglected diseases as “diseases primarily affecting those living in poverty, especially in rural areas, in low-income countries,” including tropical or poverty-related diseases, such as leishmaniasis (kala-azar), onchocerciasis (river blindness), Chagas disease, leprosy, schistosomiasis (bilharzias), lymphatic filariasis, African trypanosomiasis (sleeping sickness), and dengue.”²⁷

For the purposes of this analysis, HIV/AIDS, malaria, and tuberculosis are also considered neglected diseases as they primarily affect impoverished populations, especially those living in LDCs. Overall, 50 percent of the case studies submitted addressed some form of neglected disease; half of these involved HIV/AIDS or malaria through for instance developing a malaria vaccine, research collaborations with academic institutions, and enabling drug discovery and development through funding, consortiums and partnerships.

One case study elaborated on the involvement of vulnerable populations in the research process and clinical trials. Sanofi, in partnership with DNDi, has established a risk management plan designed to build pharmacovigilance within sub-Saharan Africa and to monitor the efficacy and safety of their drugs in real-life scenarios.

²⁷ UN, 2008.

Part 3: Key Findings

As we reflect on the year since the GPAH Principles were signed, it's clear that much work has been done to continue improving access to healthcare. A microcosm of the myriad activities under way, these case studies represent only a small fraction of the initiatives being driven by signatory companies, who together represent a small portion of the entire sector's work. We must ponder, however, whether this activity equals progress.

The GPAH case studies begin to tell us a story. By looking collectively at these initiatives from independent healthcare companies, this report reveals key lessons—on the one hand, in regard to access to healthcare and, on the other, in regard to the principles themselves. Healthcare companies should take these findings into account as the industry strives to make progress on providing access to healthcare.

What Do the Case Studies Tell Us about Access to Healthcare?

A number of cross-cutting key findings emerged from the case studies, which together represent success factors that future access initiatives should leverage:

- » **One size does not fit all.**
- » **Partnership is critical.**
- » **Technology enhances access.**
- » **Linking to global health agendas underlines collective progress.**
- » **Measurement is key to evaluating and driving progress.**
- » **Connecting to business drives systemic change.**

One Size Does Not Fit All

Access to healthcare requires a variety of often multipronged approaches.

One look at the variety of the shared case studies uncovers that companies are approaching access through numerous methods designed to produce an equally broad number of outcomes. This diversity demonstrates the very complexity of access to healthcare and reveals the avenues that companies pursue in their endeavors to improve access to healthcare:

- » Addressing local healthcare issues (e.g., Takeda and its healthcare education program in Thailand and Indonesia or Sanofi's StarBem diabetes initiative in Brazil)
- » Eradicating a disease (Sanofi Pasteur's polio eradication effort or Merck & Co.'s efforts to eliminate river blindness)
- » Leveraging other sector capabilities (e.g., Janssen's Coca-Cola distribution channels)
- » Setting up multistakeholder initiatives (Merck KGaA's and Astellas's participation in the Pediatric PZQ Consortium)
- » Developing flagship programs (GSK 20-percent reinvestment initiative)
- » Joining global multicountry initiatives (BMS's agreement with the MPP)

There is no single approach, no single solution, simply because there is more than one problem to be solved. These cases exemplify that current and future unmet medical and healthcare needs are diverse and complex; in order to provide solutions, companies need to develop initiatives tailored to the problem at hand and closely linked to their own strengths and capabilities.

Partnership Is Critical

Collaborations are critical to improving access to healthcare. Time and again, collaboration and partnerships emerge as elements vital to addressing access to healthcare. One out of four case studies list collaboration as their primary principle, and no fewer than 79 percent include partnership or collaboration in some capacity. The point is driven home through examples of collaboration involving several dozen organizations in a single initiative.

This point speaks to the complexity of the challenges facing the healthcare sector; they demand a level of resources and skill sets that often exceed the capacity of an individual player, including the GPAH signatories. When developing the GPAH, the signatory companies recognized that tackling access to healthcare requires all the stakeholders of a healthcare system to work together and bring in complementary capabilities to help develop sustainable solutions. By entering partnerships and collaborations, healthcare companies leverage their partners' unique expertise, whether it is technological, geographical, scientific, commercial, or logistical.

