

MEETING REPORT



Global health security: addressing the threat of short supplies of essential medicines and vaccines

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On 3 February 2022, the Access to Medicine Foundation organised a virtual forum to identify ideas and solutions for strengthening the global supply of essential medicines and vaccines. Experts from across the healthcare industry, policymaking and procurement worlds joined the event, sharing strategies and insights that can help to reinforce global health security.

Vulnerabilities in the global medical supply chain have been a concern for some time - as highlighted in our 2018 paper on weaknesses in antibiotic supply chains. However, the COVID-19 crisis brought fresh attention to the scale and importance of the issue. Supply chains urgently need to become more robust and resilient in order to absorb disruptions that could otherwise threaten the continuous delivery of critical medicines and vaccines to the people who need them, especially in low- and middle-income countries (LMICs).

This event formed the latest in the Foundation's series of Amsterdam Sessions, which are roundtables convened to address priority topics and challenges in improving access to medicine. This latest Session built on a key theme that emerged in the June 2021 Amsterdam Session on lessons learned from COVID-19, during which supply chain resiliency was central to the discussion.

The Session was productive, with participants sharing best practices around safeguarding and strengthening supply chains (e.g., keeping buffer stocks; planning; and reducing reliance on a small number of suppliers), as well as best practices in procurement policies that can help stimulate better access and quality (e.g., measures to ensure better local availability; closer relationships with suppliers). It is clear that the realities of the last two years have prompted many within the industry to adjust their approach and to address the risk of future shocks, whether that be another pandemic, a geopolitical crisis, a natural disaster, or climate change.

The outcomes are summarised in the following sections:

- 1. Challenges to global health security
- 2. Planning: How producers and procurers can plan more effectively to reduce the risk of shortages.
- 3. **Production:** How manufacturers can manage their supply chains and safeguard continuous supply.
- 4. Procurement: How procurers and policy makers can mitigate the risk of stockouts and help build healthy supply chains.
- 5. Key Takeaways

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 in improving access to medicine. The Foundation is funded by the UK and Dutch governments, the Bill & Melinda Gates Foundation, AXA Investment Managers, the Leona M. and Harry B. Helmsley Charitable Trust, and the Wellcome Trust.

Challenges to global health security

Workshop participants shared the varied challenges their organisations have faced with supplying essential medicines and vaccines. These challenges have included sudden peaks in demand for particular products, as well as shortages, stockouts, and large increases in prices for raw materials. Some participants reported that they had been hit by disruptions in international shipping, while others experienced shortages of skilled labour.

That said, many participants emphasised that global health supply chains continued to function despite the COVID-19 pandemic, and shortages and stockouts have not been universal – thanks, in part, to some of the solutions and shifts set out below.

More broadly, there was discussion of problems posed by reliance on a small number of suppliers for raw materials such as active pharmaceutical ingredients (APIs), excipients and packaging materials. Issues not directly related to COVID-19, such as manufacturing sites unexpectedly going 'offline' for periods of time or leaving the market altogether, have also had knock-on effects within certain product supply chains.

This further highlights the danger of overreliance on small numbers of suppliers, or on suppliers concentrated in one region or country. Among other risks, a highly concentrated group of raw material suppliers leaves global supply chains vulnerable to the effects of unexpected disasters, such as a fire breaking out at a manufacturing centre, earthquakes, regional conflicts, or crises caused by climate change.

Meanwhile, on the procurement side, reliance on imported essential health products is a potential weakness for many areas of the world, as the steady and reliable supply of a critical medicine or vaccine could be interrupted by unforeseen trade issues such as sudden export restrictions or disruptions to shipping.

