

## AMSTERDAM SESSION

# What can be learned from COVID-19 to solve chronic issues in access to health care in low- and middle-income countries?

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*The workshop took place on Wednesday 16 June, 2021 as part of a series of Amsterdam Sessions.*

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COVID-19 has had an enormous impact on health systems globally, exposing critical gaps and highlighting the importance of building strong and responsive systems to protect patients and prevent the spread of disease. As attempts to control the pandemic gathered pace, governments and industry faced new access-to-medicine challenges. Demands for existing health products needed to be met alongside the urgent need to develop new products to address the pandemic and to deliver them to all corners of the world as quickly as possible. Innovative medicines, vaccines and diagnostics for COVID-19 have been developed, manufactured and distributed at an unprecedented speed. The pandemic spurred new types of collaboration, never before seen at the same scale and magnitude.

The pandemic has also had an impact on the functioning of pharmaceutical companies by putting pressure on internal resources, manufacturing capacity and supply chains. Additionally, it exposed vulnerabilities and pre-existing gaps within product delivery systems, and disrupted access to key products in multiple markets, and particularly in low- and middle-income countries. Further action is required to curb this pandemic and prepare for the future, including the safe and secure delivery of COVID-19 products to the people in low-and-middle income countries that need them the most.

On 16 June 2021, the Access to Medicine Foundation convened a roundtable to examine lessons learned by industry through this pandemic: practical solutions that pharmaceutical companies deployed to remove barriers, resolve unanticipated issues and increase access. Discussions emphasised innovative approaches to ensure a continuous supply of essential health products.

### **In this report:**

1. 7 key lessons from the COVID-19 pandemic
2. Strong pre-existing partnerships are key to successfully navigating a crisis
3. Supply chain continuity requires innovation and agility
4. Multisectoral collaboration is key. Protectionist approaches can hinder manufacturing and supply
5. Expanding production capacity to a global scale requires strategic thinking and advance planning

The event was held under the Chatham House Rule, and quotes are unattributed. Participants were invited to share their companies' experiences of this pandemic and exchange strategies for applying its lessons to future crises. Experts from 21 pharma companies joined the two sessions, including from the innovative and the generic industry, as well as from the investment community.

### **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 the pharmaceutical industry to play a greater role in improving access to medicine. The Foundation is funded by the UK and Dutch governments, the Bill & Melinda Gates Foundation, AXA Investment Managers, and Wellcome Trust. The Foundation is grateful for special funding from AXA Investment Managers and Wellcome Trust to specifically support the roundtable and this report.

## 7 key lessons from the pandemic

### **1. Recognise own limitations, complement strengths through partnerships and downstream collaborations.**

Innovative ideas and state-of-the-art facilities can help advance urgent global health challenges, but they can only bring a company so far. Each company must recognise its own limitations and be realistic about its capacity to bring access to scale. Once this is clear, they can activate and build effective partnerships to ensure supply can meet demand on a global scale. Collaborating downstream by working more closely with local governments and NGOs to secure access to specific products, not just for COVID-19, but to maintain existing treatment plans for patients, is essential for building resiliency in health systems in LMICs.

**2. Identify and resolve supply chain challenges, building on pilots and developing new ideas.** The resilience of health systems, supply chains and manufacturing hubs in LMICs have been put to the test by COVID-19. Companies must continue to build on solutions piloted during the pandemic to help better prepare for the next pandemic, to ensure continuity of care and to build local capacity to address ongoing access challenges. Companies must also continue to create and invest in innovative solutions, for example to diversify manufacturing sites where possible and to plan ahead for inventory reserves to prevent shortages and stockouts.

### **3. Embrace innovations in information-sharing to improve supply chain alignment to reach more people.**

Improved communication, including between companies, can help ensure treatments reach more people globally. Specifically for stock management and appropriate planning, for example, where cold-storage of vaccines is concerned and when securing supply routes despite national or regional border closures. Investing in new telemedicine and telemonitoring and building capacity to enable such services can improve continuity of care, especially for people in hard-to-reach places or when travel is restricted. Pandemic preparedness means continuing to invest in stronger, more innovative and collaborative communication channels and platforms.

