STRATEGIC DIRECTION 2022 - 2026

How we will mobilise five essential healthcare sectors to address healthcare inequity

DECEMBER 2021

The world's most vulnerable people need better access to healthcare. In many areas of healthcare, just a few large firms hold the key to making this possible, whether through their market presence, dominance of manufacturing and distribution or via innovation and intellectual property rights. The Access to Medicine Foundation has developed a tried-and-tested model for incentivising such companies to do more to reach people in low- and middle-income countries. Over the next five years, the Foundation will expand this model to cover a total of five healthcare sectors: Big Pharma, generic medicine manufacturers, vaccine manufacturers, diagnostics companies and medical gas companies. Moving the big players in each of these sectors would transform many millions of lives. This Strategic Direction for 2022-2026 describes a six-part approach for expanding this model and mobilising a diverse range of essential healthcare companies to achieve global equity in access to healthcare.

> access to medicine FOUNDATION

THE PLAN IN BRIEF

The next five years: driving deeper and broader access

The world's most vulnerable people need better access to healthcare. The chronic inequalities in access are more glaring than ever in the wake of the coronavirus pandemic with acute issues of access to medicines, vaccines and other essential health products such as medical oxygen. Over the next five years, the Access to Medicine Foundation intends to save more lives by expanding its tried-and-tested model of incentivising companies to help more people living in low- and middle-income countries. We will build on our strengths as we begin to work with a wider range of firms across more sectors to elicit systematic improvements in access to innovative medicines, vaccines, generic treatments, diagnostics and medical gases. In broadening and deepening our work, we will focus on the largest players that dominate their respective markets, whether through control of supply and distribution or via innovation and intellectual property rights. This approach has been shown to work in the case of Big Pharma – as demonstrated by the success of the Access to Medicine Index – and we believe it can be equally effective in other parts of the healthcare supply chain. In this strategy, we set out how we will expand our model to cover a total of five healthcare sectors.

To meet the scale of our ambition, we will engage more companies and mobilise data, rankings, analyses and a network of powerful allies – including investors, policymakers in governments and global health organisations – to drive the uptake of best practices. It is only by addressing the continuum of care that the world can truly help the two billion people who still lack access to the medicines and healthcare products they need.

BY 2026: FOUR STRATEGIC OUTCOMES

We will work to enable four shifts in the industry that improve healthcare in low- and middle-income countries:

A critical mass of companies is brought to the table
A diverse range of essential healthcare companies, in addition to Big Pharma,
address access as a core priority, including suppliers of generic and branded medicines,
vaccines, diagnostics, devices and medical oxygen. Access-related objectives that
include vulnerable populations are becoming embedded in commercial strategies and
company actions are being tracked by the Foundation.

Access to medicine is expanding along the continuum of care
Gaps in care provision start to close rapidly as best-practice access strategies
accelerate across low- and middle-income countries, and there is a portfolio of new
products in the pipeline. Increasing numbers of people can rely on a steady, sufficient,
timely and equitable supply of essential healthcare products.

Driving access at scale to help achieve universal health coverage

Healthcare companies improve local availability of products and relieve pressure
on health services through supply chain, product licensing and technology transfer programmes. Companies also improve affordability by matching prices to local economies
and people's ability to pay.

The public, investors and policymakers are empowered to drive change Investors and policymakers stimulate companies to step up action on access through conditional funding and regulatory measures, leveraging the Foundation's tracking mechanisms to push for behavioural and strategic change within boardrooms. They are supported by an informed and engaged public.

WHY NOW, WHY US?

The challenge for this next decade

The need for equitable access to medicine has never been more important or more urgent. The challenge for the global community this decade must be to close what is an unacceptable gap between the "haves" and the "have-nots" so that the most vulnerable people, including millions of women, girls and children, are not left at the back of the line. This applies just as much to life-saving products against non-communicable diseases, such as cancer and diabetes, as to interventions against infectious diseases. With the world striving to achieve the Sustainable Development Goals (SDGs) by 2030, there is no time to lose.

The COVID-19 pandemic, which has already destroyed so many lives and livelihoods, has been a stark reminder of the damage caused when billions of people living in low- and middle-income countries are relegated to the end of the queue for vaccines and treatments, and how inequity undermines global health security. The crisis also highlights the key role that just a few companies play in the development, manufacture and distribution of essential health products. Actions by these companies and the enabling conditions set by governments to facilitate access make the ultimate difference for patients.

Why transformation of the healthcare ecosystem is needed

Global health has seen important advances in recent decades and many leading pharmaceutical companies have made progress in improving access to medicine since the Foundation started benchmarking their performance in 2008. Yet the fact remains that billions of people still cannot access the medicines that they need, and essential healthcare services are out of reach for half the world's population. The people on the frontline of this crisis are the 83% of humanity who live in low- and middle-income countries.

Too many medicines and other essential healthcare products – both old and new – remain unaffordable and unavailable. The skewed incentives driving industry investment patterns mean that innovations routinely fail to reach the people who need them most. A lack of lucrative markets in low- and middle-income countries too often leads healthcare companies and their investors to ignore access in these countries. This has resulted in much of the industry overlooking essential areas of medicine, such as the hunt for new life-saving antibiotics and cures for crippling tropical diseases.

There is a pressing need to marshal resources more efficiently and to motivate more companies to step up. Although this is a daunting task, we know what needs to change – and we have proved we can move the dial by encouraging companies to do more. The Foundation has demonstrated the power of data, collaboration and persuasion to trigger action by the pharmaceutical industry over many years and ensure expanded access to products.

We plan to exploit our mechanisms of action to move Big Pharma more systematically and rapidly, while expanding our work to encompass more manufacturers of healthcare products in four additional sectors: generic medicines, vaccines, diagnostics and medical gases. This will enable us to be a catalyst to transform the healthcare ecosystem for the better. The Foundation's solutions-oriented approach and its unique ability to convene all stakeholders to address the pressing issues will be needed more than ever in the wake of the COVID-19 pandemic as the global health community prepares for future challenges.