Seeking solutions – the three 'P's

Discussions on the day were divided into two panel sessions. The Foundation invited speakers and participants from industry, government and procurement bodies with a wide range of experiences and perspectives. Joining us as moderators and guest speakers across the event were:

- Peter Beyer, Unit Head Impact Initiatives and Research Coordination, AMR division, WHO moderator
- Jayasree K. Iyer, CEO, Access to Medicine Foundation moderator
- Jordi Balleste, Unit Chief Procurement, Strategic Fund, PAHO
- Janet Byaruhanga, Senior Program Officer for Public Health, NEPAD
- Akthem Fourati, Chief of Medicines and Nutrition Centre, UNICEF Supply Vision
- Sinead Griffiths, Head of Global Supply Chain, Viatris
- Umesh K, Senior Vice President Global Anti-Virals & Licensing, Aurobindo
- Steffen Lang, Global Head of Novartis Technical Operations
- Glaudina Loots, Director of Health Innovation at the Department of Science and Technology for the Government of South Africa
- Sreenivas Rao Nandigam, Global Head of Supply Chain, Sun Pharma

The solutions identified are summarised below under three themes, dubbed the 'three Ps': Planning, Production and Procurement.

1. Planning

• Just in case, not just in time: Improving global health security requires a shift in thinking, with the past two years demonstrating the limitations of the just-in-time supply chain. Moving towards a just-in-case approach can help to prevent shortages — e.g., by building up safety stocks of key manufacturing components and products. More companies now see value in holding higher stock levels, in order to be able to absorb some degree of shock in the supply chain. This trend applies across the whole supply chain; from building up safety stocks of APIs and raw materials, to all the way through to ensuring sufficient buffer stocks of finished products within the regions or countries where they will be needed.

"From 'just in time', we've actually moved to 'just in case'... one of the biggest learnings for us is to create backups."

- Forecasting: As a complement to the above, smart forecasting for supply and demand plays a central role in reducing the risk of shortages, even in times of crisis when supply can be disrupted, and demand can be less predictable. An on-the-ground, localised approach to forecasting and demand planning is helpful especially in LMICs.
- Identifying and prioritising essential medicines: It is necessary for companies and healthcare systems to identify which medicines and materials are absolutely critical, in order to prioritise their manufacture and procurement and prevent shortages and stockouts. There are particular problems with the supply of anti-infectives (e.g., antibiotics) in LMICs, such as disincentives to supply and stock older antibiotics, as the Access to Medicine Foundation explores in the 2021 Antimicrobial Resistance Benchmark.
- Collaboration with other pharma companies: While companies have previously come together on R&D projects, e.g., in the fight against HIV and malaria, recently we have seen companies develop new forms of collaboration to augment supply, prevent shortages, and ensure local availability of essential medicines globally with mutual benefits to those involved. Beyond COVID-19, this spirit of collaboration could be harnessed across the supply chain as different stakeholders work to improve global health security.

"During the past two years, I saw an unprecedented tendency amongst pharma companies to collaborate... We reached out to our competitors. And easily found partnerships."

• Making full use of technology in logistics: Technology can help the supply chain run more smoothly, e.g., with greater use of software to track shipments, handle shipping documents, understand and foresee potential delays, and confirm timely receipt of the products. Technology has been well-utilised by many companies over the past decade, e.g., in stock management, as previous Indexes have found – but the COVID-19 pandemic expedited the adoption of good practice in this area.

2. Production

• Whole supply chain approach: Security of supply must be considered across the whole supply chain, as a single missing component – e.g., sterile glass vials – can entirely disrupt the production of an essential product. It's not just about specific critical components; it's about ensuring continuity of supply of all components. It is sensible to identify multiple sources of all necessary materials well ahead of time.

"You need to focus on the continuity of supply of every last component, because it can be the smallest component that can cause a disruption in your supply chain."

• **Dual supply chains:** One effective strategy deployed by a company participating in the workshop was to use 'dual supply chains', ensuring that essential products have at least two separate supply chains or sources.