### **4. Ensure new products quickly reach people in LMICs by involving generic medicine manufacturers early in the development process.**

Supply shortages continue to prohibit the equitable distribution of COVID-19 products. Yet future products could reach people in LMICs much more quickly if generic medicine manufacturers are involved early on in the product development process. Fostering stronger manufacturing alliances through cooperation between large R&D based companies and generic medicine manufacturers can help expedite delivery of new and existing products and meet global demands. This pandemic has demonstrated that it is possible to plan for generic options of a product while it is still being developed. This way, innovative medicines, vaccines and diagnostics can reach high-income countries and LMICs at the same time.

### **5. Invest in a larger network of partners that can quickly ramp up local manufacturing capacity.**

Longer-term contingency planning and strategic coordination is needed to maximise the resilience of manufacturing networks. Companies must have a broad community of partners to rely on. They can explore partnerships with new and existing local manufactures and build more localised capacity, including through well-trained personnel, technology transfers, and by working with partners to bring quality standards are up to par. This will enable companies to draw on a larger pool of partners when large volumes of new products are urgently required at expedited speeds. Local capacity building will help the industry become resilient to shocks, that go well beyond COVID-19.

### **6. Build inventory reserves, supported by large networks of API suppliers.**

Manufacturing should be diversified to prevent situations where issues in specific countries prevent planned exports to other countries. To help resolve this issue, inventory reserves in other countries can be built up effectively and strategically. Companies can develop plans for stockpiling and expand communication channels with a large network of API suppliers.

**7. Plan for the unexpected, including protectionism.** The role and autonomy of governments must not be overlooked. Companies should plan for the unexpected. When countries address their own interests first, global supply chains may be impacted, including bans or severe limits on the export of raw materials, manufacturing supplies, PPE, human resources and medical products. Unanticipated issues with border closures, natural disasters or regional conflicts can have ripple effects when multiple companies rely on exports from one country. Anticipating disruptions mitigates the risk of shortages and stockouts and supports reliable mass production. Companies can explore mechanisms for better coordination of essential production materials and basic equipment to keep manufacturing plants running, despite unexpected shortages of essential materials.

## 1. Strong pre-existing partnerships are key to successfully navigating a crisis

The roundtable was opened by Jayasree K. Iyer, Executive Director of the Access to Medicine Foundation, who used concrete examples from the latest Access to Medicine Index to demonstrate the central role of pharmaceutical companies in making lasting improvements to supply chains and ensuring sustainable deployment of essential health products.

In terms of product deployment, a core theme that emerged was the significance of leveraging existing partnerships. Participants referenced that already working on other product candidates with public partners and generic manufactures enabled a more streamlined and trusted approach to collaboration on COVID-19 products. Further, by having plans already in place to ramp up manufacturing, they were able to pivot quickly to respond.

Existing collaborations, either between large R&D-based companies, with generic partners or with government research foundations, was also considered an enabling factor in early responsiveness. In turn, these relationships helped facilitate early buy-in from senior leadership.

*“Existing relationships provide agility when crisis strikes.”*

Established and pre-existing partnerships with other manufacturers meant that partners already trusted in each other’s expert knowledge, capacity, knowledge of pathways and existing networks to accelerate approvals in their respective countries. These proven assets helped accelerate the process of sharing intellectual property (IP), facilitating tech transfers, ramping up production and swiftly determining distribution channels.

*“We don’t always have the solutions, but we can bring the connections”.*

Conversely, newer relationships were referenced as being generally more challenging than existing ones, for example when developing a full new set of products. As one participant explained: “knowing how to do it and getting internal buy-in are two different things.”

Underpinning collaborations between specific partners, participants also referred to multi-party forums for discussion as important for building consensus on priority access-to-medicine issues and potential solutions, such as at the CEO roundtables coordinated by the Bill & Melinda Gates Foundation. Scaling up such initiatives was noted as a strong and efficient mechanism of encouraging companies to work together more frequently and to achieve consensus on access measures and best practice. Formalised multi-party collaborations, for example, the Access to COVID-19 Tools Accelerator, were noted for accelerating the industry’s response, being seen as key to achieving the unprecedented speed of R&D for COVID-19 products.