83% of all people alive today live in the 106 countries covered by the research of the Access to Medicine Foundation

Motivating the pivotal players

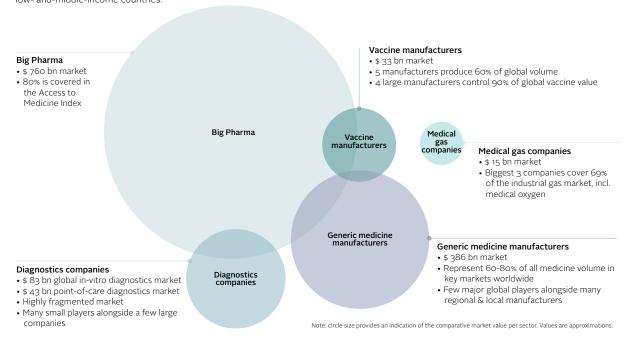
The next five years offer a major opportunity for the Foundation to continue to drive change within Big Pharma, while expanding its proven tactics to other crucial players in the global healthcare supply chain, thereby covering more essential health products. This will involve making the case for far-reaching change not only to companies but also to policymakers and investors. Governments, multilateral organisations and the financial backers of healthcare businesses all have a crucial role to play in shifting access policies. Healthcare is not only about medicines and vaccines; a wider group of companies is also critical in providing patients with a continuum of care. In many cases these firms hold the key to increasing access to scientific innovation in low- and middle-income countries and the Foundation's established system of incentivising better access standards can be applied equally across these supportive products.

Two clear examples here are medical gases – including medical oxygen – and diagnostics: sectors where there are a handful of large players with pivotal roles in bringing solutions to health systems. Indeed, it is a common feature of all the sectors where the Foundation currently operates and where it plans to step up activities that a relatively small number of companies control the market, whether through dominance of manufacturing and distribution or via innovation and intellectual property rights. Moving these big players therefore holds the key to improving the scale of access globally and delivering on the SDGs.

This approach of focusing on the largest companies has already worked in the case of the large research-based pharmaceutical companies covered by the Access to Medicine Index. We believe this strategy can also prove highly effective in motivating pivotal suppliers of other essential health products.

FIGURE 1 The five overlapping groups of essential healthcare industries

The Foundation's model works best when the ecosystem that is being incentivised consists primarily of a small group of players that have effective control of the market for specific products, either via their ability to innovate, their holding of patents or through market dominance. There are five groups here that are important in high-burden disease areas: Big Pharma, generic medicine manufacturers, vaccine manufacturers, diagnostics companies and medical gas companies. In all cases, there are a few dominant players that can have a big impact on healthcare in low- and-middle-income countries.



BIG PHARMA

Continuing to drive Big Pharma's uptake of scalable solutions

As innovators and producers of medicines, pharmaceutical companies have a clear societal duty to improve health. They must ensure availability of their products to all people.

The Foundation's analysis shows that there has been a steady improvement over time, with eight of the top 20 research-based pharmaceutical companies now developing systematic access planning approaches to make future medicines and vaccines accessible in poor countries at launch. Nonetheless, fewer than half of all late-stage R&D projects are currently supported by an access plan and products already on the market are largely overlooked when it comes to efforts to improve access.

Big Pharma still needs to do much more in four key areas, all of which will be a focus of the Foundation's work over the medium term.

Firstly, companies must increase and sustain R&D investment in the areas of greatest need, addressing priorities such as innovation for poverty-related diseases, the hunt for replacement antibiotics or child-friendly formulations of existing medicines. Investors and other stakeholders must push management teams to invest in more sustainable business models where financial returns are driven not by chasing higher margins, but by delivering more effective treatments to the largest number of patients. Governments, too, need to rethink and reform policies in public financing of research, product regulation and international trade to encourage investment in priority areas and ensure broad access.

Secondly, companies must expand the availability of new and existing products to more populations, especially the most neglected and vulnerable groups in the world's low-income countries. Just 13% of essential products that must be administered by a healthcare practitioner – such as injectable treatments for cancer and new medicines for mental health conditions – are currently offered through access strategies in low-income countries, according to the latest Foundation findings. This rises to 26% in the case of self-administered products – mainly pills – which is still an unacceptably low figure.

Thirdly, companies should be doing much more to support healthcare systems in low- and middle-income countries and help to lay the foundations for universal health coverage (UHC). This requires pharmaceutical companies to take a pragmatic and flexible view on pricing, bearing in mind the range of payers for their products – from government-run health systems to patients paying out of pocket. Access strategies with the biggest impact on UHC will be those that aim to make products affordable for all patients across the income pyramid. And Big Pharma has a role in ensuring that its actions align with local, national and international players in infrastructure, supply chains and capacity building.

Finally, pharmaceutical executives need to embrace access in low- and middle-income countries as a core part of business strategies. It is no longer acceptable to park the access issue in a separate silo labelled "philanthropy" or "corporate social responsibility" where it does not receive daily board-level attention or investment.

Addressing all of these points will involve a structural rethink by some pharmaceutical companies. However, this shift may not be as wrenching as some in the industry fear, since it is aligned with the thinking of many of the pharmaceutical industry's biggest investors. As concerns over environmental, social and governance (ESG) issues grow across all industry sectors, more and more investors are actively pushing for pharmaceutical companies to demonstrate a truly sustainable profile.

In the 21st century, the key to that sustainability for Big Pharma will lie in meeting societal demands for improved healthcare. From the investor perspective, this goal is vital for the long-term commercial success and viability of companies, on the grounds of good citizenship, attracting and retaining talented staff and commercial self-interest as emerging markets become ever more important.

ROLE IN ACCESS

Here are the three key areas where Big Pharma companies play a role in ensuring access to medicine:

Increase and sustain R&D investment

- Engage in R&D for set global health priorities
- Ensure that, upon launch, the products they develop reach those global populations that are most in need

Expand the availability of new and existing products to more populations

- Register products widely in low- and middle-income countries
- Ensure supply security and sustained local availibility of marketed
- Support healthcare systems in developing countries and help to lay the foundations for universal health coverage (UHC)

Embrace access in low- and middle-income countries as a core part of business strategies

- Ensure continuous supply of essential health products
- Address shortages and stockouts
- Improve local availability and strengthen supply chains

GENERIC MEDICINE MANUFACTURERS

Ensuring generic medicine manufacturers supply for the world

The world's generic medicine manufacturers possess the adaptive R&D capability and large-scale manufacturing capacity to supply billions of much-needed medicines to poorer countries. In recent years, many of these manufacturers – including those based in low- and middle-income countries such as India, China, Brazil and South Africa – have strengthened their capabilities. Some have even developed proprietary technologies, thereby fortifying their global portfolio and footprint. Yet generic treatments, from medicines used to control hypertension and diabetes to biosimilars used to fight cancers, are not always available or accessible to everyone who needs them, due to issues of inadequate or insecure supply, insufficient manufacturing in low- and middle-income country markets, unaffordability, lack of compatibility with local environments and substandard quality.