- **Preventing shutdowns:** During the COVID-19 pandemic, it has been vital to prevent disease outbreaks at production sites, which could cause shutdowns. With the onset of the COVID-19 pandemic, pharma companies moved swiftly to reduce the number of people on-site, and to provide these essential workers with PPE, while other employees switched to working virtually.
- Local and regional production as a strategy: One major area of discussion was the role of local production in global health security, and especially its role in preventing shortages or stockouts of essential medicines and vaccines in LMICs. Workshop panellists and participants offered varied perspectives, such as:
 - ⇒ Local production is key, especially to increase preparedness for crisis situations that can lead to significant challenges because, for local production to be effective during a crisis, it must already be operational and fully functioning before the crisis. Crises can lead to issues including trade barriers, shipping delays, or restrictions on international exports (e.g. of vaccines). Local production may have the strongest impact on security of supply when it is end-to-end, rather than focused on a specific element or component in the product supply chain (e.g. APIs, fill and finish, or packaging). For multinational companies, a diverse global network of manufacturers can also be a benefit as it mitigates risks posed by centralised production.
 - ⇒ Not every single medicine would need to be manufactured in every single country this would be inefficient, costly, and could lead to increased prices, as economies of scale would be difficult to achieve. However, regional production could offer solutions, increasing local availability in, e.g., Sub-Saharan Africa and ensuring LMICs are less vulnerable to disruptions to imports and problems in the broader global supply chain. Regional production also can empower neighbouring countries to produce and procure products that are the most relevant to the diseases disproportionately impacting their populations.
 - ⇒ For local production to become more prevalent, there must be a focus on how potential manufacturers in LMICs can obtain financial backing and/or support, and on how pharmaceutical companies can help, e.g., via tech transfers, or by supporting local vaccine manufacturing hubs. Key examples of how companies are taking action in this area can be found in the 2021 Antimicrobial Resistance Benchmark, and tech transfers will also be explored in the 2022 Access to Medicine Index.

3. Procurement

• Beyond price and quality: Participants in the session felt it was important to think not just about pricing and quality when making procurement decisions, but also about security and continuity of supply. There is increasing awareness that promoting long-term sustainability should be a key decision-making factor in procurement. One way to approach this is by procuring from multiple sources to maintain a strong market, and to prevent other companies from retreating if they are not awarded an exclusive contract.

"We can see today that procurement is much more than handing out a request for proposals, selecting the cheapest offer and getting the product."

- Choose suppliers carefully: As part of the process of expanding and developing the supplier base, the criteria used to evaluate potential suppliers should expand to take account of whether those suppliers follow safe and responsible practices. Companies and procurers should seek to use suppliers with a good track record on EHS (Environmental Health and Safety), which can be determined by, e.g., checking whether the supplier has had warning letters from regulators. One tangible benefit is that this can reduce the likelihood of sudden disruption caused by a factory being shut down due to a lack of compliance.
- Consider suppliers' ESG performances: In addition to the EHS considerations explored above, participants highlighted the benefits of working with suppliers who perform well in ESG (Environmental, Social and Governance) metrics. Rewarding responsible practices by suppliers boosts global health security, ensuring that manufacturing is sustainable in the long-term. Participants suggested that considering ESG as a factor in supplier selection will soon be the standard, mainstream approach.

"Using suppliers with high level of ESG compliance has been actually a big winner for us... this is one more filter we will put in to evaluate a vendor or supplier."

- Role of pooled procurement: In volatile times, supranational bodies involved in pooled procurement can ensure redirection of essential medical supplies to those within the network of buyers that have an urgent need, maintaining equitable distribution in the international context. In terms of continuity of supply, there are significant advantages to pooled procurement, on both the supply and demand side i.e., ensuring security of supply for the governments involved, and offering manufacturers certainty around volume.
- Suppliers and procurers working more closely together: Procurers can benefit from ensuring an open line of communication with their suppliers, so that both parties can adapt to supply and demand and get ahead of upcoming challenges. Participants reported that clear, regular communication between procurers and manufacturers has led to more productive relationships.

"COVID has taught us that we had to be closer to suppliers... Listening to suppliers has helped us respond and be more agile."