*“No-one did business as usual... We thought and partnered differently... The collaborative efforts across industry initiatives need to be fostered.”*

## 2. Supply chain continuity requires innovation and agility

When supply chain challenges arose, due to the pandemic, several companies responded by deploying “issues management teams”. Issues management is a specialism dedicated to identifying and resolving issues relating to an area of the business or its operations. For example, these teams addressed potential or realised reductions in the supply, for example of active pharmaceutical ingredients (API), where production sites are heavily concentrated in India and China, and other raw materials to manufacturing centres. Companies explained that, when they were required to operate at limited capacity, they faced the challenge of ensuring the manufacturing of other products could continue. This required continuous engagement with all buyers in different markets. Restrictions on exporting raw materials from the US was noted as a significant challenge, with some companies experiencing a roadblock of 6-7 months for sourcing materials from the US, hampering efforts to scale up production.

The pandemic reinforced the need to prioritise human resourcing along the supply chain, including by providing safe and sterile working conditions within manufacturing centres and throughout supply chains. Some companies referenced specific examples where border closures impacted the ability of their workers to travel from neighbouring countries, with one example of factory workers moving between countries to keep working (and thus enabling production of essential products) despite neighbouring border closures and controls.

Others noted new challenges with addressing safe transportation of workers to and from the plants. Some acknowledged that procuring and providing personal protective equipment (PPE) along the supply chain, particularly when shortages occurred in the early months of the pandemic, was an essential and previously unforeseen role of pharma companies. Some companies reported sourcing and supplying PPE for their suppliers, in order to enable production to continue.

For the future, a few participants highlighted that the physical transfer of products could be streamlined, with multiple routes into a market from various companies and NGO partners potentially being consolidated. Kenya was referenced as an example where multiple companies run their own access programmes, each with its own supply chain. Suggested solutions include tech enabled interfaces and securing collaborative transportation channels for high priority products. Participants specifically referenced the need and potential for successful collaboration approaches in R&D to be transferred to other areas of the value chain downstream, such as product delivery.

*“In the area of R&D, we can combine databases but we hardly collaborate downstream with implementation activities – we rely on the same NGOs but rarely collaborate or align to use infrastructure on the ground, even though this is not a competitive activity.”*

## 3. Multisectoral collaboration is key. Protectionist approaches can hinder manufacturing and supply

Nationalistic policies and actions from just one party can severely impact global production and distribution efforts, signalling a strong lesson learned that governments can have an immense impact on manufacturing and the rollout of key products. Better multisectoral collaboration was an important and reoccurring theme throughout the roundtable.

Working with governments and local partners on the ground is also pertinent for quickly onboarding new partners and addressing critical emerging issues. This type of multisectoral collaboration from pharmaceutical companies, governments, and NGOs is critical for ensuring patient care continues even when a pandemic hits. Inefficiencies and gaps in health systems were grossly exacerbated by COVID-19.

*“We definitely need a better system of crisis preparation and response but we need preserve what is currently in place and try to work together and more closely.”*

To help promote treatment continuity, some companies came up with innovative solutions to ensure access during lockdown. For example, one company noted that it began producing multi-month packs of medications, where 30-day packs had previously been the norm. Turning these into 90-day packs helps to meet the current reality of lockdowns and social distancing measures that were contributing to a reduction of patient visits to health centres.

Another company mapped the patient journey and how COVID-19 would affect this. For example, in oncology, it identified that fewer and fewer patients were coming back to receive treatment. In some cases, this was due to even basic factors, such as the prevention or discouraging of suitable transportation and free movement during lockdown. The company noticed that it needed to accelerate innovation in patient access programmes and ensure access in new ways, referencing that collaboration between government and industry was critical.

*“If we try and do something on our own the impact is minimal.”*

Supply chain capacity building is not enough if patients are not in the system. Some companies expressed the need to come together for other diseases in the same way they have done for COVID-19 interventions.