Just as the world depends heavily on a small number of Big Pharma companies for developing innovative medicines in key areas, the industry's deep supply chain is also increasingly dominated by large generic medicine manufacturers, both of finished medicines and vaccines and of bulk active pharmaceutical ingredients (API). As a result, such companies are well placed to participate in delivering on global health priorities. Due to generic medicine companies' strong position in lowand middle-income country markets, they can push for adaptive R&D for products where treatments are already on the market but where there are clear gaps in access and supply, such as for child-friendly formulations and new regimens for infectious diseases.

The interplay between R&D-based pharmaceutical companies and generic medicine manufacturers is critical to solving such problems – and constructive relations between the two in areas such as technology transfer and the licensing of intellectual property rights can be one of the strongest drivers to delivering truly equitable access and improve local availability.

Generic medicine manufacturers are responsible today for supplying more than 80% of all essential medicines. Importantly, as licensees they produce a wide range of life-saving treatments for major killers, making them a vital conduit for new products into low- and middle-income countries. HIV/AIDS shows what is possible. In this case a global commitment to universal access to antiretroviral therapy, delivered via generic medicine suppliers, has turned the tide of infection over the past decade and saved millions of lives. But HIV/AIDS is just one disease, and similar efforts are needed in other areas such as tuberculosis and other infectious diseases – including those which could become future pandemics – as well as non-communicable diseases that are a growing burden on health in poorer countries. Ensuring that generic medicine manufacturers optimise their access

strategies for low- and middle-income country markets and deliver on licensing opportunities is therefore crucial to future global health across multiple fronts.

Generic medicine manufacturers can reach many more underserved populations with both off-patent products and innovative, high-priority medicines in several ways. One route, for example, is by ensuring earlier product launches in low-and middle-income countries for medicines covered by licensing agreements – a vital first step in facilitating sustainable access to treatments. At the same time, generic medicine manufacturers need to commit to registering their in-licensed products as rapidly as possible in countries where the burden of disease is high.

Security of supply is another challenge, particularly when demand increases due to unforeseen circumstances, as was the case with the COVID-19 pandemic. To help achieve global health security and prevent shortages of existing manufactured products, while at the same time ramping up global supply of new or urgently needed products, manufacturers need to consider several elements.

In the manufacture of APIs, for example, trade and foreign policy feuds between sovereign states and border closures when supplies of particular ingredients are tight, often create a fragile supply situation. This vulnerability to raw material shortages is exacerbated by the fact that most APIs are produced in just two countries: China and India.

The vulnerable position of low- and middle-income countries, including those in sub-Saharan Africa, is increased substantially by the fact that these countries typically have little if any on-the-ground pharmaceutical manufacturing capacity. This leaves local populations at the mercy of sometimes unreliable shipments from other nations. Building up manufacturing capacity and improving local availability of finished products in poorer countries must be made a priority in future if the world is to improve the security of supply. Creating a more broadbased and resilient manufacturing base will also help individual companies to mitigate shortages and stockouts.

Failure to address the innate fragility of the supply chain risks causing more problems and will lead to more cost spikes in future – and the hardest hit patients will be those in the world's poorest and least profitable markets.

The complementary efforts of the Foundation and various patent pools to expand the use and impact of non-exclusive voluntary licensing is a prime example of what can be achieved. Since 2012, such deals have led to more than 30 million patient-years of treatment for people with serious diseases such as HIV/AIDS, hepatitis C and tuberculosis.

At present there is no comprehensive platform to track the progress of the generics industry or identify key opportunities

for companies to be more responsive to global health challenges, although the Foundation has made a start through its pioneering work in addressing the role of generic medicine manufacturers in the Antimicrobial Resistance Benchmark.

The current gap in information about the role of the generics industry in access to medicine creates a significant opportunity for the Foundation in monitoring the registration of new products, tracking the speed of their availability in various markets, and scrutinising how manufacturers work with different global organisations in priority areas.

ROLE IN ACCESS

There are three key areas where generic medicine manufacturers play a role in ensuring access to medicine:

Invest in R&D for global health priorities (where applicable)

 Invest in R&D where applicable and engage in partnerships to adapt priority products for low- and middle-income country settings and vulnerable populations

Engage in partnerships for needed products

- Engage in non-exclusive voluntary licences (VL)
- Deliver to and prioritise underserved populations
- Register in-licensed products widely in low- and middle-income countries
- Expand sustained access for vulnerable populations* and ensure continuous local availability of affordable products

Improve supply security and ensure product quality

- · Ensure continuous supply
- Increase local manufacturing
- Address shortages and stockouts
- Strengthen supply chain
- Ensure Good Manufacturing Practice (GMP) standards are applied
- Vulnerable populations include displaced individuals, women & girls, children, people living at the base of the income pyramid.

VACCINE MANUFACTURERS

Enabling greater vaccine access

Vaccination is one of the most powerful and cost-effective health interventions available. Vaccines currently prevent 2-3 million deaths every year from diseases including diphtheria, tetanus, pertussis, influenza and measles. As such, they are among our strongest tools for preventing epidemics and pandemics. Yet despite tremendous progress, far too many people around the world – including nearly 20 million infants each year - have insufficient access to vaccines, and preventable diseases still cost millions of lives each year. Low- and middle-income countries represent a disproportionate burden of vaccine-preventable disease and often have lower vaccine coverage than high-income countries. Despite their broad social and economic benefits, vaccines face extensive access issues including inadequate supply, specifically to low- and middle-income countries, as well as gaps in R&D and limited corporate involvement in the vaccine space.

The need for vaccines has never been greater. Over the past 10 to 15 years, a succession of serious infectious disease outbreaks has occurred, including Ebola, Zika and COVID-19, with the latter expecting to cause USD 28 trillion worth of damage by 2025. Vaccine manufacturers have a critical role to play in ensuring that immunisation reaches people living in low- and middle-income countries. The world relies on the industry to ramp up global supply and provide vaccines at scale when they are needed.

Many vaccines currently on the market are not necessarily tailored to address the specific needs of low- and middle-income country markets, resulting in limited access and inadequate coverage of populations against vaccine-preventable diseases. For example, many vaccines require cold storage, which is often unavailable in remote areas in low- and middle-income countries. Local manufacturers, when equipped to do so, can contribute to the development of vaccines that take such requirements into account.