Companies partner or collaborate with a broad spectrum of organizations and stakeholders, from NGOs to governments, multilateral organizations, companies from other sectors, and increasingly their peers. While the vast majority of projects shared in the case studies involve partnering with several organizations, they often included both local and global organizations, each bringing its own unique strengths. Local NGOs provide knowledge about local needs and culture, inject expertise, capacity, and knowledge to accurately target populations and deliver medicines to the patients in need, and know how to witness, record, and measure progress on the ground. Global entities, on the other hand, help with scaling and deploying initiatives or mobilizing forces in several regions at once, leveraging the strength of their much larger networks.

Perhaps most interesting are the complex, long-term partnerships that leverage the strength of individual partners. One illustrative example is GSK's partnership with Save the Children, a long-term initiative with forward-looking, ambitious goals that build on the strength of its two main partners. When well-managed, this type of broad partnership promotes the strengths of all actors involved in order to meet the initiative's ambitious goals.

Technology Enhances Access

Breakthroughs and innovative technological partnerships can be leveraged to enhance access to healthcare. Healthcare companies are embracing technology and technological partnerships in a big way, creating innovative solutions to access issues. The most common examples include the use of e-learning, social media, and mobile phones to increase access to healthcare products and information.

For instance, Novartis has developed an e-learning platform for teaching better maternal and neonatal care and is also leveraging technology through social media to raise awareness, and therefore overall impact, for its Power of One campaign with Malaria No More. Social media enables this campaign to reach a wider, younger audience. Similarly, Merck & Co. is utilizing mobile phones to teach mothers about the healthcare they should receive when pregnant and to rate their experience of the care they receive.

These findings demonstrate that pharmaceutical companies have a valuable card to play by combining innovative ICT technology with medicine. Being on the lookout for innovation, identifying opportunities, and partnering with relevant ICT firms are promising ways forward for healthcare companies to improve access to

medical information, control their supplies, inform their patients, train their medical practitioners, perform remote diagnostics, and more. One of the challenges healthcare companies will continue to face is the fast-paced evolution of cutting-edge technologies, as well as ensuring that the infrastructure required to use these new technologies is in place.

Linking to Global Health Agendas Underlines Collective Progress

Almost all the reviewed case studies are, in some capacity, working to advance global health agendas, such as the MDGs. This is a key, very positive element, and companies should continue to align initiatives with them as we move to the post-2015 development agenda. Below are a few highlights of how the case studies link to global health agendas.

- » **Working to fulfill the MDGS, and beyond:** There is a clear emphasis on women and children. About one third of the case studies focus on children's health, and many are centered on reducing child mortality and morbidity and the prevalence of HIV/AIDs among children and adolescents.

About 20 percent specifically address women's health needs, including maternal mortality, reproductive health, family planning, and breast cancer. Merck for Mothers, for instance, focuses on postpartum hemorrhaging (bleeding after childbirth) and preeclampsia/eclampsia (a hypertensive disorder) in order to reduce maternal mortality, while Novartis's e-learning initiative uses technological tools to scale up training on childhood diseases and maternal health.

Other case studies focused on other vulnerable populations, including tribal and rural populations in India and the working poor.

When it comes to disease types, 12 percent illustrated approaches to increasing access to treatment for HIV/AIDS, and three case studies specifically described initiatives focused on malaria and other diseases affecting LDCs most acutely.

Efforts to provide access to affordable essential drugs in developing countries were demonstrated in several cases.

- » **Eliminating diseases,** such as Sanofi Pasteur's work to eradicate polio and Merck & Co.'s work to eliminate river blindness.
- » **Strengthening health systems:** Forty percent either focus specifically on capacity building of local health care stakeholders or incorporate capacity building as a critical component. Inadequate infrastructure, low stakeholder engagement, weak healthcare capacity, and limited availability of trained healthcare providers and pharmacies are critical weaknesses for access, especially for the most vulnerable populations in developing countries.
- » **Tackling the increasing threat from NCDs**—mainly cancer, cardiovascular disease, chronic respiratory diseases, and diabetes: They represent a major challenge to health and development in the 21st century by being the leading cause of death and disability worldwide.²⁸

As we look toward the post-2015 development agenda and such goals as reducing the global maternal mortality ratio to fewer than 70 per 100,000 live births, it is clear that improved access to healthcare will continue to be a major development goal around the world. Even more efforts and increased

²⁸ NCD Alliance, 2014.

contribution toward meeting these global goals will be expected from pharmaceutical and healthcare companies, especially in a world that is growing considerably and, at times, with unpredictable demographic changes. Signatories will have an opportunity to link the GPAH to these development agendas to ensure that a comprehensive approach to access to healthcare is pursued and achieved.