*“[Pharmaceutical companies] need to step up and show that collaboration is key.”*

#### **4. Expanding production capacity at a global scale is a significant challenge that requires strategic thinking and advance planning**

Prior to the pandemic, the affordability of health products was often referenced within the global health community as one of the biggest constraints for achieving equitable access to medicine in LMICs. However, the (un)fair allocation of new products, exacerbated by insufficient supply, has become an even more prominent concern during the pandemic, as a result of limited supply and unprecedented global demand, particularly of COVID-19 vaccines. Preparing the ecosystem for a future pandemic is critical. There is a need to ensure increased manufacturing capacity is in place to meet global demand faster. There was recognition from participants that collaboration on R&D can help build capacity, while thinking strategically about how to adequately meet demand early on in the R&D process should be a core consideration.

For some companies, manufacturing capacity has more than doubled since the pandemic began. Companies need to plan ahead to align with raw material suppliers to ensure they too can double their capacity. Some methods of achieving supply at scale that were referenced, including the use of non-exclusive voluntary licences, provided that quality could be ensured and skilled workforce is in place with the appropriate infrastructure, as well as consistent supplies of ingredients.

Companies emphasised the need to continue manufacturing other vaccines on the portfolio even during a pandemic, to prevent resurgences of other infectious diseases. For example, immunisation against measles, rubella, HPV and other diseases have slowed during the pandemic and raise the risk of outbreaks as a result. One solution is to ensure the continuation of vaccine manufacturing through yearly advanced market commitments from high-income countries to prevent manufacturing plants from remaining idle. Stockpiling planning, where applicable, to prepare for surges in demand of other vaccines in the event of a pandemic could also be a viable option.

*“We need to be honest as an industry – scalability is our biggest issue.”*

Participants stressed the need to keep investing in vaccines to maintain stability and ensure vaccine manufacturers can stay afloat. Some companies also noted efforts to have systems in place that are better able to anticipate demand for future pandemics and enable adequate planning time to stockpile and potentially manufacture net new products. Some participants noted that investments in manufacturing capacity should be leveraged when the pandemic is over. Stand-by options require investments without an immediate or even guaranteed returns. Utilising new capacity built for manufacturing pandemic vaccines should be appropriately redistributed to ramp up the global supply of other vaccines or health products once the pandemic is halted globally, for example, by aiding with the global HPV vaccine rollout. Investors also should consider the need for a shift to a longer-term perspective to help support companies in creating greater resiliency in supply chains and to prepare better for future pandemics. Maintaining spare capacity is likely to impact financial metrics and this should be recognised by the financial community, even if such approaches may not be what’s best for a company’s immediate bottom line or next quarter earnings.

*“The impact of inequity is huge. Specific groups such as women, people living in certain countries, those who cannot pay and those who have experienced border closures and are reliant on imports, are being left the furthest behind. We need tailored solutions to address these unique challenges. Access to healthcare is not a single issue or responsibility, it transfers between business and government.”*

*– Jayasree K. Iyer, Executive Director of the Access to Medicine Foundation*

## Next steps

The Access to Medicine Foundation will build on these highly relevant conversations to unpack the best next steps and consider recommendations for future action. The insights captured in this report will inform the Foundation’s research and analyses moving forward, as well as its engagement work to bring lessons learnt from this pandemic into ongoing discussions on pandemic preparedness with companies, investors, governments and global health stakeholders working closely with the industry to build on what worked and to improve on what did not, moving forward.

If you have questions or would like to know more, please contact Marijn Verhoef:

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### About the Amsterdam Sessions

The Amsterdam Sessions, organised by the Access to Medicine Foundation, provide a unique space for people working with and within pharmaceutical companies to come together and discuss access to medicine. Each Session focuses on a specific area where pharmaceutical companies have a clear role to play, and are joined by independent experts working within governments, NGOs or the investor community, for example, to improve access on the ground. The Amsterdam Sessions follow a unique change-making model of pharmaceutical industry engagement developed by the Access to Medicine Foundation through its 15+ years working to stimulate and guide the pharmaceutical industry to do more for people living in low- and middle-income countries. The model identifies critical emerging and existing access issues and brings industry players to the table on issues where they have a specific role to perform, endorsed by investors and bolstered by perspectives and priorities set by key global health stakeholders. The Foundation has organised roundtables and Amsterdam Sessions on: access to cancer care; best practices and impact; appropriate access and AMR, and access to medical oxygen.