A more fundamental problem is the absence of vaccines for a number of critical diseases that are predominantly prevalent in poorer countries, including Lassa fever, chikungunya and Nipah virus. New funding or collaboration models are needed to share the financial risks of developing vaccines against such diseases, with local manufacturers having an important role to play in partnering with large R&D-based vaccine manufacturers, research institutions and biotech companies to co-develop and deliver products. Local vaccine manufacturers with the required manufacturing capacity can bridge the gaps in access by collaborating to deliver to markets and populations that are commonly left behind.

Supply security is vital for vaccine access in low- and middle-income countries, in particular for children in many African countries where local availability is limited. Shortages and stockouts of vaccines are among the most frequent occurrences seen in health systems worldwide, alongside antibiotic shortages.

Local manufacturers should be encouraged to invest in their production plants and build resilience so that they are better equipped to respond to rises in demand, including in times of crisis. Advance market commitments from pooled procurement agencies and clear prioritisation from global immunisation campaigns can give them a financial incentive to take these steps.

Finally, local manufacturers can engage in capacity building initiatives in partnership with local organisations to improve the supply chain infrastructure. Such initiatives could include technical support or improved cold storage management.

Since the COVID-19 pandemic began, the importance and responsibilities of local vaccine manufacturers in ensuring supply and access has received increased recognition from the global health community. While it is paramount that these companies' efforts are supported and sustained, monitoring and evaluation of their activities should also be a priority for global health stakeholders.

ROLE IN ACCESS

There are three key areas where vaccine manufacturers play a role in ensuring access to medicine:

Invest in R&D for global health priorities

- Invest in adapting priority products to suit the needs of low- and middle-income countries
- Engage in R&D for identified and future gaps in infectious diseases, including epidemics and pandemics

Deliver to and prioritise underserved populations

- Engage in licensing or manufacturing partnerships with major vaccine innovators (including Big Pharma and biotechnology companies)
- Engage where available with other local vaccine manufacturers to enhance local/regional availability
- Partner with international organisations to enable broad access and delivery of vaccines to low- and middle-income countries
- Ensure underserved populations are included in vaccine access

Improve supply security

- Strengthen supply chains
- Address shortages and stockouts

DIAGNOSTICS COMPANIES

Unlocking the potential of diagnostics for all

Diagnostics and monitoring devices are an essential element of the health system and a critical part of the continuum of care. Whether performed on blood, tissue or other patient samples, diagnostic tests are a vital source of information for disease management and patient care. They help determine the disease from which the patient suffers and which treatment should be prescribed, and can be used to monitor the progress of treatment.

In developed markets, they are now an integral part of decision-making at every step along the care pathway, and their importance is increasing all the time as healthcare becomes more and more personalised. Yet in low- and middle-income countries, diagnosis remains one of the weakest links in the care cascade, resulting in unnecessary suffering and deaths. This has been highlighted during the COVID-19 pandemic, with high-income countries having testing rates for SARS-CoV-2 10 times higher than low- and middle-income countries.

The diagnostics sector remains highly fragmented and there is a lack of joined-up strategy for realising the potential of diagnostic testing in lower-income countries. This results in gaps in the supply of and in access to testing and monitoring devices across multiple therapeutic areas, including infectious diseases, maternal and neonatal health conditions and pregnancy, and prevalent NCDs such as diabetes and cardiovascular disease. Significant challenges exist in realising this promise, as R&D priorities remain skewed to wealthier markets, laboratory capacity is a frequent bottleneck, and delivery obstacles persist even for relatively simple diagnostic kits.

Looking at R&D, in addition to new diagnostics for priority diseases, there is also an urgent need for technologies that are better suited to lower-income countries – whether through more robust and easy-to-use design, or via less reliance on central laboratory systems and fixed utilities (electricity, internet, gas, etc). Partnerships can incentivise global companies to foster this kind of adaptive R&D ecosystem. Such partnerships can be forged with local manufacturers, which have better visibility of the market and the needs of patients.

Diagnostics also need to be affordable for every payer, from a supranational donor, such as the Global Fund or UNICEF, to public health systems, to patients paying out-of-pocket for self-test and monitoring devices. Beyond pricing strategies for the actual diagnostic device or test, companies need to factor in all the elements that will be required to perform the test, such as reagent liquids or assay tips/cups, and maintenance costs.

Additionally, there is a need to increase the availability of diagnostics in low- and middle-income countries by increasing the on-the-ground presence of suppliers in underserved

markets and through the creation of sustainable supply chains. This can be done by companies setting up partnerships with regional stakeholders that already have a footprint in key markets and by entering technology transfer agreements with established manufacturers. Diagnostics companies can also support capacity building initiatives, for example, for setting up equipment, training maintenance experts, and building up the skills needed to use diagnostics and devices in local markets.

Finally, the Foundation has identified a clear trend for more companies and global organisations to partner together in order to bring diagnostics and treatments together in a single care package – but so far this is concentrated on only a few diseases in a few countries, thus benefiting only a small number of patients.

Despite the fragmented nature of the diagnostics sector overall, there is a concentration of the biggest companies in several key therapeutic areas, which provides an opportunity to use the Foundation's tried-and-tested model of incentivisation. In the medium term, we intend to engage a few big players to deliver the maximum impact.

ROLE IN ACCESS

There are four key areas where diagnostics companies play a role in ensuring access to medicine:

R&D

- Invest in R&D to address identified global priority gaps
- Invest in R&D to translate existing diagnostic and monitoring technologies to meet specific low- and middle-income country needs
- Plan for access early in development to ensure broad access to populations in need at launch

Manufacturing and Quality

- Produce high quality diagnostics and devices
- Ensure local availability by securing manufacturing capacity to multiple global sites

Deliver to and prioritise underserved populations

- Ensure diagnostics are available at scale for health systems and different payers*
- Prioritise access to underserved and vulnerable populations often left behind

Diagnostic capacity building

- Build local capacity by ensuring healthcare professionals have training on proper usage and administration
- Provide support for maintenance and upgrades

*Different payers refer to reimbursed systems, patients paying out of pocket, etc.

MEDICAL GAS COMPANIES

Tackling the crisis in medical oxygen supply

The COVID-19 pandemic has highlighted a chronic crisis in medical oxygen supply that should have been tackled long ago and now needs to be addressed as a matter of urgency. Many low- and middle-income countries have faced horrific shortages, resulting in unnecessary patient deaths and huge bills for families forced to purchase costly cylinders on the private market for unwell relatives.