- Speeding up tender processes: Streamlining this process can make procurement more agile and responsive to demand, and more attractive to suppliers.
- Harmonising regulated markets: If regulatory requirements are harmonised across regions or continents, this can remove one barrier in procurement. On the industry side, wide registration of new and existing products should be encouraged in LMICs where both the Benchmark and the Index have identified the biggest registration gaps; and on the policy side, local regulatory requirements can be made clearer, less burdensome, and more standardised. Progress on setting up the African Medicines Agency is a positive sign that this challenge is being understood and addressed.
- Strategies to procure locally produced medicines and vaccines: Building on the conversations around localised production summarised above, participants discussed how and whether procurers can use local production and procurement to ensure continuity of supply and local availability of essential products. Participants and panellists shared their thoughts, such as:
 - ⇒ Supranational procurement bodies have a certain responsibility to ensure that procurement decisions support economic development in the LMICs involved, e.g. in terms of opportunities for local industry and workers, and by building up local capacity.
 - ⇒ If national governments favour suppliers within their own countries, companies based abroad may perceive that certain governments will favour the procurement of products from within their own jurisdiction and retreat from specific markets as a result. This could lead to higher pricing and a less diverse supplier base. On the other hand, it is understandable that governments will want to support local suppliers, especially in the context of security of supply and economic development.
 - ⇒ Producing locally, close to the patients who will use the product, could help to keep pricing steadier (e.g. by reducing risks associated with inflation, global currency fluctuations, high transportation costs) and help guarantee regional stocks.

"We have the intention to shape healthy markets, where supply is sufficient to meet demands, products are affordable and there is competition and sufficient geographic diversity of suppliers that can lead to more sustainable and secure markets."

3 key takeaways

Considering all of the challenges companies, governments and procurers faced over the last two years, it is remarkable that so many innovative approaches and solutions have emerged, as those involved in the global medical supply chain sought to ensure a continuous supply of medicines, vaccines and other essential healthcare products. Producers, policymakers and procurers alike are awake to the importance of addressing the risk of shortages of essential medicines and vaccines. Yet, significant and deep-rooted issues must still be addressed. For this reason, it is vital to act on these three key takeaways from the Amsterdam Session:

- 1. Global health security must be a top priority: Challenges to global health security can be both chronic (e.g. the overconcentration of suppliers) and sudden (e.g. geopolitical crises), posing serious threats to global access to medicine and essential healthcare.
 - It is vital that global health security is front-of-mind in decision-making whether that means companies shifting from a 'just in time' to a 'just in case' approach to manufacturing, or procurers considering continuity of supply as a factor in tender processes, or institutional investors making this a priority at the boardroom level. All stakeholders in the global medical supply chain will benefit from working closely together to prepare for future shocks, and then collaborating and cooperating when crises do occur.
- 2. Widen and strengthen the supplier base: Manufacturers and procurers alike should move away from singlesource or limited supply chains of both raw materials and finished products.
 - For companies, this may involve expanding the raw material supplier network and looking carefully at which suppliers to use; and for procurers, this may involve awarding tenders to a more diverse range of suppliers. Technology transfers, capacity building, and collaborations between multinational corporations and local manufacturers can boost local availability of essential medicines and vaccines.
- 3. Identify and fix the weakest links in access to medicine: The last two years have highlighted the many interconnections between different parts of the pharmaceutical and healthcare industries, as well as specific challenges in certain sectors and supply chains. In order to make sure that everyone has access to the medicines, vaccines and healthcare products they need – and in order to reach the UN's goal of Universal Health Coverage (UCH) by 2030 – we must bolster global health security by making sure there are no weak links across the entire continuum of care.

This involves identifying the biggest vulnerabilities in access, e.g. in specific healthcare sectors and specific regions of the world, and taking action. More players need to get involved, including those who produce essential products such as diagnostics, vaccines, and medical gases. This approach is part of the Access to Medicine Foundation's new Strategic Direction, as we bring a broader range of essential healthcare companies to the table.

To discuss the contents of this report, please get in touch with Kelly De Baene: kdebaene@accesstomedicinefoundation.org.

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 is joined by independent experts working within governments, NGOs or the investor community. Through moderated working groups, the Sessions facilitate the sharing of best practices and approaches. Participants use the insights to redefine access strategies and internal metrics. In turn, the Sessions inform the Foundation's own metrics for tracking pharmaceutical company performance on access to medicine and antimicrobial resistance (AMR). The Foundation has organised Sessions on: lessons learned from COVID-19; access to cancer care; best practices and impact; appropriate access; and AMR.