Measurement Is Key to Evaluating and Driving Progress

As identified in BSR's 2012 report *Toward Transformational Health Partnerships*,²⁹ it is challenging to measure the impact of partnerships. In terms of access to healthcare, while most companies are publicly sharing their initiatives and results, stakeholders grapple with tracking progress and assessing achievements.

Aligning ambition with the broader context of global health needs, defining clear objectives and targets (time-bound quantitative and/or qualitative), and then tracking results relative to those targets (for instance, the number of patients treated, vaccinations administered, or milestones achieved) are essential, not only to assess progress year over year, but also to drive it.

Transparency in terms of ambition and goals and investment in effective management systems, combined with relevant measurements that allow the organization to evaluate results and ensure that resources are being deployed effectively, provide valuable insight for the company and external stakeholders. These insights help individual companies assess whether they are pursuing the most effective avenues for advancing access.

This report highlights a number of initiatives that demonstrate the importance of defining ambition and context and sharing metrics and data to evaluate progress. For instance, to cite only a few, Janssen and the Colalife project, the Sanofi StarBem project, Novartis Arogya project, GSK and Save the Children Partnership, and Novo's BoP project are all reliable examples of data sharing and relevant metrics. Most involve a combination of qualitative and quantitative data.

Connecting to Business Drives Systemic Change

The GPAH Principles state the need for the healthcare sector to seek sustainable solutions that promote access to care. Initiatives that go beyond philanthropy and link to core business strategy and provide tangible business benefits are more likely to be viable and sustainable.

A number of initiatives illustrate this particular point. They link to the company's core business operations, products, and/or strategic objectives and are designed to drive returns for the organization, whether in terms of market development or financial growth.

Four examples of such initiatives provide commercial returns and are expected to be the right basis for a sustainable long-term impact by closely linking to business:

- » GSK's 20-percent reinvestment initiative in which the company reinvests 20 percent of the profits it generates in LDCs into local community programs that strengthen healthcare systems, ultimately helping develop its markets.

²⁹ BSR, 2012.

- » Novartis’s Arogya Parivar project for which the results to date most notably state that it is commercially viable, auguring for its long-term impact.
- » Novo Nordisk’s BoP project, which focuses on creating new business models through integrated approaches to diagnosing, treating, and controlling diabetes and aims to create value for both the community and company.
- » Roche’s differential pricing initiative in Egypt, which combines the introduction of a second brand of its hepatitis C treatment, the redesign of its packaging, and differential pricing, is being replicated in other countries and for other products.

While these examples are merely illustrative, they demonstrate a trend—and for some organizations a full shift—toward integrating access to healthcare as a core operational element.

What Do the Case Studies Tell Us about the GPAH?

Our broader analysis of case studies also shined a light on the principles themselves. Below are a few of our key findings:

- » **The principles are interconnected and interoperable.**
- » **GPAH provides a view on collective efforts.**
- » **Sharing case studies is important for learning and replication.**
- » **The groundwork has been laid for a framework to analyze progress.**

The Principles are Interconnected and Interoperable

One of the first elements that jumped out in our research is the fact that the principles, although clearly defined and separated, somehow constitute an artificial split. Each of the case studies covered at minimum one principle and most initiatives covered more than one, once again proving the complexity of access to healthcare, the need to consider multiple elements, and the need to work on many fronts to effectively address access issues.

Throughout this study, important synergies and overlaps in the principles emerged: One out of four case studies listed collaboration as its primary principle, but various levels of collaboration and partnerships were found in nearly 80 percent of the cases. The human rights principle, which at first glance seemed absent, is arguably present in each and every initiative.

This interconnectivity and interoperability demonstrates that while the GPAH help define what is being addressed when we discuss access to healthcare, companies cannot and should not artificially pursue one principle to the detriment of the others. In fact, the complexities of access to healthcare require that companies address multiple principles at once.

GPAH Provides a View on Collective Efforts

The GPAH Principles were designed by a group of companies and stakeholders as aspirational guidelines to frame the industry’s efforts to enable access to healthcare to those in need. They were designed to drive both independent and collective action.

It has become clear by publishing this status report that the GPAH provide a view of the collective work being conducted by independent organizations. While raising the question of whether the work of a group of companies could expand access to healthcare more significantly than individual companies could, it also

further explores whether access issues require even more alignment from healthcare companies, as the increased peer-to-peer collaborations suggest.