Clearly, an integrated solution is necessary to address the problem of medical oxygen supply, not only to help deal with the COVID-19 pandemic but to save millions of lives in the long term. Oxygen is vital for treating other deadly conditions, including pneumonia, which claims the life of a child every 39 seconds. It is also a common requirement during complications in childbirth. Essential efforts to reduce gaps in this area are needed to progress toward universal health coverage and reach the various targets of the SDGs.

In most of Europe and North America, medical oxygen is delivered by tanker, stored in large vessels, and eventually piped directly to bedsides. But many poor countries lack this infrastructure and rely instead on cylinders, which increases the price per volume used.

There are several challenges to improving access to medical oxygen in low- and middle-income countries, including market concentration, with the biggest three companies responsible for 69% of the global industrial gas market. Historically, the industry has not prioritised public health, as medical oxygen represents only a small proportion of its overall business. Access is also hampered by a fragmented supply chain, involving complicated logistics and distribution networks, which can make supplies unaffordable.

The leading manufacturers of medical gases have a vital role to play in providing sustainable supplies to health centres globally, and therefore have a duty to invest in capacity to ensure improved access. They must prioritise and invest in low- and middle-income countries, be proactive in finding new ways of increasing supply and reducing the cost in poorer countries when an emergency strikes, and engage in long-term sustainable access approaches for health systems. So far, the disjointed approach by the industry is reminiscent of the position pharmaceutical companies were in several years back, underscoring the potential for change.

Fixing the problem requires leadership from the companies that dominate the industry. The medical oxygen supply chain involves many distributors, but six manufacturers – including the three market leaders – dominate the market, making it ripe for the application of the Foundation's system of encouragement that it has used for more than 15 years in the pharmaceutical sector. This work has already started, in partnership with the Every Breath Counts Coalition and others, but there is more to be done.

ROLE IN ACCESS

There are four key areas where medical gas companies play a role in ensuring access to medicine:

Prioritise and invest in access in low- and middle-income countries

- · Establish a clear access strategy and implement access KPIs
- Ensure delivery of medical oxygen to a broad array of countries and across different regions and provinces
- Delivery of required additional materials (e.g. cylinders) or strategic sourcing of necessary additional equipment to ensure appropriate use upon delivery
- Create more capacity for liquid medical oxygen vs. for industrial use

Engage rapidly during emergencies (e.g. in pandemics)

- Engage with multilateral organisations to expand access (e.g. the ACT-A Oxygen Emergency Taskforce) to sign formal Memorandums of Understanding (MOU) and agreements
- Engage in bilateral agreements to expand access during emergencies
- Provide transparent information on MOUs and the stipulations of bilateral agreements
- · Deliver on existing commitments

Engage in sustainable access approaches for health systems

- Develop long-term contracts for liquid oxygen
- Include ongoing service and maintenance support within such contracts
- Demonstrate approaches to enable affordability for and within different hospital and care settings within specific countries (e.g. a private hospital in Rio vs. a public hospital in a rural/remote area or resource-deprived area)

Strengthen sustainable supply

- Improve delivery mechanisms and delivery speed, including last mile delivery
- Capacity building in collaboration with local partners and governments in low- and middle-income countries to ensure continuity and appropriate use/maintenance/forecasting techniques

HOW WE WORK

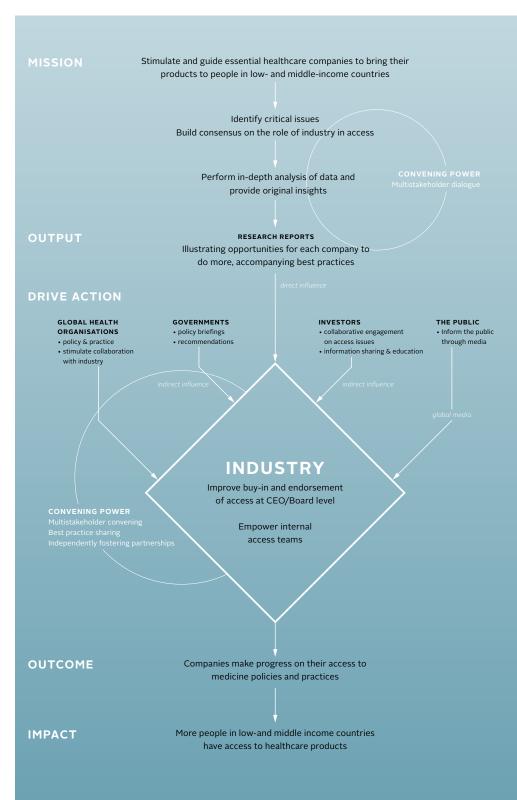
A unique catalyst for action

The Foundation is in a unique position to act as a catalyst for this much-needed change by ensuring that more companies play their part and raise their game on access. We do this by working alongside other stakeholders on systemic access challenges, signalling where gaps exist, highlighting patterns of corporate behaviour that work, and driving solutions. Our independence and long-running specialisation in industry practices also allows us to track objectively the progress made by companies.

To trigger radical transformative change inside companies, the Foundation now uses a combination of data, research insights, rankings and report cards, while leveraging a network of influential stakeholders, including investors, policymakers in governments and the public.

The Foundation's leadership has an open line to many boardrooms. In addition, we carry out direct change-making activities with companies, from regular interactions with top executives to town hall meetings for hundreds of employees. All these activities – and the media attention we engender as the go-to independent expert source on access to medicine – help to motivate and empower company access teams by showcasing concrete examples of what works and what does not.

Independent third-party evaluation confirms that our work has made a significant contribution to advancing the pharmaceutical industry's engagement with access issues. At the same time, the Access to Medicine Index has evolved into the primary benchmark in the space. By providing a tool for learning and discussion, the Foundation helps companies understand the scope of their own activities and how to put best practices to use, while spurring healthy competition between firms to do better.



MODEL IN ACTION

How we put our model for change into practice

To trigger radical transformative change inside pharmaceutical companies, the Foundation combines data, research insights, rankings and report cards, while leveraging diverse networks of influential stakeholders.

Here, a series of snapshots of our current research and engagement work demonstrates how the teams working at the Access to Medicine Foundation put this model for change into practice.



BUILD CONSENSUS ON URGENT PRIORITIES

Since 2008, the Foundation has systematically built consensus on what we can expect from pharma companies on access to medicine. We consult 150+ experts and stakeholders to ensure a diverse range of viewpoints and technical expertise. In balancing these views, we have defined the priority actions for pharma companies, what 'good' looks like and how to get there, in governance and compliance, R&D and product delivery.



AGENDA-SETTING RESEARCH REPORTS

Our research uncovers where progress is being made, where gaps remain, and which companies perform best. Our insights are drawn from a unique combination of sources, from companies, public sources, and expert organisations. With our thematic reports, we bring emerging or hidden issues into the forefront, such as the fragility of antibiotic supply chains. These reports are proven agenda-setters and have practical recommendations for companies,

NGOs, governments and investment circles. All our reports are online and open-access, including the detailed company comparisons and validated best practices, and have been downloaded more than 100,000 times.



SUPPORTING THE GLOBAL HEALTH AGENDA

For the global health community. we bring 15+ years' experience of engaging pharma companies with specific access issues and achieving a sustained level of industry responsiveness. Our research incentivises and tracks how pharma companies respond to global health priorities, such as in the WHO's Model List of Essential Medicines. We assess whether companies are taking action in areas where priorities are yet to be set, such as non-communicable diseases incl. heart diseases and cancer. Through strategic briefings, collaborative activities, committees and working groups, we help maximise the impact of global health organisations, e.g., in 2021, to establish a guide for good practice in stewardship and access planning (SAP), to help curb antimicrobial resistance.



INFORM GOVERNMENT DECISION-MAKING

We equip global health leaders with the most relevant research

findings and policy advice, enabling evidence-based decision-making. Governments play a central role in setting the global health agenda and prioritising disease areas, sustainable procurement decisions, and specific policy developments. By working closely on disseminating our findings, the Foundation supports governments in moving the needle further and faster on key access issues. In 2020, the UK government used the methodology and results of the AMR Benchmark to inform the criteria for selecting companies and to set expectations for the pilot of its first-ever Antibiotic Subscription Model. In 2021, the Norwegian government drew on the results of the 2021 Access to Medicine Index in identifying its four principles for urgent pharma action to combat COVID-19.



MOBILISE THE POWER OF INVESTORS

150+ institutional investors, with USD 25 trillion in AUM, use our research to trigger change in the pharma industry. Investors are strongest when they pool their influence and speak with one voice to a company. Through 200+ engagements per research cycle, e.g., workshops and research launches, we inform investor teams on specific opportunities for each company to improve access. The Index Investor Statement is the 4th largest ESG investor initiative and the only one focused on health.



INDEPENDENT SOURCE FOR MEDIA

Global media seek out the Foundation for insight into how pharma companies are responding to global health issues. Journalists use our research as a trusted, independent source on complex topics, such as medical oxygen shortages, superbug dangers and pricing dilemmas. Each research report is covered widely at launch in 20+ articles in quality global and national media, including journals and op-eds. In this way, the media translate our research into standards of behaviour that the public can demand from pharma companies.



CREATE CONDITIONS FOR NEW COLLABORATIONS

Since our beginnings as a research organisation, we have steadily deepened our engagement streams,

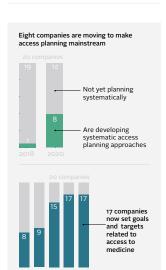
building a platform for experts with diverse perspectives to unpack pharma's actions on critical access topics, as well as to validate current best practices and to assess progress. Today, we use this platform to convene working sessions on urgent and unaddressed topics, inviting hand-picked experts from across industry and global health, where they often meet each other for the first time before they start collaborating. Starting in September 2020, the Foundation co-convened a series of Access to Medical Oxygen roundtables, the first to bring medical gas companies to the table. In June 2021, these roundtables led to landmark agreements from two companies to address oxygen shortages in low- and middle-income countries.



CO-DEVELOP COMPANIES' EXPERTISE

We engage directly with healthcare companies at many levels, targeting their biggest opportunities to deliver change. With executive leadership, we discuss strategic improvements to develop, scale up and supply essential health products to reach more people. We work with companies' access teams to match the daily reality of their business operations with best practices. Each publication starts a new cycle of briefings and workshops, totalling 300+ engagements annually, reaching 58 healthcare companies in 2020. Each year, company experts join our

custom workshops for sharing good practices validated by the Foundation. Through these, we unpack tough topics with peers and independent experts from, e.g., governments or investors. Participants use the insights to steer access initiatives. Our most recent session identified 7 lessons from COVID-19 for pharma companies.



PHARMA COMPANIES ARE MAKING GRADUAL PROGRESS ON GLOBAL HEALTH

During the past decade, pharma companies have gradually changed how they do business, with 100+ best practices identified since 2012. Several companies now aim to reach people on very low incomes. R&D pipelines have grown, particularly for diseases such as malaria, HIV/AIDS and TB. Equitable pricing, voluntary licensing and product donations are being used more frequently to improve access. The Foundation sees the biggest progress where there are clear global health priorities in place, supported by publicly funded market-shaping

mechanisms as well as long-term and coordinated financial support from multiple donors and national governments.



INDEPENDENT CONFIRMATION OF IMPACT

In 2020, the Foundation commissioned an independent evaluation of its progress in advancing access to medicine in low- and middle-income countries. This evaluation concluded that "the work of the Foundation has likely already contributed to improve access to medicine for millions of people and also produced millions in cost savings for low- and middle-income countries."

WHAT LEADERS SAY

The expert view on the value of our work



"I've been impressed by the Access to Medicine Index. It presents wellbalanced stakeholder views on good practices for the pharmaceutical industry and it provides clear standards against which the performance of individual companies can be judged."

Mary Robinson, Chair of the Elders, First woman President of Ireland, former UN High Commissioner for Human Rights



"When I talk to executives from pharmaceutical companies, they tell me that they want to do more for neglected diseases, but they at least need to get credit for it. The Access to Medicine Index does exactly that."

Bill Gates, Co-chair, Bill & Melinda Gates Foundation



"There is more that we can do and are doing. This year, the index is tougher than ever. It challenges us to think harder about how we drive innovation and enable access to our products. This is a challenge that we are ready and willing to take on. We will continue to push ourselves to go further and faster to make sure our medicines and vaccines reach more people."