Sharing Case Studies Is Important for Learning and Replication

Sharing and analyzing case studies provides important elements for addressing efforts but also for learning, replication, and inspiration. Lessons learned and shared collectively, at the very least, prevent others from repeating the same mistakes and can inspire them. It is important for companies to continue providing a high level of transparency in their case studies, i.e., the information shared about successes but also challenges, in order to drive progress.

The Groundwork Has Been Laid for a Framework to Analyze Progress

The signing of the GPAH was a call to action to expand access to quality healthcare, and to date, GPAH signatories have demonstrated momentum in fulfilling this original aspiration. While the scope of this report covered a limited number of cases, many more initiatives are taking place, demonstrating that companies are indeed working on numerous issues to advance progress on a range of diseases and pathologies and address broad access challenges from R&D to pricing to capability building.

The GPAH, by defining the topic of access under five principles, provide a structured way to look at access efforts and understand them from an individual company perspective as well as collectively. This common understanding has laid the groundwork for industry action, but whether and how this groundwork can be leveraged to develop a framework to measure access efforts in a unified, comparable manner remains a challenge.

Conclusions

Despite the tremendous progress made around the world, access to healthcare remains a complex, persistent challenge for people from all walks of life, from the least developed countries to the most developed nations. Inextricably intertwined with issues of poverty, economic development, infrastructure, water, and sanitation, among others, this challenge will remain a top priority for global development agendas and institutions in the future. The Guiding Principles on Access to Healthcare, therefore, play a pivotal role in articulating the key elements critical to solving these global health challenges. It is not simply enough to increase availability of products—the GPAH demonstrate that all five principles are fundamental: collaboration, research and development, availability, health system resources, and human rights. The fact that CEOs from 13 of the world’s largest pharmaceutical companies have committed to these principles provides a very strong foundation for progress.

As we look forward, there are three important next steps to ensure these commitments are realized. First, the signatories will review the lessons learned in producing this report as well as any feedback received to enhance their own individual efforts and to identify further opportunities for collaboration. In addition, they will use this feedback to identify the best ways to continue to evaluate and communicate progress on the GPAH commitments going forward.

Second, we hope that other companies will read this report and benefit from the collective experience of the case studies represented. Companies within the healthcare space may consider signing the GPAH as well, or use the lessons to shape their own access initiatives. Companies who do not directly provide healthcare products can also glean important lessons from our evaluation, and we encourage those in supplementary sectors who may contribute services, infrastructure, or other resources to review our findings and share ideas for collaboration.

Finally, the GPAH were developed with critical input from global health stakeholders, and these organizations continue to play an invaluable role in solving many of the persistent health challenges. We hope these stakeholders will also review this report and its findings, provide feedback, and share ideas and innovations so that we may collectively drive greater progress.

While much progress has been made, and many more efforts are under way than we can recount here, there remains a daunting challenge of providing all global citizens access to quality healthcare. The GPAH have become an important framework to guide this progress, and we look forward to many more years of collaborative efforts to make these commitments a reality.

Looking Forward

While this report has reflected on the past year's activities (since the signing of the GPAH), we realize the need to look to the future. These key lessons will be incorporated into future conversations and initiatives put forward by the GPAH signatories, but as we have learned, it will take a collective group of stakeholders working together to drive true systemic change on access issues.

And so we turn to you, our reader, to help the GPAH signatories and the healthcare industry make further progress. Below are key questions we are asking ourselves, and we invite you to share your perspective and feedback on these and this report's overall findings:

- » What specific actions could GPAH signatories take to advance access to healthcare?
- » What collaborative opportunities are there to increase impact?
- » How can this report be leveraged to find a way to better analyze access to healthcare initiatives?
- » What additional information would you like to see to evaluate progress against the GPAH?

Please send any questions or feedback to gpah@bsr.org.

Appendices

Glossary

access to healthcare The ability of a person to receive healthcare services, which is a function of accessibility, availability and affordability.

accessibility The degree and ease to which a population can reach health services and supplies.

Access to Medicine Index (ATMI) The Access to Medicine Index independently ranks pharmaceutical companies' efforts to improve access to medicine in developing countries. Funded by the Bill & Melinda Gates Foundation and the UK and Dutch governments, the Index has been published every two years since 2008.

affordability The capacity for individuals to pay for and, therefore, access healthcare services and supplies.

availability As defined in the GPAH, the practice of ensuring that innovations are available to patients.

bottom of the pyramid (BoP – also known as base of the pyramid) A socio-economic concept that groups the world's poorest citizens. A member of the BOP lives with less than \$2.50 a day.

capacity building The process by which individuals, groups, organizations, institutions, and societies increase their abilities to perform core functions, solve problems, define and achieve objectives, and understand and deal with their development needs in a broad context and sustainable manner.