Sir Andrew Witty, former CEO of GSK



"I welcome this comprehensive article on ending the burden of HIV, malaria and TB in children, and especially appreciate the strong emphasis on the crying need for children living with HIV to access the most up-to-date paediatric ARVs."

Sister Mary Owens, Executive
Director, COGRI - Nyumbani programs for children living with HIV



"As an early supporter of the Access to Medicine Foundation, I have been impressed by its growth and impact. Its credibility is based on consistent rigour and integrity, and these underpin the Foundation's authoritative voice for urgent action to improve access to healthcare. Bringing transparency to the pharmaceutical industry, it incentivises companies to direct resources to improving healthcare in under-served markets. Since its effects are systemic, it represents good value for public money." Michael Anderson, CEO MedAccess and former Director-General, UK Department for International Development



"The Sustainable Development Goals and human rights demand accountability, which consists of monitoring, review and remedial action. By deepening monitoring, the Access to Medicine Foundation makes an indispensable contribution towards the accountability of pharmaceutical companies for the SDGs."

Paul Hunt, Former UN Special Rapporteur on the Right to the Highest Attainable Standard of Health



"This independent Antimicrobial Resistance Benchmark is a huge step forward and shines a light on the pharmaceutical industry's progress in tackling drug-resistant infections. It can help pave the way for a transparent learning culture where best practice is shared, progress celebrated, and gaps where further work is needed are identified."

Dame Sally Davies, UK Special Envoy for AMR



"The Access to Medicine Foundation has made an important contribution in stimulating pharmaceutical companies to do more in the global fight against AIDS, TB and malaria. The AMR Benchmark is an important addition to the Foundation's toolkit." Peter Sands, Executive Director, Global Fund to Fight AIDS, Tuberculosis and Malaria



"The Access to Medicine Foundation's research sheds light on issues that would otherwise remain underreported when it comes to the pharma industry and access to medicine and vaccines. This research informs priority setting and policy interventions based on the identified agos."

John-Arne Røttingen, Global Health Ambassador, Norwegian Ministry of Foreign Affairs



"The Access to Medicine Index is a powerful tool for guiding and incentivising companies to do more for people living in low-and-middle-income countries, and especially in the field of NCDs. The Access to Medicine Foundation also uses its research findings to help advance the work of other partnering organisations, such as the NCD Alliance. With its unique and important role, the Foundation's model for change encourages companies to address noted access issues."

Katie Dain, CEO NCD Alliance



"The pandemic has exposed the urgent need to expand the Access the Medicine Foundation's proven model of engaging pharmaceutical companies to the oxygen industry. The big oxygen companies all need robust, long-term access to oxygen strategies, with performance indicators that can highlight best practices and areas where more attention is needed. The Foundation can help oxygen companies increase

their impact during the pandemic, and long after the pandemic is over, by strengthening health systems to do a better job of treating tens of millions of hypoxemic patients each year."

Leith Greenslade, Coordinator Every Breath Counts Coalition



"The Access to Medicine Foundation has recruited hundreds of investors and trillions of dollars to champion the cause of vulnerable populations in low and middle-income countries. This will significantly influence the way in which healthcare companies do business around the world and contribute substantially to the achievement of the Sustainable Development Goals. AXA IM has actively been collaborating with and supporting the activities of the Access to Medicine Foundation for many years. We believe this is essential to positively influence the behaviors of companies we invest in and to ensure a robust and sustainable financial performance for those companies, to the ultimate benefit of our clients.'

Marco Morelli, Executive Chairman, Axa Investment Managers



"Africa has been overlooked when it comes to research and development of life-saving medical commodities, including COVID-19 vaccines. Free market demand and supply principles will not work on their own without an equitable access dimension. The Access to Medicine Foundation is important for accountability - tracking how and where healthcare companies live up to their commitments; as well as encouraging them to do better – in bridging gaps in equitable access to health products and achieving universal health coverage."

Dr Githinji Gitahi, Group CEO, Amref Health Africa

ROADMAP TO 2026

How the Foundation will leverage its approach to achieve change

Since 2003, the Access to Medicine Foundation has evolved from a research organisation providing a definitive ranking of pharmaceutical companies into a powerhouse producing unique and independent insights about the industry. It has demonstrated an ability to move the needle on access issues that are critical in low- and middle-income countries. Two independent impact assessments have confirmed its capacity for stimulating change, concluding respectively that the Foundation "has made commendable contributions towards advancing the engagement of the pharmaceutical industry with the issue of access to medicine" and that "the work of the Foundation has likely already contributed to improve access to medicine for millions of people and also produced millions in cost savings for low-and middle-income countries". The independent assessments also highlight a "clear appetite" from stakeholders for additional research and analysis by the Foundation, including from the pharmaceutical industry, governments, global health organisations and investors.

There is now a strategic opportunity for the Foundation, with its special position in the global health ecosystem, to expand its sphere of influence into the areas of greatest untapped potential. The Foundation's strategic direction for 2022–2026 builds on the success of the organisation since its establishment more than a decade ago, and on its ability to guide and incentivise positive action from the private sector by:

- preserving existing research areas and continuing to deliver research and analysis with demonstrated impact on industry behaviour;
- expanding and tailoring its successful model to new healthcare sectors to help more people across multiple disease areas; and
- amplifying our change-making capacity to incentivise companies further to address access at scale.

To achieve this, we will develop the Foundation's organisation and strengthen and solidify its presence within the global health ecosystem.

We will take a six-part approach to ensure that the current cohort of companies in scope continues to bridge the vast gaps in access and, in parallel, bring in a diverse range of other healthcare companies to also play their part.

Approach in six parts Bring Build Clarify Develop Enable Track roles and policy shifts, on board a networks to appropriate progress and critical mass influence society's tools to validate best effective tackle each expectations collaboration of companies new sectors practices sector and and increase from industry and more activities theme investment from different with existing companies actors

Bring on board a wider critical mass of companies Engaging a number of companies that are new to the Foundation will be one pillar of the strategy, while at the same time we will sustain and strengthen interactions with existing priority businesses. Several companies within the Foundation's strategic expansion framework are already the target of some engagement, and have been for several years: via the Antimicrobial Benchmark (generics), via the Access to Medicine Index (diagnostics) and via our recent work on COVID-19 (medical oxygen). However, to ensure that access is prioritised, the Foundation needs to develop closer ties with the senior leadership and access teams in these companies and ensure that they are willing to share practices and are keen to improve their performance. In many cases, this will involve educating and training company staff via workshops and townhall meetings on key access issues and potential solutions. The Foundation benefits from its independent status, its unique position and presence in many communities, and its international network. This creates an opportunity to develop an understanding around the issues that each individual company faces, supported by validated solutions identified through our research, and to educate the corporate decision-makers who can make a difference on the ground in bridging gaps in access.

Build networks to influence new sectors and increase activities with existing companies

The Foundation has a large network of stakeholders who routinely use its work, including international health organisations, institutional investors, governments, NGOs and the general public, as well as the companies themselves. For each sector and access issue, the Foundation builds and activates new networks of influence, to ensure that tailored approaches are used. For example, the Antimicrobial Resistance Benchmark is of particular interest to the policy-shaping sector, prompting the Foundation to work closely in the interface between donors, companies and governments. In other cases, where the Foundation's work is especially relevant to publicly listed companies, investors have been instrumental in shifting the mindsets and decisions of company boards. This experience can be further leveraged when targeting new healthcare companies. As we bring more private companies on board, new channels, such as with procurers, governments and local NGOs, will be established to widen the sphere of influence and guide more change.

Clarify roles and society's expectations from industry

Healthcare companies play many roles, from conducting R&D and developing new products to building capacity and advancing access to the products they manufacture. These roles – and the responsibilities they carry – need to be well defined

and agreed upon by stakeholders. Currently, many of the roles that companies carry out are poorly articulated. This is particularly the case in the new sectors we will be focusing on, and there is little agreement on what firms should be doing and how to do it responsibly and effectively. The Foundation will leverage its expertise in building multistakeholder consensus between different players across multiple sectors, in order to set priorities, and work out what best practice looks like in differing situations.

Develop appropriate tools to tackle each sector and theme

In order to to address the changes needed to improve access, every sector and every company will require a tailored approach. The Foundation will build on its existing toolkits for indexing and benchmarking, best practice sharing, and policy shaping interventions, as well as on its convening power, while adapting the approaches and mechanisms of influence set out above. For example, the emergency created by the COVID-19 pandemic requires an immediate response by medical gas companies – which means tracking the response also needs to be immediate. Yet at the same time the industry's solutions must be sustainable and address chronic shortages in medical oxygen. We will therefore need a mix of tools to incentivise long-term strategic shifts for this sector.

Track progress and validate best practices

Measuring performance is central to the Foundation's approach and its credibility. Clear metrics have established the Foundation as the only independent organisation that has consistently evaluated industry progress on global health issues over time. They have also made it a trusted partner for multiple stakeholders. By reporting its access data in the public domain, the Foundation fosters transparency and accountability, thereby creating a platform for sharing validated best practices. This is crucial for amplifying the access solutions to more companies.

Enable policy shifts, effective collaboration and more investment from different actors

To foster change in a sector, the enabling conditions, incentives and policy environment around the companies need to move in tandem. The Foundation's strong voice and position in different forums enables it to facilitate this process by helping shape the policy decisions that are taken by governments, investors, donors and others involved in global health. While the Foundation's primary focus is measuring and monitoring the performance of companies, it also has a key role to play in contributing insights and information to enable better country-level policies and practices to expand access to medicine and reach many more people.

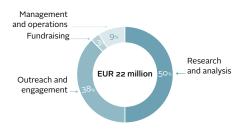
WORKPLAN AND BUDGET

Stepwise expansion across the sectors

In the five years to 2026, the Foundation will grow its output in tandem with its capacities in a structured, step-wise manner. It will invest in its research and outreach capacities concurrently as it expands its activities to five sectors. In the years 2022-2023, we will focus on the few key players in each sector that have an opportunity to deliver critical and urgently needed change, building in scope for continuous learning. These learnings will be applied during the years 2024-2026, as we broaden our activities into a fully-fledged research programme for each sector, with a focus on both current and future health challenges. Throughout, the Foundation will maintain its established work to mobilise Big Pharma on the chronic need to sustain investment in R&D and scale up access programmes for low- and middle-income countries.

In order to maintain its influence and credibility, the Foundation is committed to remaining fully independent from healthcare companies. The Foundation now comprises a 30-member team structured in well-established units for research, engagement, communications and supporting functions that together implement its current programmes. To deliver our full roadmap up to 2026, we aim to secure long-term funding from diverse sources for a total of EUR 22 million for the five-year period. With new investments across the organisation and into the research programmes, both new and current, we will also realise significant economies of scale as we expand and achieve the goals of this strategy.

Funding allocation 2022-2026



2022 - 2023

Deliverables

- 2022 Access to Medicine Index
- Antimicrobial Resistance (AMR) Research Programme that unpacks critical resistance issues and the role for companies
- Sector-specific reports from Programmes on generic medicine manufacturers, vaccine manufacturers, diagnostics companies and medical gas companies
- Articles and analyses on critical access topics, such as: affordability; equitable distribution of health products; access to products associated with sexual and reproductive health; access to products for non-communicable diseases, including diabetes; pandemic preparedness and advances in universal healthcare

2024 - 2026 Deliverables

- Full-fledged Research Programmes in each sector, including company-specific report cards
- Up to three thematic studies per year from the Research Programmes, including on AMR and cross-sector opportunities
- 2024 Access to Medicine Index
- Independent impact assessment report 2025/6
- Continuous publication of articles and analysis on critical access topics

OF INFLUENCE

MECHANISM

⋖

BUILDING

CONTINUOUSLY

YEAR 3-4-5

YEAR 1-2

Building a mechanism of influence

- Engaging companies from the different sectors
- Convening meetings for companies to share practices and experiences in a neutral, solutions-oriented forum
- Establishing and strengthening collaborations with organisations that influence access to medicine across the five sectors
- Coordinating action-oriented investor collaborative engagements
- Convening multi-stakeholder events on access issues, held in low- and middleincome countries
- Making specific and applicable recommendations tailored to individual companies
- Frequently distilling detailed information for investors and policymakers to inform decision-making
- Providing specific recommendations and insight for policymakers and donors on the initiatives they support, e.g., in R&D, product development partnerships, and international procurement

RESEARCH DRIVEN OUTPUTS

ABOUT THE ACCESS TO MEDICINE FOUNDATION

The Access to Medicine Foundation is an independent non-profit organisation based in the Netherlands. It aims to advance access to medicine in low- and middle-income countries by stimulating and guiding essential healthcare companies to play a greater role.

FUNDERS

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Scribble Design

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