Centers for Disease Control and Prevention (CDC) CDC is one of the major operating components of the U.S. Department of Health and Human Services. CDC works to protect the U.S.A. from health, safety and security threats, both foreign and in the U.S.

collaboration As defined in the GPAH, the participation and cooperation of numerous diverse stakeholders, with complementary responsibilities and capabilities, to solve systemic challenges.

communicable disease An illness caused by an infectious agent or its toxins that occurs through direct or indirect transmission of an infectious agent or its products from an infected individual or via an animal, vector, or the inanimate environment to a susceptible animal or host.³⁰

Declaration of Helsinki A statement of ethical principles developed by the World Medical Association to: "provide guidance to physicians and other participants in medical research involving human subjects". The Declaration includes principles on: Safeguarding research subjects; Informed consent; Minimizing risk; Adhering to an approved research plan/protocol. The Declaration is considered a fundamental document in the ethics of healthcare research.

Drugs for Neglected Diseases initiative (DNDi) A collaborative, patients' needs-driven, non-profit drug research and development (R&D) organization that is developing new treatments for Neglected Diseases.

³⁰ CDC, 2012

Guiding Principles on Business and Human Rights A set of guidelines for States and companies to prevent and address human rights abuses committed in business operations.

health system resources As defined in the GPAH, the strength and capacity of local health systems to meet the health needs of a population. Includes capacity building, detection, prevention and awareness around health threats, and investing in employees and suppliers.

International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) A global nonprofit, nongovernmental organization that represents the research-based pharmaceutical industry, including the biotechnology and vaccine sectors.³¹

Intergovernmental Panel on Climate Change (IPCC) An international body for the assessment of climate change established by the United Nations Environment Programme (UNEP) and the World Meteorological Organization (WMO) in 1988 to provide the world with a clear scientific view on the current state of knowledge in climate change and its potential environmental and socio-economic impacts.

least developed countries (LDCs) As defined by the UN, low-income countries suffering from structural impediments to sustainable development. These handicaps are manifested in a low level of human resource development and a high level of structural economic vulnerability.³²

London Declaration on Neglected Tropical Diseases A collaborative disease eradication program launched in January 2012 in London that aims to eliminate or control 10 neglected diseases by 2020.

Medicines Patent Pool (MPP) A United Nations-backed organization that aims to improve access to appropriate, affordable HIV medicines and technologies for people living with HIV in developing countries.

Millennium Development Goals (MDGs) A set of development targets (eight international development goals) agreed by the international community, which center on halving poverty and improving the welfare of the world's poorest by 2015.

neglected tropical diseases (NTDs) A group of parasitic and bacteria diseases that cause substantial illnesses for more than 1 billion people globally and can impair physical and cognitive development, make it hard to earn a living, and contribute particularly to illness and death in mothers and young children.³³

noncommunicable diseases (NCDs) Also known as chronic diseases, these do not result from an (acute) infectious process and therefore are not contagious. These diseases are rarely cured completely.³⁴

Organisation for Economic Cooperation and Development (OECD) A forum where the governments of 34 democracies with market economies work with each other, as well as with more than 70 non-member economies to promote economic growth, prosperity, and sustainable development.

³¹ IFPMA, 2014.

³² UN, 2013.

³³ CDC, 2014.

³⁴ CDC, 2014.

registration According to the WHO, the publication of internationally agreed-upon information about the design, conduct, and administration of clinical trials.

Universal Declaration on Human Rights (UDHR) An international document that states basic rights and fundamental freedoms to which all human beings are entitled. The Universal Declaration recognizes that 'the inherent dignity of all members of the human family is the foundation of freedom, justice and peace in the world'. It declares that human rights are universal – to be enjoyed by all people, no matter who they are or where they live, and includes civil and political rights, like the right to life, liberty, free speech and privacy. It also includes economic, social and cultural rights, like the right to social security, health and education.

World Health Organization (WHO) The directing and coordinating authority for health within the United Nations system. It is responsible for providing leadership on global health matters, shaping the health research agenda, setting norms and standards, articulating evidence-based policy options, providing technical support to countries, and monitoring and assessing health trends.

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